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 September 30, 2001

OR

☐ **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 0-32405

SeattleGenetics

SEATTLE GENETICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**91-1874389**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

21823 30th Drive SE
Bothell, Washington 98021
(Address of principal executive offices, including zip code)

(425) 527-4000
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 ☐

As of October 31, 2001, there were 29,317,524 shares of the registrant's Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

Seattle Genetics, Inc.
(a development stage company)
Balance Sheets

Assets	**September 30, 2001** (Unaudited)	**December 31, 2000**
Current assets		
Cash and cash equivalents	$ 5,169,624	$ 2,618,986
Short-term investments	30,601,054	21,711,460
Interest receivable	940,408	279,070
Prepaid expenses	599,266	759,339
Total current assets	37,310,352	25,368,855
Property and equipment, net	5,808,906	894,304
Restricted investments	1,000,687	3,421,247
Long-term investments	23,893,125	-
Other assets	891	189,419
Total assets	$ 68,013,961	$ 29,873,825
Liabilities, Mandatorily Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 780,291	$ 141,992
Accrued liabilities	2,123,884	668,698
Deferred revenue	141,667	-
Total current liabilities	3,045,842	810,690
Deferred rent	61,173	-
Deferred revenue, net of current portion	236,111	-
Total long-term liabilities	297,284	-
Commitments and contingencies		
Mandatorily redeemable convertible preferred stock, $0.001 par value, 17,450,000 (2000) shares authorized:		
Series A convertible preferred stock, 7,000,000 shares designated, 6,950,000 shares issued and oustanding (liquidation preference of $6,950,000)	-	6,924,550

Series B convertible preferred stock, 10,437,072 shares issued and outstanding (liquidation preference of $30,684,992)	-	30,631,457
Stockholders' equity (deficit)		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued	-	-
Common stock, $0.001 par value, 100,000,000 shares authorized, 29,301,064 and 4,581,077 issued and oustanding, respectively	29,301	4,581
Additional paid-in capital	98,497,221	14,798,044
Notes receivable from stockholders	(387,133)	(408,384)
Deferred stock compensation	(5,732,937)	(10,193,778)
Accumulated other comprehensive income	618,891	69,196
Deficit accumulated during the development stage	(28,354,508)	(12,762,531)
Total stockholders' equity (deficit)	64,670,835	(8,492,872)
Total liabilities, mandatorily redeemable convertible preferred stock and stockholders' equity (deficit)	$ 68,013,961	$ 29,873,825

The accompanying notes are an integral part of these financial statements

Seattle Genetics, Inc.
(a development stage company)
Statements of Operations
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,		Cumulative from inception (January 1, 1998) to September 30,
	2001	2000	2001	2000	2001
Revenues					
License agreements	$ 59,307	$ -	$ 93,891	$ -	$ 1,093,891
Government grants	11,024	27,202	11,024	83,422	109,656
Total revenues	70,331	27,202	104,915	83,422	1,203,547
Expenses					
Research and development (excludes non-cash stock-based compensation expense of $409,938, $223,205, $1,439,969, $440,982 and $2,878,899, respectively)	5,093,631	1,296,285	11,468,735	3,058,533	20,216,188
General and administrative (excludes non-cash stock-based compensation expense of $815,732, $747,889, $2,707,783, $1,266,213 and $5,479,692, respectively)	787,105	459,140	2,344,606	1,077,238	5,746,917
Non-cash stock-based compensation expense	1,225,670	971,094	4,147,752	1,707,195	8,358,591
Total operating expenses	7,106,406	2,726,519	17,961,093	5,842,966	34,321,696
Loss from operations	(7,036,075)	(2,699,317)	(17,856,178)	(5,759,544)	(33,118,149)
Investment income, net	800,372	504,024	2,264,201	1,459,583	4,763,641
Net loss	(6,235,703)	(2,195,293)	(15,591,977)	(4,299,961)	$ (28,354,508)
Deemed dividend upon issuance of Series B mandatorily redeemable preferred stock	-	-	-	(484,386)	
Accretion on mandatorily redeemable preferred stock	-	(4,942)	(3,295)	(14,578)	
Net loss attributable to common stockholders	$ (6,235,703)	$ (2,200,235)	$ (15,595,272)	$ (4,798,925)	
Basic and diluted net loss per share	$ (0.22)	$ (0.66)	$ (0.70)	$ (1.50)	
Weighted-average shares used in computing basic and diluted net					

loss per share	28,781,416	3,317,887	22,300,257	3,190,685

The accompanying notes are an integral part of these financial statements

Seattle Genetics, Inc.
(a development stage company)
Statements of Cash Flows

(Unaudited)

