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

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended December 31, 2009

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 0-23837

SurModics, Inc.

(Exact name of registrant as specified in its charter)

MINNESOTA	41-1356149
(State of incorporation)	(I.R.S. Employer Identification No.)

9924 West 74th Street
Eden Prairie, Minnesota 55344
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (952) 829-2700

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer ☑	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No ☑

The number of shares of the registrant's Common Stock, $.05 par value per share, outstanding as of February 3, 2010 was 17,441,119.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

SurModics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

(In thousands, except share data)	December 31, 2009	September 30, 2009
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 11,129	$ 11,636
Short-term investments	8,135	8,932
Accounts receivable, net of allowance for doubtful accounts of $168 and $82 as of December 31 and September 30, 2009, respectively	11,661	11,320
Inventories	3,443	3,330
Deferred tax asset	594	353
Prepaids and other	3,765	1,443
Total current assets	38,727	37,014
Property and equipment, net	68,117	66,915
Long-term investments	32,239	27,300
Deferred tax asset	—	2,548
Intangible assets , net	17,051	17,458
Goodwill	21,820	21,070
Other assets, net	12,554	13,257
Total assets	$ 190,508	$ 185,562
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,144	$ 3,468
Accrued liabilities	2,640	2,563
Accrued income taxes payable	—	186
Deferred revenue	838	905
Other current liabilities	918	862
Total current liabilities	6,540	7,984
Deferred revenue, less current portion	4,060	623
Other long-term liabilities	4,717	4,583
Total liabilities	15,317	13,190
Commitments and contingencies		
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; 17,473,260 and 17,471,472 shares issued and outstanding	874	874
Additional paid-in capital	67,418	66,005
Accumulated other comprehensive income	992	1,504
Retained earnings	105,907	103,989
Total stockholders' equity	175,191	172,372
Total liabilities and stockholders' equity	$ 190,508	$ 185,562

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

SurModics, Inc. and Subsidiaries
Condensed Consolidated Statements of Income

(In thousands, except per share data)	Three Months Ended December 31, 2009	2008
	(Unaudited)	
Revenue		
Royalties and license fees	$ 9,198	$ 47,747
Product sales	4,548	3,856
Research and development	3,635	11,613
Total revenue	17,381	63,216
Operating costs and expenses		
Product	1,957	1,515
Customer research and development	3,323	3,705
Other research and development	4,719	5,648
Selling, general and administrative	4,614	4,683
Purchased in-process research and development	—	3,200
Restructuring charges	—	1,798
Total operating costs and expenses	14,613	20,549
Income from operations	2,768	42,667
Other income (loss)		
Investment income, net	297	734
Other income (loss), net	—	(149)
Other income, net	297	585
Income before income taxes	3,065	43,252
Income tax provision	(1,148)	(16,167)
Net income	$ 1,917	$ 27,085
Basic net income per share	$ 0.11	$ 1.53
Diluted net income per share	$ 0.11	$ 1.53
Weighted average shares outstanding		
Basic	17,396	17,683
Dilutive effect of outstanding stock options and nonvested stock	44	64
Diluted	17,440	17,747

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

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

(In thousands)	Three Months Ended December 31, 2009	2008
	(Unaudited)	
Operating Activities		
Net income	$ 1,917	$ 27,085
Adjustments to reconcile net income to net cash provided by operating activities		
Depreciation and amortization	1,744	1,674
Loss on equity method investments and sales of investments	—	201
Amortization of premium on investments	35	35
Stock-based compensation	1,535	1,911
Purchased in-process research and development	—	3,200
Restructuring charges	—	1,798
Deferred tax	2,840	9,597
Tax benefit from exercise of stock options	38	258
Change in operating assets and liabilities:		
Accounts receivable	(341)	2,837
Inventories	(113)	(42)
Accounts payable and accrued liabilities	(262)	(1,607)
Income taxes	(2,501)	6,438
Deferred revenue	3,370	(35,759)
Prepaids and other	(12)	(213)
Net cash provided by operating activities	8,250	17,413
Investing Activities		
Purchases of property and equipment	(3,572)	(4,284)
Purchases of available-for-sale investments	(8,284)	(9,080)
Sales/maturities of investments	3,970	8,522
Business acquisition	(750)	(3,352)
Other investing activities	—	(8)
Net cash used in investing activities	(8,636)	(8,202)
Financing Activities		
Tax benefit from exercise of stock options	(38)	(258)
Issuance of common stock	282	2
Purchase of common stock to pay employee taxes	(365)	(375)
Repurchase of common stock	—	(11,751)
Repayment of notes payable	—	(236)
Net cash used in financing activities	(121)	(12,618)
Net change in cash and cash equivalents	(507)	(3,407)
Cash and Cash Equivalents		
Beginning of period	11,636	15,376
End of period	$ 11,129	$ 11,969
Supplemental Information		
Cash paid for income taxes	$ 809	$ 117
Noncash transaction — acquisition of property, plant, and equipment on account	$ 214	$ 2,346
Noncash transaction — accrued contingent consideration in connection with business acquisition	$ —	$ 2,218
Noncash transaction — acquisition of intangible assets on account	$ 210	$ 841
Noncash transaction — purchase of common stock	$ —	$ 1,085

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

SurModics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
Period Ended December 31, 2009
(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 ("GAAP") and reflect all adjustments, consisting solely of normal recurring adjustments, needed to fairly present the financial results for the periods presented. These financial statements include some 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 earnings in the period in which the change in estimate is identified. The results of operations for the three-month period ended December 31, 2009 are not necessarily indicative of the results that may be expected for the entire 2010 fiscal year.

In accordance with the rules and regulations of the United States Securities and Exchange Commission, the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited financial statements of the Company. These unaudited condensed consolidated financial statements should be read together with the audited consolidated financial statements for the year ended September 30, 2009, and footnotes thereto included in the Company's Form 10-K/A as filed with the United States Securities and Exchange Commission on December 14, 2009.

In September 2008, following a strategic review of Merck & Co., Inc.'s ("Merck) business and product development portfolio, Merck gave notice to SurModics of Merck's intent to terminate a collaborative research and license agreement ("Merck Agreement") as well as the supply agreement entered into in June 2007. The termination was effective December 16, 2008. The Company recognized revenue in the first quarter of fiscal 2009 related to the Merck Agreement that previously had been deferred and amortized under the accounting treatment required for revenue arrangements with multiple deliverables. In addition, the Company also recognized a $9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program that was part of the Merck Agreement. The first quarter of fiscal 2009 revenue associated with the multiple element arrangement is reflected in royalties and license fees ($37.6 million) and in research and development fees ($6.5 million).

Subsequent events have been evaluated through February 5, 2010, the date the financial statements were issued.

(2) Recent Accounting Pronouncements

New Accounting Guidance Recently Adopted

Revenue recognition

Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) shipment has occurred or delivery has occurred if the terms specify destination; (3) the sales price is fixed or determinable; and (4) collectability is reasonably assured. When there are additional performance requirements, revenue is recognized when all such requirements have been satisfied. Under revenue arrangements with multiple deliverables, the Company recognizes each separable deliverable as it is earned.

The Company's revenue is derived from three primary sources: (1) royalties and license fees from licensing its proprietary drug delivery and surface modification technologies to customers; (2) the sale of polymers and reagent chemicals, stabilization products, antigens, substrates and microarray slides to the diagnostics and biomedical research industries; and (3) research and development fees generated on customer projects.

Royalties and licenses fees. The Company licenses technology to third parties and collects royalties. Royalty revenue is generated when a customer sells products incorporating the Company's licensed technologies. Royalty revenue is recognized as licensees' report it to the Company, and payment is typically submitted concurrently with the report. For stand-alone license agreements, up-front license fees are recognized over the term of the related licensing agreement. Minimum royalty fees are recognized in the period earned and collectability is reasonably assured.

Revenue related to a performance milestone is recognized upon the achievement of the milestone, as defined in the respective agreements and provided the following conditions have been met:

- The milestone payment is non-refundable;
- The milestone is achieved, involved a significant degree of risk, and was not reasonably assured at the inception of the arrangement;
- Accomplishment of the milestone involved substantial effort;
- The amount of the milestone payment is commensurate with the related effort and risk; and
- A reasonable amount of time passed between the initial license payment and the first and subsequent milestone payments.

If these conditions have not been met, the milestone payment is deferred and recognized over the term of the agreement.

Product sales. Product sales to third parties are recognized at the time of shipment, provided that an order has been received, the price is fixed or determinable, collectability of the resulting receivable is reasonably assured and returns can be reasonably estimated. The Company's sales terms provide no right of return outside of the standard warranty policy. Payment terms are generally set at 30-45 days.

Research and development. The Company performs third party research and development activities, which are typically provided on a time and materials basis. Generally, revenue for research and development is recorded as performance progresses under the applicable contract.

Arrangements with multiple deliverables. Prior to October 1, 2009, arrangements such as license and development agreements were analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and development, could be separated, or whether they must be accounted for as a single unit of accounting in accordance with accounting guidance. The Company recognized up-front license payments under these agreements over the economic life of the technology licensed. If the fair value of the undelivered performance obligations could be determined, such obligations would then be accounted for separately. If the license was considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations could not be determined, the arrangement would then be accounted for as a single unit of accounting, and the license payments and payments for performance obligations would be recognized as revenue over the estimated period of when the performance obligations are performed, or the economic life of the technology licensed to the customer. When the Company determined that an arrangement should be accounted for as a single unit of accounting, it recognized the related revenue based on either an attribution model where revenue is allocated to each deliverable, or a time-based accounting model.

The Company had one significant multiple element arrangement prior to October 1, 2009 that was accounted for as a single unit of accounting resulting in deferral and recognition of all related cash received for license and research and development activities using a time-based model. This arrangement was terminated during the first quarter of fiscal 2009 as described in Note 1 above.

In October 2009, the Financial Accounting Standards Board (FASB) amended the accounting standards for multiple deliverable revenue arrangements to:

(i) provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and how the consideration should be allocated;

(ii) require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of deliverables if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and

(iii) eliminate the use of the residual method and require an entity to allocate revenue using the relative selling price method.

The Company elected to early adopt this accounting guidance at the beginning of its first quarter of fiscal 2010 on a prospective basis for applicable transactions originating or materially modified after October 1, 2009.

The Company enters into license and development arrangements that may consist of multiple deliverables that could include license to SurModics technology, research and development activities, manufacturing services, and product sales based on the needs of its customers. For example, a customer may enter into an arrangement to obtain a license to SurModics intellectual property which would also include research and development activities, and supply of products manufactured by SurModics. For these services provided, SurModics could receive upfront license fees upon signing of a contract and granting the license, fees for research and development activities as such activities are performed, milestone payments contingent upon advancement of the product through development and clinical stages to successful commercialization, fees for manufacturing services and supply of product, and royalty payments based on customer sales of product incorporating SurModics' technology.

Under the new accounting guidance, the Company is still required to evaluate each deliverable in a multiple element arrangement for separability. The Company is then required to allocate revenue to each separate deliverable using a hierarchy of VSOE, TPE, or ESP. In many instances, the Company is not able to establish VSOE for all deliverables in an arrangement with multiple elements. This may be a result of the Company infrequently selling each element separately or having a limited history with

multiple element arrangements. When VSOE cannot be established, the Company attempts to establish selling price of each element based on TPE. TPE is determined based on competitor prices for similar deliverables when sold separately.

When the Company is unable to establish selling price using VSOE or TPE, the Company uses ESP in its allocation of arrangement consideration. The objective of ESP is to determine the price at which the Company would transact a sale if the product or service were sold on a stand-alone basis. ESP is generally used for highly customized offerings.

The Company determines ESP for undelivered elements by considering multiple factors including, but not limited to, market conditions, competitive landscape and past pricing arrangements with similar features. The determination of ESP is made through consultation with the Company's management, taking into consideration the marketing strategies for each clinical market.

Net sales as reported and pro forma net sales that would have been reported during the three-month period ended December 31, 2009, if the transaction entered into or materially modified after September 30, 2009 was subject to the Company's accounting policies under the previous accounting guidance, is shown in the following table (*in thousands*):

Three-Month Period Ended December 31, 2009	As Reported	Pro Forma Basis as if the Previous Accounting Guidance Were in Effect
Total multiple element arrangement revenue	$1,022	$56

The impact to total revenue during the three-month period ended December 31, 2009 associated with adoption of the new accounting guidance was primarily related to research and development services performed during the quarter. The Company's accounting policies under the previous accounting guidance would have resulted in partial recognition of the research and development revenue in the current period with the remainder deferred and recognized over the economic life of the technology. Under the new accounting guidance the Company is recognizing research and development revenue as the activities are being performed.

In terms of timing and pattern of revenue recognition, the new accounting guidance for revenue recognition is expected to have a significant effect on total revenue from contracts whose multiple elements include license fees, research and development activities, product sales, and other identified deliverables. Specifically, the Company expects that it will be able to better match revenue recognition as the activities are performed. The Company expects that this new accounting guidance will better align the economics of an arrangement and the associated accounting.

Other accounting areas

In April 2008, the FASB issued authoritative accounting guidance which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of intangible assets under goodwill and other intangible asset accounting. The authoritative guidance is intended to improve the consistency between the useful life of a recognized intangible asset under goodwill and intangible asset accounting and the period of the expected cash flows used to measure the fair value of the asset under business combination accounting and other GAAP. The authoritative guidance is effective for the Company in fiscal 2010, with early adoption prohibited. The adoption of the authoritative guidance did not have a material impact on the Company's consolidated financial statements.

In December 2007, the FASB issued authoritative accounting guidance which establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in an acquiree, including the recognition and measurement of goodwill acquired in a business combination. The authoritative guidance was adopted effective October 1, 2009, and will impact recognition and measurement of future business combinations.

In September 2006, the FASB issued authoritative accounting guidance associated with fair value measurements. This guidance defines fair value, establishes a consistent framework for measuring fair value, gives guidance regarding methods used for measuring fair value and expands disclosures about fair value measurements. These provisions were implemented in fiscal 2009. See Note 3 for additional information regarding fair value measurements. However, in February 2008, the FASB issued guidance which delayed the effective date from fiscal 2009 to fiscal 2010 for all nonfinancial assets and liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The adoption of the authoritative guidance did not have any impact on the Company's consolidated financial statements.

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

(3) Fair Value Measurements

Effective October 1, 2008, the Company adopted the new accounting guidance on fair value measurements. The new guidance 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's Level 1 asset consists of its investment in OctoPlus, N.V. (see Note 7 for further information). The fair market value of this investment is based on the quoted price of OctoPlus shares traded on the Amsterdam Stock Exchange.

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 consist of money market funds, U.S. Treasury securities, corporate bonds, municipal bonds, U.S. agency securities, agency and municipal securities, certain asset-backed securities and mortgage-backed securities. Fair market values for these assets are based on quoted vendor prices and broker pricing where all significant inputs are observable.

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.

The Company's Level 3 assets include other U.S. government agency securities and a mortgage-backed security. The fair market values of these investments were determined by broker pricing where not all significant inputs were observable.

In valuing assets and liabilities, the Company is required to maximize the use of quoted market prices and minimize the use of unobservable inputs. The Company did not significantly change our valuation techniques from prior periods.

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 financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2009 *(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 December 31, 2009
Assets:				
Cash equivalents	$ —	$ 9,426	$ —	$ 9,426
Short-term investments	—	7,122	—	7,122
Long-term investments	—	26,959	1,077	28,036
Other assets	2,997	—	—	2,997
Total assets measured at fair value	$ 2,997	$ 43,507	$ 1,077	$ 47,581

Short-term and long-term investments disclosed in the condensed consolidated balance sheets include held-to-maturity investments totaling $5.2 million as of December 31, 2009. Held-to-maturity investments are carried at an amortized cost.

Changes in Level 3 Instruments Measured at Fair Value on a Recurring Basis

The following table is a reconciliation of financial assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) *(in thousands)*:

	Three Months Ended December 31, 2009
Balance, beginning of period	$ 1,203
Total realized and unrealized gains:	
Included in other comprehensive income	(2)
Purchases, issuances and settlements, net	(95)
Transfer in (out) of Level 3	(29)
Balance, end of period	$ 1,077

As of December 31, 2009, marketable securities measured at fair value using Level 3 inputs was comprised of $1.0 million of U.S. government agency securities and a $0.1 million mortgage-backed security within the Company's available-for-sale investment portfolio. These securities were measured using observable market data and Level 3 inputs as a result of the lack of market activity and liquidity. The fair value of these securities was based on the Company's assessment of the underlying collateral and the creditworthiness of the issuer of the securities.

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

The Company's investments in non-marketable securities of private companies are accounted for using the cost or equity method. These investments as well as held-to-maturity securities are measured at fair value on a non-recurring basis when they are deemed to be other-than-temporarily impaired. In determining whether a decline in value of non-marketable equity investments in private companies has occurred and is other-than-temporary, an assessment is made by considering available evidence, including the general market conditions in the investee's industry, the investee's product development status and subsequent rounds of financing and the related valuation and/or the Company's participation in such financings. The Company also assesses the investee's ability to meet business milestones and the financial condition and near-term prospects of the individual investee, including the rate at which the investee is using its cash and the investee's need for possible additional funding at a lower valuation. The valuation methodology for determining the decline in value of non-marketable equity securities is based on inputs that require management judgment and are Level 3 inputs.

(4) Investments

Investments consist principally of U.S. government and government agency obligations and mortgage-backed securities and are classified as available-for-sale or held-to-maturity at December 31 and September 30, 2009. Available-for-sale investments are reported at fair value with unrealized gains and losses net of tax excluded from operations and reported as a separate component of stockholders' equity, except for other-than-temporary impairments, which are reported as a charge to current operations. 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 income (loss). This adjustment results in a new cost basis for the investment. Investments which management has the intent and ability to hold to maturity are classified as held-to-maturity and reported at amortized cost. If there is an other-than-temporary impairment in the fair value of any individual security classified as held-to-maturity, the Company will write down the security to fair value with a corresponding adjustment to other income (loss). Interest on debt securities, including amortization of premiums and accretion of discounts, is included in other income (loss). Realized gains and losses from the sales of debt securities, which are included in other income (loss), are determined using the specific identification method.

The original cost, unrealized holding gains and losses, and fair value of available-for-sale investments as of December 31, 2009 and September 30, 2009 were as follows (*in thousands*):

	December 31, 2009			
	Original Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government obligations	$ 16,041	$ 214	$ (46)	$ 16,209
Mortgage-backed securities	6,991	159	(85)	7,065
Municipal bonds	5,830	176	(4)	6,002
Asset-backed securities	1,944	44	(116)	1,872
Corporate bonds	4,008	3	(1)	4,010
Total	$ 34,814	$ 596	$ (252)	$ 35,158

	September 30, 2009			
	Original Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government obligations	$ 10,837	$ 253	$ —	$ 11,090
Mortgage-backed securities	7,938	177	(106)	8,009
Municipal bonds	7,210	232	—	7,442
Asset-backed securities	2,334	65	(143)	2,256
Corporate bonds	1,181	3	—	1,184
Total	$ 29,500	$ 730	$ (249)	$ 29,981

The original cost and fair value of investments by contractual maturity at December 31, 2009 were as follows (*in thousands*):

	Amortized Cost	Fair Value
Debt securities due within:		
One year	$ 7,078	$ 7,122
One to five years	20,136	20,476
Five years or more	7,600	7,560
Total	$ 34,814	$ 35,158

The following table summarizes sales of available-for-sale securities for the three-month period ended December 31, 2009 (*in thousands*):

Proceeds from sales	$2,970
Gross realized gains	$ —
Gross realized losses	$ —

At December 31, 2009, the amortized cost and fair market value of held-to-maturity debt securities was $5.2 million and $5.4 million, respectively. Investments in securities designated as held-to-maturity consist of tax-exempt municipal bonds and have maturity dates ranging between one and three years from December 31, 2009. At September 30, 2009, the amortized cost and fair market value of held-to-maturity debt securities were $6.3 million and $6.4 million, respectively. A held-to-maturity security with an amortized cost of $1.0 million matured in the three-month period ended December 31, 2009.

(5) Acquisitions

PR Pharmaceuticals, Inc. On November 4, 2008, the Company's SurModics Pharmaceuticals, Inc. subsidiary entered into an asset purchase agreement with PR Pharmaceuticals, Inc. ("PR Pharma") whereby it acquired certain contracts and assets of PR Pharma for $5.6 million consisting of $2.9 million in cash on the closing date, additional consideration of $2.4 million upon successful achievement of specified milestones and $0.3 million in transaction costs. $3.4 million of the total consideration was paid in the three-month period ended December 31, 2008. PR Pharma is eligible to receive up to an additional $3.6 million in cash upon the successful achievement of milestones for contract signing and invoicing, successful patent issuances and product development. Management believes this acquisition strengthens the Company's portfolio of drug delivery technologies for the pharmaceutical and biotechnology industries. As part of the acquisition, the Company recognized fair value associated with in-process research and development

(IPR&D) of $3.2 million. The IPR&D was expensed on the date of acquisition and relates to polymer-based drug delivery systems. The value assigned to IPR&D is related to projects for which the related products have not achieved commercial feasibility and have no future alternative use. The amount of purchase price allocated to IPR&D was based on estimating the future cash flows of each project and discounting the net cash flows back to their present values. The discount rate used was determined at the time of acquisition in accordance with accepted valuation methods. These methodologies include consideration of the risk of the project not achieving commercial feasibility. The research efforts ranged from 5% to 50% complete at the date of acquisition. The Company used the Relief from Royalty valuation method to assess the fair value of the projects with a risk-adjusted discount rate of 25%. The Company determined the method was appropriate based on the nature of the projects and future cash flow streams. The research and development work performed is billed to customers, in most cases, using standard commercial billing rates which include a reasonable markup. Accordingly, the Company has no fixed cost obligations to carry projects forward. There have been no significant changes to the development plans for the acquired incomplete projects. Significant net cash inflows would commence with the commercial launch of customer products that are covered by the intellectual property rights and related agreements acquired from PR Pharma.

(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. Inventories consisted of the following components *(in thousands)*:

	December 31, 2009	September 30, 2009
Raw materials	$ 1,416	$ 1,287
Finished products	2,027	2,043
Total	$ 3,443	$ 3,330

(7) Other Assets

Other assets consist principally of strategic investments. The Company accounts for its strategic investments under the cost method. The Company accounts for its investment in OctoPlus N.V. common stock as an available-for-sale investment rather than a cost method investment following an initial public offering of OctoPlus N.V. common stock in October 2006. Available-for-sale investments are reported at fair value with unrealized gains and losses reported as a separate component of stockholders' equity, except for other-than-temporary impairments, which are reported as a charge to current operations, recorded in the other income (loss) section of the condensed consolidated statements of income. The cost basis in the Company's investment in OctoPlus N.V. was adjusted to $1.7 million in fiscal 2008 based on a significant decline in the stock price of OctoPlus N.V. that was determined to be an other-than-temporary impairment.

The Company has made equity investments in Paragon Intellectual Properties, LLC ("Paragon") and a Paragon subsidiary, Apollo Therapeutics, LLC ("Apollo"). In October 2008, Paragon, announced that it had restructured, along with its subsidiaries, including Apollo, moving from a limited liability company with seven subsidiaries to a single C-corporation named Nexeon MedSystems, Inc. ("Nexeon"). The Company accounted for the investments in Paragon and Apollo under the equity method in the first quarter of fiscal 2009, as both entities reported results to us on a one-quarter lag. Commencing in the second quarter of fiscal 2009, the Company accounted for the investment in Nexeon under the cost method as the Company's ownership level is less than 20%. The Company made an additional investment of $0.5 million in Nexeon in fiscal 2009.

In August 2009, the Company invested $2.0 million in a medical technology company. The Company's investment is accounted for under the cost method, as the Company's ownership interest is less than 20%. This investment is included in the category titled "Other" in the table below.

Other assets consisted of the following components *(in thousands):*

	December 31, 2009	September 30, 2009
Investment in OctoPlus N.V.	$ 2,997	$ 3,700
Investment in Nexeon MedSystems	5,651	5,651
Investment in ThermopeutiX	1,185	1,185
Investment in Novocell	559	559
Other	2,162	2,162
Other assets	$ 12,554	$ 13,257

The Company recognized revenue of $0.1 million and $0.4 million for the three-month periods ended December 31, 2009 and 2008, respectively, from activity with companies in which it had a strategic investment.

(8) Intangible Assets

Intangible assets consist principally of acquired patents and technology, customer relationships, licenses, and trademarks. The Company recorded amortization expense of $0.4 million and $0.8 million for the three-month periods ended December 31, 2009 and 2008, respectively.

Intangible assets consisted of the following *(in thousands):*

	Useful life (in years)	December 31, 2009	September 30, 2009
Customer list	9 — 11	$ 8,657	$ 8,657
Core technology	8 — 18	8,330	8,330
Patents and other	2 — 20	3,076	3,076
Trademarks		600	600
Less accumulated amortization of intangible assets		(3,612)	(3,205)
Intangible assets, net		$ 17,051	$ 17,458

Based on the intangible assets in service as of December 31, 2009, estimated amortization expense for each of the next five fiscal years is as follows (*in thousands*):

Remainder of 2010	$1,220
2011	1,604
2012	1,602
2013	1,602
2014	1,602
2015	1,591

Future amortization amounts presented above are estimates. Actual future amortization expense may be different, as a result of future acquisitions, impairments, changes in amortization periods, or other factors.

(9) Goodwill

Goodwill represents the excess of the cost of the acquired entities over the fair value assigned to the assets purchased and liabilities assumed in connection with the Company's acquisitions. 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.

In the first quarter of fiscal 2010 a milestone was achieved associated with the July 2007 acquisition of SurModics Pharmaceuticals, Inc. and $0.8 million of additional purchase price was recorded as an increase to goodwill.

(10) Revolving Credit Facility

In February 2009, the Company entered into a two-year $25.0 million unsecured revolving credit facility. Borrowings under the credit facility, if any, will bear interest at a benchmark rate plus an applicable margin based upon the Company's funded debt to EBITDA ratio. In connection with the credit facility, the Company is required to maintain certain financial and nonfinancial covenants. As of December 31, 2009, the Company had no debt outstanding under this credit facility and was in compliance with all covenants.

(11) Stock-based Compensation

The Company has stock-based compensation plans under which it grants stock options and restricted stock awards. 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 as follows *(in thousands):*

	Three months ended December 31,	
	2009	2008
Product costs	$ 35	$ 24
Customer research and development	153	165
Other research and development	615	744
Selling, general and administrative	732	978
Total	$ 1,535	$ 1,911

As of December 31, 2009, approximately $10.3 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.1 years. The unrecognized compensation costs include $3.5 million associated with performance share awards that are currently not anticipated to be fully expensed because the performance conditions are not expected to be met.

Stock Option Plans

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 value of stock options granted during the three-month periods ended December 31, 2009 and 2008 was $8.40 and $8.63, respectively. The assumptions used as inputs in the model were as follows:

	Three months ended December 31,	
	2009	2008
Risk-free interest rates	1.8%	2.2%
Expected life (years)	4.8	4.8
Expected volatility	41.4%	37.9%
Dividend yield	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 award. The expected life of options granted is determined based on the Company's experience. Expected volatility is based on the Company's stock price movement over a period approximating the expected term. Based on management's judgment, dividend rates are expected to be zero for the expected life of the options. The Company also estimates forfeitures of options granted, which are based on historical experience.

The Company's Incentive Stock Options ("ISO") are granted at a price of at least 100% of the fair market value of the common stock of the Company on the date of the grant or 110% with respect to optionees who own more than 10% of the total combined voting power of all classes of stock. ISOs expire in seven years or upon termination of employment and are exercisable at a rate of 20% per year commencing one year after the date of grant. Nonqualified stock options are granted at fair market value on the date of grant. Nonqualified stock options expire in 7 to 10 years or upon termination of employment or service as a Board member. Nonqualified stock options granted prior to May 2008 generally become exercisable with respect to 20% of the shares on each of the first five anniversaries following the grant date such that the entire option is fully vested five years after date of grant, and nonqualified stock options granted subsequent to May 2008 generally become exercisable with respect to 25% on each of the first four anniversaries following the grant date such that the entire option is fully vested four years after the grant date.

The total pre-tax intrinsic value of options exercised during the three-month period ended December 31, 2009 was not meaningful as our stock price of $22.60 on December 31, 2009 was below the value of options exercised earlier in the quarter. The total pre-tax intrinsic value of options exercised during the three-month period ended December 31, 2008 was $5,000. The intrinsic value represents the difference between the exercise price and the fair market value of the Company's common stock on the last day of the respective fiscal period end.

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 will be released to the key employees if they are employed by the Company at the end of the vesting period. The stock-based compensation table above includes Restricted Stock expenses of $279,000, and $661,000 during three-month periods ended December 31, 2009 and 2008, respectively.

Performance Share Awards

The Company has entered into performance share agreements with certain key employees, covering the issuance of common stock ("Performance Shares"). The Performance Shares vest upon the achievement of all or a portion of certain performance objectives, which must be achieved during the performance period. Compensation is recognized in each period based on management's best estimate of the achievement level of the grants' specified performance objectives and the resulting vesting amounts. The Company recognized an expense of $32,000 related to Performance Shares for the three-month period ended December 31, 2009. For the three-month period ended December 31, 2008, the Company reversed expenses related to Performance Shares previously recognized of $38,000. The stock-based compensation table above includes the Performance Shares expenses or expense reversal.

1999 Employee Stock Purchase Plan

Under the 1999 Employee Stock Purchase Plan ("Stock Purchase Plan"), the Company is authorized to issue up to 200,000 shares of common stock. All full-time and part-time 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 December 31, 2009 and 2008, there were $516,000 and $561,000 of employee contributions, respectively, included in accrued liabilities in the accompanying condensed consolidated balance sheets. Stock compensation expense recognized related to the Stock Purchase Plan for the three-month periods ended December 31, 2009 and 2008 totaled $72,000 and $58,000, respectively. The stock-based compensation table above includes the Stock Purchase Plan expenses.

(12) Restructuring Charges

In November 2008, the Company announced a functional reorganization to better serve its customers and improve its operating performance. As a result of the reorganization, the Company eliminated 15 positions, or approximately 5% of the Company's workforce. These employee terminations occurred across various functions and the reorganization plan was completed by the end of the first quarter of fiscal 2009. The Company also vacated a leased facility in Eden Prairie, Minnesota, consolidating into its owned office and research facility also in Eden Prairie, as part of the reorganization plan.

The Company recorded total restructuring charges of approximately $1.8 million in connection with the reorganization. These pre-tax charges consisted of $0.5 million of severance pay and benefits expenses and $1.3 million of facility-related costs. The restructuring was expected to result in approximately $2.2 million in annualized cost savings. Cash payments totaled $0.9 million as of December 31, 2009 leaving a balance of $0.9 million. The balance is expected to be paid within the next 12 months and the liability is recorded as a current liability within other accrued liabilities on the condensed consolidated balance sheets.

(13) Comprehensive Income

The components of comprehensive income are as follows (*in thousands*):

	Three months ended December 31,	
	2009	2008
Net income	$ 1,917	$ 27,085
Other comprehensive income:		
Unrealized holding gains (losses) on available-for-sale securities arising during the period	(512)	534
Less reclassification adjustment for realized gains included in net income, net of tax	—	(201)
Other comprehensive income (loss)	(512)	333
Comprehensive income	$ 1,405	$ 27,418

(14) Income Taxes

The Company recorded income tax provisions of $1.1 million and $16.2 million for the three-month periods ended December 31, 2009 and 2008, respectively, representing effective tax rates of 37.5% and 37.4%, respectively. The difference between the U.S. federal statutory tax rate of 35% and the Company's effective tax rate reflects state taxes.

The October 2008 adoption of the Emergency Economic Stabilization Act of 2008, retroactively extended the term of the federal tax credit for research activities through calendar 2009. The tax credit for research activities for the three-month period ended December 31, 2009 was $39,000. During the three-month period ended December 31, 2008, the Company recognized a discrete benefit of approximately $120,000 related to the nine-month period ended September 30, 2008.

The total amount of unrecognized tax benefits including interest and penalties that, if recognized, would affect the effective tax rate as of December 31, 2009 and September 30, 2009, respectively, are $2.2 million and $2.0 million. Currently, the Company does not expect the liability for unrecognized tax benefits to change significantly in the next twelve months. Interest and penalties related to the unrecognized tax benefits are recorded in income tax expense.

The Company files income tax returns, including returns for its subsidiaries, in the United States (U.S.) federal jurisdiction and in various state jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. U.S. tax returns for fiscal years ended September 30, 2006, 2007, 2008 and 2009 remain subject to examination by federal tax authorities. Tax returns for state and local jurisdictions for fiscal years ended September 30, 2003 through 2009 remain subject to examination by state and local tax authorities.

(15) Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance.

The Company manages its business on the basis of the markets noted in the table below, which are comprised of the Company's four business units. "Therapeutic" contains: (1) the Cardiovascular business unit, which provides drug delivery and surface modification technologies to customers in the cardiovascular market; (2) the Ophthalmology business unit, which is currently focused on the advancement of treatments for eye diseases, such as age-related macular degeneration (AMD) and diabetic macular edema (DME), two of the leading causes of blindness; and (3) the SurModics Pharmaceuticals business unit, which provides proprietary polymer-based drug delivery technologies to companies developing improved pharmaceutical products in cardiovascular, ophthalmology and other clinical markets. Revenue results in the Therapeutic segment are presented below by the clinical market areas in which the Company's customers participate (Cardiovascular, Ophthalmology and Other Markets). "Diagnostic" contains the In Vitro Technologies business unit, which includes the Company's microarray slide technologies, stabilization products, antigens and substrates for immunoassay diagnostics tests, and its *in vitro* diagnostic format technology.

The Company's results are aggregated into one reportable segment, as each business unit has similar economic characteristics, technology, manufacturing processes, customers, regulatory environments, and shared infrastructures. The Company manages its expenses on a company-wide basis, as many costs and activities are shared among the business units. The focus of the business units is providing solutions to customers and maximizing financial performance over the long term. The table below presents revenue from the markets, with Therapeutic broken out further by focus area, for the three-month periods in fiscal 2010 and 2009, (*in thousands*):

	Three months ended December 31,	
	2010	2009
Therapeutic		
Cardiovascular	$ 10,714	$ 10,403
Ophthalmology	2,497	44,772
Other Markets	1,884	3,772
Total Therapeutic	15,095	58,947
Diagnostic	2,286	4,269
Total revenue	$ 17,381	$ 63,216

(16) Commitments and Contingencies

Litigation. From time to time, the Company has been, and 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 revenues. The Company records a liability in the 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.

InnoRx, Inc. In January 2005, the Company entered into a merger agreement whereby SurModics acquired all of the assets of InnoRx, Inc. ("InnoRx"), an early stage company developing drug delivery devices and therapies for the ophthalmology market. SurModics will be required to issue up to approximately 480,059 additional shares of its common stock to the stockholders of InnoRx upon the successful completion of the remaining development and commercial milestones involving InnoRx technology acquired in the transaction.

BioFX Laboratories, Inc. In August 2007, the Company acquired 100% of the capital stock of BioFX Laboratories, Inc. ("BioFX"), a provider of substrates to the *in vitro* diagnostics industry. The sellers of BioFX are still eligible to receive up to $3.5 million in additional consideration based on specific revenue targets through calendar 2011.

SurModics Pharmaceuticals, Inc. In July 2007, the Company acquired 100% of the capital stock of SurModics Pharmaceuticals, a drug delivery company that provides proprietary polymer-based technologies to companies developing pharmaceutical products. The sellers of SurModics Pharmaceuticals are still eligible to receive up to $16.2 million in additional consideration based on successful achievement of specific milestones through calendar 2011.

Alabama Jobs Commitment. In April 2008, the Company purchased a 286,000 square foot office and warehouse facility to support Current Good Manufacturing Practices manufacturing needs of customers and the anticipated growth of the SurModics Pharmaceuticals business. At the same time, SurModics Pharmaceuticals entered into an agreement with various governmental authorities to obtain financial incentives associated with creation of jobs in Alabama. Some of the governmental agencies have recapture rights in connection with the financial incentives if a specific number of full-time employees is not hired by June 2012, with an extension to June 2013 if circumstances or events occur that are beyond the control of SurModics Pharmaceuticals, Inc. ("SurModics Pharmaceuticals") or could not have been reasonably anticipated by SurModics Pharmaceuticals. As of December 31, 2009, SurModics Pharmaceuticals has received $1.7 million in connection with the agreement, and the Company has recorded the payment in other long-term liabilities.

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

The following discussion and analysis of our financial condition, results of operations and trends for the future should be read together with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this report. Any discussion and analysis regarding trends in our future financial condition and results of operations are forward-looking statements that involve risks, uncertainties and assumptions, as more fully identified in "Forward-Looking Statements." Our actual future financial condition and results of operations may differ materially from those anticipated in the forward-looking statements.

Overview

SurModics is a leading provider of drug delivery and surface modification technologies to the healthcare industry. In November 2008, we announced a change in our organizational structure into four clinically and market focused business units: Cardiovascular, Ophthalmology, SurModics Pharmaceuticals, and In Vitro Technologies. We believe this structure improves the visibility, marketing and adoption of the Company's broad array of technologies within specific markets and helps our customers in the medical device, pharmaceutical and life science industries better solve unmet clinical needs. In addition, a new centralized research and development function (R&D) has been formed to serve the needs of the Company's clinically and market focused business units, other than the SurModics Pharmaceuticals business unit, which continues to maintain certain R&D operations.

The reorganization change resulted in the Company being comprised of new market focused business units. "Therapeutic" contains: (1) the Cardiovascular business unit, which provides drug delivery and surface modification technologies to customers in the cardiovascular market; (2) the Ophthalmology business unit, which is dedicated to the advancement of treatments for eye diseases, such as age-related macular degeneration (AMD) and diabetic macular edema (DME), two of the leading causes of blindness; and (3) the SurModics Pharmaceuticals business unit, which provides proprietary polymer-based drug delivery technologies to companies developing improved pharmaceutical products. Revenue results in Therapeutic are presented by the clinical market areas in which our customers participate (Cardiovascular, Ophthalmology and Other Markets). "Diagnostic" contains the In Vitro Technologies business unit, which includes our microarray slide technologies, our stabilization products, antigens and substrates for immunoassay diagnostic tests, and our *in vitro* diagnostic format technology.

The Company's revenue is derived from three primary sources: (1) royalties and license fees from licensing our proprietary drug delivery and surface modification 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; (2) the sale of polymers and reagent

chemicals, stabilization products, antigens, substrates and microarray slides to the diagnostics and biomedical research industry; and (3) research and 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 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; the value of reagent chemicals and other products sold to customers; and the timing of future acquisitions we complete, if any.

For financial accounting and reporting purposes, we report our results in one reportable segment. We made this determination because each business unit has similar economic characteristics; a significant percentage of our employees provide support services (including research and development) to each business unit; technology and products from each business unit are marketed to the same or similar customers; each business unit uses the same sales and marketing resources; and each business unit operates in the same regulatory environment.