	Nine months ended September 30,		Cumulative from inception (January 1, 1998) to September 30, 2001
	2001	2000	
Cash flows from operating activities			
Net loss	$ (15,591,977)	$ (4,299,961)	$ (28,354,508)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization of deferred compensation	4,147,752	1,707,195	8,311,571
Depreciation and amortization	334,020	116,359	679,728
Gain on disposal of fixed assets	(38,534)	-	(38,534)
Realized loss on sale of securities	22,214	8,023	28,961
Amortization/ accretion on investments	351,235	(28,491)	301,521
Common stock bonus provided to employees			47,020
Deferred rent	61,173	-	61,173
Changes in operating assets and liabilities			
Interest receivable	(661,338)	(352,539)	(940,408)
Prepaid expenses and other assets	(208,162)	(76,604)	(600,156)
Accounts payable	638,299	93,647	780,291
Accrued liabilities	1,020,262	46,707	1,688,960
Deferred revenue	377,778	-	377,778
Net cash used in operating activities	(9,547,278)	(2,785,664)	(17,656,603)
Cash flows from investing activities			
Purchases of investments	(51,276,956)	(26,695,445)	(81,385,915)
Proceeds from sale and maturities of investments	21,091,043	571,728	26,179,457
Purchase of property and equipment	(4,850,164)	(566,469)	(6,090,176)
Proceeds from disposal of fixed assets	75,000	-	75,000
Net cash used in investing activities	(34,961,077)	(26,690,186)	(61,221,634)
Cash flows from financing activities			
Net proceeds from issuance of common stock	47,037,742	1,851	46,501,258
Net proceeds from issuance of Series A preferred stock	-	-	6,907,052
Proceeds from subscription receivable	-	2,545,001	2,545,001
Collection of notes receivable	21,251	-	21,251
Net proceeds from issuance of Series B preferred stock	-	500,364	28,073,299
Book overdraft	-	91,506	-
Net cash provided by financing activities	47,058,993	3,138,722	84,047,861
Net increase (decrease) in cash and cash equivalents	2,550,638	(26,337,128)	5,169,624
Cash and cash equivalents, at beginning of period	2,618,986	30,362,568	-
Cash and cash equivalents, at end of period	$ 5,169,624	$ 4,025,440	$ 5,169,624
Supplemental disclosure of cash information			
Non-cash investing and financing activities			
Issuance of common stock in exchange for notes receivable	$ -	$ -	$ 408,384
Issuance of Series B preferred stock for subscription notes receivable	$ -	$ -	$ 2,545,001
Conversion of preferred stock to common stock	$ 37,559,302	$ -	$ 37,559,302

Building construction costs accrued	$ 434,924	$ -	$ 434,924

The accompanying notes are an integral part of these financial statements

Seattle Genetics, Inc.
(a development stage company)
Notes to Financial Statements
(Unaudited)

1. Basis of Presentation

The accompanying unaudited financial statements of Seattle Genetics, Inc. ("Seattle Genetics" or the "Company") have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and reflect all adjustments consisting of normal recurring adjustments which, in the opinion of management, are necessary for a fair presentation of the results for the periods shown. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The results of operations for such periods are not necessarily indicative of the results expected for the full fiscal year or for any future period.

The balance sheet at December 31, 2000 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. These financial statements should be read in conjunction with the audited financial statements and footnotes included in the Company's Registration Statement on Form S-1 (File No. 333-50266) as filed with the Securities and Exchange Commission and the related prospectus dated March 6, 2001.