In June 2007, we signed a collaborative research and license agreement with Merck & Co., Inc. ("Merck") to pursue the joint development and commercialization of the I-vation™ sustained drug delivery system with triamcinolone acetonide and other products that combine Merck proprietary drug compounds with the I-vation system for the treatment of serious retinal diseases. Under the terms of our agreement with Merck, we received an up-front license fee of $20 million and had the potential to receive up to an additional $288 million in fees and development milestones associated with the successful product development and attainment of appropriate U.S. and EU regulatory approvals for these new combination products.

In September 2008, Merck gave notice that it was terminating the collaborative research and license agreement, as well as the supply agreement entered into in June 2007, following a strategic review of Merck's business and product development portfolio. The termination was effective December 16, 2008. SurModics recognized revenue previously deferred, totaling $34.8 million, under the accounting treatment required for revenue arrangements with multiple deliverables. In addition, we received and recognized a $9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program in the first quarter of fiscal 2009.

On October 5, 2009, we entered into a License and Development Agreement with F. Hoffmann-La Roche, Ltd. ("Roche") and Genentech, Inc., a wholly owned member of the Roche Group ("Genentech"). Under the terms of the agreement, Roche and Genentech will have an exclusive license to develop and commercialize a sustained drug delivery formulation of Lucentis® (ranibizumab injection) utilizing SurModics' proprietary biodegradable microparticles drug delivery system. We received an up-front licensing fee of $3.5 million and are eligible to receive potential payments of up to approximately $200 million in fees and milestone payments in the event of the successful development and commercialization of multiple products, as well as payment for development work done on these products. Roche and Genentech will have the right to obtain manufacturing services from SurModics. In the event a commercial product is developed, we will also receive royalties on sales of such product.

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 sensitive to result in materially different results under different assumptions and conditions. For a detailed description of our critical accounting policies, see the notes to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended September 30, 2009.

Results of Operations

(Dollars in thousands)	Three Months Ended December 31, 2009	December 31, 2008	Increase (Decrease)	Change %
Revenue:				
Therapeutic				
Cardiovascular	$ 10,714	$ 10,403	$ 311	3%
Ophthalmology	2,497	44,772	(42,275)	(94)%
Other Markets	1,884	3,772	(1,888)	(50)%
Total Therapeutic	15,095	58,947	(43,852)	(74)%
Diagnostic	2,286	4,269	(1,983)	(46)%
Total revenue	$ 17,381	$ 63,216	$ (45,835)	(73)%

Revenue. Revenue during the first quarter of fiscal 2010 was $17.4 million, a decrease of $45.8 million or 73% compared with the first quarter of fiscal 2009. The decreases in Therapeutic and Diagnostic revenue, as detailed in the table above, are further explained in the narrative below.

Therapeutic. Revenue in Therapeutic was $15.1 million in the first quarter of fiscal 2010, a decrease of 74% compared with $58.9 million in the first quarter of fiscal 2009. The decrease in total revenue reflects the recognition of revenue of approximately $34.8 million that had previously been deferred, associated with the Merck collaborative research and license agreement and recognition of a $9 million milestone payment received in the first quarter of fiscal 2009 associated with the termination of the triamcinolone acetonide development program. The collaborative research and license agreement was terminated effective in the first quarter of fiscal 2009. Excluding these significant event-specific items in fiscal 2009, revenue was comparable for both periods. Therapeutic revenue is further characterized by the market-focused areas detailed above.

Cardiovascular derives a substantial amount of revenue from royalties and license fees and product sales attributable to Cordis Corporation, a Johnson & Johnson company, on its CYPHER® Sirolimus-eluting Coronary Stent. The CYPHER® stent incorporates a proprietary SurModics polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions. The CYPHER® stent faces continuing competition from Boston Scientific, Medtronic and Abbott Laboratories. Stents from these companies compete directly with the CYPHER® stent both domestically and internationally. Future royalty and reagent sales revenue could decrease as a result of lower CYPHER® stent sales from ongoing and expected future competition. We anticipate that royalty revenue from the CYPHER® stent may be volatile throughout fiscal 2010 and beyond as the various marketers of drug-eluting stents compete in the marketplace and as other companies enter the marketplace. We also receive a royalty on the Medtronic Endeavor® drug-eluting stent delivery system incorporating our hydrophilic technology, which is sold in the United States and internationally and commenced sales in Japan in May 2009.

Cardiovascular revenue increased $0.3 million, or 3%, in the first quarter of fiscal 2010, compared with the first quarter of fiscal 2009 with the increase principally in royalties and license fees and product sales, offset partially by a decrease in R&D revenue. Our royalty revenue from Cordis decreased as a result of 18% lower CYPHER® stent sales.

Ophthalmology revenue decreased $42.3 million, or 94%, in the first quarter of fiscal 2010, compared with the first quarter of fiscal 2009. The significant decrease relates to the recognition of previously deferred revenue associated with the terminated collaborative research and license agreement with Merck. In September 2008, following a strategic review of Merck's business and product development portfolio, Merck gave notice that it was terminating the collaborative research and license agreement as well as the supply agreement entered into in June 2007. The termination became effective in December 2008. In the first quarter of fiscal 2009, we recognized the revenue previously deferred totaling $34.8 million. In addition, we received and recognized a $9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program.

Ophthalmology revenue, other than the Merck event-specific items in the first quarter of fiscal 2009, increased by approximately $1.5 million, or 151%, principally as a result of higher R&D revenue from activities with Genentech and other customers and royalties and license fees.

Other Markets revenue decreased $1.9 million, or 50%, in the first quarter of fiscal 2010, compared with the first quarter of fiscal 2009. Lower R&D revenue was the main contributor to the decrease. There continues to be select customers that have delayed, slowed or cancelled development projects as a result of various factors including current economic conditions. Other Markets revenue is derived from more than 50 customers.

Diagnostic. Revenue in Diagnostic was $2.3 million in the first quarter of fiscal 2010, a decrease of 46% compared with $4.3 million in the prior-year period. This decrease was attributable to lower royalties and license fees. In past quarters, Diagnostic derived a significant percentage of revenue from Abbott Laboratories. Our diagnostic format patent license agreement with Abbott Laboratories ceased following the expiration of licensed patents, which occurred in December 2008. Product sales increased 4% compared with fiscal 2009 when customer purchases slowed considerably. We expect product sales to increase in the remainder of fiscal 2010.

Product costs. Product costs were $2.0 million in the first quarter of fiscal 2010, compared with $1.5 million in the prior-year period. The $0.5 million increase in product costs principally reflects higher product sales. Overall product margins averaged 57%, compared with 61% reported last year. The decrease in product margins reflects a shift in the mix of products sold.

Customer research and development expenses. Customer research and development ("Customer R&D") expenses were $3.3 million, a decrease of 10% compared with the first quarter of fiscal 2009. The decrease principally reflects the impact of lower R&D revenue, adjusted for Merck. Customer R&D margins were 9%, compared with 68% in the first quarter of fiscal 2009. The margins were 32% for the first quarter of fiscal 2009, after adjusting for Merck deferred revenue recognition. The decrease in the first quarter of fiscal 2010 margins reflects increased fixed overhead costs attributable to our Alabama research and development operations.

Other research and development expenses. Other research and development ("Other R&D") expenses were $4.7 million for the first quarter of fiscal 2010, a decrease of 16% compared with the first quarter of fiscal 2009. The decrease principally reflects lower labor costs as a result of a decrease in our R&D headcount as well as lower overhead costs being allocated to Other R&D.

Selling, general and administrative expenses. Selling, general and administrative expenses were $4.6 million for the three months ended December 31, 2009, which were comparable to expenses of $4.7 million in the prior-year period. Our headcount remained constant in both periods. Lower incentive and stock-based compensation costs were offset by higher facility expenses in the first quarter of fiscal 2010.

Purchased in-process research and development. In November 2008, we acquired certain assets comprised of intellectual property and collaborative programs from PR Pharmaceuticals, Inc. The fair value of $3.2 million associated with the in-process research and development intangible asset was determined by management and recognized as an expense in the three-months ended December 31, 2008.

Restructuring charges. In November 2008, we announced a functional reorganization to better serve our customers and improve our operating performance. As a result of the reorganization, we eliminated 15 positions, or approximately 5% of our workforce. These employee terminations occurred across various functions, and the reorganization plan was completed by the end of the first quarter of fiscal 2009. The reorganization also resulted in SurModics vacating a leased office facility in Eden Prairie, Minnesota, and consolidating into our owned office and research facility also in Eden Prairie.

We recorded total restructuring charges of approximately $1.8 million in connection with the reorganization. These pre-tax charges consisted of $0.5 million of severance pay and benefits expenses and $1.3 million of facility-related costs. Costs totaling $0.9 million have been paid, and we anticipate paying the remaining $0.9 million within the next twelve months.

Other income, net. Other income was $0.3 million in the first quarter of fiscal 2010, compared with $0.6 million in the first quarter of fiscal 2010. Income from investments was $0.3 million, compared with $0.7 million in the prior-year period. The decrease primarily reflects lower investment balances. In the first quarter of fiscal 2009, our *pro rata* net loss on our equity method investments was partially offset by $0.3 million of gains from our investment portfolio.

Income tax expense. The income tax provision was $1.1 million in the first quarter of fiscal 2010, compared with $16.2 million in the prior-year period. The effective tax rate was 37.5%, compared with 37.4% in the prior-year period.

Liquidity and Capital Resources

As of December 31, 2009, the Company had working capital of $32.2 million, of which $19.3 million consisted of cash, cash equivalents and short-term investments. Working capital increased $3.2 million from the September 30, 2009 level, driven principally by higher prepaid balances, income taxes receivable and lower accounts payable balances. Our cash, cash equivalents and short-term and long-term investments totaled $51.5 million at December 31, 2009, an increase of $3.6 million from $47.9 million at September 30, 2009. The Company's investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. The Company's policy requires that no more than 5% of investments be held in any one credit 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 meeting or exceeding a benchmark (Merrill Lynch 1-3 Year Government-Corporate Index) total rate of return. Management plans to continue to direct its investment advisors to manage the Company's investments primarily for the safety of principal for the foreseeable future as it assesses other investment opportunities and uses of its investments.

We had cash flows from operating activities of approximately $8.3 million in the first quarter of fiscal 2010, compared with $17.4 million in the first three months of fiscal 2009. The decrease compared with prior-year results primarily reflects receipt of a $9 million contract termination payment from Merck in the first three months of fiscal 2009.

In November 2007, our Board of Directors authorized the repurchase of $35.0 million of the Company's common stock in open-market transactions, private transactions, tender offers, or other transactions. The repurchase authorization does not have a fixed expiration date. No shares were repurchased during the three months ended December 31, 2009. Under the current authorization, the Company has $7.3 million remaining available for share repurchases.

As of December 31, 2009, we had no debt under our $25 million unsecured revolving credit facility. As of December 31, 2009, the Company was in compliance with all covenants.

We do not have any other credit agreements and believe that our existing cash, cash equivalents and investments, together with cash flow from operations, will provide liquidity sufficient to meet the below stated needs and fund our operations 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 the Company's ability to access capital in a timely manner and on attractive terms, if at all. Our anticipated liquidity needs for the remainder of fiscal 2010 include, but are not limited to, the following: capital expenditures related to the Alabama cGMP facility in the range of $3 million to $4 million; general capital expenditures in the range of $3 million to $5 million; contingent consideration payments, if any, related to our acquisitions of SurModics Pharmaceuticals, BioFX Laboratories, Inc. as well as the purchase of certain assets from PR Pharmaceuticals, Inc.; and any amounts associated with the repurchase of common stock under the authorization discussed above.

Off-Balance Sheet Arrangements

As of December 31, 2009, the Company did not have any off-balance sheet arrangements with any unconsolidated entities.

Forward-Looking Statements

Certain statements contained in this report, or in other reports of the Company and other written and oral statements made from time to time by the Company, do not relate strictly to historical or current facts. As such, they are considered "forward-looking statements" that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements can be identified by the use of terminology such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar words or expressions. Any statement that is not a historical fact, including estimates, projections, future trends and the outcome of events that have not yet occurred, are forward-looking statements. The Company's forward-looking statements generally relate to its growth strategy, financial prospects, product development programs, sales efforts, and the impact of the Cordis and Genentech agreements, as well as other significant customer agreements. You should carefully consider forward-looking statements and understand that such statements involve a variety of risks and uncertainties, known and unknown, and may be affected by inaccurate assumptions. Consequently, no forward-looking statement can be guaranteed and actual results may vary materially. The Company undertakes no obligation to update any forward-looking statement.

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

- the Company's reliance on a small number of significant customers, 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, the outcome of which could adversely affect the royalty revenue we derive based on the sales of licensed products;
- general economic conditions we are subject to which are beyond our control, including the impact of recession, business investment and changes in consumer confidence;
- frequent intellectual property litigation in the medical device and pharmaceutical industries that may directly or indirectly adversely affect our customers' ability to market their products incorporating our technologies;
- our ability to protect our own intellectual property;
- healthcare reform efforts, including reduced reimbursement rates and new taxes on medical devices and pharmaceutical products that may adversely affect our customers' ability to cost-effectively market and sell devices incorporating our technologies or affect the prices they receive for such products thereby affecting the Company's revenue;
- the Company's ability to attract new licensees and to enter into agreements for additional product applications with existing licensees, the willingness of potential licensees to sign license agreements under the terms offered by the Company, changes in the development and marketing priorities of our licensees and development partners and the Company's ability to maintain satisfactory relationships with its licensees;
- the Company's ability to increase the number of market segments and applications that use its technologies through its sales and marketing and research and development efforts;
- the decrease in available financing for the Company's customers and for new ventures which could potentially become customers can reduce the Company's potential opportunities;
- market acceptance of products sold by customers incorporating our technologies and the timing of new product introductions by licensees;
- market acceptance of products sold by customers' competitors and the timing and pricing of new product introductions by customers' competitors;

- 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 FDA marketing clearances or approvals, which may result in lost market opportunities or postpone or preclude product commercialization by licensees;
- efficacy or safety concerns with respect to products marketed by us and our licensees, whether scientifically justified or not, that may lead to product recalls, withdrawals or declining sales;
- the ability to secure raw materials for reagents the Company sells;
- the Company's ability to successfully manage clinical trials and related foreign and domestic regulatory processes for the I-vation™ intravitreal implant or other products under development by the Company, whether delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances or approvals postpone or preclude product commercialization of the intravitreal implant or other products, and whether the intravitreal implant and any other products remain viable commercial prospects;
- product liability claims against which we are not indemnified or that are not covered by insurance;
- the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors;
- the trend of consolidation in the medical device and pharmaceutical industries, resulting in more significant, complex and long term contracts than in the past and potentially greater pricing pressures;
- the Company's ability to identify suitable businesses to acquire or with whom to form strategic relationships to expand its technology development and commercialization, its ability to successfully integrate the operations of companies it may acquire from time to time and its ability to create synergies from acquisitions and other strategic relationships;
- the Company's ability to successfully internally perform certain product development activities and governmental and regulatory compliance activities which the Company has not previously undertaken in any significant manner;
- acts of God or terrorism which impact the Company's personnel or facilities; and
- other factors described below in "Risk Factors" and other sections of SurModics' Annual Report on Form 10-K, which you are encouraged to read carefully.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company's investment policy requires the Company to invest in high credit quality issuers and limits the amount of credit exposure to any one issuer. The Company's investments principally consist of U.S. government and government agency obligations and investment-grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. Because of the credit criteria of the Company's investment policies, the primary market risk associated with these investments is interest rate risk. The Company does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. A one percentage point increase in interest rates would result in an approximate $0.7 million decrease in the fair value of the Company's available-for-sale and held-to-maturity securities as of December 31, 2009, but no material impact on the results of operations or cash flows. 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.

Although we conduct business in foreign countries, all sales transactions are denominated in U.S. dollars. Accordingly, we do not expect to be subject to material foreign currency risk with respect to future costs or cash flows from our foreign sales. 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

As of the end of the period covered by this report, the Company conducted an evaluation under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer regarding

the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934 (the "Exchange Act"). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are 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 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 principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls

There was no change in the Company's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

There have been no material developments in the legal proceedings previously disclosed in the Company's Form 10-K for the fiscal year ended September 30, 2009.

Item 1A. Risk Factors.

There have been no material changes from risk factors as previously disclosed in the Company's Form 10-K for the fiscal year ended September 30, 2009 in response to Item 1A to Part I of Form 10-K.

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 December 31, 2009, 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	(a) Total Number of Shares Purchased(1)	(b) Average Price Paid Per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs(2)
10/01/09 — 10/31/09	0	NA	0	$ 7,333,728
11/01/09 — 11/30/09	13,080	$ 23.38	0	$ 7,333,728
12/01/09 — 12/31/09	0	NA	0	$ 7,333,728
Total	13,080	$ 23.38	0	$ 7,333,728

(1) The purchases in this column were repurchased by the Company to satisfy tax withholding obligations in connection with so-called "stock swap exercises" related to the vesting of restricted stock awards.

(2) On November 15, 2007, our Board of Directors announced the authorization of the repurchase of $35 million of outstanding common stock. As of December 31, 2009, we have repurchased a cumulative 921,648 shares at an average price of $30.02 per share. Under the current authorization the Company has $7.3 million available for authorized share repurchases as of December 31, 2009. The repurchase authorization does not have an expiration date.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit	Description
3.1	Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-QSB for the quarter ended December 31, 1999, SEC File No. 0-23837
3.2*	Restated Bylaws of SurModics, Inc., as amended November 30, 2009
10.1+	License and Development Agreement between Genentech, Inc., F. Hoffmann-La Roche, Ltd., and SurModics, Inc., dated October 5, 2009

Exhibit	Description
10.2+	Master Services Agreement by and between Genentech, Inc., F. Hoffmann-La Roche, Ltd. and SurModics, Inc., dated October 5, 2009
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002

+ Confidential treatment requested as to portions of the exhibit. Confidential portions omitted and provided separately to the Securities and Exchange Commission.

* Filed herewith.

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.

February 5, 2010

SurModics, Inc.

By: /s/ Philip D. Ankeny
Philip D. Ankeny
Senior Vice President and Chief Financial Officer

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
EXHIBIT INDEX TO FORM 10-Q
For the Quarter Ended December 31, 2009
SURMODICS, INC.

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* Filed herewith.

Exhibit 3.2

RESTATED BYLAWS

OF

SURMODICS, INC.

As amended November 30, 2009

ARTICLE 1.

OFFICES

1.1) Offices. The corporation may have offices at such places within or without the State of Minnesota as the Board of Directors shall from time to time determine or the business of the corporation requires.

ARTICLE 2.

MEETINGS OF SHAREHOLDERS

2.1) Annual Meeting. The annual meeting of the shareholders of the corporation entitled to vote shall be held at the principal office of the corporation or at such other place, within or without the State of Minnesota, as is designated by the Board of Directors at such time on such day of each year as shall be determined by the Board of Directors or by the Chief Executive Officer.

2.2) Special Meetings. Special meetings of the shareholders entitled to vote shall be called by the Secretary at any time upon request of the Chairman of the Board, the Chief Executive Officer, the Chief Financial Officer or two or more members of the Board of Directors, or upon request by shareholders holding ten percent or more of the voting power of all shares entitled to vote (except that a special meeting for the purpose of considering any action to directly or indirectly effect a business combination, including any action to change or otherwise affect the composition of the Board of Directors for that purpose, must be called by shareholders holding not less than 25 percent of the voting power of all shares entitled to vote).

2.3) Notice of Meetings. There shall be given to each shareholder entitled to vote, at his address as shown by the books of the corporation, a notice setting out the place, date and hour of the annual meeting or any special meeting, which notice shall be given at least five days prior to the date of the meeting; provided, that (i) notice of a meeting at which a plan of merger or exchange is to be considered shall be delivered to all shareholders of record, whether or not entitled to vote, at least 14 days prior thereto, (ii) notice of a meeting at which a proposal to dispose of all, or substantially all, of the property and assets of the corporation is to be considered shall be delivered to all shareholders of record, whether or not entitled to vote, at least

ten days prior thereto, and (iii) notice of a meeting at which a proposal to dissolve the corporation or to amend the Articles of Incorporation is to be considered shall be delivered to all shareholders of record, whether or not entitled to vote, at least ten days prior thereto. Notice of any special meeting shall state the purpose or purposes of the proposed meeting. Notice may be given to a shareholder by means of electronic communication if the requirements of Minnesota Statutes Section 302A.436, Subdivision 5, as amended from time to time, are met. Notice to a shareholder is also effectively given if the notice is addressed to the shareholder or a group of shareholders in a manner permitted by the rules and regulations under the Securities Exchange Act of 1934, so long as the corporation has first received the written or implied consent required by those rules and regulations. Attendance at a meeting by any shareholder, without objection in writing by him, shall constitute his waiver of notice of the meeting.

2.4) Quorum and Adjourned Meetings. The holders of a majority of all shares outstanding and entitled to vote, represented either in person or by proxy, shall constitute a quorum for the transaction of business at any annual or special meeting of the shareholders. In case a quorum is not present at any meeting, those present shall have the power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until the requisite number of voting shares shall be represented. At such adjourned meetings at which the required amount of voting shares shall be represented, any business may be transacted which might have been transacted at the original meeting.

2.5) Voting. At each meeting of the shareholders, every shareholder having the right to vote shall be entitled to vote in person or by proxy duly appointed by such shareholder. Each shareholder shall have one vote for each share having voting power standing in his name on the books of the corporation. All elections shall be determined and all questions decided by a majority vote of the number of shares entitled to vote and represented at any meeting at which there is a quorum except in such cases as shall otherwise be required by statute, the Articles of Incorporation or these Bylaws. Directors shall be elected by a plurality of the votes cast by holders of shares entitled to vote thereon.

2.6) Record Date. The Board of Directors (or an officer of the corporation, if so authorized by the Board of Directors) may fix a time, not exceeding 60 days preceding the date of any meeting of shareholders, as a record date for the determination of the shareholders entitled to notice of and to vote at such meeting, notwithstanding any transfer of any shares on the books of the corporation after any record date so fixed.

2.7)Business Conducted at a Meeting of Shareholders. The business conducted at a special meeting of shareholders is limited to the purposes stated in the notice of the special meeting. At an annual meeting of shareholders, only such business (other than the nomination and election of directors, which is subject to Section 3.11) may be conducted as is appropriate for consideration at the meeting and as shall have been brought before the meeting (i) by or at the direction of the Board of Directors or (ii) by any shareholder who (1) was a shareholder of record at the time of giving the notice required by this Section 2.7, (2) is a shareholder of record at the

time of the meeting, (3) is entitled to vote at the meeting, and (4) complies with the procedures set forth in this Section 2.7.

(a) For business to be properly brought before an annual meeting by a shareholder, the shareholder must have given timely notice thereof in writing to the Secretary. To be timely, a shareholder's notice must be delivered to the Secretary, or mailed and received at the principal executive office of the corporation, not less than 90 days before the first anniversary of the date of the preceding year's annual meeting of shareholders. If, however, the date of the annual meeting of shareholders is more than 30 days before or after such anniversary date, notice by a shareholder is timely only if so delivered or so mailed and received not less than 90 days before the annual meeting or, if later, within ten days after the first public announcement of the date of the annual meeting. Except to the extent otherwise required by law, the adjournment of an annual meeting of shareholders will not commence a new time period for the giving of a shareholder's notice as required above.

(b) A shareholder's notice to the corporation must set forth as to each matter the shareholder proposes to bring before the annual meeting: (i) a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting, (ii) the name and address, as they appear on the corporation's books, of the shareholder proposing such business, (iii) (A) the class or series (if any) and number of shares of the corporation that are beneficially owned by the shareholder, (B) any option, warrant, convertible security, stock appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the corporation or with a value derived in whole or in part from the value of any class or series of shares of the corporation, whether or not such instrument or right shall be subject to settlement in the underlying class or series of capital stock of the corporation or otherwise (a "Derivative Instrument") owned beneficially by such shareholder and any other opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of the corporation, (C) any proxy, contract, arrangement, understanding, or relationship pursuant to which such shareholder has a right to vote any shares of the corporation, (D) any short interest in any security of the corporation (for purposes of these Bylaws, a person shall be deemed to have a "short interest" in a security if such person has the opportunity to profit or share in any profit derived from any decrease in the value of the subject security), (E) any rights to dividends on the shares of the corporation owned beneficially by such shareholder that are separated or separable from the underlying shares of the corporation, (F) any proportionate interest in shares of the corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such shareholder is a general partner or, directly or indirectly, beneficially owns an interest in a general partner and (G) any performance-related fees (other than an asset-based fee) that such shareholder is entitled to based on any increase or decrease in the value of shares of the corporation or Derivative Instruments, if any, as of the date of such notice, including without limitation

any such interests held by members of such shareholder's immediate family sharing the same household (which information called for by this Section 2.7(b)(iii) shall be supplemented by such shareholder not later than ten days after the record date for the meeting to disclose such ownership as of the record date), (iv) any material interest of the shareholder in such business, and (v) a representation that the shareholder intends to appear in person or by proxy at the meeting to make the proposal.

(c) The presiding officer at such meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the procedures described in this Section 2.7 and, if the presiding officer so determines, any such business not properly brought before the meeting shall not be transacted.

(d) For purposes of this Section 2.7 and Section 3.11, "public announcement" means disclosure (i) when made in a press release reported by the Dow Jones News Service, Associated Press, or comparable national news service, (ii) when contained in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14, or 15(d) of the Securities Exchange Act of 1934, as amended, or (iii) when given as the notice of the meeting pursuant to Section 2.3.

(e) With respect to this Section 2.7 and Section 3.11, a shareholder must also comply with all applicable requirements of Minnesota law and the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder with respect to the matters set forth in this Section 2.7 and Section 3.11.

ARTICLE 3.

DIRECTORS

3.1) General Powers. The property, affairs and business of the corporation shall be managed by a Board of Directors.

3.2) Number, Term, Election and Qualifications. At each annual meeting the shareholders shall determine the number of directors, which shall be not less than three; provided, that between annual meetings the authorized number of directors may be increased by the shareholders or Board of Directors or decreased by the shareholders. However, notwithstanding the foregoing no increase or decrease in the number of directors may be effected except according to the further provisions contained in this Section 3.2. The directors shall be divided into three classes, designated Class I, Class II and Class III. Each class shall consist, as nearly as possible, of one-third of the total number of directors constituting the entire Board of Directors. At the 1999 Annual Meeting of Shareholders, Class I directors shall be elected for a one-year term, Class II directors for a two-year term and Class III directors for a three-year term. At each succeeding annual meeting of the shareholders beginning in 2000, successors to the class of directors whose term expires at that annual meeting shall be elected for a three-year term. A

director shall hold office until the annual meeting for the year in which his or her term expires and until his or her successor shall be elected and shall qualify, or until his or her resignation or removal from office. If the number of directors is changed, any increase or decrease shall be apportioned among the classes so as to maintain, as nearly as possible, an equal number of directors in each class. In the event an increase or decrease makes it impossible to maintain an equal number of directors in each class, increases shall be allocated to the class or classes with the longest remaining term, and decreases shall be allocated to the class with the shortest remaining term. Any director elected to fill a vacancy resulting from an increase in such class shall hold office for a term that shall coincide with the remaining term of that class. In no event will a decrease in the number of directors result in the elimination of an entire class of directors, cause any class to contain a number of directors two or more greater than any other class, or shorten the term of any incumbent director. Any director elected to fill a vacancy not resulting from an increase in the number of directors shall have the same remaining term as that of his or her predecessor. No amendment to these Bylaws shall alter, change or repeal any of the provisions of this Section 3.2 unless the amendment effecting such alteration, change or repeal shall receive the affirmative vote of the holders of two-thirds of all shares of stock of the corporation entitled to vote on all matters that may come before each meeting of shareholders.

3.3) Vacancies. Vacancies on the Board of Directors shall be filled by the remaining members of the Board, though less than a quorum; provided that newly created directorships resulting from an increase in the authorized number of directors shall be filled by two-thirds of the directors serving at the time of such increase. Persons so elected shall be directors until their successors are elected by the shareholders, who may make such election at their next annual meeting or at any special meeting duly called for that purpose.

3.4) Quorum and Voting. A majority of the whole Board of Directors shall constitute a quorum for the transaction of business except that when a vacancy or vacancies exist, a majority of the remaining directors (provided such majority consists of not less than two directors) shall constitute a quorum. Except as otherwise provided in the Articles of Incorporation or these Bylaws, the acts of a majority of the directors present at a meeting at which a quorum is present shall be the acts of the Board of Directors.

3.5) First Meeting. As soon as practicable after each annual election of directors, the Board of Directors shall meet for the purpose of organization and transaction of other business, at the place where the shareholders' meeting is held or at the place where regular meetings of the Board of Directors are held. No notice of such meeting need be given. Such first meeting may be held at any other time and place specified in a notice given as hereinafter provided for special meetings or in a waiver of notice signed by all the directors.

3.6) Regular Meetings. Regular meetings of the Board of Directors shall be held from time to time at such time and place as may from time to time be fixed by resolution adopted by a majority of the entire Board of Directors. No notice need be given of any regular meeting.

3.7) Special Meetings. Special meetings of the Board of Directors may be held at such time and place as may be designated in the notice or the waiver of notice of the meeting. Special meetings of the Board of Directors may be called by the Chairman of the Board, the Chief Executive Officer or by any two directors. Unless notice shall be waived by all directors, notice of such special meeting (including a statement of the purposes thereof) shall be given to each director at least 24 hours in advance of the meeting. Attendance at a meeting by any director, without objection in writing by him, shall constitute a waiver of notice of such meeting.

3.8) Compensation. Directors who are not salaried officers of the corporation shall receive such fixed sum per meeting attended or such fixed annual sum as shall be determined from time to time by resolution of the Board of Directors. Nothing herein contained shall be construed to preclude any director from serving this corporation in any other capacity and receiving proper compensation therefor.

3.9) Executive Committee. The Board of Directors may, by unanimous affirmative action of the entire Board, designate two or more of its number to constitute an Executive Committee, which, to the extent determined by unanimous affirmative action of the entire Board, shall have and exercise the authority of the Board in the management of the business of the corporation. Any such Executive Committee shall act only in the interval between meetings of the Board and shall be subject at all times to the control and direction of the Board.

3.10) Removal. Directors may be removed only for cause by vote of the shareholders or for cause by vote of a majority of the entire Board of Directors. No amendment to these Bylaws shall alter, change or repeal any of the provisions of this Section 3.10 unless the amendment effecting such, alternation, change or repeal shall receive the affirmative vote of the holders of two-thirds of all shares of stock of the corporation entitled to vote on all matters that may come before each meeting of shareholders.

3.11) Director Nominations. Only persons who are nominated in accordance with the procedures set forth in this Section 3.11 are eligible for election as directors. Nominations of persons for election to the Board of Directors may be made at a meeting of shareholders (i) by or at the direction of the Board of Directors or (ii) by any shareholder who (1) was a shareholder of record at the time of giving the notice required by this Section 3.11, (2) is a shareholder of record at the time of the meeting, (3) is entitled to vote for the election of directors at the meeting, and (4) complies with the procedures set forth in this Section 3.11.

(a) Nominations by shareholders must be made pursuant to timely notice in writing to the Secretary. To be timely, a shareholder's notice of nominations to be made at an annual meeting of shareholders must be delivered to the Secretary, or mailed and received at the principal executive office of the corporation, not less than 90 days before the first anniversary of the date of the preceding year's annual meeting of shareholders. If, however, the date of the

annual meeting of shareholders is more than 30 days before or after such anniversary date, notice by a shareholder is timely only if so delivered or so mailed and received not less than 90 days before the annual meeting or, if later, within ten days after the first public announcement of the date of the annual meeting. If a special meeting of shareholders is called in accordance with Section 2.2 for the purpose of electing one or more directors, for a shareholder's notice of nominations to be timely it must be delivered to the Secretary, or mailed and received at the principal executive office of the corporation, not less than 90 days before the meeting or, if later, within ten days after the first public announcement of the date of the meeting. Except to the extent otherwise required by law, the adjournment of an annual or special meeting will not commence a new time period for the giving of a shareholder's notice as described above.

(b) A shareholder's notice to the corporation of nominations for an annual or a special meeting of shareholders must set forth (x) as to each person whom the shareholder proposes to nominate for election or re-election as a director: (i) the person's name, (ii) all information relating to the person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or that is otherwise required, pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended, and (iii) the person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected; and (y) as to the shareholder giving the notice: (i) the name and address, as they appear on the corporation's books, of the shareholder, (ii) the information called for by Section 2.7(b)(iii) hereof, and (iii) a representation that the shareholder intends to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice.

(c) The presiding officer at such meeting shall, if the facts warrant, determine and declare to the meeting that a nomination was not made in accordance with the procedures prescribed in this Section 3.11 and, if the presiding officer so determines, the defective nomination shall be disregarded.

ARTICLE 4.

OFFICERS

4.1) Number and Designation. The Board of Directors shall elect a Chief Executive Officer, a Chief Financial Officer and a Secretary, and may elect or appoint a Chairman of the Board, one or more Vice Presidents, and such other officers and agents as it may from time to time determine. Any two or more of the offices may be held by one person.

4.2) Election, Term of Office and Qualifications. No less than annually, the Board shall elect the officers provided for in Section 4.1 and such officers shall hold office until their successors are elected or appointed and qualify; provided, however, that any officer may be

removed with or without cause by the affirmative vote of a majority of the entire Board of Directors (without prejudice, however, to any contract rights of such officer).

4.3) Resignations. Any officer may resign at any time by giving written notice to the Board of Directors or to the Chairman, Chief Executive Officer or Secretary. The resignation shall take effect at the time specified in the notice and, unless otherwise specified therein, acceptance of the resignation shall not be necessary to make it effective.

4.4) Vacancies in Office. If there be a vacancy in any office of the corporation, by reason of death, resignation, removal or otherwise, such vacancy shall be filled for the unexpired term by the Board of Directors at any regular or special meeting.

4.5) Chairman of the Board. The Board of Directors may, in its discretion, elect one of its number as Chairman of the Board. The Chairman shall preside at all meetings of the shareholders and of the Board and shall exercise general supervision and direction over the more significant matters of policy affecting the affairs of the corporation, including particularly its financial and fiscal affairs. The Chairman of the Board may call a meeting of the Board whenever he deems it advisable.

4.6) Chief Executive Officer. The Chief Executive Officer shall have general active management of the business of the corporation. In the absence of the Chairman of the Board, he shall preside at all meetings of the shareholders and Board of Directors. He shall see that all orders and resolutions are carried into effect. He shall perform all duties usually incident to the office of Chief Executive Officer and such other duties as may from time to time be assigned to him by the Board.

4.7) Vice President. Each Vice President shall have such powers and shall perform such duties as may be specified in these Bylaws or prescribed by the Board of Directors. In the event of absence or disability of the Chief Executive Officer, the Board of Directors may designate a Vice President or Vice Presidents to succeed to the powers and duties of the Chief Executive Officer.

4.8) Secretary. The Secretary shall be secretary of and shall attend all meetings of the shareholders and Board of Directors. He shall act as clerk thereof and shall record all the proceedings of such meetings in the minute book of the corporation. He shall give proper notice of meetings of shareholders and directors. He may, with the Chairman of the Board, Chief Executive Officer or Vice President, sign all certificates representing shares of the corporation and shall perform the duties usually incident to his office and such other duties as may be prescribed by the Board of Directors from time to time.

4.9) Chief Financial Officer. The Chief Financial Officer shall keep accurate accounts of all monies of the corporation received or disbursed, and shall deposit all monies, drafts and checks in the name of and to the credit of the corporation in such banks and depositories as the Board of Directors shall designate from time to time. He shall have power to endorse for deposit

the funds of the corporation as authorized by the Board of Directors. He shall render to the Chairman of the Board, Chief Executive Officer and the Board of Directors, whenever required, an account of all of his transactions as Chief Financial Officer and statements of the financial condition of the corporation, and shall perform the duties usually incident to his office and such other duties as may be prescribed by the Board of Directors from time to time.

4.10) Other Officers. The Board of Directors may appoint such other officers, agents and employees as the Board may deem advisable. Each officer, agent or employee so appointed shall hold office at the pleasure of the Board and shall perform such duties as may be assigned to him by the Board, Chairman of the Board or Chief Executive Officer.

ARTICLE 5.

INDEMNIFICATION

5.1) Indemnification of Directors and Officers. To the full extent permitted by Minnesota Statutes, Section 302A.521, as amended from time to time, or by other provisions of law, each person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, wherever brought, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was a director or officer of the corporation or by reason of the fact that such person is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise at the request of the corporation, shall be indemnified by the corporation against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding; provided, however, that the indemnification with respect to a person who is or was serving as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise shall apply only to the extent such person is not indemnified by such other corporation, partnership, joint venture, trust or other enterprise. The indemnification provided by this section shall continue as to a person who has ceased to be a director or officer of the corporation and shall inure to the benefit of the heirs, executors and administrators of such person.

5.2) Indemnification of Employees and Agents. Each person who is not eligible for indemnification pursuant to Section 5.1 above and who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, wherever brought, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was an employee or agent of the corporation or by reason of the fact that such person is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, may be indemnified by the corporation by action of the Board of Directors to the extent permitted and in accordance with the procedures described by Minnesota Statutes, Chapter 302A, as amended from time to time, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement, actually and reasonably incurred by such person in connection with such action, suit

or proceeding; provided, however, that the indemnification with respect to a person who is or was serving as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise shall apply only to the extent such person is not indemnified by such other corporation, partnership, joint venture, trust or other enterprise. The indemnification provided by this section shall continue as to a person who has ceased to be an employee or agent and shall inure to the benefit of the heirs, executors and administrators of such person.

5.3) Nonexclusivity. The foregoing right of indemnification in the case of a director or officer and permissive indemnification in the case of an agent or employee shall not be exclusive of other rights to which a director, officer, employee or agent may be entitled as a matter of law.

5.4) Advance Payments. To the full extent permitted by Minnesota Statutes, Section 302A.521, as amended from time to time, or by other provisions of law, the corporation may pay in advance of final disposition expenses incurred in actions, suits and proceedings specified in Sections 5.1 and 5.2 above.

5.5) Insurance. To the full extent permitted by Minnesota Statutes, Section 302A.521, as amended from time to time, or by other provisions of law, the corporation may purchase and maintain insurance on behalf of any indemnified party against any liability asserted against such person and incurred by such person in such capacity.

ARTICLE 6.

SHARES AND THEIR TRANSFER

6.1) Certificated and Uncertificated Shares.

(a) Form of Shares. The shares of the corporation shall be either certificated shares or uncertificated shares. Each holder of duly issued certificated shares is entitled to a certificate of shares.

(b) Form of Certificates. Each certificate of shares of the corporation shall bear the corporate seal, if any, and shall be signed by the Chief Executive Officer, or the President or any Vice President, and the Chief Financial Officer, or the Secretary or any Assistant Secretary, but when a certificate is signed by a transfer agent or a registrar, the signature of any such officer and the corporate seal upon such certificate may be facsimiles, engraved or printed. If a person signs or has a facsimile signature placed upon a certificate while an officer, transfer agent or registrar of the corporation, the certificate may be issued by the corporation, even if the person has ceased to serve in that capacity before the certificate is issued, with the same effect as if the person had that capacity at the date of its issue.

(c) Designations. A certificate representing shares issued by the corporation shall, if the corporation is authorized to issue shares of more than one class or series, set

forth upon the face or back of the certificate, or shall state that the corporation will furnish to any shareholder upon request and without charge, a full statement of the designations, preferences, limitations and relative rights of the shares of each class or series authorized to be issued, so far as they have been determined, and the authority of the Board of Directors to determine the relative rights and preferences of subsequent classes or series.

(d) Uncertificated Shares. The Board of Directors or an officer of the corporation may determine that some or all of any or all classes and series of the shares of the corporation will be uncertificated shares. Any such determination shall not apply to shares represented by a certificate until the certificate is surrendered to the corporation.

6.2) Stock Record. As used in these Bylaws, the term " shareholder" shall mean the person, firm or corporation in whose name outstanding shares of capital stock of the corporation are currently registered on the stock record books of the corporation. A record shall be kept of the name of the person, firm or corporation owning the stock represented by such certificates respectively, the respective dates thereof and, in the case of cancellation, the respective dates of cancellation. Every certificate surrendered to the corporation for exchange or transfer shall be cancelled and no new certificate or certificates shall be issued in exchange for any existing certificate until such existing certificate shall have been so cancelled (except as provided for in Section 6.4 of this Article 6).

6.3) Transfer of Shares. Shares of the corporation may be transferred only on the books of the corporation by the holder thereof, in person or by such person's attorney. In the case of certificated shares, shares shall be transferred only upon surrender and cancellation of certificates for a like number of shares. The Board of Directors, however, may appoint one or more transfer agents and registrars to maintain the share records of the corporation and to effect transfers of shares.

6.4) Lost Certificates. Any shareholder claiming a certificate of stock to be lost or destroyed shall make an affidavit or affirmation of that fact in such form as the Board of Directors may require, and shall, if the Board of Directors so requires, give the corporation a bond of indemnity in a form and with one or more sureties satisfactory to the Board of Directors of at least double the value, as determined by the Board of Directors, of the stock represented by such certificate in order to indemnify the corporation against any claim that may be made against it on account of the alleged loss or destruction of such certificate, whereupon a new certificate may be issued in the same tenor and for the same number of shares as the one alleged to have destroyed or lost.

ARTICLE 7.

GENERAL PROVISIONS

7.1) Fiscal Year. The fiscal year of the corporation shall be established by the Board of Directors.

7.2) Seal. The corporation shall have such corporate seal or no corporate seal as the Board of Directors shall from time to time determine.

7.3) Securities of Other Corporations.

(a) Voting Securities Held by the Corporation. Unless otherwise ordered by the Board of Directors, the Chief Executive Officer shall have full power and authority on behalf of the corporation (i) to attend and to vote at any meeting of security holders of other companies in which the corporation may hold securities; (ii) to execute any proxy for such meeting on behalf of the corporation and (iii) to execute a written action in lieu of a meeting of such other company on behalf of this corporation. At such meeting, by such proxy or by such writing in lieu of meeting, the Chief Executive Officer shall possess and may exercise any and all rights and powers incident to the ownership of such securities that the corporation might have possessed and exercised if it had been present. The Board of Directors may, from time to time, confer like powers upon any other person or persons.

(b) Purchase and Sale of Securities. Unless otherwise ordered by the Board of Directors, the Chief Executive Officer shall have full power and authority on behalf of the corporation to purchase, sell, transfer or encumber any and all securities of any other company owned by the corporation and may execute and deliver such documents as may be necessary to effectuate such purchase, sale, transfer or encumbrance. The Board of Directors may, from time to time, confer like powers upon any other person or persons.

ARTICLE 8.

MEETINGS

8.1) Waiver of Notice. Whenever any notice whatsoever is required to be given by these Bylaws, the Articles of Incorporation or any of the laws of the State of Minnesota, a waiver thereof in writing, signed by the person or persons entitled to such notice, whether before, at or after the time stated therein, shall be deemed equivalent to the actual required notice.

8.2) Participation by Conference Telephone. Members of the Board of Directors, or any committee designated by the Board, may participate in a meeting of the Board of Directors or of such committee by means of conference telephone or similar communications equipment whereby all persons participating in the meeting can hear and communicate with each other, and participation in a meeting pursuant to this Section shall constitute presence in person at such meeting. The place of the meeting shall be deemed to be the place of origination of the conference telephone call or similar communication technique.

8.3) Authorization Without Meeting. Any action of the shareholders, the Board of Directors, or any lawfully constituted Executive Committee of the corporation which may be taken at a meeting thereof, may be taken without a meeting if authorized by a writing signed by

all of the holders of shares who would be entitled to notice of a meeting for such purpose, by all of the directors, or by all of the members of such Executive Committee, as the case may be.

ARTICLE 9.

AMENDMENTS OF BYLAWS

9.1) Amendments. Except as otherwise provided in specific provisions of these Bylaws, these Bylaws may be altered, amended, added to or repealed by the affirmative vote of a majority of the members of the Board of Directors at any regular meeting of the Board or at any special meeting of the Board called for that purpose, subject to the power of the shareholders to change or repeal such Bylaws and subject to any other limitations on such authority of the Board provided by the Minnesota Business Corporation Act.

Exhibit 10.1

CONFIDENTIAL

LICENSE AND DEVLOPMENT AGREEMENT

BETWEEN

GENENTECH, INC.,

F. HOFFMANN-LA ROCHE, LTD.

AND

SURMODICS, INC.

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.

License and Development Agreement

This License and Development Agreement ("Agreement") is made and entered into as of the 5th day of October, 2009 (the "Effective Date") by and between SurModics, Inc., a Minnesota corporation with a principal place of business at 9924 West 74th Street, Eden Prairie MN 55344 (together with its Affiliates, "SurModics"), Genentech, Inc., a Delaware corporation, with offices located at 1 DNA Way, South San Francisco, CA 94080 ("GNE") and F. Hoffmann-La Roche, Ltd., Grenzacherstrasse 124, CH 4070 Basel, Switzerland ("Roche") (GNE and Roche together referred to as "Genentech"). SurModics and Genentech are each referred to herein individually as a "Party" and collectively as the "Parties."

Recitals

WHEREAS SurModics possesses certain expertise and proprietary technologies relating to controlled-release drug delivery;

WHEREAS Genentech is a health care company with expertise and capability in researching, developing, manufacturing and marketing human therapeutics and diagnostics;

WHEREAS Genentech, Inc., and SurModics' Affiliate, SurModics Pharmaceuticals, Inc., have entered into that certain Feasibility Study Agreement [*] (the "Existing Feasibility Study"); and

WHEREAS concurrently with this Agreement, Genentech and SurModics are entering into a separate Master Services Agreement (as defined below) pursuant to which SurModics will supply materials and provide certain services, each in connection with the Development (as defined below) of Licensed Products (as defined below) in the Field (as defined below);

WHEREAS SurModics and Genentech wish to collaborate in the development of Microparticles (as defined below) for the controlled-release delivery of Genentech's products in the Field under this Agreement and the MSA.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

Article 1. Definitions

Capitalized terms used in this Agreement, whether used in the singular or plural, shall have the meanings set forth below, unless otherwise specifically indicated herein:

1.1 "Accounting Standard" means (a) with respect to SurModics, United States generally accepted accounting principles ("GAAP"); and (b) with respect to Genentech, International Financial Reporting Standards ("IFRS") or the applicable international accounting standard in use.

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1.2 "Affiliate" means any entity that, directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with a Party. For purposes of this Section 1.2, "control" means (a) the direct or indirect ownership of fifty percent (50%) or more of the voting stock or other voting interests or interest in the profits of the Party, or (b) the ability to otherwise control or direct the decisions of the board of directors or equivalent governing body thereof. Notwithstanding the foregoing, unless expressly specified otherwise, for the purposes of this Agreement, [*] and all entities controlled by [*], shall not be considered an Affiliate of Genentech unless and until Genentech provides written notice to SurModics specifying Chugai Pharmaceutical Co., Ltd as an Affiliate of Genentech.

1.3 "Combination Know-How" is defined in Section 10.3(a).

1.4 "Combination Patents" mean Patents which during the Term are Controlled by Genentech in accordance with Section 10.3(a) of this Agreement, which claim or cover the Combination Know-How.

1.5 "Commercially Reasonable Efforts" means, with respect to particular obligations or tasks of a Party **[*]**. The efforts and resources of a Party's Affiliates and sublicensees will be considered as a Party's activities under this Agreement for purposes of determining whether a Party is exercising, or has exercised, "Commercially Reasonable Efforts."

1.6 "Commercial Sale" means, with respect to a particular Licensed Product in a given country, a bona fide arms length commercial sale to a Third Party of such Licensed Product following final Regulatory Approval in such country by or under authority of Genentech, its Affiliates or Genentech sublicensees or their Affiliates. Commercial Sale shall not include the provision of any Licensed Product for use in clinical trials or for compassionate use prior to the receipt of necessary marketing approvals.

1.7 "Commercialization" means manufacturing for commercial sale; marketing; promotion; sale; and/or distribution of Licensed Product. "Commercialize" has a correlative meaning.

1.8 "Compound" means [*].

1.9 "Confidential Information" is defined in Section 9.1.

1.10 "Control(s)" or **"Controlled"** means the possession, as of the Effective Date or during the Term, of (a) with respect to materials, data or information, physical possession or the right to such physical possession of those items, with the right to provide them to Third Parties; and (b) with respect to intellectual property rights, rights sufficient to grant the applicable license or sublicense under this Agreement; in each case without violating the terms of any agreement with any Third Party.

1.11 "Development" means all activities that relate to (a) obtaining, maintaining or expanding Regulatory Approval of a Licensed Product, (b) studies conducted to expand the scientific or medical understanding of a Licensed Product, whether for publication in a peer-reviewed journal or not, but not necessarily for the intent of obtaining, maintaining or expanding

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Regulatory Approval of a Licensed Product (e.g., investigator-sponsored trials) or (c) developing the ability to manufacture clinical and commercial quantities of Licensed Product. Such activities include: (i) research, preclinical testing, toxicology, and clinical studies of a Licensed Product; (ii) preparation, submission, review, and development of data or information for the purpose of obtaining, maintaining and/or expanding Regulatory Approval of a Licensed Product; (iii) manufacturing, process development and scale-up, bulk production and fill/finish work associated with the supply of Licensed Product for preclinical and clinical studies, and related quality assurance and quality control activities; and (iv) post-Regulatory Approval product support for a Licensed Product (including manufacturing and quality assurance support, and laboratory and clinical efforts directed toward the further understanding of the safety and efficacy of a Licensed Product). "Develop" has a correlative meaning.

1.12 [*].

1.13 [*].

1.14 "FDA" means the U.S. Food and Drug Administration or corresponding governmental authority in another country, or any successor thereto.

1.15 "Feasibility Study" is defined in Section 2.3(c)(ii)(C), and include the Existing Feasibility Study.

1.16 "Field" means [*]

1.17 "Genentech IP Rights" means the Genentech Know-How and the Genentech Patents.

1.18 "Genentech Know-How" means [*].

1.19 "Genentech Microparticle Formulation" means [*].

1.20 "Genentech Patents" means [*].

1.21 "GXP" means (a) the current Good Manufacturing Practices pursuant to the U.S. Food, Drug and Cosmetic Act and any U.S. regulations found in Title 21 of the U.S. Code of Federal Regulations (including Parts 11, 210 and 211) and other regulations, policies, or guidelines, as applicable to the manufacture, labeling, packaging, handling, storage, supply and transport of Licensed Products. "GXP" also includes comparable laws, rules and regulations of any jurisdiction where Licensed Products are or may be marketed, but that are not governed by United States law; (b) the then-current FDA regulations and guidelines for "Good Laboratory Practice," as promulgated by the FDA under Title 21 of the U.S. Code of Federal Regulations Part 58, as amended from time to time, or any foreign equivalents thereto in the country in which research is conducted; and (c) the then current FDA regulations and guidelines for "Good Clinical Practice," as promulgated by the FDA under 21 CFR Parts 50, 54, 56 and 312, as amended from time to time, or any foreign equivalents thereto (*e.g.*, ICH Guideline for Good Clinical Practice) in the country in which such studies or clinical trials are conducted.

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1.22 "IND" means an Investigational New Drug Application filed with the FDA pursuant to 21 CFR Part 312 before the commencement of clinical trials for a Licensed Product.

1.23 "IND-Enabling Study" means a study conducted by or on behalf of Genentech, a Genentech Affiliate or sublicensee, in a non-rodent animal, of the toxicological effects (and, in some cases, pharmacokinetic properties) of a compound or other substance that the entity directing the study believes may be useful as a drug, where (i) such study is conducted to Good Laboratory Practices standards, and (ii) the data is intended to be used to file an IND with the FDA.

1.24 "Initial [*]**"** means [*].

1.25 "Injection Vehicle" means [*].

1.26 "Joint Project IP Rights" is defined in Section 10.4(b)(i).

1.27 "Know-How" means information, materials, results, compositions of matter and uses thereof, techniques, data and other know-how and technical information, including inventions, improvements, developments, practices, methods, processes, concepts, trade secrets, documents, computer data, computer code, apparatus, clinical and regulatory strategies, test data, analytical and quality control data, formulation, manufacturing, patent data or descriptions, development information, drawings, specifications, designs, plans, proposals and technical data and manuals and all other proprietary information.

1.28 "Licensed Product" means any preparation of a Compound formulated as Microparticles, including, without limitation the Ranibizumab Product, that [*].

1.29 "Master Services Agreement" or **"MSA"** means the Master Services Agreement between the Parties dated as of the Effective Date and attached hereto as Exhibit A (as modified, amended, or restated from time to time).

1.30 "Major EU Market" is any one of the following countries: [*].

1.31 "Microparticles" means injectable, biodegradable microparticles composed of any polymer, including without limitation, the SurModics Polymers.

1.32 "Milestone Event" means a milestone event set forth in the table in Section 7.3.

1.33 "Net Sales."

(a) Definition. "Net Sales" means, subject to the provisions of this Section 1.33(a), the gross amounts invoiced for sales of Licensed Products (in final form for end use) by Genentech and its Affiliates, and their respective sublicensees and their Affiliates, less the following reasonable and customary deductions from such invoiced amounts that are actually incurred:

[*]

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(b) All of the foregoing elements of Net Sales calculations shall be determined in accordance with Accounting Standards.

(c) Sales Among Affiliates and Sublicensees. Sales between or among a Party and its Affiliates, and their respective sublicensees and their Affiliates, shall be excluded from the computation of Net Sales, but Net Sales shall include the first sales to Third Parties by any such Affiliates or sublicensees and their Affiliates.

(d) [*].

(e) Licensed Products Sold in Combinations.

(i) In the event a Licensed Product is sold in combination with one or more other active ingredients that are not the subject of this Agreement (for purposes of this Section 1.33(d), a "Combination"), the gross amount invoiced for such Licensed Product shall be calculated **[*].**

(ii) In the event that such other active ingredient(s) are not sold separately (but such Licensed Product is), the gross amount invoiced for such Licensed Product shall be calculated **[*]**.

1.34 "Net Sales Report" is defined in Section 8.1.

1.35 "Option Term" means [*].

1.36 "Patent" means a patent or a patent application, including any additions, divisions, continuations, continuations-in-part, invention certificates, substitutions, reissues, reexaminations, extensions, registrations, patent term extensions, supplementary protection certificates and renewals of any of the above.

1.37 "Phase I Clinical Trial" means, as to a specific Licensed Product, a controlled and lawful study in humans designed with the principal purpose of preliminarily determining the safety of a pharmaceutical product in healthy individuals or patients, and for which there are no primary endpoints related to efficacy, as further defined in 21 C.F.R. § 312.21(a); or similar clinical study in a country other than the United States.

1.38 "Phase II Clinical Trial" means, as to a specific Licensed Product, a controlled and lawful study in humans designed with the principal purpose of determining initial efficacy and dosing of such Product in patients for the indication(s) being studied, as further defined in 21 C.F.R. § 312.21(b); or similar clinical study in a country other than the United States.

1.39 "Phase III Clinical Trial" means, as to a specific Licensed Product, a controlled and lawful study in humans of the efficacy and safety of such Product, which is prospectively designed to demonstrate statistically whether such Product is effective and safe for use in a particular indication in a manner sufficient to file an application to obtain Regulatory Approval to market and sell that Licensed Product in the United States or another country for the indication being investigated by the study, as further defined in 21 C.F.R. § 312.21; or similar clinical study in a country other than the United States.

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1.40 "Program Budget" means the budget associated with a Feasibility Study, Project Plan, or (if applicable) an SOW to the MSA, which [*].

1.41 "Project Know-How" means any and all Know-How (whether or not patentable) first conceived, first reduced to practice, or otherwise first made, discovered, or created as a direct result of (a) the use of any Confidential Information disclosed by one Party to the other Party hereunder, (b) the exercise by either Party of the rights licensed under this Agreement, or (c) a Party's activities under this Agreement, the Existing Feasibility Study, or the MSA, in each case; whether solely by one Party or its Affiliates and/or their respective employees, contractors or consultants, or jointly by the Parties and/or their employees, contractors or consultants, or solely or jointly by a Third Party engaged to perform work thereunder. For clarity, "Project Know-How" shall not cover any information made, discovered, or created by a Party independently of activities under this Agreement, the Existing Feasibility Study, or the MSA

1.42 "Project Plan" is defined in Section 4.2.

1.43 "Prosecution and Maintenance" or **"Prosecute and Maintain,"** with regard to a particular Patent, means the preparation, filing, prosecution and maintenance of (including a decision to abandon) such Patent, as well as re-examinations, reissues, applications for patent term extensions and the like with respect to that Patent, together with the conduct of interferences, the defense of oppositions and other similar proceedings with respect to that Patent.

1.44 "Ranibizumab Product" means [*].

1.45 "Regulatory Approval" means all approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity, necessary for the manufacturing, use, storage, import, transport, marketing and/or sale of a particular Licensed Product in a country or regulatory jurisdiction.

1.46 "SurModics FTE Rates" [*]

1.47 "SurModics IP Rights" means [*].

1.48 "SurModics Know-How" means [*].

1.49 "SurModics Patents" means [*].

1.50 "SurModics Polymers" means [*].

1.51 "SurModics Project Deliverables" means [*].

1.52 "SurModics Raw Materials" mean [*].

1.53 "SurModics Technology" means [*].

1.54 [*]

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1.55 "Term" is the term of this Agreement, in accordance with Section 12.1.

1.56 "Territory" means [*].

1.57 "Third Party" means any party other than SurModics or Genentech or their Affiliates.

1.58 [*].

1.59 "Valid Claim" means a claim of an issued and unexpired patent that has not been: (a) disclaimed, cancelled, withdrawn or abandoned, (b) dedicated to the public; (c) declared invalid, unenforceable, unpatentable or revoked by a decision of a court, government agency or other authority of competent jurisdiction from which no appeal can be or has been taken; or (d) admitted to be invalid or unenforceable through reexamination, reissue or otherwise.

Article 2. License Grant

2.1 License Grant to Genentech.

(a) SurModics hereby grants to Genentech and its Affiliates, under the **[*]**, the following licenses:

(i) an exclusive **[*]** license to make, use, offer to sell, sell, and import Licensed Products in the Field in the Territory;

(ii) an exclusive **[*]** license to make, use, offer to sell, sell, and import the Injection Vehicle exclusively for use with the Development and Commercialization of Licensed Products in the Field in the Territory; and

(iii) **[*]**

(b) The licenses granted to Genentech in this Section 2.1, are subject to a retained right by SurModics under **[*]** as necessary for SurModics to perform any of the obligations assigned to it under this Agreement, the Existing Feasibility Study, or the MSA.

2.2 [*]

2.3 Option to Acquire Rights to [*]**.**

(a) Genentech **[*]** Option. Subject to Third Party rights granted by SurModics as of the Effective Date, or otherwise granted by SurModics after the Effective Date (in each case, so long as such Third Party rights remain in effect), and on the terms and conditions of this Section 2.3, SurModics hereby grants to Genentech the option to obtain **[*]** additional exclusive, worldwide, sublicensable licenses for Licensed Products **[*]**.

(b) [*]

(c) Procedure for Obtaining Rights **[*]**.

(i) Option Notice. At any time during the Option Election Term, Genentech may, in good faith, notify SurModics of its interest in evaluating the feasibility of

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Microparticles as a sustained delivery **[*]** by submitting a written selection notice to SurModics (each, an "Option Notice"). **[*]**.

(ii) Determination Regarding an **[*]**. Within thirty (30) days after receiving an Option Notice, SurModics will determine whether the **[*]** identified in such Option Notice is available for licensing to Genentech. **[*]**

(A) **[*]**

(B) Excluded [*]. In the event that SurModics determines that a particular [*] is not available for licensing to Genentech **[*],** then such [*] will be considered an "Excluded [*]." **[*]**

(C) Feasibility Study. As soon as reasonably practical following delivery of a Notice of Availability with respect to a particular [*], SurModics shall prepare and deliver to Genentech a good faith proposal for a feasibility study aimed at evaluating the *in vitro* and *in vivo* feasibility of Microparticles [*] incorporating a molecule selected by Genentech that is Directed to such [*] (each, a "Feasibility Study"). The Feasibility Study shall [*]. Within **[*]** of the date of Genentech's receipt of the Feasibility Study proposal with respect to a particular [*], the Parties shall in good faith finalize the details of such proposal to allow Genentech, in its sole discretion, to Initiate a Feasibility Study (as defined below) with respect to such [*].

(iii) Exercise of a Genentech [*] Option. **[*]** Upon Genentech's exercise of a Genentech [*] Option in accordance with this Section 2.3(c)(iii) for a particular [*], Genentech shall have the following rights:

(A) If such [*] is an Available [*], then, at Genentech's sole discretion, Genentech may request that such [*] be automatically be included **[*]** and shall be subject to the terms and conditions of this Agreement, including, without limitation the automatic grant to Genentech of the exclusive and non-exclusive licenses under and in accordance with Section 2.1; and

(B) [*]

(iv) Failure to Exercise. **[*]**

2.4 License Grant to SurModics. Genentech hereby grants SurModics a non-exclusive, non-sublicensable (except to the extent SurModics is permitted to use a Third Party in performing its obligations under this Agreement in accordance with Section 4.3(b)), royalty-free right and license under the Genentech IP Rights solely to the extent necessary for SurModics to perform the activities assigned to it under this Agreement, a Feasibility Study, Project Plan or the MSA.

2.5 No Other Licenses. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the rights and licenses that are expressly granted under this Agreement.

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2.6 Reservation of Rights. Genentech acknowledges that the licenses granted under this Article 2 are limited to the scope expressly granted and all other rights under the SurModics IP Rights are expressly reserved to SurModics. Without limiting the foregoing, as between the Parties, SurModics retains all of its rights under the SurModics Technology and the SurModics IP Rights for all purposes not expressly licensed under this Agreement. Genentech acknowledges that SurModics' business involves the application of the SurModics Technology and/or the SurModics IP Rights to molecules, compounds and products and that SurModics retains the right (expressly subject to SurModics' obligations under, and the terms and conditions of, this Agreement or any other agreement between the Parties) to apply such SurModics Technology and/or the SurModics IP Rights to compounds, molecules or products, *other than* Licensed Products, or compounds or molecules Directed to a **[*]** in the Field. For clarity, the foregoing reservation of rights is not meant to limit in any manner Genentech's rights in and to any Project IP Rights.

Article 3. Governance

3.1 Joint Steering Committee. Within thirty (30) days after the Effective Date, SurModics and Genentech shall form a joint steering committee (the "JSC") responsible for monitoring the activities under each Feasibility Study, Project Plan, and, as appropriate, the MSA. The JSC shall be composed of [*] representatives designated by SurModics and [*] representatives designated by Genentech, or such other number of representatives as the Parties may agree to in writing. Such representatives will be appropriate, in terms of their seniority, availability, function in their respective organizations, training and experience, for the JSC tasks then being undertaken and the stage and scope of the activities being performed. Each Party shall designate one of its representatives as its primary JSC contact. Each Party may replace its JSC representatives at any time upon prior written notice to the other Party. From time to time, the JSC may establish subcommittees to oversee particular projects or activities, and such subcommittees will be constituted and will operate as determined by the JSC. The JSC shall continue to exist until [*] after the later of: (a) expiration of the Option Term [*], or (b) completion of the last Project Plan, Feasibility Study or SOW (as defined in Section 2.1.1 of the MSA) (the "JSC Term"). Notwithstanding the foregoing, either Party may, at its sole discretion, terminate its participation on the JSC at any time after the [*] anniversary of the Effective Date by providing thirty (30) days written notice to the other Party. Should either Party elect to terminate its JSC participation, the Parties will amend the respective decision making and disclosure rights and obligations enumerated in this Agreement to preserve the Parties' respective decision making and disclosure rights and obligations in the absence of participation through the JSC.

3.2 Meetings of the JSC. Unless otherwise agreed by the Parties, the JSC shall meet at least twice each calendar year during the JSC Term. In addition, the JSC or a JSC designated subcommittee shall meet prior to the commencement, and within thirty (30) days after the completion, of each Project Plan and/or Feasibility Study. Such meetings shall be held on such dates and at such times and places as reasonably agreed to by the Parties. Meetings may be held in person, by teleconference or videoconference. Each Party shall bear the expense of its respective representatives' participation in JSC meetings. If a Party's representative is unable to attend a given meeting, such Party may designate an alternate to attend such meeting and perform the functions of such representative. Each Party may invite a reasonable number of

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additional participants to attend JSC meetings where deemed appropriate by the Parties' primary JSC contact, provided that each are bound by appropriate confidentiality obligations.

3.3 Minutes; Other Documentation. The JSC shall keep minutes of its meetings that record in writing all decisions made, action items assigned or completed and other appropriate matters. The responsibility for keeping meeting minutes shall alternate between the Parties, beginning with Genentech. Meeting minutes shall be sent to all members of the JSC promptly after a meeting for review and comment.

3.4 Responsibilities of the JSC. The JSC shall have the responsibility and authority to:

[*]

3.5 Updates. The regularly scheduled meetings of the JSC will include as an agenda item an update of (a) Genentech's progress and plans for Development and Commercialization of Licensed Products, and (b) any serious adverse events which Genentech determines to be reasonably attributable to the SurModics Technology as incorporated into any Licensed Product. All updates, and all information contained in any such update, are Genentech's Confidential Information, except to the extent such updates or information incorporate SurModics' Confidential Information.

3.6 Areas Outside the JSC's Authority. [*]

3.7 JSC Decisions.

(a) Consensus; Good Faith; Action Without Meeting. With respect to the responsibilities of the JSC each Party shall [*] in all decisions, and the Parties shall attempt in good faith to make decisions by consensus. The members of the JSC shall act in good faith and cooperate with one another in discussing and seeking to reach agreement on all matters before the JSC. A decision that may be made at a JSC meeting may also be made without a meeting, if such decision is agreed to in writing (including by email) by each Party's primary JSC contact (or its designee), provided that each Party's writing clearly indicates that such decision is a formal decision by such Party's primary JSC contact.

(b) [*]

3.8 No Deliverables. The Parties acknowledge and agree that the JSC under this Agreement is strictly for the purposes of decision making and governance of the activities conducted under a Feasibility Study, Project Plan, or an SOW to the MSA, and does not in any way include any significant deliverable of either Party.

Article 4 Project Plans

4.1 Overview. For each **[*]**, Genentech may request that SurModics perform certain activities related to Compounds Directed to such **[*]** and the Genentech Microparticle Formulations generated pursuant to a Feasibility Study. In particular, Genentech may request that SurModics, using the SurModics Technology, work on certain projects designed to develop and optimize the Genentech Microparticle Formulations and/or Injection Vehicles, and generate

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such other SurModics Project Deliverables as the Parties may agree. In all cases the Parties intend the details of such activities to be set forth in a Project Plan; notwithstanding the foregoing, the Parties acknowledge that certain activities may be agreed between the Parties outside of a formalized Project Plan, and, provided there is a clear intent and agreement between the Parties, such activities will be deemed to be part of a Project Plan hereunder.

4.2 Project Plans. The Parties shall mutually agree upon project plans (each a "Project Plan") detailing the specific activities to be performed by SurModics in connection with a Genentech Microparticles Formulation, **[*]**. Genentech will compensate SurModics for the activities conducted and expenses incurred under a Project Plan as set forth in Section 7.2. For each new Project Plan the specific activities to be performed by SurModics will be established as follows: Genentech shall notify SurModics in writing as to the general scope of the work Genentech would like SurModics to perform. Promptly thereafter, Genentech and SurModics shall, in good faith develop and mutually agree on a detailed written Project Plan and Program Budget. Each Project Plan and Program Budget shall be agreed by the Parties in writing prior to its commencement.

4.3 Conduct of Project Plans.

(a) In General. SurModics and Genentech shall each conduct their respective responsibilities under each Project Plan in good scientific manner, and in compliance in all material respects with all requirements of applicable laws, rules and regulations (including, as applicable, GXPs) and shall attempt to achieve their objectives efficiently and expeditiously. Each Party's tasks under each Project Plan shall include cooperating with and providing reasonable support to the other Party in such other Party's performance of its responsibilities under the Project Plan. SurModics and Genentech shall each use their respective Commercially Reasonable Efforts in the performance of their obligations under each Project Plan by allocating sufficient time, effort, equipment and facilities to the Project Plan and using personnel with sufficient skills and experience as are required to accomplish the Project Plan in accordance with its terms and the terms of this Agreement.

(b) Third Party Contractors. **[*]** SurModics may use the services of Third Parties to perform its Project Plan **[*]** or as otherwise explicitly set forth in a Project Plan. **[*]**

(c) Updates and Disclosure of SurModics' Technology. From time to time, and on Genentech's request, during the term of a Project Plan, SurModics shall disclose to Genentech the SurModics IP Rights necessary or useful for Genentech to conduct its activities under such Project Plan and to exercise the rights granted to Genentech under this Agreement.

(d) Project Reports. SurModics shall maintain complete and accurate records of its activities conducted under each Project Plan. From time to time during the conduct of each Project Plan, at Genentech's request, SurModics and Genentech shall discuss SurModics progress (including, without limitation, anticipated and incurred costs) under any Project Plan. In addition, SurModics shall provide Genentech with a written update **[*]** summarizing in reasonable detail all Project Plan activities assigned to SurModics and its Affiliates, sublicensees, and Third Party contractors during such month. Within **[*]** of the conclusion of its activities

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under each Project Plan, SurModics shall provide Genentech with a complete and detailed report summarizing its observations and results from such Project Plan (the "Report") for Genentech's review and approval. In addition, as reasonably requested by Genentech, within **[*]** of its receipt of the Report, SurModics will provide Genentech with any additional documentation and data (including raw data) in SurModics' Control generated under the Project Plan related to any SurModics' Project Deliverables or any Project Know-How. **[*].**

4.4 [*].

Article 5. Development and Commercialization

5.1 In General. As between the Parties, Genentech shall be solely responsible for, have complete control of, and bear all costs for the Development and Commercialization of Licensed Products, including without limitation all regulatory activities. Except as provided in Article 6 below, as between the Parties, Genentech shall be responsible for, have complete control of, and bear all costs for, the manufacturing (or otherwise obtaining supply) of Licensed Products in bulk and finished form for use by Genentech, its Affiliates, and its sublicensees in conducting Development and Commercialization in the Field in the Territory.

5.2 General Diligence.

(a) Commercially Reasonable Efforts by Genentech. Subject to SurModics' fulfillment of its obligations under each respective Feasibility Study, Project Plan, and SOW to the MSA, and under Sections 4.3(c), 5.3, or 6.3 of this Agreement, and Sections 13.3.7 and 13.3.8 of the MSA (if applicable), Genentech shall use Commercially Reasonable Efforts to Develop and Commercialize at least one Licensed Product [*] in the Territory.

(b) Commercially Reasonable Efforts by SurModics. Subject to Genentech's fulfillment of its obligations under this Agreement, SurModics shall use Commercially Reasonable Efforts to execute and perform all Development activities (including the manufacturing and/or scale up and transfer of manufacturing capabilities performed under an SOW to the MSA) reserved for or assigned to SurModics under this Agreement or the MSA.

5.3 SurModics' Cooperation. At Genentech's request, SurModics will, and will cause its Affiliates, employees, contractors and agents to, cooperate with and provide all necessary and reasonable support, Know-How, expertise and assistance to Genentech in its conduct of any activities in the Development and Commercialization of Licensed Products, including, without limitation, assistance related to Genentech's preparation of materials for regulatory authorities. Genentech shall reimburse SurModics for pre-approved time expended and pre-approved expenses by SurModics in providing such assistance in accordance with Section 7.2.

Article 6 Manufacturing

6.1 In General. As between the Parties Genentech will be solely responsible for, have complete control over, and bear all costs for the manufacturing (or otherwise obtaining supply) of Licensed Products (including without limitation, related SurModics Polymers, Injection Vehicles or any component thereof) for use by Genentech, its Affiliates and

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sublicensees in conducting all research, Development and Commercialization of Licensed Products in the Field and in the Territory.

6.2 Manufacture and Supply by SurModics

[*]

Article 7 Payments

7.1 Up Front Payment. Genentech shall pay SurModics a one-time, non-refundable, upfront payment of three million five hundred thousand dollars (US$3,500,000) within thirty (30) days of the Effective Date.

7.2 Program Funding.

(a) Program Budgets. In consideration of SurModics' performance of its activities under each Feasibility Study, Project Plan and (to the extent applicable) SOW, Genentech shall reimburse SurModics for all undisputed amounts incurred by SurModics in accordance with the associated Program Budget. SurModics will provide Genentech with an invoice for SurModics' activities, **[*]**. Genentech shall pay SurModics **[*]** in accordance with Program Budgets, **[*]** after Genentech's receipt of an invoice. Each invoice will include **[*]**

(b) Costs. [*] SurModics will notify Genentech through the JSC (or JMT under the MSA as applicable) promptly during the course of a Feasibility Study Project Plan, or SOW if it believes its costs and expenses will exceed those estimated in the applicable Program Budget **[*]**.

(c) Cooperation. Genentech shall pay SurModics **[*]** for any other SurModics' activities related to providing additional cooperation to Genentech under and in accordance with Sections 4.3(c), 5.3 or 6.3 of this Agreement, and as provided under Section 13.3.6 of the MSA, **[*]**.

7.3 Development Milestone Payments. With respect to each **[*]**, Genentech shall pay to SurModics the following milestone payments [*] after the first achievement by Genentech, its Affiliates or sublicensees or their Affiliates of each of the corresponding Milestone Events by the first Licensed Product Directed to such **[*]**:

[*]

7.4 Valid Claim Royalty Payment. Subject to the provisions of this Article 7, on a country-by-country and Licensed Product-by-Licensed Product basis, for the applicable Royalty Term, Genentech shall pay SurModics a royalty (the "Valid Claim Royalty") on Net Sales by Genentech, its Affiliates and sublicensees of Licensed Products, **[*]**:

[*]

7.5 [*].

7.6 [*]

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7.7 Single Royalty. In no event shall more than one royalty payment be due to SurModics hereunder with respect to the sale of a particular Licensed Product even, without limitation, if the sale of such Licensed Product is covered by more than one Valid Claim in the SurModics IP Rights or Combination Patent Rights.

7.8 Royalty Term. On a Licensed Product-by-Licensed Product and country-by-country basis, Genentech's obligation to pay SurModics royalty payments based on Net Sales of a particular Licensed Product in a specific country in accordance with Sections 7.4, 7.5, or 7.6 shall commence on the first Commercial Sale of such Licensed Product in such country [*]. Upon expiration of the Royalty Term for a particular Licensed Product in a given country, the licenses granted to Genentech under this Agreement with respect to such Licensed Product in such country shall become fully paid-up and irrevocable.

7.9 [*].

Article 8 Reports, Audits and Financial Terms

8.1 Net Sales Reports and Royalty Payment. Genentech's obligation to pay royalties under Article 7 accrues on the sale of each Licensed Product during its Royalty Term. For Net Sales occurring within the United States, within [*] days after [*] in which a royalty payment under Article 7 has accrued, Genentech shall pay SurModics the total royalty payment owed based on the royalty obligations that accrued [*], which payment will be accompanied by a report of Net Sales of Licensed Product for which a royalty is due (each, a "Net Sales Report"). [*] Genentech shall pay SurModics the total royalty payment owed based on the royalty obligations that accrued in [*], which payment will be accompanied by a Net Sales Report. Each Net Sales Report will set forth for [*] the following information: [*].

8.2 Additional Financial Terms.

(a) Currency. All payments to be made under this Agreement shall be made in United States dollars, unless expressly agreed otherwise by the Parties in writing. Amounts invoiced in a currency other than dollars must be expressed in the United States dollar equivalent as well as any local currency. Net Sales outside of the United States shall be first determined in the currency in which they are earned and shall then be converted into an amount in United States dollars. In each calendar quarter, whenever conversion of payments from any foreign currency shall be required, such conversion shall be made using Genentech's (or Genentech Affiliate's or sublicensee's) then-current policy used for external financial reporting.

(b) Payment Type. Amounts paid by one Party to the other Party under this Agreement shall be paid in immediately available funds, by means of wire transfer to an account identified by the payee.

(c) Withholding of Taxes. Genentech may withhold from the royalty payments due to SurModics the amount of any withholding taxes that are required by law to be paid to any taxing authority with respect to such payments. Genentech shall provide to SurModics (a) all relevant documents and correspondence, and (b) any other cooperation or assistance on a reasonable basis, in each case as may be necessary to enable SurModics to claim

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exemption from such withholding taxes and to receive a full refund of such withholding tax or claim a foreign tax credit. Genentech, upon SurModics' request, shall provide SurModics with proper documentation to prove such taxes have been paid within the time period required by applicable laws. The Parties shall cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force.

(d) Late Payments. Any amounts not paid within thirty (30) calendar days after the date due under this Agreement are subject to interest from the date due through and including the date upon which payment is received. Interest is calculated, over the period between the date due and the date paid, at a rate equal to **[*]**, calculated on the number of days such payment is past due, compounded monthly.

(e) Blocked Currency. If, at any time, legal restrictions prevent the prompt remittance of part or all royalties based on Net Sales in any country where a Licensed Product is sold, payment shall be made through such lawful means or methods as the Party paying may determine. When, in any country, laws or regulations prohibit both the transmittal and deposit of royalties or other payments; the Party paying shall continue to report all such amounts, but may suspend payment for as long as such prohibition is in effect. As soon as such prohibition ceases to be in effect, all amounts that would have been obligated to be transmitted or deposited, but for the prohibition, shall forthwith be deposited or transmitted promptly.

8.3 Accounts and Audit.

(a) Records. To the extent applicable, Genentech shall keep full, true and accurate books of account containing the particulars of Net Sales and the calculation of royalties, and SurModics shall keep full, true and accurate books of account containing the particulars of all time, materials and expenses invoiced to Genentech hereunder. Such books of account and the supporting data will be maintained available for examination for **[*]**, and otherwise as required to comply with the Accounting Standard relevant for each Party.

(b) Appointment of Auditor. A Party may appoint an independent certified public accounting or consulting firm reasonably acceptable to the other Party to inspect the relevant books of account of such other Party to verify any reports or statements provided, or amounts paid or invoiced (as appropriate), by the audited Party. The accounting or consulting firm (and any individuals, if applicable) appointed to perform the examination under this Agreement must execute a confidential disclosure agreement with the audited Party or otherwise be subject to terms governing non-use and non-disclosure of information that the audited Party has agreed in writing are acceptable.

(c) Procedures for Audit. A Party may exercise its right to have relevant records **[*]**. The audited Party is required to make its records available for inspection only during regular business hours, only at such place or places where such records are customarily kept, and only upon receipt of at least thirty (30) calendar days written advance notice from the auditing Party.

(d) Audit Report. The independent accountant or consultant will be instructed to provide an audit report containing its conclusions regarding the audit, and specifying whether the amounts paid were correct, and, if incorrect, the amount of any underpayment or overpayment. The independent accountant or consultant further will be

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instructed to provide that audit report first to the audited Party, and to redact any proprietary information of the audited Party not relevant to the calculation of royalties or other applicable payment information prior to providing that audit report to auditing Party. That audit report shall be deemed to be Confidential Information of the audited Party, and used only for purposes germane to this Section 8.3.

(e) Underpayment and Overpayment. After review of the auditor's report: (i) if the auditor determines there has been an underpayment by the audited Party for the period in question, then the audited Party shall pay to the auditing Party the full amount of that underpayment, and (ii) if the auditor determines there has an overpayment by the audited Party for the period in question, then the audited Party shall have a credit against future payments due to the auditing Party (such credit equal to the full amount of that overpayment), or, if the audited Party is not obligated to make any future payments, then the auditing Party shall pay to the audited Party the full amount of that overpayment. **[*]**

Article 9 Confidentiality

9.1 Confidential Information. As used in this Agreement, "Confidential Information" means nonpublic information, including, without limitation Know-How, disclosed by one Party to the other Party in connection with this Agreement. Whether or not marked as confidential, Genentech's Confidential Information shall include, without limitation, the Option Notice provided under Section 2.3, updates provided by Genentech in accordance with Section 3.5, the work plan for each Feasibility Study, each Project Plan, any Reports provided under Section 4.3(d), all information (and not materials) in the SurModics Project Deliverables, and Net Sales Reports provided to SurModics in accordance with Section 8.1; and SurModics' Confidential Information will include non-public patent applications provided by SurModics to Genentech under this Agreement, if any.

9.2 Limitations on Use. Except to the extent expressly authorized by this Agreement, during the Term and for [*] years following its expiration or termination each Party agrees (a) to use such Confidential Information only for the purposes contemplated under this Agreement, (b) to protect such Confidential Information as it would its own proprietary information which in all events shall be with a reasonable standard of care, and (c) to prevent the unauthorized disclosure of such Confidential Information to a Third Party.

9.3 Limitations of Confidentiality. The obligations of confidentiality, non-disclosure, and non-use set forth in this Article 9 shall not apply to Confidential Information of a particular Party to the extent that the other Party (the "Recipient") can demonstrate through written records that such Confidential Information: (a) is in the public domain, other than as a result of actions of the Recipient, its Affiliates, employees, licensees, agents or subcontractors, in breach of this Agreement; (b) is received by the Recipient or its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality; (c) is independently developed by the Recipient or its Affiliates without any access to or use of any Confidential Information of the disclosing Party (as applicable); or (d) is information generated from a clinical trial sponsored or undertaken by Genentech or its sublicensee (which will be Genentech's Confidential Information, and not the Confidential Information of SurModics). Further, the obligations of confidentiality, non-disclosure, and non-

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use set forth in this Article 9 shall not apply to specific Confidential Information of a disclosing Party to the extent that the Recipient can demonstrate through written records that such Confidential Information was rightfully known by the Recipient or its Affiliates prior to the date of disclosure to the Recipient by the disclosing Party.

9.4 Exceptions. Notwithstanding the foregoing, a Party may use and disclose Confidential Information of the other Party (a) if required by applicable law, rule, regulation (including securities laws and regulations), government requirement and/or court order, including as may be required in connection with any filings made with, or by the disclosure policies of a major stock exchange, *provided, that*, the Party proposing such disclosure promptly notifies the other Party of its notice of any such requirement and provides the other Party a reasonable opportunity to seek a protective order or other appropriate remedy and/or to waive compliance with the provisions of this Agreement; (b) to the extent such use and disclosure is necessary for undertaking clinical trials or the filing or publication of any patent application or patent on inventions in accordance with the provisions of Section 10; (c) as reasonably necessary for securing any Regulatory Approvals, including pricing approvals, for any Licensed Products, *provided, that*, the disclosing Party shall take all reasonable steps to limit disclosure of the Confidential Information outside such regulatory agency and to otherwise maintain the confidentiality of the Confidential Information; and (d) to the extent necessary or reasonably useful, to its Affiliates, directors, officers, employees, consultants, sublicensees (and potential sublicensees), and other Third Parties under written agreements of confidentiality at least as restrictive on those set forth in this Agreement, who have a need to know such information in the normal conduct of a Party's internal business operations or in connection with a Party performing its obligations or exercising its rights under this Agreement, including, without limitation to Third Parties involved in the clinical development of a Licensed Product.

9.5 Return of Confidential Information. On expiration or termination of the entirety of this Agreement, at the request of the disclosing Party, the receiving party shall use reasonable efforts to return or destroy all Confidential Information of the disclosing party that remains in the receiving party's possession and that is not reasonably necessary to exercise rights that survive such expiration or termination, except one copy of which may be retained for archival purposes to ensure compliance with the terms of this Agreement.

9.6 Publicity and Public Announcements. Without limiting the exclusions to Confidential Information under Section 9.3, neither Party shall issue any public announcement, press release or other publicity materials, or make any public presentation with respect to the existence of, or any of the terms or conditions of, this Agreement or the programs or efforts being conducted hereunder, in each case without the prior written consent of the other Party; provided that no consent shall be required for any press release, publicity material or public presentation (a) that has already been made or authorized by the Parties, to the extent a Party merely uses or refers to such materials, presentation or announcement, or (b) made by Genentech or a Genentech sublicensee and related to any clinical data generated in the course of Development of a Licensed Product or related to the Development status, plans and strategy for the Licensed Product. When practicable, Genentech shall provide SurModics with an advance copy of any such announcement at least [*] Business Days prior to its scheduled release. SurModics shall expeditiously review and recommend changes (if any) to any such announcement and, except as otherwise required by applicable laws, Genentech shall remove any

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Confidential Information of SurModics. Either Party may refer to the other Party as a "collaborator" on its website, provided such reference has received prior written approval from such Party. The Parties hereby consent to the disclosure of the press release attached hereto as Exhibit F.

9.7 Disclosure of Agreement. Subject to Sections 9.3, 9.4, and 9.6, during the Term and for [*] years following its expiration or termination, neither Party may disclose the existence of this Agreement or any of the terms (including, but not limited to, the financial terms) of this Agreement to a Third Party without the prior written consent of the other Party.

Article 10 Intellectual Property Matters.

10.1 Disclosure. SurModics shall disclose to Genentech any Project Know-How promptly after SurModics learns of such Project Know-How having been conceived, reduced to practice, or otherwise made, discovered, or created. Genentech shall use reasonable efforts to disclose to SurModics any Joint Project Know-How or SurModics Project Know-How promptly after Genentech learns of such Project Know-How having been made by Genentech.

10.2 Pre-Existing and Independently Developed Intellectual Property Rights. All intellectual property rights of SurModics existing as of the Effective Date, or developed, made or acquired separately from activities under the Existing Feasibility Study, any other Feasibility Study, Project Plan, or the MSA, shall remain owned and vested at all times exclusively in SurModics, and Genentech shall have no interest whatsoever in any such intellectual property rights *other than* the rights expressly granted under the Existing Feasibility Study, this Agreement or the MSA. All intellectual property rights of Genentech existing as of the Effective Date, or developed, made or acquired separately from activities under this Agreement, shall remain owned and vested at all times exclusively in Genentech, and SurModics shall have no interest whatsoever in any such intellectual property rights *other than* the rights expressly granted under this Agreement.

10.3 Ownership of Project Know-How.

(a) Genentech Project Know How. [*]

(b) SurModics Project Know How. [*]

(c) Joint Project Know How. [*]

10.4 Patent Filings.

(a) Solely Owned. Genentech may, at its sole discretion and expense, prosecute, maintain and enforce Patents covering the Genentech Project Know How (the "Genentech Project Patents") (Genentech Project Patents and Genentech Project Know-How collectively "Genentech Project IP Rights"). SurModics may, at its sole discretion and expense, prosecute, maintain and enforce Patents covering the SurModics Project Know-How (the "SurModics Project Patents") (SurModics Project Patents and SurModics Project Know-How collectively "SurModics Project IP Rights"). Notwithstanding the foregoing, SurModics agrees

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to Prosecute and Maintain in the Territory, as appropriate and upon appropriate consultation with Genentech, SurModics Patents that cover Licensed Products or their use. With respect to any such SurModics' Patents, SurModics shall keep Genentech advised of the status of any actual and prospective patent filings and, upon Genentech's request, shall provide advance copies of any papers related to the filing, prosecution and maintenance of such patent filings. SurModics shall promptly give notice to Genentech of the grant, lapse, revocation, surrender, invalidation or abandonment of any SurModics Patents licensed to Genentech for which SurModics is responsible for the Prosecution and Maintenance. For clarity, SurModics shall have the sole right, at its sole expense, to Prosecute and Maintain the SurModics Patents to the extent such Patents do not cover the Licensed Products or the Injection Vehicles (or uses thereof).

(b) Jointly Owned.

(i) Filing of Applications. The Parties shall select a mutually agreed upon outside patent counsel ("Outside Patent Counsel") to prepare and/or file any patent application claiming Joint Project Know-How (a "Joint Project Patent") (Joint Project Patents and Joint Project Know-How collectively "Joint Project IP Rights"). Should a Party wish to file a patent application for a Joint Project Patent, it shall so inform the other. With respect thereto, SurModics shall engage Outside Patent Counsel and each Party shall receive a copy of any such patent application for review and comment as set forth in (ii) below. If SurModics declines to Prosecute and Maintain a Joint Project Patent, then Genentech may elect to do so as provided under this Section 10.4(b). The Party that is Prosecuting and Maintaining a particular Joint Project Patent shall be referred to as the "Prosecuting Party."

(ii) Review and Comment. With respect to Joint Project Patents, the Prosecuting Party shall, or shall instruct the Outside Patent Counsel to: (1) keep both Parties informed as to the Prosecution and Maintenance (including as pertains to which countries in which to initiate or continue prosecution (including validation) and questions of the scope, issuance, or rejection of an interference involving or an opposition to any such Patents), such that each Party has sufficient time to review and comment on any documents intended for submission to any patent office; (2) promptly furnish to each Party a copy of any patent application and copies of documents relevant to such Prosecution and Maintenance, including copies of correspondence with any patent office, foreign associates, and outside counsel; and (3) reasonably consider and incorporate comments of both Parties on documents filed with any patent office.

(iii) Abandonment of Prosecution and Maintenance. If SurModics elects (1) not to Prosecute and Maintain a Joint Project Patent (whether worldwide or with respect to any particular country), (2) not to file a patent application with respect thereto, or (3) to allow any such Patent to lapse or become abandoned or unenforceable, then SurModics shall promptly notify Genentech in writing (which such notice shall be at least **[*]** days prior to the lapse or abandonment of any such Patent). Thereafter, Genentech may, but is not required to, undertake, at its sole expense and in its sole discretion, the Prosecution and Maintenance of such Joint Project Patent. In the event that Genentech undertakes such Prosecution, SurModics shall cooperate as set forth in this Section 10.4.

(iv) Costs. **[*]**

(v) Cooperation. The Parties agree to cooperate reasonably in the Prosecution and Maintenance of all Patents under this Section 10.4 including obtaining and

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executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the invention disclosed in each such Patent, obtaining execution of such other documents which may be needed in the Prosecution and Maintenance of each such Patent, and, as requested, updating each other regarding the status of each such Patent, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession and Control reasonably necessary to Prosecute and Maintain such Patents.

Article 11 Enforcement of Project Patent Rights and Defense of Third Party Claims

11.1 Notice. Each Party shall promptly notify, in writing, the other Party upon learning of any actual or suspected infringement of the SurModics IP Rights or a Joint Project IP Rights by a Third Party Microparticle Product, or of any claim of invalidity, unenforceability, or non-infringement of a SurModics Patent or a Joint Project Patent and shall, along with such notice, supply the other Party with all evidence in its possession pertaining thereto.

11.2 Infringement Actions.

(a) Genentech Project Know How. As between the Parties, Genentech shall have the right, but not the obligation, to seek to abate any actual or suspected infringement of the Genentech IP Rights or the Genentech Project IP Rights by a Third Party, or to file suit against any such Third Party.

(b) SurModics IP Rights. Except as otherwise provided in this Section 11.2(b), SurModics shall have the sole right, but not the obligation, to seek to abate any actual or suspected infringement of the SurModics IP Rights or the SurModics Project IP Rights by a Third Party, or to file suit against any such Third Party. Notwithstanding the foregoing, if the actual or suspected infringement by a Third Party of the SurModics IP Rights or the SurModics Project IP Rights affects a Licensed Product or [*] which is (at such time) exclusively licensed to Genentech under this Agreement (a "Field Infringement"), SurModics shall have the first right, but not the obligation, to seek to abate such actual or suspected Field Infringement of the SurModics IP Rights or the SurModics Project IP Rights by a Third Party, or to file suit against any such Third Party. If SurModics does not, within **[*]** of receipt of a notice under Section 11.1, take steps to abate the actual or suspected Field Infringement, or file and thereafter prosecute a suit to enforce the SurModics IP Rights or the SurModics Project IP Rights against such Third Party with respect to such Field Infringement, Genentech shall have the right (but not the obligation) to take action to enforce the SurModics Project IP Rights or the SurModics Project IP Rights related to the Field Infringement against such Third Party, provided that Genentech first obtains SurModics' consent to take such action, such consent not to be unreasonably withheld or delayed. The non-controlling Party shall cooperate with the Party controlling any such action (as may be reasonably requested by the controlling Party and at its expense), including, if necessary, by being joined as a party, and the Party controlling any such action shall keep the other Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.

(c) Joint Project IP Rights. SurModics shall have the first right, but not the obligation, to seek to abate any actual or suspected infringement of the Joint Project IP Rights by a Third Party, or to file suit against any such Third Party. If SurModics does not,

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within **[*]** of receipt of a notice under Section 11.1, take steps to abate the actual or suspected infringement, or file and thereafter prosecute a suit to enforce thee Joint Project IP Rights against such Third Party, Genentech shall have the right (but not the obligation) to take action to enforce the Joint Project IP Rights against such Third Party. The non-controlling Party shall cooperate with the Party controlling any such action (at the controlling Party's expense and as may be reasonably requested by the controlling Party), including, if necessary, by being joined as a party, and the Party controlling any such action shall keep the other Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.

11.3 Settlement. The Party controlling any action described in Section 11.2 may not settle the action, or consent to a judgment in the action, that adversely affects the scope, validity or enforcement of the other Party's Patents or Joint Project IP Rights (as applicable), without the express written consent of the non-controlling Party (such consent not to be unreasonably withheld or delayed).

11.4 Damages. Unless otherwise mutually agreed by the Parties, and subject to the respective indemnity obligations of the Parties set forth in Article 14, all monies recovered upon the final judgment or settlement of any action described in this Article 11, shall be used: [*]

11.5 Third Party Suits.

(a) Against Genentech. If a Third Party makes a claim or brings a suit or other proceeding against Genentech, or any of its Affiliates, sublicensees or customers, alleging that the research, development making, using selling, offering for sale, import or export of Licensed Product infringes or otherwise violates the intellectual property rights of such Third Party, Genentech shall have the sole right to defend and control the defense of such claim, suit or other proceeding as well as to initiate and control any counterclaim or other similar action. SurModics shall fully cooperate with Genentech in defense of such claim, suit or other proceeding, at Genentech's expense (including any reasonable costs or expenses incurred by SurModics in connection with such claim, suit or other proceeding, such as, costs incurred in responding to subpoenas), including by being joined as a party. Unless otherwise mutually agreed by the Parties, and subject to the respective indemnity obligations of the Parties set forth in Article 14, the provisions of Sections 11.3 and 11.4 shall apply to any proceeding covered by this Section 11.5(a), except that any license from the Third Party shall be subject to Section 7.9. Notwithstanding the foregoing, Genentech may, in its sole discretion, settle any claim or suit under this Section 11.5(a) consistent with the terms of Section 11.3

(b) Against SurModics. If a Third Party makes a claim or brings a suit or other proceeding against SurModics or any of its Affiliates, sublicensees or Third Party contractors, alleging that their activities under this Agreement or the MSA infringes or otherwise violates the intellectual property rights of such Third Party, SurModics shall have the right to defend and control the defense of such claim, suit or other proceeding. Any counterclaim or other similar action, to the extent they involve any Genentech IP Rights, SurModics IP Rights or Project IP Rights, will be treated as enforcement actions subject to Section 11.2 (as applicable). Promptly upon receipt of notice of any such claim, suit or other proceeding against SurModics, SurModics shall provide written notice thereof to Genentech. On Genentech's written request, SurModics will discuss cooperation regarding any such claims and/or will keep Genentech

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informed as to the status of the claim suit or proceeding and defense. Also on Genentech's written request, SurModics will permit Genentech to participate in the defense and settlement of any such claim, suit or proceeding, at its own expense and represented by counsel of its own choice, provided that SurModics will in all events control such defense of any claim against it. Unless otherwise mutually agreed by the Parties, and subject to the respective indemnity obligations of the Parties set forth in Article 14, the provisions of Sections 11.3 and 11.4 shall apply to any proceeding covered by this Section 11.5(b).

Article 12 Term and Termination

12.1 Term. This Agreement shall be effective as of the Effective Date and shall remain in effect on a country-by-country and Licensed Product-by-Licensed Product basis until expiration of all royalty obligations hereunder, unless sooner terminated as provided in this Article 12. Upon expiration of this Agreement, Genentech's licenses pursuant to Section 2.1 shall become fully paid-up, perpetual licenses. For the purposes of this Agreement, "Term" shall mean the period commencing with the Effective Date through to the date of such expiration or earlier termination referenced in the first sentence of this Section, and in the event this Agreement is terminated or expires only with respect to a particular Licensed Product **[*]**, "Term" of this Agreement as it applies to such Licensed Product **[*]** shall terminate as of the effective termination or expiration date for such Licensed Product **[*]** as specified in this Article 12.

12.2 Termination for Convenience. Genentech shall have the right to terminate any Feasibility Study, Project Plan, or SOW, or the MSA or this Agreement (each in its entirety [*]), at any time in its sole discretion by giving [*] prior written notice to SurModics.

12.3 Termination for Material Breach. SurModics may terminate this Agreement [*] for breach by Genentech of its material obligations hereunder. Genentech may terminate this Agreement in its entirety [*] for breach by SurModics of its material obligations hereunder. Provided, however that the terminating Party gives the breaching Party written notice of such breach indicating its intent to terminate and the breach remains uncured after the expiration of [*] after such written notice was given. Notwithstanding the foregoing, if the allegedly breaching Party disputes in good faith such material breach or its failure to cure such breach by written notice to the other Party within such [*] period, then such dispute shall be submitted to the dispute resolution procedures set forth in Article 15. In that event, the notifying Party does not have the right to terminate until it has been determined, pursuant to the procedures set forth in Article 15, that the allegedly breaching Party is in material breach of this Agreement, and such breaching Party further fails to cure such breach within [*] after the conclusion of any proceedings under Article 15.

12.4 Termination on Challenge. [*]

12.5 Termination for Bankruptcy.

(a) Bankruptcy. Genentech may terminate this Agreement immediately upon (i) the bankruptcy, insolvency, liquidation, dissolution or cessation of operations of SurModics; (ii) the filing of any voluntary petition for bankruptcy, dissolution, liquidation or

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winding-up of the affairs of SurModics; (iii) any assignment by SurModics for the benefit of creditors; (iv) the filing of any involuntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of SurModics that is not dismissed within **[*]** of the date on which it is filed or commenced; or (v) upon any final judicial or administrative determination that this Agreement violates, or if continued would violate, in a substantial manner, any provision of the Federal Internal Revenue Code.

(b) Survival of the License. The licenses granted to Genentech under this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the "Bankruptcy Code" (*i.e.*, Title 11, U.S. Code), licenses of rights to "intellectual property" as defined under Section 101(56) of the Bankruptcy Code. The Parties agree that Genentech shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code in the event of a bankruptcy by SurModics.

12.6 Effects of Termination or Expiration.

(a) In General. Termination or expiration of this Agreement shall not affect the rights and obligations of the Parties that accrued prior to the effective date of such termination or expiration. In particular, no termination or expiration of this Agreement shall relieve Genentech of its obligation to pay any milestone payments or royalty payments that accrued prior to such termination or expiration. In addition, no termination of this Agreement shall relieve Genentech of its obligation to pay SurModics for any amounts accrued by SurModics, and any non-cancelable fees and expenses committed by SurModics, in each case prior to the effective date of such termination in the performance of its activities under this Agreement and otherwise in accordance with a Program Budget. Within **[*]** after the date of any termination, SurModics shall provide Genentech with an accounting for any such accrued and/or any non-cancelable amounts which may include reasonable non-cancelable obligations properly incurred for the applicable Feasibility Study, Project Plan, or SOW and reasonable wind-down activities by SurModics prior to the effective date of termination to extent such obligations cannot reasonably be mitigated. Within **[*]** after SurModics provides Genentech with such accounting, Genentech shall pay SurModics the amounts due for such activities properly performed.

(b) Termination for Convenience; Termination for Genentech's Material Breach; Termination on Challenge. Upon any voluntary termination of this Agreement by Genentech pursuant to Section 12.2, by SurModics for a material breach by Genentech pursuant to Section 12.3, or by SurModics for a Challenge pursuant to Section 12.4 with respect to each [*] for which such right of termination is exercised (each a "Terminated [*]"): (i) to the extent not already completed, the activities under this Agreement or the MSA for such Terminated [*] shall immediately terminate; (ii) the rights and licenses granted to Genentech under Section 2.1 with respect to Licensed Products Directed to such Terminated [*], and not otherwise applicable to other [*] or Licensed Products, shall immediately terminate; (iii) all rights and licenses granted to SurModics under Section 2.4 with respect to such Terminated [*], and not otherwise applicable to other [*], shall immediately terminate; (iv) the limitations regarding Third Party Microparticles Products under Section 4.4 with respect only to a Terminated [*] shall terminate; (v) Genentech's rights under Section 2.3 (except with respect to Section 2.3(v) as may be applicable to such Terminated [*]) shall survive any termination other then a termination of this Agreement in its entirety; (vi) each Party shall return or destroy,

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subject to the terms of Section 9.6, any Confidential Information of the other Party related to such Terminated [*] and not otherwise applicable to other [*]; and (vii) Sections 10.2, 10.3, 11.2, 11.3, and 11.4 shall survive with respect to Licensed Products Directed to a Terminated [*]. Except as set forth in this Section 12.5(b), all rights and obligations of each Party under this Agreement with respect to such Terminated [*] and Licensed Products Directed to such Terminated [*] shall immediately terminate, and any provisions and rights applicable to other **[*]** or Licensed Products shall survive. **[*]**

(c) [*].

12.7 [*].

12.8 Survival. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination of this Agreement only to the extent expressly provided in this Agreement. In addition to as set forth in this Article 12, and without limiting the foregoing, Article 1, Section 2.5, Articles 9, 10, and 11 (except 11.1) Sections 12.5(c), 12.6, 12.7 and 12.8, Articles 14 and 15, and Sections 16.1, 16.4, 16.5, 16.6, and 16.7, 16.8, 16.9, and 16.10 shall survive expiration or termination of this Agreement for any reason, but in all cases shall be interpreted to exclude the subject matter of non-surviving terms.

Article 13 Representations, Warranties and Disclaimers

13.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

(a) it is duly organized and validly existing under the laws of the state of its organization and has full corporate power and authority to enter into this Agreement and carry out the provisions hereof;

(b) the execution, delivery and performance of this Agreement by it does not violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

(c) it has not, prior to the Effective Date, entered into and shall not, following the Effective Date, enter into any agreement, instrument or understanding, oral or written, that materially conflicts in any way with this Agreement or its obligations hereunder.

(d) it has the right to grant the rights and licenses described in this Agreement.

13.2 SurModics Representations and Warranties. SurModics represents and warrants to Genentech that,

(a) SurModics has the full right, power and authority, and has obtained all approvals, permits or consents necessary, to enter into this Agreement and the **[*]** (as defined in Section 1.13), to perform all of its obligations, and to grant the licenses provided hereunder.

(b) SurModics has not, prior to the Effective Date, entered into and shall not, following the Effective Date, enter into any agreement and has not granted any now existing,

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or agreed to grant any future, license, right or privilege which agreement, license, right or privilege conflicts in any way with this Agreement, the licenses granted, or SurModics' obligations hereunder.

(c) SurModics owns or Controls the SurModics IP Rights licensed to Genentech hereunder.

(d) as of the Effective Date, to its knowledge, the SurModics Patents set forth on Exhibit C are free and clear of any liens or encumbrances, and following the Effective Date SurModics will not knowingly encumber the SurModics Patents with any liens or encumbrances.

[*]

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13.3 DISCLAIMER. THE WARRANTIES SET FORTH IN THIS ARTICLE 13 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; WARRANTIES OF INTELLECTUAL PROPERTY VALIDITY OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY; WARRANTIES OF SUCCESSFUL DEVELOPMENT OR COMMERCIALIZATION; AND ALL SUCH OTHER WARRANTIES ARE HEREBY EXPRESSLY DISCLAIMED.

Article 14 Indemnification, Insurance, Limitations on Liability

14.1 Indemnification by SurModics. Unless otherwise provided herein, SurModics shall indemnify, hold harmless and defend Genentech, its Affiliates and their directors, officers, employees and agents (the "Genentech Indemnitees") from and against any and all damages, judgments, liabilities, expenses and/or losses [*]

14.2 Indemnification by Genentech. Unless otherwise provided herein, Genentech shall indemnify, hold harmless and defend SurModics and its directors, officers, employees and agents (the "SurModics Indemnitees") from and against any and all Losses to the extent that such Losses arise out of [*]

14.3 Procedure. The indemnities set forth in this Article 14 are subject to the condition that the Party seeking the indemnity shall promptly notify the indemnifying Party on being notified or otherwise made aware of Claim and the indemnifying Party being permitted to defend and control any proceedings with the other Party being permitted to participate at its own expense (unless there is a conflict of interest which would prevent representation by joint counsel, in which event the indemnifying Party shall pay for the indemnified Party's counsel). Provided, however, that (a) the Party seeking indemnity reasonably cooperates in any such defense (at the indemnifying Party's expense), and (b) the indemnifying Party may not settle the liability, claim, suit, action or expense, or otherwise consent to any judgment, without the written consent of the other Party (such consent not to be unreasonably withheld).

14.4 Insurance.

(a) General. Each Party shall maintain insurance coverage as set forth in this Section 14.4 at its own cost; provided, however, Genentech has the right, in its sole discretion, to self-insure, in part or in whole, for any such coverage. Insurance coverage shall be primary insurance with respect to each Party's own participation under this Agreement and shall be maintained with an insurance company or companies having an A.M. Best's rating (or its equivalent) of A-VII or better. On request, each Party shall provide to the other Party certificates of insurance evidencing the insurance coverage required under this Section 14.4. Each Party shall provide to the other Party at least [*] prior written notice of any cancellation, nonrenewal or material change in any of the required insurance coverages.

(b) Commercial General Liability. For as long as a Party is performing obligations under the Agreement, and thereafter as required under this Section 14.4, each Party shall maintain commercial general liability ("CGL") insurance, including contractual liability, at a combined single limit for bodily injury and property damage liability [*].

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(c) Form of CGL. The CGL insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, such Party shall maintain the insurance [*]. Each Party shall name the other Party as an additional insured under its CGL insurance policy.

(d) Workers' Compensation and Employers' Liability Insurance. Each Party shall maintain (i) workers' compensation insurance according to applicable law and (ii) employers' liability insurance, in the minimum amount of [*].

[*]

14.5 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, INDIRECT, INCIDENTAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING, WITHOUT LIMITATION LOST PROFITS, REGARDLESS OF WHETHER ARISING FROM BREACH OF CONTRACT, WARRANTY, TORT, STRICT LIABILITY, OR OTHERWISE, EVEN IF THE PARTY IS ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE OR IF SUCH LOSS OR DAMAGE COULD HAVE BEEN REASONABLY FORESEEN. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY.

Article 15 Dispute Resolution

15.1 Disputes. "Dispute" means any controversy, claim or legal proceeding arising out of or relating to this Agreement, or the breach, termination, or invalidity thereof. Notwithstanding the foregoing, Disputes shall not include any disagreements solely about decisions for which one Party has final decision making authority under this Agreement.

15.2 Internal Resolution. Except as otherwise expressly provided in this Agreement (including under Section 3.6), any Disputes shall be first referred to the Parties' Senior Executives for resolution, prior to proceeding under the other provisions of this Article 15. A Dispute shall be referred to such executives upon one Party providing the other Party with written notice that such Dispute exists, and such executives, or their designees, shall attempt to resolve such Dispute through good faith discussions. In the event that such Dispute is not resolved within **[*]** of such other Party's receipt of such written notice, either Party may initiate the Dispute resolution procedures set forth in Section 15.3. The Parties agree that any discussions between such executives, or their designees, regarding such Dispute do not constitute settlement discussions, unless the Parties agree otherwise in writing.

15.3 Arbitration.

(a) Rules. Except as otherwise expressly provided in this Agreement (including, without limitation, under Section 3.6 and this Article 15), the Parties agree that any Dispute not resolved internally by the Parties in accordance with Section 15.2 shall be resolved through binding arbitration conducted by the American Arbitration Association in accordance with the then prevailing Commercial Arbitration Rules of the American Arbitration Association

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(for purposes of this Article 15, the "Rules"), except as modified in this Agreement, applying the substantive law specified in Section 16.

(b) Arbitrators; Location. Each Party shall select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third arbitrator. All three (3) arbitrators shall serve as neutrals and have at least ten (10) years of (a) dispute resolution experience (which may include judicial experience) or (b) legal or business experience in the biotech or pharmaceutical industry. In any event, at least one (1) arbitrator shall satisfy the foregoing experience requirement under clause (b). If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third arbitrator, the necessary appointments shall be made in accordance with the Rules. Once appointed by a Party, such Party shall have no *ex parte* communication with its appointed arbitrator. The arbitration proceedings shall be conducted in San Francisco, California if SurModics initiates the arbitration or in Minneapolis, Minnesota if Genentech initiates the arbitration.

(c) Procedures; Awards. Each Party agrees to use reasonable efforts to make all of its current employees available, if reasonably needed, and agrees that the arbitrators may deem any party as "necessary." The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more [*] after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. Each Party agrees that, notwithstanding any provision of applicable laws or of this Agreement, it will not request, and the arbitrators shall have no authority to award, punitive or exemplary damages against any Party.

(d) Costs. The "prevailing" Party, as determined by the arbitrators, shall be entitled to (i) its share of fees and expenses of the arbitrators and (ii) its attorneys' fees and associated costs and expenses. In determining which Party "prevailed," the arbitrators shall consider (1) the significance, including the financial impact, of the claims prevailed upon and (2) the scope of claims prevailed upon, in comparison to the total scope of the claims at issue. If the arbitrators determine that, given the scope of the arbitration, neither Party "prevailed," the arbitrators shall order that the Parties (A) share equally the fees and expenses of the arbitrators and (B) bear their own attorneys' fees and associated costs and expenses.

(e) Interim Equitable Relief. Notwithstanding anything to the contrary in this Section 15.3, in the event that a Party reasonably requires relief on a more expedited basis than would be possible pursuant to the procedure set forth in Section 15.3, such Party may seek a temporary injunction or other interim equitable relief in a court of competent jurisdiction pending the opportunity of the arbitrators to review the decision under Section 15.3. Such court shall have no jurisdiction or ability to resolve Disputes beyond the specific issue of temporary injunction or other interim equitable relief.

(f) Protective Orders; Arbitrability. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability.

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(g) Expedited Review. With respect to any dispute brought by either Party, no later than [*] after selection of the third arbitrator in accordance with Section 15.3(b), the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking expedite in a timely manner the arbitration. Failing any such mutual agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

15.4 Subject Matter Exclusions. Notwithstanding the provisions of Section 15.3, any Dispute not resolved internally by the Parties pursuant to Section 15.2 that involves the validity, infringement or enforceability or claim construction of a Patent, or defenses to any of the foregoing (a) that is issued in the United States shall be subject to actions before the United States Patent and Trademark Office and/or submitted to a federal court of appropriate jurisdiction; and (b) that is issued in any other country (or region) shall be brought before an appropriate regulatory or administrative body or court in that country (or region), and the Parties hereby consent to the jurisdiction and venue of such courts and bodies.

Article 16 MISCELLANEOUS

16.1 Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York (other than Section 5-1401 of the New York General Obligations Law), without regard to conflict of laws principles. The Parties hereby exclude from this Agreement the application of the United Nations Convention on Contracts for the International Sale of Goods.

16.2 Assignment. Except as otherwise expressly provided in this Agreement, neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, such consent not to be unreasonably withheld. Either Party may assign this Agreement, in its entirety, to (a) an Affiliate or (b) an acquirer of all its capital stock (by reverse triangular merger or otherwise), a successor by merger or consolidation or an acquirer of all or substantially all its assets relating to the subject matter of this Agreement, provided, in each case, that the party to which this Agreement is assigned expressly agrees in writing to assume and be bound by the obligations of the assigning Party under this Agreement. A copy of such writing shall be provided to the non-assigning Party within **[*]** of the assignment. Subject to the foregoing, this Agreement will inure to the benefit of and bind the Parties' successors and assigns. Any assignment in contravention of the foregoing shall be null and void.

16.3 Force Majeure. Neither Party shall be deemed to have breached this Agreement for failure to perform its obligations under this Agreement to the extent such failure results from causes beyond the reasonable control of the affected Party, including acts of God, earthquakes, fires, floods, embargoes, wars, acts of terrorism, insurrections, riots, civil commotions and similar events. If a force majeure event occurs, the Party unable to perform shall promptly notify the other Party of the occurrence of such event, and the Parties shall meet (in person or telephonically) promptly thereafter to discuss the circumstances relating thereto. The Party unable to perform shall (a) provide reasonable status updates to the other Party from

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time to time, (b) use commercially reasonable efforts to mitigate any adverse consequences arising out of its failure to perform and (c) resume performance as promptly as possible.

16.4 Relationship of the Parties. The Parties to this Agreement are independent contractors, and nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

16.5 Notices. All notices, requests, demands, and other communications relating to this Agreement shall be in writing and shall be delivered in person or by mail, courier or facsimile transmission (with a confirmation copy forwarded by courier or mail). Notices sent by mail shall be sent by first class mail or the equivalent, registered or certified, postage prepaid, and shall be deemed to have been given on the date actually received. Notices sent by courier shall be sent using a service which provides traceability of packages. Notices shall be sent as follows:

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Notices to SurModics:

SurModics, Inc.
9924 W. 74th Street
Eden Prairie, MN 55344
Attn: Chief Executive Officer
[*]

with a required copy (which alone shall not constitute notice) to each of:

SurModics, Inc.
2855 Michelle Drive, Suite 190
Irvine, CA 92606
Attn: President, Ophthalmology Division
[*]

SurModics Pharmaceuticals Inc.
750 Lakeshore Parkway
Birmingham, Alabama 35211
Attn: President
[*]

Notices to Genentech:

Genentech Inc.
1 DNA Way
South San Francisco, CA 94080
Attention: Corporate Secretary
[*]

with a required copy (which alone shall not constitute notice) to each of:

Genentech Inc.
1 DNA Way
South San Francisco, CA 94080
Attention: Vice President, Alliance Management
[*]

and

F. Hoffmann-La Roche Ltd
Grenzacherstrasse 124
CH-4070 Basel
Switzerland
[*]

16.6 Amendment; Waiver. Except as otherwise expressly provided in this Agreement, no amendment to this Agreement shall be effective unless made in writing and executed by an authorized representative of each Party. A Party's failure to exercise, or delay in exercising, any right, power, privilege or remedy under this Agreement shall not (a) operate as a waiver thereof or (b) operate as a waiver of any other right, power, privilege or remedy. A waiver will be effective only upon the written consent of the Party granting such waiver.

16.7 Construction; Captions. Each Party acknowledges that it participated in the negotiation and preparation of this Agreement and that it had the opportunity to consult with an attorney of its choice in connection therewith. Ambiguities, if any, in this Agreement shall not be construed against either Party, irrespective of which Party may be deemed to have drafted the Agreement or authorized the ambiguous provision. Capitalized terms defined in the singular

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shall include the plural and vice versa. The terms “includes” and “including” mean “includes, without limitation,” and “including, without limitation,” respectively. Titles, headings and other captions are for convenience only and shall not affect the meaning or interpretation of this Agreement.

16.8 Severability. If any of the provisions of this Agreement are held to be illegal, invalid or unenforceable, such illegal, invalid or unenforceable provisions shall be replaced by legal, valid and enforceable provisions that will achieve to the maximum extent possible the intent of the Parties, and the other provisions of this Agreement shall remain in full force and effect.

16.9 Entire Agreement. This Agreement, the Master Services Agreement and the Existing Feasibility Study contain the entire understanding between the Parties with respect to the subject matter hereof and supersedes and terminates all prior agreements, understandings and arrangements between the Parties with respect to such subject matter, whether written or oral.

16.10 Genentech Entities. GNE and Roche shall be jointly and severally liable for all acts and omissions of Genentech, and their respective Affiliates, relating to or in connection with this Agreement, and any act or omission of, or notice to, either of them shall constitute the act or omission of, or notice to, each of them. Genentech shall cause each Affiliate who is licensed hereunder to be bound by the terms and conditions of this Agreement as if each were an original signatory to this Agreement, and shall be liable for all acts and omissions of any such Affiliate in connection therewith.

16.11 Counterparts; Facsimiles. This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. A facsimile or electronic pdf copy of this Agreement, including the signature pages hereto, will be deemed to be an original.

* * * * *

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IN WITNESS WHEREOF, the Parties hereto have caused the Agreement to be executed by their duly authorized representative.

SurModics, Inc.

By: /s/ Bruce J Barclay
Name: Bruce J Barclay
Title: President and Chief Executive Officer

Genentech, Inc.

By: [*]
Name: [*]
Title: [*]

F. Hoffmann-La Roche Ltd

By: [*]
Name: [*]
Title: [*]

By: [*]
Name: [*]
Title: [*]

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CONFIDENTIAL

EXHIBIT A

MASTER SERVICES AGREEMENT

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EXHIBIT A

MASTER SERVICE AGREEMENT

BY AND BETWEEN

GENENTECH, INC.,

F. HOFFMANN-LA ROCHE, LTD.

AND

SURMODICS, INC.

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MASTER SERVICE AGREEMENT

by and between

GENENTECH, INC. AND SURMODICS.

THIS **MASTER SERVICE AGREEMENT** (the "**MSA**") is entered into as of the 5th day of October 2009 ("**Effective Date**") by and between Genentech, Inc., a Delaware corporation**,** with offices located at 1 DNA Way, South San Francisco, CA 94080 ("GNE") and F. Hoffmann-La Roche, Ltd., Grenzacherstrasse 124, CH 4070 Basel, Switzerland ("Roche") (GNE and Roche together referred to as "**Genentech**") and SurModics, Inc. a Minnesota corporation with a principal place of business at 9924 West 74th Street, Eden Prairie, MN 55344 (SurModics, Inc. together with its Affiliates hereinafter referred to as "**SurModics**") (each individually a "**Party**" and collectively, the "**Parties**").

RECITALS

WHEREAS, the Parties have entered into a License and Development Agreement effective as of the date hereof (the "**License Agreement**"); and

WHEREAS, as part of the License Agreement, Genentech desires to purchase from SurModics, and SurModics desires to supply to Genentech, Product and Raw Materials (as hereinafter defined) in the Territory (as hereinafter defined) pursuant to the terms set forth herein.

NOW, THEREFORE, in consideration of the premises and the undertakings of the Parties hereinafter set forth, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Capitalized terms used but not defined herein shall have the meanings set forth in the License Agreement. As used in this MSA, the following terms, whether used in the singular or the plural, shall have the meanings set forth in this Article:

1.1 "**Acceptance Criteria**" shall be defined in the applicable SOW.

1.2 "**Acquisition Cost**" is defined in Section 13.3.4(b).

1.3 "**Approved Suppliers**" is defined in Section 5.5.2.

1.4 "**BLA**" means a Biologics License Application and amendments thereto filed pursuant to the requirements of the FDA, as defined in 21 C.F.R. § 600 et seq., for FDA approval of a therapeutic biological product.

1.5 "**Decommissioning**" is defined in Section 13.3.4.

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1.6 "**EMEA**" means the European Union European Medicines Evaluation Agency, or any successor agency.

1.7 "**European Union**" means the countries of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland, Sweden, United Kingdom and any additional countries that may subsequently become members of the European Union.

1.8 "**Facility**" means the SurModics' manufacturing facility at the location specified under the applicable SOW, or such other manufacturing facility of SurModics as Genentech may approve in writing.

1.9 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto.

1.10 "**GNE Materials**" means any physical embodiments, supplies or materials provided to SurModics by or on behalf of GNE in connection with the Services, including the Compounds.

1.11 "**Good Manufacturing Practices**", "**GMP**" or "**cGMP**" means current Good Manufacturing Practices pursuant to the U.S. Food, Drug and Cosmetic Act and any U.S. regulations found in Title 21 of the U.S. Code of Federal Regulations (including Parts 11, 210 and 211) and other regulations, policies, or guidelines, as applicable to the Manufacture of Products hereunder.

1.12 "**Joint Management Team**" or "**JMT**" is defined in Section 3.2.

1.13 "**Manufacture," "Manufactured"** or "**Manufacturing**" means, except as otherwise provided in a SOW, the manufacture, inspection, storage and/or packaging of Product.

1.14 "**Manufacturing Documentation**" means all data, documents and records describing or otherwise related to the Manufacturing Process (or any part thereof) provided to SurModics by or on behalf of GNE or provided to GNE by or on behalf of SurModics as required by, and in connection with, this MSA or the Quality Agreement [*].

1.15 "**Manufacturing Process**" means the process for the Manufacture of Product pursuant to this MSA, the Quality Agreement and the Manufacturing Documentation, as such process may be changed from time to time in accordance with this MSA.

1.16 "**Manufacturing Joint Steering Committee**" or "**Manufacturing JSC**" is defined in Section 3.3.

1.17 "**Non-Conforming**" means, (a) with respect to a Product, a Product Manufactured by SurModics pursuant to this MSA that (i) fails to conform to the Specifications or Acceptance Criteria; or (ii) was not Manufactured in compliance with the Specifications,

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cGMPs, the Manufacturing Documentation, the Quality Agreement, the Standard Operating Procedures and all applicable laws and (b) with respect to any other deliverable, a deliverable that fails to conform to the requirements of this MSA or the Quality Agreement.

1.18 "**PFSB**" means the Japan Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour, and Welfare and its review agency, the Pharmaceutical and Medical Devices Agency, or any successor agency thereto.

1.19 "**Product**" means the Licensed Product or the SurModics Raw Material specified in the applicable SOW.

1.20 "**Quality Agreement**" means that certain quality agreement entered into by the Parties, as the same may be amended from time to time by the Parties.

1.21 "**Raw Materials**" means the materials used in the Manufacturing Process, including, but not limited to, chemicals, reagents, chromatography resins, and filters; and any materials used for testing, validation, qualification or other activities required to implement and support the Manufacturing Process at the Facility. Raw Materials include the SurModics Raw Materials.

1.22 "**Regulatory Authority**" means any national (*e.g.*, the FDA), supra-national (*e.g.*, the EMEA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction of the world, involved in the granting of Regulatory Approval.

1.23 "**Services**" means the activities in support of GXP compliant Development and/or Manufacturing of a Product, including: manufacturing, process development and scale-up, bulk production and fill/finish work associated with the supply of such Product for research, preclinical and clinical studies and related quality assurance and quality control activities, packaging, storage, stability, release testing, and/or quality control services and other related services provided by SurModics to GNE with respect to such Product under this MSA, as further defined in the applicable SOW.

1.24 "**Specifications**" are defined in the applicable SOW and/or Quality Agreement.

1.25 "**Standard Operating Procedures**" or "SOPs" means the standard operating procedures established by SurModics generally.

1.26 "**Term**" is defined in Section 13.1.

1.27 "**United States**" means the United States of America, its territories and possessions, Guam and the Commonwealth of Puerto Rico.

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ARTICLE 2
RELATED AGREEMENTS AND EXHIBITS

2.1 Statements of Work.

2.1.1 **In General.** A description of the Services to be performed and the Product to be Developed and/or Manufactured and supplied by SurModics for each project agreed upon by the Parties (each, a "**Project**") shall be contained in individual appendices to this MSA (each, a "**SOW**", a form of which is attached hereto as **Exhibit A**), executed by a duly authorized officer of each Party. Each SOW shall include all applicable process requirements, a list of any deliverables, regulatory compliance requirements, the anticipated period of performance, a Program Budget for Services [*], delivery schedules, [*], and quantity requirements. The Parties agree to negotiate, in good faith, payment criteria for each task in a SOW under a Program Budget [*]. Each SOW shall be subject to and deemed a part of this MSA. No SOW, or any modification thereto, shall be attached to or made a part of this MSA without first being executed by the Parties hereto in a writing which specifically references this MSA. To the extent any terms set forth in a SOW conflict with the terms set forth in this MSA, the terms of this MSA shall control unless otherwise expressly agreed by the Parties in such SOW.

2.1.2 **Changes to a SOW**. Except as otherwise provided in Section 5.8 below for changes related to regulatory requirements, if GNE reasonably determines that modifications to a SOW are required, GNE shall communicate those proposed modifications to SurModics and the reasons therefore in writing, and the Parties shall negotiate in good faith to implement mutually acceptable modifications in an amended SOW, including any change in the timelines, budget and fees.

2.1.3 **Change Order Process**.

(a) Any change in the scope of work, timeline, the corresponding Program Budget, and/or the Project specific compensation terms or payment schedule for an individual Project will require a written amendment to the applicable SOW ("**Change Order**"). For clarity, Change Orders amend only the applicable SOW and not the terms and conditions of this MSA. Each Change Order will detail the requested changes to the applicable scope of work, timeline, corresponding Program Budget, Project specific compensation terms, or payment schedule. Both Parties agree to act in good faith and promptly when considering a Change Order requested by the other Party.

(b) If the scope of a Project does not change but SurModics must perform additional work in order to perform the Services for the Project in accordance with the applicable SOW (i.e. in compliance with the Manufacturing Process), and such additional work is due to circumstances primarily within SurModics' control, SurModics will perform the additional work at no charge to GNE. For clarity, and except as set forth in Section 6.2.2 below, Genentech will be responsible for the cost of any additional GNE Material required in the performance of such additional work,. The Parties agree that termination of either a Project or some of the Services to be performed in furtherance of the completion of a Project, in each case before the completion of

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the Project, are changes in Project scope, and the affected Project budget and payment schedule shall be modified accordingly.

2.2 Quality Agreement. The Parties have entered into a Quality Agreement effective as of the date hereof (attached hereto as **Exhibit B**) that governs the responsibilities related to quality systems and defines quality requirements for the Product, including quality control, testing and release of the Product.

ARTICLE 3
MANAGEMENT OF PROJECT

3.1 In General. Each Party will be responsible for its internal decision making process and for reasonably informing the other Party of decisions made affecting the Services in a regular and timely manner. Without limiting the foregoing, the Parties shall establish the joint team set forth herein to advise the Parties and execute on certain matters relating to the Services under this MSA.

3.2 Joint Management Team (JMT)

3.2.1 **Formation.** Within thirty (30) days of the Effective Date, the Parties will establish a joint management team (the "**Joint Management Team**" or "**JMT**") to oversee and manage the Services under each SOW. If there are multiple SOWs hereunder the Parties may specify separate JMT's in the applicable SOW's, and each reference herein to "the JMT" or "the Joint Management Team" shall be a reference to the JMT applicable to each SOW. The Joint Management Team shall consist of such number of representatives of each Party as are reasonably necessary to accomplish the goals of the SOW. Each Party shall promptly notify the other Party of its initial appointees to each JMT. Subject to Section 3.2.2 (a), each Party shall be free to change its JMT representatives effective upon written notice to the other Party.

3.2.2 **Management Team Leader.**

(a) Appointment. Within thirty (30) days of the Effective Date, each Party shall appoint an employee to act as a primary contact for such Party in connection with this MSA, including without limitation, all SOWs and any Services and other activities conducted under any Project (each, a **"Management Team Leader"**). The GNE Management Team Leader will be responsible for overall leadership of the Joint Management Team. A Party may replace its Management Team Leader at any time by providing written notice of the change to the other Party: provided, SurModics shall have good faith consultation with GNE prior to the change and provided further, any such new representative shall be no less qualified than the representative being replaced and shall be mutually agreed to by the Parties. GNE shall not unreasonably withhold its agreement to any such new representative proposed by SurModics.

(b) Responsibilities. The Joint Management Team, led by the Management Team Leaders, will be responsible for [*]. The Management Team Leaders will dialog regularly about the progress of the Services and use good faith efforts to resolve any difficult issues

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regarding the Services addressed by the Joint Management Team as well as facilitate expeditious resolution of any issues escalated to the Manufacturing JSC.

3.3 Manufacturing Joint Steering Committee (Manufacturing JSC).

3.3.1 **Formation.** Within thirty (30) days of the Effective Date, the Parties will establish a Manufacturing Joint Steering Committee (the "**Manufacturing Joint Steering Committee**" or "**Manufacturing JSC**") to give direction and advice to the Joint Management Team (or Teams if more than one Project is being worked on by SurModics) relating to the Services. The Manufacturing Joint Steering Committee will be made up of at least two senior level members from each Party, representing functions within each Party directly involved in the Services; provided, however, that no Party's representative will serve on both the Manufacturing JSC and either a JMT or JSC established under the License Agreement. Either Party may replace any or all of its representatives at any time by providing written notice to the other Party.

3.3.2 **Responsibilities**. The Manufacturing Joint Steering Committee will be responsible for [*].

3.4 Meetings.

3.4.1 **JMT Meetings.** The JMT shall meet at least monthly during the course of any SOW. These meetings may be called on a more frequent basis as reasonably determined by the GNE Management Team Leader. These meetings may be held via teleconference or videoconference but should be held face to face at least two times per year, alternating between the Parties facilities or at such other location as the Parties may otherwise agree. Each Party shall be responsible for all of its own expenses of traveling to and participating in any of the JMT meetings. SurModics will assume the project management responsibility for each Project; documenting meetings, maintaining a project timeline, enabling risk management planning and resource forecasting, and otherwise tracking the progress of the Services under each Project for the Joint Management Team.

3.4.2 **Manufacturing JSC Meetings**. The Manufacturing JSC shall meet at least two (2) times per year during the term of this MSA. These meetings shall be held face to face, alternating between the Parties facilities or at such other location as the Parties may otherwise agree. By mutual agreement of the Parties, meetings may also be held via teleconference or videoconference. Each Party shall be responsible for all of its own expenses associated with travel to and participating in any of Manufacturing JSC meetings.

3.5 Decisions.

3.5.1 **In General.** The Management Team Leaders will be responsible for making all decisions on day to day activities that do not materially impact critical milestones, Program Budgets, or supply of materials. These decisions may be made in the context of discussion at the Joint Management Team; [*]. Notwithstanding the foregoing, either Management Team Leader may escalate material issues and disputes to the Manufacturing JSC.

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3.5.2 **GNE Decisions.** Notwithstanding anything to the contrary in the License Agreement, this MSA and/or the Quality Agreement, with respect to issues relating to: (i) interpretation of quality or cGMPs, (ii) acceptability of validation results, (iii) acceptability of Product testing (including in-process testing), results or procedures, (iv) disposition of any Product (including Non-Conforming Product) and/or (v) changes to a Manufacturing Process and/or Specifications, in each case, [*]. SurModics shall use Commercially Reasonable Efforts to effect any such implementation in accordance with a timeline approved by GNE. [*]

3.6 Disputes. If the Manufacturing JSC is unable to resolve a material issue or dispute presented to it, then either Party's Manufacturing JSC representative may escalate such Dispute to the JSC established under the License Agreement, and such dispute shall be resolved in accordance with ARTICLE 3 of the License Agreement.

3.7 Committee Term Limits. Either Party may, at its sole discretion, terminate its participation on the JMT or the Manufacturing JSC at any time [*] of the Effective Date by providing [*] written notice to the other Party. Should either Party elect to terminate its JMT or Manufacturing JSC participation, the Parties will amend the respective decision making and disclosure rights and obligations enumerated in this Agreement to preserve the Parties' respective decision making and disclosure rights and obligations in the absence of participation through the JMT or Manufacturing JSC.

3.8 No Deliverables. The Parties acknowledge and agree that the Manufacturing JSC under this Agreement is strictly for the purposes of decision making and governance of the activities conducted under a SOW to this MSA, and does not in any way include any significant deliverable of either Party.

ARTICLE 4
SERVICES

4.1 General Obligations. Subject to the terms and conditions set forth in this MSA and the License Agreement, during the Term, GNE hereby retains SurModics to perform the Services specified in the SOW(s).

4.2 Compliance with Law; **Facility Permits and Licenses**. SurModics shall, and shall ensure that its Project Personnel, perform the Services in accordance with all applicable laws and regulations, including, without limitation applicable GXPs. SurModics shall be responsible for obtaining and maintaining all applicable licenses and permits required for it to perform the Services hereunder.

4.3 Manufacturing Facility. Unless otherwise expressly agreed by the Parties in writing (including in a SOW), all Services shall be performed by SurModics at the Facility or by other SurModics' personnel at SurModics' locations. [*]

4.4 Project Personnel. It is understood that GNE is entering into this MSA, each SOW and the Quality Agreement in reliance on the commitment by SurModics to staff the Facility

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with managers, supervisors, engineers, technicians, inspectors, and other personnel including, but not limited to, temporary employees, consultants and sub-contractors (in accordance with Section 4.5 below), as SurModics deems necessary, in each case having sufficient technical expertise to perform its obligations under this MSA and the Quality Agreement (collectively, **"Project Personnel"**). Without limiting any other provision of this MSA, so long as such Project Personnel remain employed by SurModics, SurModics will ensure that such individuals (not specific individuals but individuals with similar functional expertise) are available to perform the obligations, as appropriate, to be provided by SurModics hereunder. In addition, SurModics shall ensure that the Management Team Leader and Project Personnel have read, understood and agreed to be bound by obligations of confidentiality and non-use at least as restrictive as those applicable to this MSA.

4.5 Subcontracting. SurModics shall not subcontract all or any portion of its obligations under this MSA without GNE's prior written approval and in accordance with the Quality Agreement. In the event of such approval, the applicable subcontract shall be consistent with the terms and conditions of this MSA. [*]For the avoidance of doubt, SurModics may [*] to the extent such [*] are under the general supervision of SurModics' Project Personnel, and have sufficient technical expertise, and SurModics is responsible to Genentech for their performance.

4.6 [*]

ARTICLE 5
FACILITY MODIFICATIONS, EQUIPMENT, MATERIALS, DOCUMENTATION AND IMPLEMENTATION

5.1 In General. Modification of the Facility and/or transfer of equipment, materials and/or processes to be carried out in order to perform the Services at the Facility, are summarized below and may be further described in detail in a SOW, if applicable.

5.2 [*]

5.3 [*]

5.4 GNE Materials. GNE shall transfer to SurModics the GNE Materials and any Manufacturing Documentation in Genentech's Control necessary to perform the Services as specified in the applicable SOW. Such transfer will be in accordance with the applicable SOW. GNE and SurModics will make their personnel available at the Facility and/or other facilities to enable the transfer and implementation of each of the foregoing. Prior to delivery of GNE Materials to SurModics, GNE shall provide documentation similar to that described in the Quality Agreement and a Certificate of Analysis or other documentation (i.e. certificate of testing, etc) as appropriate for the development stage of the GNE Material for SurModics' review and approval. SurModics shall approve or reject such documents not more than [*] after receipt thereof, and may reject such documents only as specifically set forth in the applicable Quality Agreement. Upon SurModics' approval of such documents, SurModics shall release GNE Material for delivery to SurModics and GNE shall deliver the GNE Material to SurModics

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in accordance with the terms and conditions of this MSA. The provisions set forth in the Quality Agreement regarding release shall control the procedures and standards for release. For purposes hereof, "**Certificate of Analysis**" means, as further specified in the Quality Agreement, for each shipment of GNE Material, a document prepared by GNE: (a) listing the Manufacturing date(s) of such GNE Material, and (b) certifying that all GNE Material in the shipment conform to the specifications and were Manufactured in compliance with specifications, cGMPs, the Quality Agreement, standard operating procedures and all applicable laws. The Parties shall from time to time agree upon a format or formats for the Certificate of Analysis to be used under this MSA.

5.5 Raw Materials & Change Parts.

5.5.1 **Raw Materials**. [*] Specifications for the Raw Materials shall be set forth in the SOW(s).

5.5.2 [*]

5.5.3 **Testing and Evaluation of Raw Materials.** SurModics shall perform all testing and evaluation of the Raw Materials as required by the applicable SOW, Specifications, Manufacturing Documentation, cGMPs, the Quality Agreement and Standard Operating Procedures.

5.5.4 [*]

5.6 Product Documentation. SurModics will maintain and retain true and accurate books, records, test and laboratory data, validation data, reports and copies of all other information related to the Services, including all information required to be maintained and retained under the License Agreement, this MSA, the Quality Agreement or applicable law (including cGMPs) (the "**Records"**). SurModics will maintain all Records in separate forms and notebooks to the extent reasonably possible (i.e., not commingled with other information) and will maintain Records for at least that period specified in the License Agreement and the Quality Agreement (or longer if required by law). GNE shall have the right to review the Records at the Facility during the time such Records are required to be maintained, as part of any audit conducted pursuant to Section 7.2.

5.7 Changes to the Manufacturing Process. Except as otherwise expressly set forth in the Quality Agreement, in the event that GNE is required by a Regulatory Authority to change the Manufacturing Process, SurModics shall use Commercially Reasonable Efforts to accommodate such required change, provided, that if any such change to the Manufacturing Process renders obsolete or unusable any Raw Materials used to manufacture the Product, and to the extent such Raw Materials can not be utilized by SurModics for its other manufacturing operations, GNE shall reimburse SurModics for the documented costs of such materials and disposal costs, if any.

5.8 Regulatory Requirements for the Manufacturing Process and the Product. In accordance with the terms of this MSA and the License Agreement, GNE shall be responsible

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for obtaining and maintaining all Regulatory Approvals required to Develop and Manufacture Product at the Facility; provided that SurModics shall use Commercially Reasonable Efforts to timely prepare, assist and enable GNE with obtaining and maintaining such Regulatory Approvals, including, without limitation, by preparing, filing and maintaining IND amendments to any existing FDA licenses held by SurModics.

ARTICLE 6
SUPPLY

6.1 In General. During the Term, and subject to the terms and conditions of this MSA and the License Agreement (including, without limitation, for supply of Licensed Product [*], SurModics agrees to supply to GNE, and GNE agrees to purchase from SurModics, such amounts of Product and other deliverables as set forth in the applicable SOW.

6.2 Acceptance of Product and Other Deliverables.

6.2.1 **Acceptance.**

(a) Product. Prior to delivery of Product to GNE, SurModics shall provide Genentech with [*]. Upon GNE's approval of such documents, GNE shall release the Product for delivery in accordance with the Quality Agreement, and SurModics shall deliver the Product in accordance with the terms and conditions of this MSA. The provisions set forth in the Quality Agreement regarding release shall control the procedures and standards for release. For purposes hereof, "**Certificate of Analysis**" means, as further specified in the Quality Agreement, for each shipment of Product, a document prepared by SurModics: [*]. The Parties shall from time to time agree upon a format or formats for the Certificate of Analysis to be used under this MSA.

(b) Other Deliverables. Upon receipt of any deliverable specified in an SOW other than Products, GNE (or its designee) shall, as appropriate, perform any testing and review required for such deliverable per any Acceptance Criteria in the SOW, and for the requirements of the Quality Agreement. Such testing and review will be completed within [*] of its receipt or such other period of time specified in a SOW.

6.2.2 **Non-Conforming Product**. In accordance with Section 7.1 of the Quality Agreement, GNE will notify SurModics of any claim that Product is Non-Conforming upon GNE discovering such Product is Non-Conforming, but no later than [*] after receipt of such Product and its associated Manufacturing Documentation by GNE from SurModics. [*]

6.2.3 **Replacement Product.** [*]

6.3 Delivery of Product.

6.3.1 **Shipping; Title**.

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(a) SurModics shall ship the Product (and any other deliverables) to such destinations chosen by GNE to the extent that such shipments are permitted by law for SurModics given the regulatory requirements of the exporting and the importing countries. Unless otherwise requested by GNE, SurModics shall arrange for the delivery of Product (or such other deliverables) from the Facility to such permitted destinations by carriers acceptable to, and in accordance with, GNE's shipping instructions on [*].

(b) SurModics will provide customary export documentation, as specified by GNE or by separate delivery and shipment documentation instructions, together with each shipment of Product (or such other deliverables). At SurModics' request, GNE shall assist SurModics with export consultant expertise regarding shipment of Product. SurModics shall also provide GNE with all relevant shipping information (e.g., carrier, shipment details, scheduled arrival date, quantity) prior to or coincident with shipping any Product (or such other deliverables) to GNE. SurModics shall also provide GNE with all relevant storage and handling instructions for such Product with each shipment and GNE agrees to comply with such instructions.

(c) GNE shall be the importer of record of each shipment of Product (or such other deliverables) shipped to GNE. In conjunction therewith, prior to shipping any Product (or such other deliverables), GNE shall obtain all appropriate approvals and consents of any governmental authority necessary for the import, transportation or shipment of such Product (or such other deliverables).

(d) Any customs, freight, insurance and other shipping expenses, as well as any special packaging expense incurred by SurModics prior to delivery to GNE shall be paid by GNE upon delivery to GNE (or its designee) at the Facility. GNE shall also bear all applicable taxes, duties and similar charges that may be assessed against the Product (or such other deliverables) after delivery to GNE (or its designee) at the Facility.

6.3.2 **Storing, Packaging and Shipping Containers.** SurModics shall provide sufficient and suitable cGMP storage facilities that meet the Specifications for storage of Product for a period of up [*] after release thereof. SurModics shall store, package, label and ship the Product according to the Specifications, the Quality Agreement, and according to procedures and using storage containers mutually agreed upon by GNE and SurModics in writing. [*]

ARTICLE 7
QUALITY COMPLIANCE

7.1 Quality Agreement. Both Parties are obligated to adhere to the provisions of the Quality Agreement and agree that all elements of quality assurance, quality control and the like shall be governed by the terms and conditions of the Quality Agreement. In the event of a conflict between this MSA and the Quality Agreement, this MSA shall prevail over those of the Quality Agreement, with the exception of quality-related matters and provisions that are in violation of cGMPs.

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7.2 Compliance Audits. Genentech will have the right to perform compliance audits as set forth in Section 8.1 of the Quality Agreement.

7.3 Responsibility for Recalled Products. GNE shall notify SurModics promptly if any Product manufactured by SurModics is the subject of a threatened or actual recall, market withdrawal or correction attributable to any activities conducted by of SurModics. The responsibility for any such recall shall be as set forth in the Quality Agreement.

ARTICLE 8
CONSIDERATION

8.1 Pricing. [*]

8.2 Invoices. SurModics shall invoice GNE for Services performed under this MSA in accordance with Section 7.2 of the License Agreement or the applicable SOW. [*]

8.3 Payment Terms. The provisions contained in Section 7.2 and Article 8 of the License Agreement are hereby incorporated by reference as if set forth herein in full

ARTICLE 9
OWNERSHIP OF INTELLECTUAL PROPERTY, MATERIALS AND EQUIPMENT

9.1 Equipment and Materials. [*]

9.2 Intellectual Property. The provisions contained in Articles 10 and 11 of the License Agreement are hereby incorporated by reference as if set forth herein in full.

ARTICLE 10
CONFIDENTIALITY

The provisions contained in Article 9 of the License Agreement are hereby incorporated by reference as if set forth herein in full.

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

11.1 General Representations and Warranties. The provisions contained in Article 13 of the License Agreement are hereby incorporated by reference as if set forth herein in full. In addition:

11.1.1 **SurModics Representations and Warranties**. SurModics represents and warrants that all Product, at the time of delivery to GNE's designated carrier, shall: [*].

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11.1.2 **GNE Manufacturing Representations and Warranties.** GNE represents and warrants to SurModics that: [*].

11.1.3 **Services Warranties** SurModics represents and warrants that: (a) the Services shall be performed and completed in a good and workmanlike manner; and (b) SurModics, and SurModics' employees and/or subcontractors assigned to perform the Services, are qualified and equipped therefor, have the requisite expertise and have all rights, licenses, permits and consents necessary to perform the Services hereunder.

11.1.4 **Compliance with Anti-Corruption Practices.** SurModics represents and warrants that SurModics and its directors, officers, employees and permitted subcontractors will not, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any official or employee of any government, or of any agency or instrumentality of any government (including any official or employee of any government-controlled hospital or other healthcare organization) in connection with any Services except in exchange for legitimate services provided by such official, employee, agency, or instrumentality to achieve the purposes of this MSA. In the event that SurModics learns of any activities in violation of this Section 11.1.4, it shall immediately notify GNE and provide detailed information about the nature and extent of such activities.

ARTICLE 12
INDEMNIFICATION, INSURANCE, LIMITATION OF LIABILITY

The provisions contained in Article 14 of the License Agreement are hereby incorporated by reference as if set forth herein in full.

ARTICLE 13
TERM AND TERMINATION

13.1 Term. This MSA shall commence on the Effective Date and, unless earlier terminated in accordance with the provisions of this Article 13, shall continue in full force and effect until terminated by mutual agreement of the Parties (the "**Term**"**)**.

13.2 Termination. This MSA may be terminated in accordance with Article 12 of the License Agreement (in its entirety or as to any SOW). In addition, either Party may terminate any SOW for any material breach of the MSA or such SOW by the other Party, provided, however, that the nonbreaching Party shall give the breaching Party written notice detailing such breach and indicating its intent to terminate, and, if the breaching Party fails to cure or dispute in good faith, that breach within (a) [*] after receipt of written notice of breach of an obligation to make a payment under this MSA and (b) [*] after receipt of written notice of any other breach, or a longer period of time not to exceed [*] if the breaching Party is working diligently to cure such breach.

13.3 Effect of Expiration or Termination.

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13.3.1 **In General.** In the event of any termination of this MSA, or any SOW to the MSA, the terms of Sections 12.6, 12.7, and 12.8 of the License Agreement shall apply (as applicable). In addition:

13.3.2 **Effect of Termination.** Following any termination of this MSA, Product or other deliverables that has been, or is in the process of being, Manufactured as of the date of notice of such termination (or which result from Manufacturing initiated prior to delivery of such notice), shall remain subject to the terms and conditions of this MSA, and such terms and conditions shall continue to survive with respect to such Product.

13.3.3 **Return of Materials**. In the event of termination of this MSA or any SOW to this MSA for any reason, SurModics agrees promptly to surrender and deliver to GNE (a) all applicable GNE Materials, Product and deliverables, and (b) records, materials, equipment, drawings, documents, data and any work product of any nature in each case directly pertaining to applicable GNE Confidential Information, Product, deliverables and/or Genentech Project IP Rights, or Joint Project IP Rights, excluding original notebooks, and all other materials belonging to GNE, in SurModics' possession. Notwithstanding the foregoing, (i) SurModics may retain and continue to use copies of such records, as required to comply with all applicable laws, and (ii) SurModics' legal department may retain one (1) copy of the foregoing, in each case, subject to its continuing obligation of confidentiality related to this MSA.

13.3.4 **Decommissioning**. Upon termination of the License Agreement, this MSA or any SOW for any reason, unless otherwise provided in this Section 13.3.4, SurModics shall promptly perform the Decommissioning, taking into account that such actions may be delayed to the extent necessary for SurModics to fulfill any obligations continuing as of the date of such termination. As used herein, "**Decommissioning**" means the process of verifying that all GNE contractual commitments applicable to such termination have been met, including the requirements related to the return of information and material set forth in Section 13.3.3. In addition, Decommissioning shall include the following actions by SurModics:

(a) Cease and refrain from all Services for GNE applicable to the termination;

(b) [*]

(c) Any GNE equipment in SurModics' possession shall, at GNE's election and cost, either be (i) removed and returned to GNE, (ii) removed and destroyed, or (iii) rendered inoperable. In the event GNE does not elect to have GNE equipment removed and returned to GNE under 13.3.4(c)(i) herein, at SurModics' election, SurModics may request GNE enter negotiations for the sale of such GNE equipment to SurModics prior to GNE making an election under 13.3.4(c)(ii) or 13.3.4(c)(iii).

13.3.5 **Costs Incurred in Decommissioning**. Prior to Decommissioning, and during the period of any Decommissioning, the JMT shall meet, discuss in good faith and agree upon a plan and budget for such Decommissioning. The actual costs and expenses incurred by SurModics in performing the activities identified in Section 13.3.4 shall be borne by the Parties as follows:

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(a) [*]

(b) [*]

(c) [*]

13.3.6 **No Conflict.** The foregoing rights and obligations are not meant to limit any rights or obligations (including other payments or reimbursements due to SurModics) of either Party set forth in Article 12 of the License Agreement.

13.3.7 [*]

13.3.8 **Transition of Manufacturing and Supply.** Notwithstanding any provision of this MSA to the contrary, upon an early termination by GNE pursuant to Sections 12.3 or 12.5 of the License Agreement, or Section 13.2 of this MSA (for SurModics' material breach or bankruptcy), SurModics agrees to extend the term of any SOW at GNE's written request (which shall be at least [*] prior to the date that this MSA with respect to such SOW would terminate or expire) in order to continue Manufacturing and Supply of Product to GNE under such SOW for a reasonable period after the date the MSA as to such SOW would have terminated. If, in connection with a termination of this MSA as to a SOW, the Parties enter into arbitration in accordance with Article 15 of the License Agreement, then the effective date of termination for purposes of this Section shall not be earlier than the final resolution thereof, unless expressly agreed otherwise in writing by the Parties. GNE shall give SurModics at least [*] prior written notice of the date after which Genentech will no longer require SurModics to perform the Manufacturing and Supply of Product under such SOW.

13.4 Survival. In addition to provisions that survive pursuant to the License Agreement, the following provisions shall survive termination of this MSA: Articles 1, 9, 10, 12, 14, and Sections 13.3 and 13.4.

ARTICLE 14
DISPUTE RESOLUTION

The provisions contained in Article 15 of the License Agreement are hereby incorporated by reference as if set forth herein in full.

ARTICLE 15
MISCELLANEOUS

15.1 In General. The provisions contained in Article 16 of the License Agreement are hereby incorporated by reference as if set forth herein in full, except that Section 16.3 of the License Agreement shall not apply and instead the terms of Section 15.2 shall govern this Agreement.

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15.2 Force Majeure.

15.2.1 **Effect of Force Majeure Event**. Neither Party shall be deemed to have breached this Agreement for failure to perform its obligations under this Agreement to the extent such failure results from acts of God, earthquakes, fires, floods, embargoes, wars, acts of terrorism, insurrections, riots, civil commotions or similar events (each a **"Force Majeure Event"**).

15.2.2 **Notice of Force Majeure**. If a Force Majeure Event occurs, the Party unable to perform shall promptly notify the other Party of the occurrence of such event, and the JMT shall meet (in person or telephonically) promptly thereafter to discuss in good faith the circumstances relating thereto and possible ways to mitigate any adverse consequences arising out of the Party's failure to perform. The Party unable to perform shall (a) provide reasonable status updates to the other Party from time to time, (b) use Commercially Reasonable Efforts to mitigate any adverse consequences arising out of its failure to perform and (c) resume performance as promptly as possible.

15.2.3 **Recovery from Force Majeure**. If a Force Majeure Event prevents SurModics from Manufacturing or supplying Product under this Agreement, the Parties shall in good faith discuss changes to scheduling and production to so as to remedy any shortfall, shortage or delay. SurModics shall use Commercially Reasonable Efforts to accommodate any such changes to scheduling and production. Notwithstanding the foregoing, in the event the Force Majeure Events affects SurModics' other customers, the changes to scheduling and production agreed upon by GNE and SurModics shall be no less favorable to GNE than those arrangements provided by SurModics to any other of its customers.

****

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IN WITNESS WHEREOF, the Parties hereto have caused this MSA to be executed by their duly authorized representatives as set forth below.

SurModics, Inc.

By: /s/ Bruce J Barclay
Name: Bruce J Barclay
Title: President and CEO

Genentech, Inc.

By: [*]
Name: [*]
Title: [*]

F. Hoffmann-La Roche Ltd

By: [*]
Name: [*]
Title: [*]

By: [*]
Name: [*]
Title: [*]

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EXHIBIT A

FORM OF SOW

This statement of work (the "Exhibit") is entered into pursuant to the Master Service Agreement by and between Genentech, Inc. ("Genentech") and SurModics, Inc. ("SurModics") dated <Insert Date> (the "Agreement"), and is effective as of <Insert Date> (the "Exhibit Effective Date"). Capitalized terms used in this Exhibit and not otherwise defined will have the same meaning as set forth in the Agreement.

The parties hereby agree as follows:

1. Exhibit. This document constitutes an Exhibit to the Agreement, and the Services to be provided hereunder are subject to the terms and conditions of the Master Service Agreement.

2. Services and Payments of Fees and Expenses. The specific Services contemplated by this Exhibit are set forth on the following attachments, which are incorporated herein by reference. [*]

Scope of Work, Timeline and Budget	ATTACHMENT I
Project Specific Compensation Terms	ATTACHMENT II
Change Order Process	ATTACHMENT III

3. Term. The term of this Exhibit will commence on the Exhibit Effective Date set forth above and will continue until the Services described on Attachment II are complete or this Exhibit is terminated in accordance with the Agreement.

4. Affiliates and Subcontractors. Genentech agrees that SurModics may use the services of its Affiliates or subcontractors to fulfill SurModics's obligations under this Exhibit. SurModics will be responsible to Genentech for the performance of such Affiliates and subcontractors, and all such performance will be in accordance with the terms and conditions of the Agreement and this Exhibit.

Subcontractors: [List as needed]

5. Contact Information

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SurModics Pharmaceuticals

Contact Name	Site	Department	Telephone	Email
		Proposal Administration		
		Project Management		
		Business Development		

Genentech

Contact Name	Address	Telephone	Email
<Manufacturing Collaborations Site Manager>	1 DNA Way South San Francisco CA 94080		

6. Amendments. No modification, amendment, or waiver of this Exhibit shall be effective unless in writing and signed by a duly authorized representative of each party, in accordance with the Change Order process described in ATTACHMENT III to this Exhibit.

ACCEPTED AND AGREED:

SurModics Pharmaceuticals: Genentech, Inc.:

[Insert Signature Blocks]

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Attachment I: SOW Scope & Budget

INSERT PROPOSAL TASKS HERE

INSERT PROPOSAL TIMELINE HERE

Attachment II: Project Specific Compensation & Terms

1) Project Budget and Total Compensation

[*]

2) Payments

SURMODICS shall submit (email) all invoices for this contract as follows:

Send Attn:

<Genentech Project Contact>

1 DNA Way, MS <#>

South San Francisco, CA 94080

Email / Carbon Copy: <Genentech Relationship Manager>

All invoices must reference the PO number assigned to this contract. The purchase order number will be sent via email after the contract is executed.

Genentech shall forward payment to SurModics as follows:

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Attachment III: Change Order Process

15.3 *Scope Change Form (SCF)*

Genentech / SurModics Exhibit #_____ **SOW #_____** **Change Order Form**

(a)

Change Order Number: [#_____]
(i) Description of Change(s) and Assumptions (b)
[*]

(c)

Total Contract Budget Summary

Document	Effective Date	Labor Amount	Expenses Amount	Total Contract
Exhibit [#]		$ —	$ —	$ —
Change Order #1		$ —	$ —	$ —
Change Order #2		$ —	$ —	$ —
Change Order #3, etc.		$ —	$ —	$ —
Total Revised Contract:				**$ —**

(d) Payment Schedule Revision

Is a revised payment schedule required? o **YES**, It is included as an Attachment. o **NO**

If **NO**, please explain:

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15.3.2 CHANGE ORDER APPROVAL

SurModics	**Genentech, Inc.**
Print Name: _____	Print Name: _____
Signature: _____	Signature: _____
Approval Date: __/__/_____	Approval Date: __/__/_____

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EXHIBIT B

QUALITY AGREEMENT

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GOOD MANUFACTURING PRACTICE
TECHNICAL QUALITY AGREEMENT

Between

Genentech, Inc.

(Contract Giver)

and

SurModics, Inc.

(Contract Acceptor)

We the undersigned, agree to the terms, conditions, roles and responsibilities described in this Quality Agreement and its appendices.

Genentech, Inc.		**SurModics, Inc.**	
[*]	9/30/09	/s/ Michael Shoup	10/1/09
[*]	DATE	Michael Shoup,	DATE
[*]		Vice President Quality, Regulatory and	
[*].		Clinical Affairs SurModics, Inc.	
		[*]	10/1/09
		[*]	DATE
		[*]	
		[*]	

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1.0 GENERAL INFORMATION

1.1 Introduction

1.1.1 Genentech, Inc. is a leading biotechnology company engaged in the manufacture, marketing and sales of pharmaceutical products. It operates under one common quality management system in compliance with current Good Manufacturing Practices (cGMP).

1.1.2 SurModics, Inc. is a leading pharmaceutical and biotechnology company engaged in the contractual manufacture of pharmaceutical and medical device products. It operates under one common quality management system in compliance with cGMP.

1.1.3 Genentech Inc. ("GNE") desires to entrust SurModics, Inc. ("SurModics") to perform activities related to the manufacture of GNE Products. GNE and SurModics are to define their roles and responsibilities hereunder according to the intentions of the GMP regulations. The manufacturing arrangements relating to the manufacture of the Product are governed under the Master Service Agreement between GNE and SurModics effective September 30, 2009 (the "Master Service Agreement").

1.1.4 Capitalized terms not defined in the Glossary attached as Appendix I shall have the meaning set forth in the Master Services Agreement.

1.2 Parties to Agreement

1.2.1 This GMP Technical Quality Agreement (the "Quality Agreement") is hereby entered into by and between GNE, a Delaware corporation, and SurModics, a Minnesota corporation, and must be adhered to in the processing of the Product for GNE governed by the Master Service Agreement. SurModics and Genentech are each referred to herein individually as a "Party" and collectively as the "Parties." The addresses of the Parties are:

GENENTECH, Inc.	**SurModics, Inc.**
1 DNA Way	9924 West 74th Street
South San Francisco, CA 94080	Eden Prairie, MN 55344

1.3 Scope

1.3.1 Subject to Section 1.3.4, this Quality Agreement is applicable to the manufacturing, processing, testing, and storage of the Product by SurModics for GNE.

1.3.2 The appendices and enclosures to this Quality Agreement are an integral part of this Quality Agreement and are incorporated into this Quality Agreement by this reference.

1.3.3 In addition to this Quality Agreement, SurModics and GNE shall create, approve, and maintain a document that details Product specific requirements (hereinafter referred to as the "PSR Document") for each Product. This

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document shall, at a minimum, contain contact information for designated representatives from SurModics and GNE who shall oversee the respective obligations regarding the Product and this Agreement, a process overview of the Product, a list of raw materials and suppliers required to produce the Product, disposition cycle times, list of batch documentation, any special shipping and handling requirements, and any additional applicable information as required per this Quality Agreement or deemed necessary by both parties.

1.3.4 This Quality Agreement pertains to the processing of the Products for administration to humans as governed by clinical trial authorizations and marketing authorizations (e.g. Investigational New Drug applications and Biologics License applications). It does not pertain to the supply of Products for research and development use. The mutual roles and responsibilities between GNE and SurModics related to the Quality system requirements for, as well as the Product-specific Quality requirements are defined.

1.4 Duration, Review and Changes to this Agreement

1.4.1 This Quality Agreement shall be effective as of the last date all required signatures are appended above (the “Effective Date”) and shall expire at the termination of the Master Service Agreement for the Product. The following sections shall survive termination of the Master Service Agreement until such time as defined in this Quality Agreement: sections 7.6, 7.7, 7.8, 7.9, 8.2, 8.3, and such other sections that by their terms are understood to survive the termination of the Master Service Agreement. The Parties acknowledge and agree that a similar quality agreement will be executed upon termination of the Master Service Agreement in the event an agreement for the manufacture of Phase III/IV material or commercial Product is negotiated between the Parties.

1.4.2 This Quality Agreement shall be reviewed for accuracy and compliance with the GMP regulations by both parties on at least a biennial cycle. Changes or supplements to this Quality Agreement or to the appendices and enclosures can only be made by mutual consent of amendments in writing. Such amendments to the Quality Agreement will be recorded and filed in APPENDIX II: — Change History Log, with each subsequent revision.

1.4.3 It is the responsibility of both parties to replace a superseded provision with an approved amendment. Superseded copies may be retained for historical records, but should be marked to appropriately indicate the historical status of the document.

1.4.4 It is the responsibility of both parties to ensure that their staff is adequately informed and any procedural or documentary changes resulting from an amendment are implemented in the areas affected by the changes.

1.5 Ultimate Quality Responsibility

1.5.1 In the event of a conflict between this Quality Agreement and the Master Service Agreement, the Master Service Agreement shall govern, except to the extent such provisions are in violation of the GMP regulations. Notwithstanding the foregoing, this Quality Agreement shall govern with respect to the assignment of responsibilities and obligations of each party to

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undertake those measures to assure the Quality of the Products and with respect to determinations of ability for release.

1.5.2 GNE's Quality Unit has sole authority for final disposition of Product for clinical use.

1.5.3 SurModics has the responsibility to implement and operate all quality systems as required by GMP regulations where the Product will be distributed. SurModics shall ensure that all quality systems operated by SurModics are compliant for GMP production and that they operate to a standard mutually agreed upon by both parties.

1.5.4 If not otherwise defined in this Quality Agreement, the provisions of SurModics' Quality management systems and Standard Operating Procedures shall be applied to these operations.

1.6 Quality Oversight and Person-in-Plant (PIP)

1.6.1 GNE shall have the right to provide GNE employees on SurModics' premises (the GNE employees hereinafter referred to as the "PIP") for the purpose of providing advice and coordinating reviews, approvals or other actions required by this Quality Agreement upon reasonable notice and as mutually agreed upon. Such GNE employees shall conduct themselves in accordance with SurModics' visitor policy. The GNE PIP activities, at the discretion of GNE, can also be performed remotely.

1.6.2 SurModics shall provide adequate space for the PIP when on site and shall ensure that the PIP is kept fully informed of all issues that arise that may affect the Quality of the Product. The PIP shall act as a single liaison between SurModics and GNE for Quality issues.

1.6.3 [*]

1.7 GMP Commissioning

1.7.1 GMP Commissioning is a process for approving the initiation of GMP activities at SurModics for a new manufacturing facility or a new manufacturing process related to the Product.

1.7.2 Prior to the initiation of GMP production, SurModics shall allow the GNE Quality Unit to perform GMP commissioning activities. This commissioning exercise is to document that the facility, process, procedures and personnel are ready to initiate GMP production as it relates to the Product.

1.7.3 The commissioning checklist and acceptance criteria shall be drafted by GNE and approved by both SurModics and GNE prior to execution.

1.7.4 SurModics shall not perform new GMP activities for the Product until the GMP Commissioning is complete and approved by the GNE and SurModics Quality Units.

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1.8 Execution of Responsibilities

1.8.1 In the execution of their relevant responsibilities, both Parties agree to conduct the necessary reviews, approvals, rejections and consents in a timely manner and within the time limits specified. Where any party requires the consent of the other, such consent will not be unreasonably withheld or delayed.

1.8.2 In this Agreement, “approval,” “authorization,” or “written communication” shall mean on official letterhead or approved forms, and signed by the authoring party’s Quality Assurance (QA) representative. Transmission of such written documentation may be by mail or electronic system (i.e., facsimile, scan).

2.0 LICENSES

2.1 Establishment License

2.1.1 If applicable, SurModics shall obtain and maintain a valid manufacturer’s license for the facilities [*].

2.2 Product Licenses

2.2.1 GNE shall, in accordance with applicable regulations, have sole authority for applying for any Product licenses with the regulatory agencies per section 5.1 of License and Option Agreement. GNE shall inform the appropriate regulatory authorities of any change to the approved licenses for the Product through supplements or amendments and informing SurModics of the same.

2.2.2 Upon request of any governmental or regulatory authority, both Parties shall provide to each other, any data and information relating to the Product which may be necessary for regulatory approval and maintenance efforts with respect to the licenses.

3.0 GOVERNING REGULATIONS, RULES AND PROCEDURES

3.1 Governing Regulations and Rules

3.1.1 SurModics shall ensure that the systems for the manufacture, processing, testing, packing, holding and shipping of the Product at SurModics comply with:

- Current Good Manufacturing Practice, including but not limited to US 21 CFR Part 11, 210, 211, and if applicable 820.
- The requirements of this Quality Agreement.
- The approved master documentation records (i.e., production records, specifications).
- Any additional regulations adopted by the regulatory authorities where the Product will be distributed. GNE shall inform SurModics, in advance, of any other countries where the Product will be distributed and any registration differences.

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3.1.2 GNE shall have the right to ensure SurModics' compliance with Section 3.1.1 above as described per Section 1.6 (PIP) and Section 8.1 (Compliance audits).

3.2 SurModics Procedures

3.2.1 SurModics shall create and maintain Quality systems compliant with cGMP, with associated Standard Operating Procedures that enable both Parties to execute their roles and responsibilities under the terms and conditions as described herein.

3.2.2 SurModics shall provide GNE with copies of effective Standard Operating Procedures related to the manufacture, processing, testing, packing and holding of the Product upon reasonable request by GNE.

4.0 MATERIALS

4.1 Sources

4.1.1 SurModics and/or GNE shall supply all materials required for the Product in accordance with the MSA and certify that their Quality is in compliance with the current "Note for Guidance on minimizing the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products" EMEA/410/01, Rev. 2 or update ("TSE Guidelines").

4.1.2 GNE shall provide the bulk drug substance to SurModics for further processing in accordance with the MSA. GNE certifies that the provided bulk will be processed according to GMP and the materials used in its processing will be sourced in compliance with the TSE Guidelines.

4.2 Suppliers

4.2.1 [*]

4.2.2 SurModics shall perform, or arrange to have performed, assessments of suppliers of raw materials and components required for GNE Products to ensure that the supplier's Quality and manufacturing system are compliant with cGMPs.

4.2.3 [*]

4.2.4 SurModics shall notify the GNE Quality Unit when a supplier's qualification status changes. Upon request by GNE, SurModics shall request from its suppliers permission to allow GNE to review SurModics audit reports.

4.2.5 If GNE supplies any raw materials and components to SurModics for use in processing of the Product, SurModics will rely on GNE's certification that the supplier's Quality systems are adequate.

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4.3 Receipt, Testing, Control and Release

4.3.1 SurModics/GNE shall receive, sample, test, control and release components and raw materials for the Product in accordance with the approved material specifications.

4.3.2 SurModics shall implement and maintain approved material specifications, analytical methods, inspection methods, and sampling plans as required per each material required for GNE Products. The GNE Quality Unit's prior written approval of such documentation is required. GNE's approval of the material specifications, analytical methods, inspection methods, and sampling plans shall be performed via SurModics' quality control system.

5.0 PROCESSING OF PRODUCT

5.1 Batch Numbering

5.1.1 SurModics shall use the GNE batch numbering system for all GMP Product produced by SurModics.

5.1.2 GNE shall issue batch numbers to SurModics, who shall assign a batch number to each Product batch. For purposes of tracking, SurModics may assign an internal SurModics batch number in addition.

5.1.3 SurModics shall record the GNE batch number onto the appropriate production records. SurModics shall keep track of GNE batch numbers to ensure batch numbers are assigned appropriately.

5.1.4 SurModics shall record the GNE batch number on the appropriate Product Batch labeling (i.e., vial label, shippers)

5.2 Holding, Shipping, and Destruction of Samples

5.2.1 SurModics shall hold the Product and raw materials in storage according to the PSR and cGMP requirements. SurModics shall ensure that appropriate cGMP controls are in place to prevent cross-contamination, theft, interference, or mix-up with any other materials.

5.2.2 SurModics shall ship the Product according to GNE shipping requirements per approved procedures. GNE shall communicate the shipping requirements to SurModics in writing.

5.2.3 Upon receipt of the Product from GNE for further processing, SurModics shall read the temperature monitors and report any temperature Deviations to the GNE Quality Unit within [*].

5.2.4 Any temperature Deviations observed during shipment and/or holding of the Product at SurModics will be handled per Section 7.2. SurModics shall investigate the root cause and identify appropriate corrective actions for Deviations that occur while the Product is under SurModics' control.

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5.2.5 GNE shall be responsible for assessing the impact on Product as a result of temperature Deviations either during Product shipment and/or during holding of the Product at SurModics.

5.2.6 SurModics shall destroy Product rejects (for example, inspection rejects, bulk waste, and rejected batches) per SurModics' procedures. SurModics shall ensure that proper handling, segregation, and documentation of any destruction is performed.

5.3 Reprocessing and Reworking

5.3.1 Prior to any Product batch being reprocessed or reworked, SurModics must obtain approval of the GNE Quality Unit in advance. Reprocessing and reworking are considered Significant Deviations and shall be handled in accordance to Section 7.2. [*]

5.3.2 [*]

6.0 QUALITY CONTROL TESTING

6.1 Analytical Methods

6.1.1 SurModics shall implement and maintain in-process material and final Product analytical methods.

6.1.2 The GNE Quality Unit's prior written approval for all Product-specific analytical methods is required.

6.2 Quality Control Testing and Approval

6.2.1 SurModics shall sample and test in-process and final Product batches according to the approved specifications, sampling plans and analytical methods.

6.2.2 SurModics shall report all quality control results on a "Certificate of Analysis" (COA). SurModics shall include all in-process results with the batch records.

6.2.3 SurModics shall not destroy any QC retain samples until the Product batch has been dispositioned by GNE.

6.2.4 GNE shall provide reference materials and critical reagents to SurModics to be used in the testing of the Product.

6.2.5 For testing performed at GNE, SurModics shall collect the samples, appropriately label and store the samples, and ship the samples per the current validated shipping procedure to GNE within [*] of collecting the samples.

6.2.6 GNE QC shall perform a review of raw quality control data for in-process and final Product batches to ensure quality standards are being maintained until such time that GNE can qualify SurModics to perform independent data review as defined per GNE procedure.

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6.3 Stability Testing

6.3.1 SurModics shall be responsible for maintaining a routine stability testing program for the Product per approved procedures.

6.3.2 SurModics shall write, approve and submit stability protocols for the Product to GNE for approval.

6.3.3 SurModics shall provide GNE with the results of stability testing in support of the approved shelf life within [*] of completion of the stability testing.

6.3.4 SurModics shall communicate any out of specification results obtained during stability testing of the Product to the GNE Quality Unit in accordance with Section 7.2.

6.3.5 GNE shall determine and approve the expiry and/or retest period, storage, and shipping conditions based on formal stability studies conducted for the Product.

6.4 Out of Specification (OOS) Quality Control Testing Results

6.4.1 In the event that SurModics obtains an initial OOS result, a preliminary lab assessment shall be conducted per SurModics' approved procedures. This assessment will include at a minimum, a review of all equipment used, sample and reagent preparation, and documentation associated with the test session. No additional testing of the Product shall be conducted during this preliminary lab assessment.

6.4.2 If no determinate error is identified in the assessment conducted pursuant to Section 6.4.1, then SurModics shall notify the GNE Quality Unit per the Section 7.2. No additional analysis shall be conducted on the Product prior to notifying the GNE Quality Unit.

6.4.3 The GNE Quality Unit shall approve OOS investigations and associated corrective and preventative actions, unless an analytical error is identified in the assessment as described in section 6.4.1 and the results are invalidated and testing is repeated on a new sample

7.0 GENERAL QUALITY SYSTEMS

7.1 Disposition of Product

7.1.1 The SurModics Quality Unit must certify in writing that each batch of Product has been manufactured, tested, packaged and stored in accordance with cGMPs, the Master Batch Production Record (MBPR) and applicable SOPs.

7.1.2 The SurModics Quality Unit shall review and approve all batch documentation according to SurModics' approved procedures prior to release of the Product batch to GNE.

7.1.3 All Deviations must be clearly identified in batch records, and must be fully investigated and completed prior to the approval of batch records. SurModics

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shall perform a cumulative assessment of all Deviations that occurred during the manufacturing, holding, and testing of the Product.

7.1.4 GNE has the sole authority for final disposition of the Product. SurModics shall notify the GNE Quality Unit of any Product batch being considered for rejection by SurModics prior to any formal reject disposition. For Product assigned a reject disposition by SurModics, GNE shall have the right to take possession of the Product. GNE shall authorize the destruction of any rejected Product batches.

7.1.5 SurModics shall not release any batches with open Major Changes or validations that are lot-release impacting.

7.1.6 Any problem discovered by GNE that would result in the rejection of a Product batch shall be communicated to SurModics as soon as practical, but in all cases within [*] following receipt of the release documentation.

7.2 Deviations

7.2.1 Any Deviation shall be documented and approved by personnel designated by SurModics from each of the relevant departments and by the SurModics Quality Unit, in accordance with SurModics' approved procedure for Deviation management.

7.2.2 Significant Deviations require notification of the GNE Quality Unit within [*] of discovery.

- Significant Deviations are defined as events that are observed during production, quality control testing including out-of-specification (OOS) results as described in section 6.4.2 above, and/or batch record review that may reasonably result in a Deviation from Product specifications, that may adversely impact the safety, identity, strength, purity or quality of the Product, and/or violate cGMPs or the Product license that could impact the releasability of the Product. Examples of Significant Deviations include:
  - Failure of Product to meet certificate of analysis (COA) specifications
  - Operations outside of validated limits
  - Suspected introduction of adventitious agents/contaminants in the Product
  - Excursions to environmental conditions (EM) in the primary filling area
  - Incorrect or unsuitable raw materials, components, or equipment used during the manufacturing of the Product
  - Reprocessing and reworking of the Product, [*]
  - Process discrepancies that adversely impact other Product process steps, lots, or Products batches whether distributed or not
  - Media fill and sterility positives/failures

7.2.3 SurModics shall obtain GNE Quality Unit approval for all Significant Deviations.

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7.2.4 SurModics shall inform the GNE Quality Unit within [*] of any Significant Deviation relating to other products, produced using the same equipment train as that used for the Product, if the Deviation could have an impact on the Product. SurModics will provide as much detail as possible regarding the Deviation. In the event that customer confidentiality agreements regarding other products prevent SurModics from providing certain documentation or detail, SurModics may provide redacted copies of documentation or a summary of the Deviation.

7.2.5 SurModics shall be responsible for investigating all Deviations per its approved procedures. SurModics will allow the GNE Quality Unit to actively participate in the development of investigation action plans related to Significant Deviations related directly to the Product or that could have impact on the Product. All investigation plans should be approved prior to implementation and should include at minimum:

- Lots impacted
- Description of action to be taken
- Rationale for this action
- Individual/department responsible for the action
- Target completion date
- Pre-approval by SurModics' QA

7.2.6 SurModics shall submit investigation plans before their implementation for all Significant Deviations. Those plans shall be evaluated by the GNE Quality Unit. Any additional testing required to support an investigation, including OOS investigations, must be pre-approved by the GNE Quality Unit.

7.2.7 When necessary, GNE shall provide a technical assessment or other data to support the investigation.

7.2.8 Significant Deviation reports shall include a description of the event, impacted lots, determination of cause, quality impact assessment, and identification of corrective and preventive actions. Quality impact assessments should determine the impact of the event on the safety, Quality, identify, potency and purity of the Product, other lots of the Product, validation, and GMP compliance.

7.2.9 After completion of the report related to Significant Deviations, SurModics shall submit to GNE a copy of a completed report. This report shall be reviewed by the GNE Quality Unit. Within [*], the GNE Quality Unit will either approve the Significant Deviation, or notify SurModics of additional information or actions required before approval of the Significant Deviation report.

7.2.10 SurModics shall [*] notify the GNE Quality Unit of any problems that are discovered that may have impact to Product batches previously shipped to GNE. Notice shall be made within [*] of the discovery of a potential quality problem with a released batch of Product.

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7.3 Validation

7.3.1 SurModics shall maintain systems that demonstrate manufacturing processes, facilities, utilities, equipment, and automation will reliably and repeatedly perform their intended function in the manufacture and testing of the Product.

7.3.2 As applicable, SurModics shall maintain a Validation Master Plan (VMP), which includes the validation program overview and requirements for the facility and equipment required to manufacture and test the Product. This VMP must be acceptable to GNE.

7.3.3 SurModics shall periodically re-validate, as appropriate, facilities, utilities, equipment, and automation per the VMP and other approved procedures.

7.3.4 GNE shall have the right to review all validation reports related to the manufacturing and testing of the Product. These validations must be acceptable to GNE. [*]

7.4 Change Control

7.4.1 SurModics shall utilize a change control system to ensure appropriate review of all changes.

7.4.2 The GNE Quality Unit shall approve any change to the following master documentation maintained by SurModics for GNE Products:

[*]

7.4.3 SurModics shall review all changes to determine if the change is a Major Change (as defined in the Glossary). If there is any doubt regarding whether a change is a Major Change, SurModics shall contact the GNE Quality Unit, and the parties shall jointly make this determination. It is understood between parties that changes as a result of pharmacopoeia test methods updates are not Major Changes.

7.4.4 In addition to Major Changes, SurModics shall notify the GNE Quality Unit in writing of any Minor Changes that affect GNE specific documents, equipment or processes, on at a minimum quarterly basis. Such notification shall contain a description of the change, the implementation date of the change, and the status of the change. Minor changes may be implemented by SurModics prior to such notification to GNE.

7.4.5 SurModics shall notify the GNE Quality Unit in writing of any Major Changes that may impact the Product Quality, validated status and/or have regulatory impact to:

[*]

7.4.6 Such notifications shall be communicated in writing in a timely manner so as to allow GNE to evaluate the affect of the change on Product Quality and/or obtain appropriate regulatory approvals prior to implementation.

7.4.7 At a minimum, such notification will contain a description of the change, the rationale for the change, the proposed implementation date, the qualification,

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validation, and/or comparability testing and acceptance criteria to prove that the Major Change does not adversely affect Product Quality.

7.4.8 SurModics shall provide all documentation of a Major Change to GNE for review and approval. This includes, but is not limited to, the description and rationale of the change and supporting documentation such as validations or technical assessments.

7.4.9 GNE's review and approval/rejection of Major Changes prior to implementation is required. Within [*], GNE shall approve the change, request additional information, or provide justification for the rejection of a change.

7.4.10 After completion of a Major Change, SurModics shall provide the GNE Quality Unit in writing with supporting data and reports that demonstrate the Major Change is valid and have been found acceptable by SurModics.

7.4.11 Emergency changes are changes that must be performed prior to the receipt of GNE approval in order to avoid Product loss or to eliminate a safety hazard. Emergency changes must be categorized and documented as previously described and notification must be provided to the GNE Quality Unit for evaluation within [*] of the change implementation.

7.4.12 For changes proposed by GNE, GNE shall notify SurModics in writing of any Product-related changes. SurModics shall implement these changes in a timely manner and in accordance with SurModics procedures and the Master Service Agreement.

7.5 New Product Introduction

7.5.1 SurModics shall not use the same facilities and/or equipment used for processing the Product for the processing of beta-lactams, e.g. penicillin or cephalosporins.

7.5.2 SurModics shall inform the GNE Quality Unit in writing per the change control Section 7.4, when [*]. For confidentiality reasons, SurModics shall only be required to provide detail to the level of the class of product.

7.5.3 Prior to introduction of a new product into the line, SurModics shall perform a cleaning verification/validation according to SurModics' procedures in order to exclude cross contamination of the Product from other product campaigns.

7.6 Product Complaints, Adverse Events, and other Post-Release Issues

7.6.1 GNE shall have sole authority for resolving all customer complaints and adverse events, related to the Product.

7.6.2 It is expected that most product complaints and adverse events for the Product shall be received by GNE. Any reports received by SurModics shall be forwarded to the GNE Quality Unit within [*].

7.6.3 If GNE requests a technical evaluation, documentation review, or sample inspection from SurModics to support a Product complaint/adverse event,

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SurModics shall report any findings to GNE in writing, signed, within [*] of notification by GNE, or as required per section 8.3.6. SurModics shall provide GNE with an update as to the progress of the investigation within [*] of notification by GNE.

7.6.4 SurModics shall notify the GNE Quality Unit within [*] of any other complaint with any other products manufactured by SurModics that by nature of similarity of material or manufacturing, that has reasonable potential to adversely impact the Product.

7.6.5 If the Product in any batch fails to comply with the agreed Quality standards, either upon receipt or during the shelf-life of the Product (i.e., during stability testing), as a result of operations conducted at SurModics, GNE will contact SurModics in writing to assist with the investigation.

7.7 Document Retention

7.7.1 SurModics shall maintain the original Batch records consisting of manufacturing, packaging, Quality Control, release, storage and delivery documentation, Raw Data and records for each Batch of Product in a secure location for a period of [*].

7.7.2 Prior to the destruction of any Product records at SurModics, SurModics shall notify the GNE Quality Unit and the records shall be sent to GNE, unless otherwise directed in writing by the GNE Quality Unit.

7.8 Sub-contracting

7.8.1 Consistent with Section 4.5 of the Master Services Agreement, SurModics shall not subcontract to a Third Party any of the work entrusted under this Quality Agreement, without the GNE Quality Unit's prior written approval.

7.8.2 In the event that SurModics, with the written permission of the GNE Quality Unit, sub-contracts any operation under this Quality Agreement to a Third Party, SurModics shall ensure that it enters into a written agreement with the sub-contractor that sets out the respective technical and quality responsibilities of each party [*].

7.8.3 SurModics may use contract laboratory testing facilities to support the testing of the Product. SurModics shall only use testing facilities that have been approved by the SurModics Quality Unit per SurModics' procedures. Quality Agreements between SurModics and those facilities must be in place.

7.9 QA Reserve Samples

7.9.1 SurModics shall maintain and inspect the reserve samples as required per cGMP regulations.

7.9.2 SurModics shall provide GNE with a summary of the results of the annual inspection of the reserve samples within [*] of completion. In the event any deterioration is observed during this inspection, SurModics shall contact GNE in accordance to the Deviation section 7.2.

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8.0 COMPLIANCE AUDITS AND INSPECTIONS

8.1 Compliance Audits

8.1.1 SurModics shall permit GNE to conduct preparatory audits for the initiation of GMP manufacture of the Product, pre-approval audits, for cause audits, and routine and follow-up compliance audits upon reasonable notice and as mutually agreed upon. Such audits are intended to assure GNE that SurModics maintains adequate premises, equipment and staff with sufficient knowledge and experience to carry out all operations relating to the Products. Such GNE auditors shall conduct themselves in accordance with all applicable SurModics' policies and procedures and in such a manner as not to disturb SurModics operations.

8.1.2 SurModics shall allow GNE to review all relevant records required to perform such audits during normal business hours. The start date and duration of the audits shall be agreed upon by both Parties. [*]

8.1.3 GNE shall provide a written report to SurModics of all observations after the completion of the audit.

8.1.4 SurModics shall provide a written response to GNE within [*] of receipt of the audit report. Such response shall describe in detail the corrective actions to be implemented by SurModics. SurModics may request an extension of time to provide a written response when necessary to prepare a comprehensive corrective action plan. Such an extension request will propose an appropriate timeframe in which to submit a final response along with justification for the extension request.

8.1.5 For-cause audits, by nature, will require scheduling as soon as possible. SurModics will make concerted efforts to schedule all such audits promptly.

8.2 Regulatory Authority Inspections

8.2.1 SurModics shall [*] notify the GNE Quality Unit of any regulatory authority contact, including facility inspections, sample requests, and written contact related to the Product.

8.2.2 [*]

8.2.3 [*]

8.2.4 SurModics shall refer any GNE submission and GNE-specific related queries from regulatory agencies about the Product to GNE.

8.2.5 Any deficiencies noted during a GNE territory regulatory authority inspection of SurModics premises, which relate directly or indirectly to the manufacturing, testing, storage, or quality systems related to the Product, must be brought to the attention of the GNE Quality Unit within [*].

8.2.6 SurModics shall secure GNE's written agreement prior to making any commitments to a regulatory authority regarding the Product.

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8.2.7 SurModics shall provide GNE a redacted copy (i.e., redacted for information pertaining to other products) of any regulatory inspection report related to the Product and SurModics' response to the inspection reports.

8.3 Regulatory Agency Contacts

8.3.1 [*] SurModics shall promptly provide GNE with a copy of any regulatory correspondence relevant to the Product.

8.3.2 GNE shall notify SurModics [*] in writing of any regulatory issues that GNE knows shall impact SurModics' ability to manufacture the Product.

8.3.3 SurModics shall maintain a Drug Master File (DMF) for their facilities and allow GNE to reference such files upon request. SurModics shall inform the GNE Quality Unit in writing any time the DMF is updated (i.e., a new product introduction).

8.3.4 GNE shall have sole authority for preparing and filing any regulatory submissions per section 5.1 of License and Option Agreement.

8.3.5 GNE shall have sole authority, as between the parties, for filing applicable reports to regulatory agencies, such as Field Alerts and Biological Product Deviation Reports related to the Product.

8.3.6 Regulatory reporting may be required for problems such as stability failures, out of specification results, Significant Deviations, product complaints, or adverse events for the Product. When requested by GNE, SurModics shall work collaboratively with GNE for filing any such report thought to be due to operations conducted by SurModics. Investigations at SurModics shall be conducted in accordance with regulatory reporting requirements. GNE and SurModics shall mutually agree upon a timeframe for completion of the investigation on a case-by-case basis.

8.3.7 Regardless of which Party receives the initial contact or inquiry from a GNE territory regulatory authority regarding the Product, such receiving party will [*] inform the other party. GNE and SurModics shall agree, on a case-by-case basis, which party shall respond to such contact/inquiry. All correspondence with a GNE territory regulatory authority regarding the Product will be shared with GNE prior to it being sent to the GNE territory regulatory authority. Copies of all correspondence by one party shall be provided to the other party.

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APPENDIX I: — Glossary

Capitalized terms used but not defined herein shall have the meanings set forth in the License Agreement or the MSA. As used in this Quality Agreement, the following terms, whether used in the singular or the plural, shall have the meanings set forth in this Article

Word/Phrase	Meaning
Analytical Method:	A document describing the procedure for sample and standard preparation, instrument parameters, system suitability requirements (as necessary), testing, calculation and reporting of results.
Annual Report:	Annual Reports are annual updates submitted to the FDA after an IND goes into effect (ref.: 21 CFR 312.33) or a New Drug Application or Biological License Application is approved (ref.: 21 CFR 314.81).
Audit:	An appraisal that determines the degree of adherence to pre-defined criteria and results in a judgment. Examples are audits of systems and documentation. Audits are typically performed by someone not involved in the activity being audited in order to give the audit a degree of independence.
Batch or Lot:	A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
Quality Control Master Document (QCMD)/Certificate of Analysis (COA):	The Quality Control Master Document is equivalent to a Certificate of Analysis is the listing of all tests performed to release a batch and the results.
Deviation:	Event in the manufacturing process, testing and/or support system that is outside of approved operating parameters, the Product license, approved procedures, policies, standards, or specifications, or a departure from accepted cGMP's.
Final Drug Product:	A finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.
Field Alert or Biological Product Deviation Report:	All drug manufacturers with approved New Drug Applications or Biological License Applications are required to submit Field Alert Reports or Biological Product Deviation Reports, respectively, to the FDA if they find any significant problems with an approved drug (ref.: 21 CFR 314.81 or 600.14).
Good Manufacturing Practice (GMP) or cGMP:	That part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use, the regulations for which are encoded in the US Code of Federal Regulations, Title 21, Sections 210, 211, 600 and the EU Commission Directive 2003/94/EC (the 'GMP Directive').

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Word/Phrase	Meaning
In-Process Material:	Any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the Drug Product.
Lot Number or Batch Number:	Any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a Batch or Lot of Drug Product or other material can be determined.
Major Change:	A change that may impact the Product Quality or validated status, and/or may require regulatory action (for example, changes requiring an Annual Report or pre-approval submission).
Minor Change:	A change that does not impact the validated status, Product Quality, or Product License.
Master Batch Production Record (MBPR):	A pre-approved record that includes the formulation and describes the procedure to be followed when manufacturing and/or packaging Products. Once approved the MBPR is reproduced in a controlled manner and the reproduction is used to record the actual processing of each batch. This reproduced record is referred to as a ***production or batch record or batch ticket***.
Quality:	The totality of features and characteristics of a product or service that affect its ability to satisfy a given need. Essential elements of Product quality are the identity, strength, purity, potency and safety. These elements are primarily controlled by Testing Monographs and Master Processing Records.
Quality Assurance (QA):	The sum total of the organized arrangements made with the purpose of ensuring that the product meets the specifications and is of the quality required for its intended use and shall specifically include, without limitation, all activities as set forth in this Quality Agreement.
Quality Control (QC):	The sampling, specification-setting, testing, documentation and analytical procedures that provide independent results of required tests, which contribute to the evaluation of the quality of a material.
Quality Unit	The organizational entity, at either GNE or SurModics, that has been identified to the other party as having responsibility for activities or approvals described in this Quality Agreement.
Raw Data:	Any original laboratory worksheets, records, memoranda, note, document, or exact copies thereof, which are the result of original observations that are necessary for reconstruction and evaluation of processing, Quality Control or Quality Assurance activities. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.
Recall:	Tracing and recovery, as far as possible, of every item of a particular batch or of several batches of finished products after they have left the manufacturer.

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Genentech, Inc.

Word/Phrase	Meaning
Reprocessing:	The repeating of an individual step, as identified in a relevant SOP, in order to fulfill the intended purpose of that step which was either completed or not completed originally, and to bring the Product into conformance with specifications.
Reworking:	The repeating of one or more step within the process or the performance of any additional process steps not covered in approved license in order to bring the Product into conformance with specifications.
Shelf Life:	The period of time during which the Product is designed to meet all registered safety, efficacy and quality requirements if stored in the prescribed manner. The re-test and/or expiry date are calculated by adding this period of time to the date of manufacture (with or without rounding to the end of the calculated month).
Specification:	A formally approved document listing the tests, Analytical Methods and acceptance criteria specific to material. It is used to determine the Quality of a material.
Standard Operating Procedure (SOP):	A document, approved by appropriate management, describing stepwise procedures for compliance with a regulation, policy or system. Compliance with an SOP is required, and Deviations must be documented.

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Genentech, Inc.

APPENDIX II: — Change History Log

Revision #	Description of, and Rationale for Changes
1.0	New Quality Agreement

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CONFIDENTIAL

EXHIBIT B

[*]

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EXHIBIT C

SURMODICS PATENTS
[*]

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CONFIDENTIAL

EXHIBIT D

FORM OF FEASIBILITY STUDY

I. Introduction

This Feasibility Study, dated as of [INSERT DATE], describes the general responsibilities and work to be performed by Genentech and SurModics in the development of Microparticles **[*]** incorporating a molecule [*]. The Feasibility Study includes (a) a description of the specific activities to be performed by Genentech and SurModics **[*]**, (b) a description of the SurModics Project Deliverables to be provided to Genentech, and (c) a Program Budget. This Feasibility Study shall be conducted pursuant to the terms of the License and Development Agreement between Genentech and SurModics dated as of October 5th, 2009 (the "License Agreement").

II. Scope

[DESCRIBE THE SCOPE OF THE FEASIBILITY STUDY HERE]

III. Objective

[DESCRIBE THE OBJECTIVE OF THE FEASIBILITY STUDY HERE]

IV. General Areas

[*]

V. Responsibilities

1. SurModics

   [Describe SurModics' responsibilities here]

2. Genentech

   [Describe Genentech's responsibilities here]

VI. Deliverables

[*]

VII. Plan of Work

[*]

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VIII. Business Section

1. Work plan schedule

   [*]

2. Program Budget

   [*]

IX. General Terms.

The Parties expressly acknowledge and agree that the provisions of the License Agreement are incorporated by reference herein, or by their terms otherwise apply hereto, and further agree that such provisions shall be given full effect in interpreting and enforcing this Feasibility Study. In the event of any inconsistency between this Feasibility Study and the License Agreement, the License Agreement shall control. This Feasibility Study may be executed (by facsimile or otherwise) in one or more counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute one and the same agreement.

****

IN WITNESS WHEREOF, the Parties have executed this Feasibility Study as of the date first set forth above.

GENENTECH, INC.	**SURMODICS, INC.**
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____

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EXHIBIT E

Genentech's requirements for Phase I/II GMP manufacturing

[*]

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EXHIBIT F

Press Release

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EXHIBIT F

FOR IMMEDIATE RELEASE

SurModics Enters Ophthalmic License and Development Agreement with Roche and Genentech

Includes Development and Commercialization of a Sustained Drug Delivery Formulation of Lucentis® and Potentially Other Genentech Compounds

EDEN PRAIRIE, Minnesota — October 6, 2009 — SurModics, Inc. (Nasdaq: SRDX), a leading provider of drug delivery and surface modification technologies to the healthcare industry, announced today that it has signed a License and Development Agreement with Roche (SIX: RO, ROG; OTCQX: RHHBY) and Genentech, Inc., a wholly-owned member of the Roche Group. Under this agreement, Roche and Genentech have obtained an exclusive license to use SurModics' proprietary biodegradable microparticles drug delivery system to develop and commercialize a sustained drug delivery formulation of Lucentis® (ranibizumab injection). The agreement further provides Roche and Genentech with opportunities to develop additional compounds for the treatment of ophthalmic diseases.

Under the terms of the agreement, SurModics will receive an up-front licensing fee of $3.5 million. In addition, SurModics could be eligible to receive up to approximately $200 million in fees and milestone payments in the event of the successful development and commercialization of multiple products. Roche and Genentech will pay SurModics for its development services and have the right to obtain manufacturing services from SurModics. Also, SurModics will receive undisclosed royalties on product sales.

"This agreement represents yet another major advancement toward realizing our strategic vision of developing technologies that address important clinical needs in the large and growing ophthalmology market," said Bruce Barclay, president and CEO of SurModics. "We believe that partnering with Genentech, among the world's largest and most prominent biotechnology companies and an established market leader in ophthalmology, serves to validate our critically enabling technologies. The agreement,

which includes Lucentis and potentially other products, addresses a wide range of ophthalmic diseases and leverages our expertise and technology platforms in ophthalmology, employs our proprietary biodegradable microparticles drug delivery system from SurModics Pharmaceuticals, and will utilize our new world-class cGMP manufacturing facility in Birmingham, Alabama."

Barclay added, "This agreement has the opportunity to provide both near- and long-term value to SurModics' shareholders. The combination of the up-front payment, R&D and manufacturing fees and contingent milestone payments underscore the unique advantages and power of our business model. The prospect of developing a sustained delivery formulation for a known, approved and highly successful drug in Lucentis, is a tremendous opportunity for SurModics."

Live Webcast

SurModics will host a webcast at 10:00 a.m. ET (9:00 a.m. CT) today to discuss the license and development agreement. To access the webcast, go to the investor relations portion of the Company's website at www.surmodics.com, and click on the corresponding webcast icon. If you do not have access to the Internet and want to listen to the audio or participate in the conference call by phone, dial 877-941-2332 (conference ID# 4167942). A replay of this conference call will be available by dialing 800-406-7325 and entering the previously stated conference call ID. The audio replay will be available beginning at noon CT on Tuesday, October 6, until noon CT on Tuesday, October 13.

About Lucentis

Lucentis® is a vascular endothelial growth factor (VEGF) inhibitor approved by the U.S. Food and Drug Administration (FDA) for the treatment of neovascular (wet) age-related macular degeneration (AMD). Lucentis is the only FDA-approved therapy for wet AMD, which in clinical trials showed an improvement in vision of three lines or more on the study eye chart in up to 41 percent of patients at two years.

Lucentis is designed to bind to and inhibit VEGF-A, a protein that is believed to play a critical role in the formation of new blood vessels (angiogenesis) and the hyperpermeability (leakiness) of the vessels.

Lucentis was discovered at Genentech and is being developed by Genentech and the Novartis Ophthalmics Business Unit for diseases or disorders of the eye. Genentech retains commercial rights in the United States and Novartis has exclusive commercial rights for the rest of the world.

Lucentis is a prescription medication given by injection into the eye. Lucentis has been associated with detached retina and serious eye infection and should not be used in patients who have an infection in or around the eye. Increases in eye pressure have been seen within one hour of an injection. Although uncommon, conditions associated with eye- and non-eye-related blood clots (arterial thromboembolic events) may occur. Serious side effects included inflammation inside the eye and, rarely, effects related to the injection procedure such as cataract. The most common non-eye-related side effects were nose and throat infection, headache, and respiratory and urinary tract infections. The most common eye-related side effects were the feeling that something is in a patient's eye, and increased tears. If a patient's eye becomes red, sensitive to light, painful, or has a change in vision, they should seek immediate care from their eye doctor.

Please see the Lucentis Full Prescribing Information on http://www.gene.com.

About SurModics, Inc.

SurModics' vision is to extend and improve the lives of patients through technology innovation. The Company partners with the world's foremost medical device, pharmaceutical and life science companies to develop and commercialize innovative products that result in improved diagnosis and treatment for patients. Core offerings include: drug delivery technologies (coatings, microparticles, nanoparticles, and implants); surface modification coating technologies that impart lubricity, prohealing, and biocompatibility capabilities; and components for in vitro diagnostic test kits and specialized surfaces for cell culture and microarrays. SurModics is headquartered in Eden Prairie, Minnesota and its SurModics Pharmaceuticals subsidiary is located in Birmingham, Alabama. For more information about the Company, visit www.surmodics.com. The content of SurModics' website is not part of this release or part of any filings the Company makes with the SEC.

Safe Harbor for Forward Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about beliefs and expectations, such as our expectations about our pipeline, the potential of biodegradable microparticles in combination with Lucentis or other compounds as a treatment for retinal diseases, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including the following: (1) realizing the full potential benefits of the Company's agreement with Genentech requires the development of new products and applications of technology, and the successful build-out of our Alabama facility in compliance with current Good Manufacturing Practice and other regulations; (2) our reliance on third parties (including our customers and licensees) and their failure to successfully develop, obtain regulatory approval for, market and sell products incorporating our technologies may adversely affect our business operations and our ability to realize the full potential of our pipeline; (3) costs or difficulties relating to the integration of the businesses of SurModics Pharmaceuticals, and the drug delivery assets and collaborative programs acquired from PR Pharmaceuticals, Inc., with SurModics' business may be greater than expected and may adversely affect the Company's results of operations and financial condition; (4) developments in the regulatory environment, as well as market and economic conditions, may adversely

affect our business operations and profitability; and (5) other factors identified under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2008, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our 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 we undertake no obligation to update them in light of new information or future events.

Contact

SurModics, Inc.
Phil Ankeny, Senior Vice President and Chief Financial Officer
(952) 829-2700

Exhibit 10.2

MASTER SERVICE AGREEMENT

BY AND BETWEEN

GENENTECH, INC.,

F. HOFFMANN-LA ROCHE, LTD.

AND

SURMODICS, INC.

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MASTER SERVICE AGREEMENT

by and between

GENENTECH, INC. AND SURMODICS.

THIS **MASTER SERVICE AGREEMENT** (the "**MSA**") is entered into as of the 5th day of October 2009 ("**Effective Date**") by and between Genentech, Inc., a Delaware corporation**,** with offices located at 1 DNA Way, South San Francisco, CA 94080 ("GNE") and F. Hoffmann-La Roche, Ltd., Grenzacherstrasse 124, CH 4070 Basel, Switzerland ("Roche") (GNE and Roche together referred to as "**Genentech**") and SurModics, Inc. a Minnesota corporation with a principal place of business at 9924 West 74th Street, Eden Prairie, MN 55344 (SurModics, Inc. together with its Affiliates hereinafter referred to as "**SurModics**") (each individually a "**Party**" and collectively, the "**Parties**").

RECITALS

WHEREAS, the Parties have entered into a License and Development Agreement effective as of the date hereof (the "**License Agreement**"); and

WHEREAS, as part of the License Agreement, Genentech desires to purchase from SurModics, and SurModics desires to supply to Genentech, Product and Raw Materials (as hereinafter defined) in the Territory (as hereinafter defined) pursuant to the terms set forth herein.

NOW, THEREFORE, in consideration of the premises and the undertakings of the Parties hereinafter set forth, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Capitalized terms used but not defined herein shall have the meanings set forth in the License Agreement. As used in this MSA, the following terms, whether used in the singular or the plural, shall have the meanings set forth in this Article:

1.1 "**Acceptance Criteria**" shall be defined in the applicable SOW.

1.2 "**Acquisition Cost**" is defined in Section 13.3.4(b).

1.3 "**Approved Suppliers**" is defined in Section 5.5.2.

1.4 "**BLA**" means a Biologics License Application and amendments thereto filed pursuant to the requirements of the FDA, as defined in 21 C.F.R. § 600 et seq., for FDA approval of a therapeutic biological product.

1.5 "**Decommissioning**" is defined in Section 13.3.4.

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1.6 "**EMEA**" means the European Union European Medicines Evaluation Agency, or any successor agency.

1.7 "**European Union**" means the countries of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland, Sweden, United Kingdom and any additional countries that may subsequently become members of the European Union.

1.8 "**Facility**" means the SurModics' manufacturing facility at the location specified under the applicable SOW, or such other manufacturing facility of SurModics as Genentech may approve in writing.

1.9 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto.

1.10 "**GNE Materials**" means any physical embodiments, supplies or materials provided to SurModics by or on behalf of GNE in connection with the Services, including the Compounds.

1.11 "**Good Manufacturing Practices**", "**GMP**" or "**cGMP**" means current Good Manufacturing Practices pursuant to the U.S. Food, Drug and Cosmetic Act and any U.S. regulations found in Title 21 of the U.S. Code of Federal Regulations (including Parts 11, 210 and 211) and other regulations, policies, or guidelines, as applicable to the Manufacture of Products hereunder.

1.12 "**Joint Management Team**" or "**JMT**" is defined in Section 3.2.

1.13 "**Manufacture," "Manufactured"** or "**Manufacturing**" means, except as otherwise provided in a SOW, the manufacture, inspection, storage and/or packaging of Product.

1.14 "**Manufacturing Documentation**" means all data, documents and records describing or otherwise related to the Manufacturing Process (or any part thereof) provided to SurModics by or on behalf of GNE or provided to GNE by or on behalf of SurModics as required by, and in connection with, this MSA or the Quality Agreement [*].

1.15 "**Manufacturing Process**" means the process for the Manufacture of Product pursuant to this MSA, the Quality Agreement and the Manufacturing Documentation, as such process may be changed from time to time in accordance with this MSA.

1.16 "**Manufacturing Joint Steering Committee**" or "**Manufacturing JSC**" is defined in Section 3.3.

1.17 "**Non-Conforming**" means, (a) with respect to a Product, a Product Manufactured by SurModics pursuant to this MSA that (i) fails to conform to the Specifications or Acceptance Criteria; or (ii) was not Manufactured in compliance with the Specifications,

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cGMPs, the Manufacturing Documentation, the Quality Agreement, the Standard Operating Procedures and all applicable laws and (b) with respect to any other deliverable, a deliverable that fails to conform to the requirements of this MSA or the Quality Agreement.

1.18 "**PFSB**" means the Japan Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour, and Welfare and its review agency, the Pharmaceutical and Medical Devices Agency, or any successor agency thereto.

1.19 "**Product**" means the Licensed Product or the SurModics Raw Material specified in the applicable SOW.

1.20 "**Quality Agreement**" means that certain quality agreement entered into by the Parties, as the same may be amended from time to time by the Parties.

1.21 "**Raw Materials**" means the materials used in the Manufacturing Process, including, but not limited to, chemicals, reagents, chromatography resins, and filters; and any materials used for testing, validation, qualification or other activities required to implement and support the Manufacturing Process at the Facility. Raw Materials include the SurModics Raw Materials.

1.22 "**Regulatory Authority**" means any national (*e.g.*, the FDA), supra-national (*e.g.*, the EMEA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction of the world, involved in the granting of Regulatory Approval.

1.23 "**Services**" means the activities in support of GXP compliant Development and/or Manufacturing of a Product, including: manufacturing, process development and scale-up, bulk production and fill/finish work associated with the supply of such Product for research, preclinical and clinical studies and related quality assurance and quality control activities, packaging, storage, stability, release testing, and/or quality control services and other related services provided by SurModics to GNE with respect to such Product under this MSA, as further defined in the applicable SOW.

1.24 "**Specifications**" are defined in the applicable SOW and/or Quality Agreement.

1.25 "**Standard Operating Procedures**" or "SOPs" means the standard operating procedures established by SurModics generally.

1.26 "**Term**" is defined in Section 13.1.

1.27 "**United States**" means the United States of America, its territories and possessions, Guam and the Commonwealth of Puerto Rico.

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ARTICLE 2
RELATED AGREEMENTS AND EXHIBITS

2.1 Statements of Work.

2.1.1 **In General.** A description of the Services to be performed and the Product to be Developed and/or Manufactured and supplied by SurModics for each project agreed upon by the Parties (each, a "**Project**") shall be contained in individual appendices to this MSA (each, a "**SOW**", a form of which is attached hereto as **Exhibit A**), executed by a duly authorized officer of each Party. Each SOW shall include all applicable process requirements, a list of any deliverables, regulatory compliance requirements, the anticipated period of performance, a Program Budget for Services [*], delivery schedules, [*], and quantity requirements. The Parties agree to negotiate, in good faith, payment criteria for each task in a SOW under a Program Budget [*]. Each SOW shall be subject to and deemed a part of this MSA. No SOW, or any modification thereto, shall be attached to or made a part of this MSA without first being executed by the Parties hereto in a writing which specifically references this MSA. To the extent any terms set forth in a SOW conflict with the terms set forth in this MSA, the terms of this MSA shall control unless otherwise expressly agreed by the Parties in such SOW.

2.1.2 **Changes to a SOW**. Except as otherwise provided in Section 5.8 below for changes related to regulatory requirements, if GNE reasonably determines that modifications to a SOW are required, GNE shall communicate those proposed modifications to SurModics and the reasons therefore in writing, and the Parties shall negotiate in good faith to implement mutually acceptable modifications in an amended SOW, including any change in the timelines, budget and fees.

2.1.3 **Change Order Process**.

(a) Any change in the scope of work, timeline, the corresponding Program Budget, and/or the Project specific compensation terms or payment schedule for an individual Project will require a written amendment to the applicable SOW ("**Change Order**"). For clarity, Change Orders amend only the applicable SOW and not the terms and conditions of this MSA. Each Change Order will detail the requested changes to the applicable scope of work, timeline, corresponding Program Budget, Project specific compensation terms, or payment schedule. Both Parties agree to act in good faith and promptly when considering a Change Order requested by the other Party.

(b) If the scope of a Project does not change but SurModics must perform additional work in order to perform the Services for the Project in accordance with the applicable SOW (i.e. in compliance with the Manufacturing Process), and such additional work is due to circumstances primarily within SurModics' control, SurModics will perform the additional work at no charge to GNE. For clarity, and except as set forth in Section 6.2.2 below, Genentech will be responsible for the cost of any additional GNE Material required in the performance of such additional work,. The Parties agree that termination of either a Project or some of the Services to be performed in furtherance of the completion of a Project, in each case before the completion of

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the Project, are changes in Project scope, and the affected Project budget and payment schedule shall be modified accordingly.

2.2 Quality Agreement. The Parties have entered into a Quality Agreement effective as of the date hereof (attached hereto as **Exhibit B**) that governs the responsibilities related to quality systems and defines quality requirements for the Product, including quality control, testing and release of the Product.

ARTICLE 3
MANAGEMENT OF PROJECT

3.1 In General. Each Party will be responsible for its internal decision making process and for reasonably informing the other Party of decisions made affecting the Services in a regular and timely manner. Without limiting the foregoing, the Parties shall establish the joint team set forth herein to advise the Parties and execute on certain matters relating to the Services under this MSA.

3.2 Joint Management Team (JMT)

3.2.1 **Formation.** Within thirty (30) days of the Effective Date, the Parties will establish a joint management team (the "**Joint Management Team**" or "**JMT**") to oversee and manage the Services under each SOW. If there are multiple SOWs hereunder the Parties may specify separate JMT's in the applicable SOW's, and each reference herein to "the JMT" or "the Joint Management Team" shall be a reference to the JMT applicable to each SOW. The Joint Management Team shall consist of such number of representatives of each Party as are reasonably necessary to accomplish the goals of the SOW. Each Party shall promptly notify the other Party of its initial appointees to each JMT. Subject to Section 3.2.2 (a), each Party shall be free to change its JMT representatives effective upon written notice to the other Party.

3.2.2 **Management Team Leader.**

(a) Appointment. Within thirty (30) days of the Effective Date, each Party shall appoint an employee to act as a primary contact for such Party in connection with this MSA, including without limitation, all SOWs and any Services and other activities conducted under any Project (each, a **"Management Team Leader"**). The GNE Management Team Leader will be responsible for overall leadership of the Joint Management Team. A Party may replace its Management Team Leader at any time by providing written notice of the change to the other Party: provided, SurModics shall have good faith consultation with GNE prior to the change and provided further, any such new representative shall be no less qualified than the representative being replaced and shall be mutually agreed to by the Parties. GNE shall not unreasonably withhold its agreement to any such new representative proposed by SurModics.

(b) Responsibilities. The Joint Management Team, led by the Management Team Leaders, will be responsible for [*]. The Management Team Leaders will dialog regularly about the progress of the Services and use good faith efforts to resolve any difficult issues

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regarding the Services addressed by the Joint Management Team as well as facilitate expeditious resolution of any issues escalated to the Manufacturing JSC.

3.3 Manufacturing Joint Steering Committee (Manufacturing JSC).

3.3.1 **Formation.** Within thirty (30) days of the Effective Date, the Parties will establish a Manufacturing Joint Steering Committee (the "**Manufacturing Joint Steering Committee**" or "**Manufacturing JSC**") to give direction and advice to the Joint Management Team (or Teams if more than one Project is being worked on by SurModics) relating to the Services. The Manufacturing Joint Steering Committee will be made up of at least two senior level members from each Party, representing functions within each Party directly involved in the Services; provided, however, that no Party's representative will serve on both the Manufacturing JSC and either a JMT or JSC established under the License Agreement. Either Party may replace any or all of its representatives at any time by providing written notice to the other Party.

3.3.2 **Responsibilities**. The Manufacturing Joint Steering Committee will be responsible for [*].

3.4 Meetings.

3.4.1 **JMT Meetings.** The JMT shall meet at least monthly during the course of any SOW. These meetings may be called on a more frequent basis as reasonably determined by the GNE Management Team Leader. These meetings may be held via teleconference or videoconference but should be held face to face at least two times per year, alternating between the Parties facilities or at such other location as the Parties may otherwise agree. Each Party shall be responsible for all of its own expenses of traveling to and participating in any of the JMT meetings. SurModics will assume the project management responsibility for each Project; documenting meetings, maintaining a project timeline, enabling risk management planning and resource forecasting, and otherwise tracking the progress of the Services under each Project for the Joint Management Team.

3.4.2 **Manufacturing JSC Meetings**. The Manufacturing JSC shall meet at least two (2) times per year during the term of this MSA. These meetings shall be held face to face, alternating between the Parties facilities or at such other location as the Parties may otherwise agree. By mutual agreement of the Parties, meetings may also be held via teleconference or videoconference. Each Party shall be responsible for all of its own expenses associated with travel to and participating in any of Manufacturing JSC meetings.

3.5 Decisions.

3.5.1 **In General.** The Management Team Leaders will be responsible for making all decisions on day to day activities that do not materially impact critical milestones, Program Budgets, or supply of materials. These decisions may be made in the context of discussion at the Joint Management Team; [*]. Notwithstanding the foregoing, either Management Team Leader may escalate material issues and disputes to the Manufacturing JSC.

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3.5.2 **GNE Decisions.** Notwithstanding anything to the contrary in the License Agreement, this MSA and/or the Quality Agreement, with respect to issues relating to: (i) interpretation of quality or cGMPs, (ii) acceptability of validation results, (iii) acceptability of Product testing (including in-process testing), results or procedures, (iv) disposition of any Product (including Non-Conforming Product) and/or (v) changes to a Manufacturing Process and/or Specifications, in each case, [*]. SurModics shall use Commercially Reasonable Efforts to effect any such implementation in accordance with a timeline approved by GNE. [*]

3.6 Disputes. If the Manufacturing JSC is unable to resolve a material issue or dispute presented to it, then either Party's Manufacturing JSC representative may escalate such Dispute to the JSC established under the License Agreement, and such dispute shall be resolved in accordance with ARTICLE 3 of the License Agreement.

3.7 Committee Term Limits. Either Party may, at its sole discretion, terminate its participation on the JMT or the Manufacturing JSC at any time [*] of the Effective Date by providing [*] written notice to the other Party. Should either Party elect to terminate its JMT or Manufacturing JSC participation, the Parties will amend the respective decision making and disclosure rights and obligations enumerated in this Agreement to preserve the Parties' respective decision making and disclosure rights and obligations in the absence of participation through the JMT or Manufacturing JSC.

3.8 No Deliverables. The Parties acknowledge and agree that the Manufacturing JSC under this Agreement is strictly for the purposes of decision making and governance of the activities conducted under a SOW to this MSA, and does not in any way include any significant deliverable of either Party.

ARTICLE 4
SERVICES

4.1 General Obligations. Subject to the terms and conditions set forth in this MSA and the License Agreement, during the Term, GNE hereby retains SurModics to perform the Services specified in the SOW(s).

4.2 Compliance with Law; **Facility Permits and Licenses**. SurModics shall, and shall ensure that its Project Personnel, perform the Services in accordance with all applicable laws and regulations, including, without limitation applicable GXPs. SurModics shall be responsible for obtaining and maintaining all applicable licenses and permits required for it to perform the Services hereunder.

4.3 Manufacturing Facility. Unless otherwise expressly agreed by the Parties in writing (including in a SOW), all Services shall be performed by SurModics at the Facility or by other SurModics' personnel at SurModics' locations. [*]

4.4 Project Personnel. It is understood that GNE is entering into this MSA, each SOW and the Quality Agreement in reliance on the commitment by SurModics to staff the Facility

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with managers, supervisors, engineers, technicians, inspectors, and other personnel including, but not limited to, temporary employees, consultants and sub-contractors (in accordance with Section 4.5 below), as SurModics deems necessary, in each case having sufficient technical expertise to perform its obligations under this MSA and the Quality Agreement (collectively, **"Project Personnel"**). Without limiting any other provision of this MSA, so long as such Project Personnel remain employed by SurModics, SurModics will ensure that such individuals (not specific individuals but individuals with similar functional expertise) are available to perform the obligations, as appropriate, to be provided by SurModics hereunder. In addition, SurModics shall ensure that the Management Team Leader and Project Personnel have read, understood and agreed to be bound by obligations of confidentiality and non-use at least as restrictive as those applicable to this MSA.

4.5 Subcontracting. SurModics shall not subcontract all or any portion of its obligations under this MSA without GNE's prior written approval and in accordance with the Quality Agreement. In the event of such approval, the applicable subcontract shall be consistent with the terms and conditions of this MSA. [*]For the avoidance of doubt, SurModics may [*] to the extent such [*] are under the general supervision of SurModics' Project Personnel, and have sufficient technical expertise, and SurModics is responsible to Genentech for their performance.

4.6 [*]

ARTICLE 5
FACILITY MODIFICATIONS, EQUIPMENT, MATERIALS, DOCUMENTATION AND IMPLEMENTATION

5.1 In General. Modification of the Facility and/or transfer of equipment, materials and/or processes to be carried out in order to perform the Services at the Facility, are summarized below and may be further described in detail in a SOW, if applicable.

5.2 [*]

5.3 [*]

5.4 GNE Materials. GNE shall transfer to SurModics the GNE Materials and any Manufacturing Documentation in Genentech's Control necessary to perform the Services as specified in the applicable SOW. Such transfer will be in accordance with the applicable SOW. GNE and SurModics will make their personnel available at the Facility and/or other facilities to enable the transfer and implementation of each of the foregoing. Prior to delivery of GNE Materials to SurModics, GNE shall provide documentation similar to that described in the Quality Agreement and a Certificate of Analysis or other documentation (i.e. certificate of testing, etc) as appropriate for the development stage of the GNE Material for SurModics' review and approval. SurModics shall approve or reject such documents not more than [*] after receipt thereof, and may reject such documents only as specifically set forth in the applicable Quality Agreement. Upon SurModics' approval of such documents, SurModics shall release GNE Material for delivery to SurModics and GNE shall deliver the GNE Material to SurModics

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in accordance with the terms and conditions of this MSA. The provisions set forth in the Quality Agreement regarding release shall control the procedures and standards for release. For purposes hereof, "**Certificate of Analysis**" means, as further specified in the Quality Agreement, for each shipment of GNE Material, a document prepared by GNE: (a) listing the Manufacturing date(s) of such GNE Material, and (b) certifying that all GNE Material in the shipment conform to the specifications and were Manufactured in compliance with specifications, cGMPs, the Quality Agreement, standard operating procedures and all applicable laws. The Parties shall from time to time agree upon a format or formats for the Certificate of Analysis to be used under this MSA.

5.5 Raw Materials & Change Parts.

5.5.1 **Raw Materials**. [*] Specifications for the Raw Materials shall be set forth in the SOW(s).

5.5.2 [*]

5.5.3 **Testing and Evaluation of Raw Materials.** SurModics shall perform all testing and evaluation of the Raw Materials as required by the applicable SOW, Specifications, Manufacturing Documentation, cGMPs, the Quality Agreement and Standard Operating Procedures.

5.5.4 [*]

5.6 Product Documentation. SurModics will maintain and retain true and accurate books, records, test and laboratory data, validation data, reports and copies of all other information related to the Services, including all information required to be maintained and retained under the License Agreement, this MSA, the Quality Agreement or applicable law (including cGMPs) (the "**Records"**). SurModics will maintain all Records in separate forms and notebooks to the extent reasonably possible (i.e., not commingled with other information) and will maintain Records for at least that period specified in the License Agreement and the Quality Agreement (or longer if required by law). GNE shall have the right to review the Records at the Facility during the time such Records are required to be maintained, as part of any audit conducted pursuant to Section 7.2.

5.7 Changes to the Manufacturing Process. Except as otherwise expressly set forth in the Quality Agreement, in the event that GNE is required by a Regulatory Authority to change the Manufacturing Process, SurModics shall use Commercially Reasonable Efforts to accommodate such required change, provided, that if any such change to the Manufacturing Process renders obsolete or unusable any Raw Materials used to manufacture the Product, and to the extent such Raw Materials can not be utilized by SurModics for its other manufacturing operations, GNE shall reimburse SurModics for the documented costs of such materials and disposal costs, if any.

5.8 Regulatory Requirements for the Manufacturing Process and the Product. In accordance with the terms of this MSA and the License Agreement, GNE shall be responsible

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for obtaining and maintaining all Regulatory Approvals required to Develop and Manufacture Product at the Facility; provided that SurModics shall use Commercially Reasonable Efforts to timely prepare, assist and enable GNE with obtaining and maintaining such Regulatory Approvals, including, without limitation, by preparing, filing and maintaining IND amendments to any existing FDA licenses held by SurModics.

ARTICLE 6
SUPPLY

6.1 In General. During the Term, and subject to the terms and conditions of this MSA and the License Agreement (including, without limitation, for supply of Licensed Product [*], SurModics agrees to supply to GNE, and GNE agrees to purchase from SurModics, such amounts of Product and other deliverables as set forth in the applicable SOW.

6.2 Acceptance of Product and Other Deliverables.

6.2.1 **Acceptance.**

(a) Product. Prior to delivery of Product to GNE, SurModics shall provide Genentech with [*]. Upon GNE's approval of such documents, GNE shall release the Product for delivery in accordance with the Quality Agreement, and SurModics shall deliver the Product in accordance with the terms and conditions of this MSA. The provisions set forth in the Quality Agreement regarding release shall control the procedures and standards for release. For purposes hereof, "**Certificate of Analysis**" means, as further specified in the Quality Agreement, for each shipment of Product, a document prepared by SurModics: [*]. The Parties shall from time to time agree upon a format or formats for the Certificate of Analysis to be used under this MSA.

(b) Other Deliverables. Upon receipt of any deliverable specified in an SOW other than Products, GNE (or its designee) shall, as appropriate, perform any testing and review required for such deliverable per any Acceptance Criteria in the SOW, and for the requirements of the Quality Agreement. Such testing and review will be completed within [*] of its receipt or such other period of time specified in a SOW.

6.2.2 **Non-Conforming Product**. In accordance with Section 7.1 of the Quality Agreement, GNE will notify SurModics of any claim that Product is Non-Conforming upon GNE discovering such Product is Non-Conforming, but no later than [*] after receipt of such Product and its associated Manufacturing Documentation by GNE from SurModics. [*]

6.2.3 **Replacement Product.** [*]

6.3 Delivery of Product.

6.3.1 **Shipping; Title**.

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(a) SurModics shall ship the Product (and any other deliverables) to such destinations chosen by GNE to the extent that such shipments are permitted by law for SurModics given the regulatory requirements of the exporting and the importing countries. Unless otherwise requested by GNE, SurModics shall arrange for the delivery of Product (or such other deliverables) from the Facility to such permitted destinations by carriers acceptable to, and in accordance with, GNE's shipping instructions on [*].

(b) SurModics will provide customary export documentation, as specified by GNE or by separate delivery and shipment documentation instructions, together with each shipment of Product (or such other deliverables). At SurModics' request, GNE shall assist SurModics with export consultant expertise regarding shipment of Product. SurModics shall also provide GNE with all relevant shipping information (e.g., carrier, shipment details, scheduled arrival date, quantity) prior to or coincident with shipping any Product (or such other deliverables) to GNE. SurModics shall also provide GNE with all relevant storage and handling instructions for such Product with each shipment and GNE agrees to comply with such instructions.

(c) GNE shall be the importer of record of each shipment of Product (or such other deliverables) shipped to GNE. In conjunction therewith, prior to shipping any Product (or such other deliverables), GNE shall obtain all appropriate approvals and consents of any governmental authority necessary for the import, transportation or shipment of such Product (or such other deliverables).

(d) Any customs, freight, insurance and other shipping expenses, as well as any special packaging expense incurred by SurModics prior to delivery to GNE shall be paid by GNE upon delivery to GNE (or its designee) at the Facility. GNE shall also bear all applicable taxes, duties and similar charges that may be assessed against the Product (or such other deliverables) after delivery to GNE (or its designee) at the Facility.

6.3.2 **Storing, Packaging and Shipping Containers.** SurModics shall provide sufficient and suitable cGMP storage facilities that meet the Specifications for storage of Product for a period of up [*] after release thereof. SurModics shall store, package, label and ship the Product according to the Specifications, the Quality Agreement, and according to procedures and using storage containers mutually agreed upon by GNE and SurModics in writing. [*]

ARTICLE 7
QUALITY COMPLIANCE

7.1 Quality Agreement. Both Parties are obligated to adhere to the provisions of the Quality Agreement and agree that all elements of quality assurance, quality control and the like shall be governed by the terms and conditions of the Quality Agreement. In the event of a conflict between this MSA and the Quality Agreement, this MSA shall prevail over those of the Quality Agreement, with the exception of quality-related matters and provisions that are in violation of cGMPs.

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7.2 Compliance Audits. Genentech will have the right to perform compliance audits as set forth in Section 8.1 of the Quality Agreement.

7.3 Responsibility for Recalled Products. GNE shall notify SurModics promptly if any Product manufactured by SurModics is the subject of a threatened or actual recall, market withdrawal or correction attributable to any activities conducted by of SurModics. The responsibility for any such recall shall be as set forth in the Quality Agreement.

ARTICLE 8
CONSIDERATION

8.1 Pricing. [*]

8.2 Invoices. SurModics shall invoice GNE for Services performed under this MSA in accordance with Section 7.2 of the License Agreement or the applicable SOW. [*]

8.3 Payment Terms. The provisions contained in Section 7.2 and Article 8 of the License Agreement are hereby incorporated by reference as if set forth herein in full

ARTICLE 9
OWNERSHIP OF INTELLECTUAL PROPERTY, MATERIALS AND EQUIPMENT

9.1 Equipment and Materials. [*]

9.2 Intellectual Property. The provisions contained in Articles 10 and 11 of the License Agreement are hereby incorporated by reference as if set forth herein in full.

ARTICLE 10
CONFIDENTIALITY

The provisions contained in Article 9 of the License Agreement are hereby incorporated by reference as if set forth herein in full.

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

11.1 General Representations and Warranties. The provisions contained in Article 13 of the License Agreement are hereby incorporated by reference as if set forth herein in full. In addition:

11.1.1 **SurModics Representations and Warranties**. SurModics represents and warrants that all Product, at the time of delivery to GNE's designated carrier, shall: [*].

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11.1.2 **GNE Manufacturing Representations and Warranties.** GNE represents and warrants to SurModics that: [*].

11.1.3 **Services Warranties** SurModics represents and warrants that: (a) the Services shall be performed and completed in a good and workmanlike manner; and (b) SurModics, and SurModics' employees and/or subcontractors assigned to perform the Services, are qualified and equipped therefor, have the requisite expertise and have all rights, licenses, permits and consents necessary to perform the Services hereunder.

11.1.4 **Compliance with Anti-Corruption Practices.** SurModics represents and warrants that SurModics and its directors, officers, employees and permitted subcontractors will not, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any official or employee of any government, or of any agency or instrumentality of any government (including any official or employee of any government-controlled hospital or other healthcare organization) in connection with any Services except in exchange for legitimate services provided by such official, employee, agency, or instrumentality to achieve the purposes of this MSA. In the event that SurModics learns of any activities in violation of this Section 11.1.4, it shall immediately notify GNE and provide detailed information about the nature and extent of such activities.

ARTICLE 12
INDEMNIFICATION, INSURANCE, LIMITATION OF LIABILITY

The provisions contained in Article 14 of the License Agreement are hereby incorporated by reference as if set forth herein in full.

ARTICLE 13
TERM AND TERMINATION

13.1 Term. This MSA shall commence on the Effective Date and, unless earlier terminated in accordance with the provisions of this Article 13, shall continue in full force and effect until terminated by mutual agreement of the Parties (the "**Term**"**)**.

13.2 Termination. This MSA may be terminated in accordance with Article 12 of the License Agreement (in its entirety or as to any SOW). In addition, either Party may terminate any SOW for any material breach of the MSA or such SOW by the other Party, provided, however, that the nonbreaching Party shall give the breaching Party written notice detailing such breach and indicating its intent to terminate, and, if the breaching Party fails to cure or dispute in good faith, that breach within (a) [*] after receipt of written notice of breach of an obligation to make a payment under this MSA and (b) [*] after receipt of written notice of any other breach, or a longer period of time not to exceed [*] if the breaching Party is working diligently to cure such breach.

13.3 Effect of Expiration or Termination.

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13.3.1 **In General.** In the event of any termination of this MSA, or any SOW to the MSA, the terms of Sections 12.6, 12.7, and 12.8 of the License Agreement shall apply (as applicable). In addition:

13.3.2 **Effect of Termination.** Following any termination of this MSA, Product or other deliverables that has been, or is in the process of being, Manufactured as of the date of notice of such termination (or which result from Manufacturing initiated prior to delivery of such notice), shall remain subject to the terms and conditions of this MSA, and such terms and conditions shall continue to survive with respect to such Product.

13.3.3 **Return of Materials**. In the event of termination of this MSA or any SOW to this MSA for any reason, SurModics agrees promptly to surrender and deliver to GNE (a) all applicable GNE Materials, Product and deliverables, and (b) records, materials, equipment, drawings, documents, data and any work product of any nature in each case directly pertaining to applicable GNE Confidential Information, Product, deliverables and/or Genentech Project IP Rights, or Joint Project IP Rights, excluding original notebooks, and all other materials belonging to GNE, in SurModics' possession. Notwithstanding the foregoing, (i) SurModics may retain and continue to use copies of such records, as required to comply with all applicable laws, and (ii) SurModics' legal department may retain one (1) copy of the foregoing, in each case, subject to its continuing obligation of confidentiality related to this MSA.

13.3.4 **Decommissioning**. Upon termination of the License Agreement, this MSA or any SOW for any reason, unless otherwise provided in this Section 13.3.4, SurModics shall promptly perform the Decommissioning, taking into account that such actions may be delayed to the extent necessary for SurModics to fulfill any obligations continuing as of the date of such termination. As used herein, "**Decommissioning**" means the process of verifying that all GNE contractual commitments applicable to such termination have been met, including the requirements related to the return of information and material set forth in Section 13.3.3. In addition, Decommissioning shall include the following actions by SurModics:

(a) Cease and refrain from all Services for GNE applicable to the termination;

(b) [*]

(c) Any GNE equipment in SurModics' possession shall, at GNE's election and cost, either be (i) removed and returned to GNE, (ii) removed and destroyed, or (iii) rendered inoperable. In the event GNE does not elect to have GNE equipment removed and returned to GNE under 13.3.4(c)(i) herein, at SurModics' election, SurModics may request GNE enter negotiations for the sale of such GNE equipment to SurModics prior to GNE making an election under 13.3.4(c)(ii) or 13.3.4(c)(iii).

13.3.5 **Costs Incurred in Decommissioning**. Prior to Decommissioning, and during the period of any Decommissioning, the JMT shall meet, discuss in good faith and agree upon a plan and budget for such Decommissioning. The actual costs and expenses incurred by SurModics in performing the activities identified in Section 13.3.4 shall be borne by the Parties as follows:

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(a) [*]

(b) [*]

(c) [*]

13.3.6 **No Conflict.** The foregoing rights and obligations are not meant to limit any rights or obligations (including other payments or reimbursements due to SurModics) of either Party set forth in Article 12 of the License Agreement.

13.3.7 [*]

13.3.8 **Transition of Manufacturing and Supply.** Notwithstanding any provision of this MSA to the contrary, upon an early termination by GNE pursuant to Sections 12.3 or 12.5 of the License Agreement, or Section 13.2 of this MSA (for SurModics' material breach or bankruptcy), SurModics agrees to extend the term of any SOW at GNE's written request (which shall be at least [*] prior to the date that this MSA with respect to such SOW would terminate or expire) in order to continue Manufacturing and Supply of Product to GNE under such SOW for a reasonable period after the date the MSA as to such SOW would have terminated. If, in connection with a termination of this MSA as to a SOW, the Parties enter into arbitration in accordance with Article 15 of the License Agreement, then the effective date of termination for purposes of this Section shall not be earlier than the final resolution thereof, unless expressly agreed otherwise in writing by the Parties. GNE shall give SurModics at least [*] prior written notice of the date after which Genentech will no longer require SurModics to perform the Manufacturing and Supply of Product under such SOW.

13.4 Survival. In addition to provisions that survive pursuant to the License Agreement, the following provisions shall survive termination of this MSA: Articles 1, 9, 10, 12, 14, and Sections 13.3 and 13.4.

ARTICLE 14
DISPUTE RESOLUTION

The provisions contained in Article 15 of the License Agreement are hereby incorporated by reference as if set forth herein in full.

ARTICLE 15
MISCELLANEOUS

15.1 In General. The provisions contained in Article 16 of the License Agreement are hereby incorporated by reference as if set forth herein in full, except that Section 16.3 of the License Agreement shall not apply and instead the terms of Section 15.2 shall govern this Agreement.

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15.2 Force Majeure.

15.2.1 **Effect of Force Majeure Event**. Neither Party shall be deemed to have breached this Agreement for failure to perform its obligations under this Agreement to the extent such failure results from acts of God, earthquakes, fires, floods, embargoes, wars, acts of terrorism, insurrections, riots, civil commotions or similar events (each a **"Force Majeure Event"**).

15.2.2 **Notice of Force Majeure**. If a Force Majeure Event occurs, the Party unable to perform shall promptly notify the other Party of the occurrence of such event, and the JMT shall meet (in person or telephonically) promptly thereafter to discuss in good faith the circumstances relating thereto and possible ways to mitigate any adverse consequences arising out of the Party's failure to perform. The Party unable to perform shall (a) provide reasonable status updates to the other Party from time to time, (b) use Commercially Reasonable Efforts to mitigate any adverse consequences arising out of its failure to perform and (c) resume performance as promptly as possible.

15.2.3 **Recovery from Force Majeure**. If a Force Majeure Event prevents SurModics from Manufacturing or supplying Product under this Agreement, the Parties shall in good faith discuss changes to scheduling and production to so as to remedy any shortfall, shortage or delay. SurModics shall use Commercially Reasonable Efforts to accommodate any such changes to scheduling and production. Notwithstanding the foregoing, in the event the Force Majeure Events affects SurModics' other customers, the changes to scheduling and production agreed upon by GNE and SurModics shall be no less favorable to GNE than those arrangements provided by SurModics to any other of its customers.

****

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IN WITNESS WHEREOF, the Parties hereto have caused this MSA to be executed by their duly authorized representatives as set forth below.

SurModics, Inc.

By: /s/ Bruce J Barclay
Name: Bruce J Barclay
Title: President and CEO

Genentech, Inc.

By: [*]
Name: [*]
Title: [*]

F. Hoffmann-La Roche Ltd

By: [*]
Name: [*]
Title: [*]

By: [*]
Name: [*]
Title: [*]

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EXHIBIT A

FORM OF SOW

This statement of work (the "Exhibit") is entered into pursuant to the Master Service Agreement by and between Genentech, Inc. ("Genentech") and SurModics, Inc. ("SurModics") dated <Insert Date> (the "Agreement"), and is effective as of <Insert Date> (the "Exhibit Effective Date"). Capitalized terms used in this Exhibit and not otherwise defined will have the same meaning as set forth in the Agreement.

The parties hereby agree as follows:

1. Exhibit. This document constitutes an Exhibit to the Agreement, and the Services to be provided hereunder are subject to the terms and conditions of the Master Service Agreement.

2. Services and Payments of Fees and Expenses. The specific Services contemplated by this Exhibit are set forth on the following attachments, which are incorporated herein by reference. [*]

Scope of Work, Timeline and Budget	ATTACHMENT I
Project Specific Compensation Terms	ATTACHMENT II
Change Order Process	ATTACHMENT III

3. Term. The term of this Exhibit will commence on the Exhibit Effective Date set forth above and will continue until the Services described on Attachment II are complete or this Exhibit is terminated in accordance with the Agreement.

4. Affiliates and Subcontractors. Genentech agrees that SurModics may use the services of its Affiliates or subcontractors to fulfill SurModics's obligations under this Exhibit. SurModics will be responsible to Genentech for the performance of such Affiliates and subcontractors, and all such performance will be in accordance with the terms and conditions of the Agreement and this Exhibit.

Subcontractors: [List as needed]

5. Contact Information

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.

SurModics Pharmaceuticals

Contact Name	Site	Department	Telephone	Email
		Proposal Administration		
		Project Management		
		Business Development		

Genentech

Contact Name	Address	Telephone	Email
<Manufacturing Collaborations Site Manager>	1 DNA Way South San Francisco CA 94080		

6. Amendments. No modification, amendment, or waiver of this Exhibit shall be effective unless in writing and signed by a duly authorized representative of each party, in accordance with the Change Order process described in ATTACHMENT III to this Exhibit.

ACCEPTED AND AGREED:

SurModics Pharmaceuticals: Genentech, Inc.:

[Insert Signature Blocks]

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.

Attachment I: SOW Scope & Budget

INSERT PROPOSAL TASKS HERE

INSERT PROPOSAL TIMELINE HERE

Attachment II: Project Specific Compensation & Terms

1) Project Budget and Total Compensation

[*]

2) Payments

SURMODICS shall submit (email) all invoices for this contract as follows:

Send Attn:

<Genentech Project Contact>

1 DNA Way, MS <#>

South San Francisco, CA 94080

Email / Carbon Copy: <Genentech Relationship Manager>

All invoices must reference the PO number assigned to this contract. The purchase order number will be sent via email after the contract is executed.

Genentech shall forward payment to SurModics as follows:

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Attachment III: Change Order Process

15.3 *Scope Change Form (SCF)*

Genentech / SurModics Exhibit #_____ **SOW #_____** **Change Order Form**

(a)

Change Order Number: [#_____]
(i) Description of Change(s) and Assumptions (b)
[*]

(c)

Total Contract Budget Summary

Document	Effective Date	Labor Amount	Expenses Amount	Total Contract
Exhibit [#]		$ —	$ —	$ —
Change Order #1		$ —	$ —	$ —
Change Order #2		$ —	$ —	$ —
Change Order #3, etc.		$ —	$ —	$ —
Total Revised Contract:				**$ —**

(d) Payment Schedule Revision

Is a revised payment schedule required? o **YES**, It is included as an Attachment. o **NO**

If **NO**, please explain:

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15.3.2 CHANGE ORDER APPROVAL

SurModics	**Genentech, Inc.**
Print Name: _____	Print Name: _____
Signature: _____	Signature: _____
Approval Date: __/__/_____	Approval Date: __/__/_____

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EXHIBIT B

QUALITY AGREEMENT

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GOOD MANUFACTURING PRACTICE
TECHNICAL QUALITY AGREEMENT

Between

Genentech, Inc.

(Contract Giver)

and

SurModics, Inc.

(Contract Acceptor)

We the undersigned, agree to the terms, conditions, roles and responsibilities described in this Quality Agreement and its appendices.

Genentech, Inc.		**SurModics, Inc.**	
[*]	9/30/09	/s/ Michael Shoup	10/1/09
[*]	DATE	Michael Shoup,	DATE
[*]		Vice President Quality, Regulatory and	
[*].		Clinical Affairs SurModics, Inc.	
		[*]	10/1/09
		[*]	DATE
		[*]	
		[*]	

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1.0 GENERAL INFORMATION

1.1 Introduction

1.1.1 Genentech, Inc. is a leading biotechnology company engaged in the manufacture, marketing and sales of pharmaceutical products. It operates under one common quality management system in compliance with current Good Manufacturing Practices (cGMP).

1.1.2 SurModics, Inc. is a leading pharmaceutical and biotechnology company engaged in the contractual manufacture of pharmaceutical and medical device products. It operates under one common quality management system in compliance with cGMP.

1.1.3 Genentech Inc. ("GNE") desires to entrust SurModics, Inc. ("SurModics") to perform activities related to the manufacture of GNE Products. GNE and SurModics are to define their roles and responsibilities hereunder according to the intentions of the GMP regulations. The manufacturing arrangements relating to the manufacture of the Product are governed under the Master Service Agreement between GNE and SurModics effective September 30, 2009 (the "Master Service Agreement").

1.1.4 Capitalized terms not defined in the Glossary attached as Appendix I shall have the meaning set forth in the Master Services Agreement.

1.2 Parties to Agreement

1.2.1 This GMP Technical Quality Agreement (the "Quality Agreement") is hereby entered into by and between GNE, a Delaware corporation, and SurModics, a Minnesota corporation, and must be adhered to in the processing of the Product for GNE governed by the Master Service Agreement. SurModics and Genentech are each referred to herein individually as a "Party" and collectively as the "Parties." The addresses of the Parties are:

GENENTECH, Inc.	**SurModics, Inc.**
1 DNA Way	9924 West 74th Street
South San Francisco, CA 94080	Eden Prairie, MN 55344

1.3 Scope

1.3.1 Subject to Section 1.3.4, this Quality Agreement is applicable to the manufacturing, processing, testing, and storage of the Product by SurModics for GNE.

1.3.2 The appendices and enclosures to this Quality Agreement are an integral part of this Quality Agreement and are incorporated into this Quality Agreement by this reference.

1.3.3 In addition to this Quality Agreement, SurModics and GNE shall create, approve, and maintain a document that details Product specific requirements (hereinafter referred to as the "PSR Document") for each Product. This

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document shall, at a minimum, contain contact information for designated representatives from SurModics and GNE who shall oversee the respective obligations regarding the Product and this Agreement, a process overview of the Product, a list of raw materials and suppliers required to produce the Product, disposition cycle times, list of batch documentation, any special shipping and handling requirements, and any additional applicable information as required per this Quality Agreement or deemed necessary by both parties.

1.3.4 This Quality Agreement pertains to the processing of the Products for administration to humans as governed by clinical trial authorizations and marketing authorizations (e.g. Investigational New Drug applications and Biologics License applications). It does not pertain to the supply of Products for research and development use. The mutual roles and responsibilities between GNE and SurModics related to the Quality system requirements for, as well as the Product-specific Quality requirements are defined.

1.4 Duration, Review and Changes to this Agreement

1.4.1 This Quality Agreement shall be effective as of the last date all required signatures are appended above (the “Effective Date”) and shall expire at the termination of the Master Service Agreement for the Product. The following sections shall survive termination of the Master Service Agreement until such time as defined in this Quality Agreement: sections 7.6, 7.7, 7.8, 7.9, 8.2, 8.3, and such other sections that by their terms are understood to survive the termination of the Master Service Agreement. The Parties acknowledge and agree that a similar quality agreement will be executed upon termination of the Master Service Agreement in the event an agreement for the manufacture of Phase III/IV material or commercial Product is negotiated between the Parties.

1.4.2 This Quality Agreement shall be reviewed for accuracy and compliance with the GMP regulations by both parties on at least a biennial cycle. Changes or supplements to this Quality Agreement or to the appendices and enclosures can only be made by mutual consent of amendments in writing. Such amendments to the Quality Agreement will be recorded and filed in APPENDIX II: — Change History Log, with each subsequent revision.

1.4.3 It is the responsibility of both parties to replace a superseded provision with an approved amendment. Superseded copies may be retained for historical records, but should be marked to appropriately indicate the historical status of the document.

1.4.4 It is the responsibility of both parties to ensure that their staff is adequately informed and any procedural or documentary changes resulting from an amendment are implemented in the areas affected by the changes.

1.5 Ultimate Quality Responsibility

1.5.1 In the event of a conflict between this Quality Agreement and the Master Service Agreement, the Master Service Agreement shall govern, except to the extent such provisions are in violation of the GMP regulations. Notwithstanding the foregoing, this Quality Agreement shall govern with respect to the assignment of responsibilities and obligations of each party to

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undertake those measures to assure the Quality of the Products and with respect to determinations of ability for release.

1.5.2 GNE's Quality Unit has sole authority for final disposition of Product for clinical use.

1.5.3 SurModics has the responsibility to implement and operate all quality systems as required by GMP regulations where the Product will be distributed. SurModics shall ensure that all quality systems operated by SurModics are compliant for GMP production and that they operate to a standard mutually agreed upon by both parties.

1.5.4 If not otherwise defined in this Quality Agreement, the provisions of SurModics' Quality management systems and Standard Operating Procedures shall be applied to these operations.

1.6 Quality Oversight and Person-in-Plant (PIP)

1.6.1 GNE shall have the right to provide GNE employees on SurModics' premises (the GNE employees hereinafter referred to as the "PIP") for the purpose of providing advice and coordinating reviews, approvals or other actions required by this Quality Agreement upon reasonable notice and as mutually agreed upon. Such GNE employees shall conduct themselves in accordance with SurModics' visitor policy. The GNE PIP activities, at the discretion of GNE, can also be performed remotely.

1.6.2 SurModics shall provide adequate space for the PIP when on site and shall ensure that the PIP is kept fully informed of all issues that arise that may affect the Quality of the Product. The PIP shall act as a single liaison between SurModics and GNE for Quality issues.

1.6.3 [*]

1.7 GMP Commissioning

1.7.1 GMP Commissioning is a process for approving the initiation of GMP activities at SurModics for a new manufacturing facility or a new manufacturing process related to the Product.

1.7.2 Prior to the initiation of GMP production, SurModics shall allow the GNE Quality Unit to perform GMP commissioning activities. This commissioning exercise is to document that the facility, process, procedures and personnel are ready to initiate GMP production as it relates to the Product.

1.7.3 The commissioning checklist and acceptance criteria shall be drafted by GNE and approved by both SurModics and GNE prior to execution.

1.7.4 SurModics shall not perform new GMP activities for the Product until the GMP Commissioning is complete and approved by the GNE and SurModics Quality Units.

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1.8 Execution of Responsibilities

1.8.1 In the execution of their relevant responsibilities, both Parties agree to conduct the necessary reviews, approvals, rejections and consents in a timely manner and within the time limits specified. Where any party requires the consent of the other, such consent will not be unreasonably withheld or delayed.

1.8.2 In this Agreement, “approval,” “authorization,” or “written communication” shall mean on official letterhead or approved forms, and signed by the authoring party’s Quality Assurance (QA) representative. Transmission of such written documentation may be by mail or electronic system (i.e., facsimile, scan).

2.0 LICENSES

2.1 Establishment License

2.1.1 If applicable, SurModics shall obtain and maintain a valid manufacturer’s license for the facilities [*].

2.2 Product Licenses

2.2.1 GNE shall, in accordance with applicable regulations, have sole authority for applying for any Product licenses with the regulatory agencies per section 5.1 of License and Option Agreement. GNE shall inform the appropriate regulatory authorities of any change to the approved licenses for the Product through supplements or amendments and informing SurModics of the same.

2.2.2 Upon request of any governmental or regulatory authority, both Parties shall provide to each other, any data and information relating to the Product which may be necessary for regulatory approval and maintenance efforts with respect to the licenses.

3.0 GOVERNING REGULATIONS, RULES AND PROCEDURES

3.1 Governing Regulations and Rules

3.1.1 SurModics shall ensure that the systems for the manufacture, processing, testing, packing, holding and shipping of the Product at SurModics comply with:

- Current Good Manufacturing Practice, including but not limited to US 21 CFR Part 11, 210, 211, and if applicable 820.
- The requirements of this Quality Agreement.
- The approved master documentation records (i.e., production records, specifications).
- Any additional regulations adopted by the regulatory authorities where the Product will be distributed. GNE shall inform SurModics, in advance, of any other countries where the Product will be distributed and any registration differences.

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3.1.2 GNE shall have the right to ensure SurModics' compliance with Section 3.1.1 above as described per Section 1.6 (PIP) and Section 8.1 (Compliance audits).

3.2 SurModics Procedures

3.2.1 SurModics shall create and maintain Quality systems compliant with cGMP, with associated Standard Operating Procedures that enable both Parties to execute their roles and responsibilities under the terms and conditions as described herein.

3.2.2 SurModics shall provide GNE with copies of effective Standard Operating Procedures related to the manufacture, processing, testing, packing and holding of the Product upon reasonable request by GNE.

4.0 MATERIALS

4.1 Sources

4.1.1 SurModics and/or GNE shall supply all materials required for the Product in accordance with the MSA and certify that their Quality is in compliance with the current "Note for Guidance on minimizing the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products" EMEA/410/01, Rev. 2 or update ("TSE Guidelines").

4.1.2 GNE shall provide the bulk drug substance to SurModics for further processing in accordance with the MSA. GNE certifies that the provided bulk will be processed according to GMP and the materials used in its processing will be sourced in compliance with the TSE Guidelines.

4.2 Suppliers

4.2.1 [*]

4.2.2 SurModics shall perform, or arrange to have performed, assessments of suppliers of raw materials and components required for GNE Products to ensure that the supplier's Quality and manufacturing system are compliant with cGMPs.

4.2.3 [*]

4.2.4 SurModics shall notify the GNE Quality Unit when a supplier's qualification status changes. Upon request by GNE, SurModics shall request from its suppliers permission to allow GNE to review SurModics audit reports.

4.2.5 If GNE supplies any raw materials and components to SurModics for use in processing of the Product, SurModics will rely on GNE's certification that the supplier's Quality systems are adequate.

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4.3 Receipt, Testing, Control and Release

4.3.1 SurModics/GNE shall receive, sample, test, control and release components and raw materials for the Product in accordance with the approved material specifications.

4.3.2 SurModics shall implement and maintain approved material specifications, analytical methods, inspection methods, and sampling plans as required per each material required for GNE Products. The GNE Quality Unit's prior written approval of such documentation is required. GNE's approval of the material specifications, analytical methods, inspection methods, and sampling plans shall be performed via SurModics' quality control system.

5.0 PROCESSING OF PRODUCT

5.1 Batch Numbering

5.1.1 SurModics shall use the GNE batch numbering system for all GMP Product produced by SurModics.

5.1.2 GNE shall issue batch numbers to SurModics, who shall assign a batch number to each Product batch. For purposes of tracking, SurModics may assign an internal SurModics batch number in addition.

5.1.3 SurModics shall record the GNE batch number onto the appropriate production records. SurModics shall keep track of GNE batch numbers to ensure batch numbers are assigned appropriately.

5.1.4 SurModics shall record the GNE batch number on the appropriate Product Batch labeling (i.e., vial label, shippers)

5.2 Holding, Shipping, and Destruction of Samples

5.2.1 SurModics shall hold the Product and raw materials in storage according to the PSR and cGMP requirements. SurModics shall ensure that appropriate cGMP controls are in place to prevent cross-contamination, theft, interference, or mix-up with any other materials.

5.2.2 SurModics shall ship the Product according to GNE shipping requirements per approved procedures. GNE shall communicate the shipping requirements to SurModics in writing.

5.2.3 Upon receipt of the Product from GNE for further processing, SurModics shall read the temperature monitors and report any temperature Deviations to the GNE Quality Unit within [*].

5.2.4 Any temperature Deviations observed during shipment and/or holding of the Product at SurModics will be handled per Section 7.2. SurModics shall investigate the root cause and identify appropriate corrective actions for Deviations that occur while the Product is under SurModics' control.

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5.2.5 GNE shall be responsible for assessing the impact on Product as a result of temperature Deviations either during Product shipment and/or during holding of the Product at SurModics.

5.2.6 SurModics shall destroy Product rejects (for example, inspection rejects, bulk waste, and rejected batches) per SurModics' procedures. SurModics shall ensure that proper handling, segregation, and documentation of any destruction is performed.

5.3 Reprocessing and Reworking

5.3.1 Prior to any Product batch being reprocessed or reworked, SurModics must obtain approval of the GNE Quality Unit in advance. Reprocessing and reworking are considered Significant Deviations and shall be handled in accordance to Section 7.2. [*]

5.3.2 [*]

6.0 QUALITY CONTROL TESTING

6.1 Analytical Methods

6.1.1 SurModics shall implement and maintain in-process material and final Product analytical methods.

6.1.2 The GNE Quality Unit's prior written approval for all Product-specific analytical methods is required.

6.2 Quality Control Testing and Approval

6.2.1 SurModics shall sample and test in-process and final Product batches according to the approved specifications, sampling plans and analytical methods.

6.2.2 SurModics shall report all quality control results on a "Certificate of Analysis" (COA). SurModics shall include all in-process results with the batch records.

6.2.3 SurModics shall not destroy any QC retain samples until the Product batch has been dispositioned by GNE.

6.2.4 GNE shall provide reference materials and critical reagents to SurModics to be used in the testing of the Product.

6.2.5 For testing performed at GNE, SurModics shall collect the samples, appropriately label and store the samples, and ship the samples per the current validated shipping procedure to GNE within [*] of collecting the samples.

6.2.6 GNE QC shall perform a review of raw quality control data for in-process and final Product batches to ensure quality standards are being maintained until such time that GNE can qualify SurModics to perform independent data review as defined per GNE procedure.

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6.3 Stability Testing

6.3.1 SurModics shall be responsible for maintaining a routine stability testing program for the Product per approved procedures.

6.3.2 SurModics shall write, approve and submit stability protocols for the Product to GNE for approval.

6.3.3 SurModics shall provide GNE with the results of stability testing in support of the approved shelf life within [*] of completion of the stability testing.

6.3.4 SurModics shall communicate any out of specification results obtained during stability testing of the Product to the GNE Quality Unit in accordance with Section 7.2.

6.3.5 GNE shall determine and approve the expiry and/or retest period, storage, and shipping conditions based on formal stability studies conducted for the Product.

6.4 Out of Specification (OOS) Quality Control Testing Results

6.4.1 In the event that SurModics obtains an initial OOS result, a preliminary lab assessment shall be conducted per SurModics' approved procedures. This assessment will include at a minimum, a review of all equipment used, sample and reagent preparation, and documentation associated with the test session. No additional testing of the Product shall be conducted during this preliminary lab assessment.

6.4.2 If no determinate error is identified in the assessment conducted pursuant to Section 6.4.1, then SurModics shall notify the GNE Quality Unit per the Section 7.2. No additional analysis shall be conducted on the Product prior to notifying the GNE Quality Unit.

6.4.3 The GNE Quality Unit shall approve OOS investigations and associated corrective and preventative actions, unless an analytical error is identified in the assessment as described in section 6.4.1 and the results are invalidated and testing is repeated on a new sample

7.0 GENERAL QUALITY SYSTEMS

7.1 Disposition of Product

7.1.1 The SurModics Quality Unit must certify in writing that each batch of Product has been manufactured, tested, packaged and stored in accordance with cGMPs, the Master Batch Production Record (MBPR) and applicable SOPs.

7.1.2 The SurModics Quality Unit shall review and approve all batch documentation according to SurModics' approved procedures prior to release of the Product batch to GNE.

7.1.3 All Deviations must be clearly identified in batch records, and must be fully investigated and completed prior to the approval of batch records. SurModics

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shall perform a cumulative assessment of all Deviations that occurred during the manufacturing, holding, and testing of the Product.

7.1.4 GNE has the sole authority for final disposition of the Product. SurModics shall notify the GNE Quality Unit of any Product batch being considered for rejection by SurModics prior to any formal reject disposition. For Product assigned a reject disposition by SurModics, GNE shall have the right to take possession of the Product. GNE shall authorize the destruction of any rejected Product batches.

7.1.5 SurModics shall not release any batches with open Major Changes or validations that are lot-release impacting.

7.1.6 Any problem discovered by GNE that would result in the rejection of a Product batch shall be communicated to SurModics as soon as practical, but in all cases within [*] following receipt of the release documentation.

7.2 Deviations

7.2.1 Any Deviation shall be documented and approved by personnel designated by SurModics from each of the relevant departments and by the SurModics Quality Unit, in accordance with SurModics' approved procedure for Deviation management.

7.2.2 Significant Deviations require notification of the GNE Quality Unit within [*] of discovery.

- Significant Deviations are defined as events that are observed during production, quality control testing including out-of-specification (OOS) results as described in section 6.4.2 above, and/or batch record review that may reasonably result in a Deviation from Product specifications, that may adversely impact the safety, identity, strength, purity or quality of the Product, and/or violate cGMPs or the Product license that could impact the releasability of the Product. Examples of Significant Deviations include:
  - Failure of Product to meet certificate of analysis (COA) specifications
  - Operations outside of validated limits
  - Suspected introduction of adventitious agents/contaminants in the Product
  - Excursions to environmental conditions (EM) in the primary filling area
  - Incorrect or unsuitable raw materials, components, or equipment used during the manufacturing of the Product
  - Reprocessing and reworking of the Product, [*]
  - Process discrepancies that adversely impact other Product process steps, lots, or Products batches whether distributed or not
  - Media fill and sterility positives/failures

7.2.3 SurModics shall obtain GNE Quality Unit approval for all Significant Deviations.

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7.2.4 SurModics shall inform the GNE Quality Unit within [*] of any Significant Deviation relating to other products, produced using the same equipment train as that used for the Product, if the Deviation could have an impact on the Product. SurModics will provide as much detail as possible regarding the Deviation. In the event that customer confidentiality agreements regarding other products prevent SurModics from providing certain documentation or detail, SurModics may provide redacted copies of documentation or a summary of the Deviation.

7.2.5 SurModics shall be responsible for investigating all Deviations per its approved procedures. SurModics will allow the GNE Quality Unit to actively participate in the development of investigation action plans related to Significant Deviations related directly to the Product or that could have impact on the Product. All investigation plans should be approved prior to implementation and should include at minimum:

- Lots impacted
- Description of action to be taken
- Rationale for this action
- Individual/department responsible for the action
- Target completion date
- Pre-approval by SurModics' QA

7.2.6 SurModics shall submit investigation plans before their implementation for all Significant Deviations. Those plans shall be evaluated by the GNE Quality Unit. Any additional testing required to support an investigation, including OOS investigations, must be pre-approved by the GNE Quality Unit.

7.2.7 When necessary, GNE shall provide a technical assessment or other data to support the investigation.

7.2.8 Significant Deviation reports shall include a description of the event, impacted lots, determination of cause, quality impact assessment, and identification of corrective and preventive actions. Quality impact assessments should determine the impact of the event on the safety, Quality, identify, potency and purity of the Product, other lots of the Product, validation, and GMP compliance.

7.2.9 After completion of the report related to Significant Deviations, SurModics shall submit to GNE a copy of a completed report. This report shall be reviewed by the GNE Quality Unit. Within [*], the GNE Quality Unit will either approve the Significant Deviation, or notify SurModics of additional information or actions required before approval of the Significant Deviation report.

7.2.10 SurModics shall [*] notify the GNE Quality Unit of any problems that are discovered that may have impact to Product batches previously shipped to GNE. Notice shall be made within [*] of the discovery of a potential quality problem with a released batch of Product.

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7.3 Validation

7.3.1 SurModics shall maintain systems that demonstrate manufacturing processes, facilities, utilities, equipment, and automation will reliably and repeatedly perform their intended function in the manufacture and testing of the Product.

7.3.2 As applicable, SurModics shall maintain a Validation Master Plan (VMP), which includes the validation program overview and requirements for the facility and equipment required to manufacture and test the Product. This VMP must be acceptable to GNE.

7.3.3 SurModics shall periodically re-validate, as appropriate, facilities, utilities, equipment, and automation per the VMP and other approved procedures.

7.3.4 GNE shall have the right to review all validation reports related to the manufacturing and testing of the Product. These validations must be acceptable to GNE. [*]

7.4 Change Control

7.4.1 SurModics shall utilize a change control system to ensure appropriate review of all changes.

7.4.2 The GNE Quality Unit shall approve any change to the following master documentation maintained by SurModics for GNE Products:

[*]

7.4.3 SurModics shall review all changes to determine if the change is a Major Change (as defined in the Glossary). If there is any doubt regarding whether a change is a Major Change, SurModics shall contact the GNE Quality Unit, and the parties shall jointly make this determination. It is understood between parties that changes as a result of pharmacopoeia test methods updates are not Major Changes.

7.4.4 In addition to Major Changes, SurModics shall notify the GNE Quality Unit in writing of any Minor Changes that affect GNE specific documents, equipment or processes, on at a minimum quarterly basis. Such notification shall contain a description of the change, the implementation date of the change, and the status of the change. Minor changes may be implemented by SurModics prior to such notification to GNE.

7.4.5 SurModics shall notify the GNE Quality Unit in writing of any Major Changes that may impact the Product Quality, validated status and/or have regulatory impact to:

[*]

7.4.6 Such notifications shall be communicated in writing in a timely manner so as to allow GNE to evaluate the affect of the change on Product Quality and/or obtain appropriate regulatory approvals prior to implementation.

7.4.7 At a minimum, such notification will contain a description of the change, the rationale for the change, the proposed implementation date, the qualification,

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validation, and/or comparability testing and acceptance criteria to prove that the Major Change does not adversely affect Product Quality.

7.4.8 SurModics shall provide all documentation of a Major Change to GNE for review and approval. This includes, but is not limited to, the description and rationale of the change and supporting documentation such as validations or technical assessments.

7.4.9 GNE's review and approval/rejection of Major Changes prior to implementation is required. Within [*], GNE shall approve the change, request additional information, or provide justification for the rejection of a change.

7.4.10 After completion of a Major Change, SurModics shall provide the GNE Quality Unit in writing with supporting data and reports that demonstrate the Major Change is valid and have been found acceptable by SurModics.

7.4.11 Emergency changes are changes that must be performed prior to the receipt of GNE approval in order to avoid Product loss or to eliminate a safety hazard. Emergency changes must be categorized and documented as previously described and notification must be provided to the GNE Quality Unit for evaluation within [*] of the change implementation.

7.4.12 For changes proposed by GNE, GNE shall notify SurModics in writing of any Product-related changes. SurModics shall implement these changes in a timely manner and in accordance with SurModics procedures and the Master Service Agreement.

7.5 New Product Introduction

7.5.1 SurModics shall not use the same facilities and/or equipment used for processing the Product for the processing of beta-lactams, e.g. penicillin or cephalosporins.

7.5.2 SurModics shall inform the GNE Quality Unit in writing per the change control Section 7.4, when [*]. For confidentiality reasons, SurModics shall only be required to provide detail to the level of the class of product.

7.5.3 Prior to introduction of a new product into the line, SurModics shall perform a cleaning verification/validation according to SurModics' procedures in order to exclude cross contamination of the Product from other product campaigns.

7.6 Product Complaints, Adverse Events, and other Post-Release Issues

7.6.1 GNE shall have sole authority for resolving all customer complaints and adverse events, related to the Product.

7.6.2 It is expected that most product complaints and adverse events for the Product shall be received by GNE. Any reports received by SurModics shall be forwarded to the GNE Quality Unit within [*].

7.6.3 If GNE requests a technical evaluation, documentation review, or sample inspection from SurModics to support a Product complaint/adverse event,

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SurModics shall report any findings to GNE in writing, signed, within [*] of notification by GNE, or as required per section 8.3.6. SurModics shall provide GNE with an update as to the progress of the investigation within [*] of notification by GNE.

7.6.4 SurModics shall notify the GNE Quality Unit within [*] of any other complaint with any other products manufactured by SurModics that by nature of similarity of material or manufacturing, that has reasonable potential to adversely impact the Product.

7.6.5 If the Product in any batch fails to comply with the agreed Quality standards, either upon receipt or during the shelf-life of the Product (i.e., during stability testing), as a result of operations conducted at SurModics, GNE will contact SurModics in writing to assist with the investigation.

7.7 Document Retention

7.7.1 SurModics shall maintain the original Batch records consisting of manufacturing, packaging, Quality Control, release, storage and delivery documentation, Raw Data and records for each Batch of Product in a secure location for a period of [*].

7.7.2 Prior to the destruction of any Product records at SurModics, SurModics shall notify the GNE Quality Unit and the records shall be sent to GNE, unless otherwise directed in writing by the GNE Quality Unit.

7.8 Sub-contracting

7.8.1 Consistent with Section 4.5 of the Master Services Agreement, SurModics shall not subcontract to a Third Party any of the work entrusted under this Quality Agreement, without the GNE Quality Unit's prior written approval.

7.8.2 In the event that SurModics, with the written permission of the GNE Quality Unit, sub-contracts any operation under this Quality Agreement to a Third Party, SurModics shall ensure that it enters into a written agreement with the sub-contractor that sets out the respective technical and quality responsibilities of each party [*].

7.8.3 SurModics may use contract laboratory testing facilities to support the testing of the Product. SurModics shall only use testing facilities that have been approved by the SurModics Quality Unit per SurModics' procedures. Quality Agreements between SurModics and those facilities must be in place.

7.9 QA Reserve Samples

7.9.1 SurModics shall maintain and inspect the reserve samples as required per cGMP regulations.

7.9.2 SurModics shall provide GNE with a summary of the results of the annual inspection of the reserve samples within [*] of completion. In the event any deterioration is observed during this inspection, SurModics shall contact GNE in accordance to the Deviation section 7.2.

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8.0 COMPLIANCE AUDITS AND INSPECTIONS

8.1 Compliance Audits

8.1.1 SurModics shall permit GNE to conduct preparatory audits for the initiation of GMP manufacture of the Product, pre-approval audits, for cause audits, and routine and follow-up compliance audits upon reasonable notice and as mutually agreed upon. Such audits are intended to assure GNE that SurModics maintains adequate premises, equipment and staff with sufficient knowledge and experience to carry out all operations relating to the Products. Such GNE auditors shall conduct themselves in accordance with all applicable SurModics' policies and procedures and in such a manner as not to disturb SurModics operations.

8.1.2 SurModics shall allow GNE to review all relevant records required to perform such audits during normal business hours. The start date and duration of the audits shall be agreed upon by both Parties. [*]

8.1.3 GNE shall provide a written report to SurModics of all observations after the completion of the audit.

8.1.4 SurModics shall provide a written response to GNE within [*] of receipt of the audit report. Such response shall describe in detail the corrective actions to be implemented by SurModics. SurModics may request an extension of time to provide a written response when necessary to prepare a comprehensive corrective action plan. Such an extension request will propose an appropriate timeframe in which to submit a final response along with justification for the extension request.

8.1.5 For-cause audits, by nature, will require scheduling as soon as possible. SurModics will make concerted efforts to schedule all such audits promptly.

8.2 Regulatory Authority Inspections

8.2.1 SurModics shall [*] notify the GNE Quality Unit of any regulatory authority contact, including facility inspections, sample requests, and written contact related to the Product.

8.2.2 [*]

8.2.3 [*]

8.2.4 SurModics shall refer any GNE submission and GNE-specific related queries from regulatory agencies about the Product to GNE.

8.2.5 Any deficiencies noted during a GNE territory regulatory authority inspection of SurModics premises, which relate directly or indirectly to the manufacturing, testing, storage, or quality systems related to the Product, must be brought to the attention of the GNE Quality Unit within [*].

8.2.6 SurModics shall secure GNE's written agreement prior to making any commitments to a regulatory authority regarding the Product.

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8.2.7 SurModics shall provide GNE a redacted copy (i.e., redacted for information pertaining to other products) of any regulatory inspection report related to the Product and SurModics' response to the inspection reports.

8.3 Regulatory Agency Contacts

8.3.1 [*] SurModics shall promptly provide GNE with a copy of any regulatory correspondence relevant to the Product.

8.3.2 GNE shall notify SurModics [*] in writing of any regulatory issues that GNE knows shall impact SurModics' ability to manufacture the Product.

8.3.3 SurModics shall maintain a Drug Master File (DMF) for their facilities and allow GNE to reference such files upon request. SurModics shall inform the GNE Quality Unit in writing any time the DMF is updated (i.e., a new product introduction).

8.3.4 GNE shall have sole authority for preparing and filing any regulatory submissions per section 5.1 of License and Option Agreement.

8.3.5 GNE shall have sole authority, as between the parties, for filing applicable reports to regulatory agencies, such as Field Alerts and Biological Product Deviation Reports related to the Product.

8.3.6 Regulatory reporting may be required for problems such as stability failures, out of specification results, Significant Deviations, product complaints, or adverse events for the Product. When requested by GNE, SurModics shall work collaboratively with GNE for filing any such report thought to be due to operations conducted by SurModics. Investigations at SurModics shall be conducted in accordance with regulatory reporting requirements. GNE and SurModics shall mutually agree upon a timeframe for completion of the investigation on a case-by-case basis.

8.3.7 Regardless of which Party receives the initial contact or inquiry from a GNE territory regulatory authority regarding the Product, such receiving party will [*] inform the other party. GNE and SurModics shall agree, on a case-by-case basis, which party shall respond to such contact/inquiry. All correspondence with a GNE territory regulatory authority regarding the Product will be shared with GNE prior to it being sent to the GNE territory regulatory authority. Copies of all correspondence by one party shall be provided to the other party.

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APPENDIX I: — Glossary

Capitalized terms used but not defined herein shall have the meanings set forth in the License Agreement or the MSA. As used in this Quality Agreement, the following terms, whether used in the singular or the plural, shall have the meanings set forth in this Article

Word/Phrase	Meaning
Analytical Method:	A document describing the procedure for sample and standard preparation, instrument parameters, system suitability requirements (as necessary), testing, calculation and reporting of results.
Annual Report:	Annual Reports are annual updates submitted to the FDA after an IND goes into effect (ref.: 21 CFR 312.33) or a New Drug Application or Biological License Application is approved (ref.: 21 CFR 314.81).
Audit:	An appraisal that determines the degree of adherence to pre-defined criteria and results in a judgment. Examples are audits of systems and documentation. Audits are typically performed by someone not involved in the activity being audited in order to give the audit a degree of independence.
Batch or Lot:	A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
Quality Control Master Document (QCMD)/Certificate of Analysis (COA):	The Quality Control Master Document is equivalent to a Certificate of Analysis is the listing of all tests performed to release a batch and the results.
Deviation:	Event in the manufacturing process, testing and/or support system that is outside of approved operating parameters, the Product license, approved procedures, policies, standards, or specifications, or a departure from accepted cGMP's.
Final Drug Product:	A finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.
Field Alert or Biological Product Deviation Report:	All drug manufacturers with approved New Drug Applications or Biological License Applications are required to submit Field Alert Reports or Biological Product Deviation Reports, respectively, to the FDA if they find any significant problems with an approved drug (ref.: 21 CFR 314.81 or 600.14).
Good Manufacturing Practice (GMP) or cGMP:	That part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use, the regulations for which are encoded in the US Code of Federal Regulations, Title 21, Sections 210, 211, 600 and the EU Commission Directive 2003/94/EC (the 'GMP Directive').

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Word/Phrase	Meaning
In-Process Material:	Any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the Drug Product.
Lot Number or Batch Number:	Any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a Batch or Lot of Drug Product or other material can be determined.
Major Change:	A change that may impact the Product Quality or validated status, and/or may require regulatory action (for example, changes requiring an Annual Report or pre-approval submission).
Minor Change:	A change that does not impact the validated status, Product Quality, or Product License.
Master Batch Production Record (MBPR):	A pre-approved record that includes the formulation and describes the procedure to be followed when manufacturing and/or packaging Products. Once approved the MBPR is reproduced in a controlled manner and the reproduction is used to record the actual processing of each batch. This reproduced record is referred to as a ***production or batch record or batch ticket***.
Quality:	The totality of features and characteristics of a product or service that affect its ability to satisfy a given need. Essential elements of Product quality are the identity, strength, purity, potency and safety. These elements are primarily controlled by Testing Monographs and Master Processing Records.
Quality Assurance (QA):	The sum total of the organized arrangements made with the purpose of ensuring that the product meets the specifications and is of the quality required for its intended use and shall specifically include, without limitation, all activities as set forth in this Quality Agreement.
Quality Control (QC):	The sampling, specification-setting, testing, documentation and analytical procedures that provide independent results of required tests, which contribute to the evaluation of the quality of a material.
Quality Unit	The organizational entity, at either GNE or SurModics, that has been identified to the other party as having responsibility for activities or approvals described in this Quality Agreement.
Raw Data:	Any original laboratory worksheets, records, memoranda, note, document, or exact copies thereof, which are the result of original observations that are necessary for reconstruction and evaluation of processing, Quality Control or Quality Assurance activities. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.
Recall:	Tracing and recovery, as far as possible, of every item of a particular batch or of several batches of finished products after they have left the manufacturer.

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Genentech, Inc.

Word/Phrase	Meaning
Reprocessing:	The repeating of an individual step, as identified in a relevant SOP, in order to fulfill the intended purpose of that step which was either completed or not completed originally, and to bring the Product into conformance with specifications.
Reworking:	The repeating of one or more step within the process or the performance of any additional process steps not covered in approved license in order to bring the Product into conformance with specifications.
Shelf Life:	The period of time during which the Product is designed to meet all registered safety, efficacy and quality requirements if stored in the prescribed manner. The re-test and/or expiry date are calculated by adding this period of time to the date of manufacture (with or without rounding to the end of the calculated month).
Specification:	A formally approved document listing the tests, Analytical Methods and acceptance criteria specific to material. It is used to determine the Quality of a material.
Standard Operating Procedure (SOP):	A document, approved by appropriate management, describing stepwise procedures for compliance with a regulation, policy or system. Compliance with an SOP is required, and Deviations must be documented.

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APPENDIX II: — Change History Log

Revision #	Description of, and Rationale for Changes
1.0	New Quality Agreement

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.

EXHIBIT 31.1

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

I, Bruce J Barclay, 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: February 5, 2010

Signature: /s/ Bruce J Barclay
Bruce J Barclay
President and
Chief Executive Officer

EXHIBIT 31.2

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

I, Philip D. Ankeny, 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: February 5, 2010

Signature: /s/ Philip D. Ankeny
Philip D. Ankeny
Senior Vice President and
Chief Financial Officer

EXHIBIT 32.1

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 December 31, 2009, as filed with the Securities and Exchange Commission (the "Report"), I, Bruce J Barclay, 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: February 5, 2010

/s/ Bruce J Barclay
Bruce J Barclay
President and
Chief Executive Officer

EXHIBIT 32.2

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 December 31, 2009, as filed with the Securities and Exchange Commission (the "Report"), I, Philip D. Ankeny, 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: February 5, 2010

/s/ Philip D. Ankeny
Philip D. Ankeny
Senior Vice President and
Chief Financial Officer