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements that effect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. Agreements and Research Grant

During August 2001, Seattle Genetics and ICOS Corporation entered into an agreement for the development and manufacture of the monoclonal antibody component of its lead antibody-drug conjugate SGN-15. Under the terms of the agreement, ICOS will perform process development, scale-up and Good Manufacturing Practice (GMP) manufacturing. SGN-15 is presently being tested in phase II trials for the treatment of breast, colon, prostate and lung cancers.

During September 2001, Seattle Genetics was awarded a research grant by the National Institutes of Health (NIH) to support the Company's development of monoclonal antibody-drug conjugates for the treatment of cancer. The grant was awarded under Phase I of the Small Business Innovation Research (SBIR) Program of the NIH. The grant will support potent monoclonal antibody drug-conjugates research.

3. Net Loss per Share

Net loss per share has been computed using the weighted–average number of shares of common stock outstanding during the period, less the weighted–average number of restricted shares of common stock issued that are subject to repurchase. The Company has excluded all outstanding options to purchase common stock and restricted shares of common stock subject to repurchase from the calculation of diluted net loss per share, as such securities are antidilutive for all periods presented.

The following table presents the calculation of basic and diluted net loss per share:

	Three months ended September 30, (Unaudited)		Nine months ended September 30, (Unaudited)	
	2001	**2000**	**2001**	**2000**
Net loss attributable to common stockholders	$ (6,235,703)	$ (2,200,235)	$ (15,595,272)	$ (4,798,925)
Basic and diluted				
Weighted-average shares used in computing basic and diluted net loss per share	28,781,416	3,317,887	22,300,257	3,190,685
Basic and diluted net loss per share	$ (0.22)	$ (0.66)	$ (0.70)	$ (1.50)
Antidilutive securities not included in net loss per share calculation				
Options to purchase common stock	2,660,213	665,000	2,660,213	665,000
Restricted shares of common stock subject to repurchase	447,867	892,084	447,867	892,084
Total	3,108,080	1,557,084	3,108,080	1,557,084

4. Comprehensive Loss

Comprehensive loss includes certain changes in equity that are excluded from net loss. Specifically, unrealized holding gains in available for sale investments, which were reported separately in stockholders' equity, are included in accumulated other comprehensive loss. Comprehensive loss and its components were as follows:

	Three months ended September 30, (Unaudited)		Nine months ended September 30, (Unaudited)		Cumulative from inception (January 1, 1998) to September 30,
	2001	2000	2001	2000	2001
Net loss	$ (6,235,703)	$ (2,195,293)	$ (15,591,977)	$ (4,299,961)	$ (28,354,508)
Unrealized gain on securities available for sale	426,996	28,500	549,695	34,292	618,891
Total	$ (5,808,707)	$ (2,166,793)	$ (15,042,282)	$ (4,265,669)	$ (27,735,617)

5. Investments

Investments consist of the following:

	Fair Value September 30, 2001 (Unaudited)	Fair Value December 31, 2000
U.S. corporate obligations	$ 40,058,514	$ 7,931,527
U.S. government and agencies	8,334,740	8,547,762
Mortgage-backed securities	6,531,662	8,653,418
Taxable municipal bonds	569,950	-
Total	$ 55,494,866	$ 25,132,707
Reported as:		
Short-term investments	$ 30,601,054	$ 21,711,460
Long-term investments	23,893,125	-
Restricted investments	1,000,687	3,421,247
Total	$ 55,494,866	$ 25,132,707

6. Property and equipment

Property and equipment consists of the following:

	September 30, 2001 (Unaudited)	December 31, 2000
Tenant improvements	$ 3,544,586	$ 20,686
Laboratory equipment	1,587,607	799,486
Furniture and fixtures	720,821	64,650
Computers and office equipment	589,224	355,190
	6,442,238	1,240,012
Accumulated depreciation and amortization	(633,332)	(345,708)
Total	$ 5,808,906	$ 894,304

7. Accrued liabilities

Accrued liabilities consists of the following:

	September 30, 2001 (Unaudited)	December 31, 2000
Contract manufacturing agreement	$ 743,056	$ 200,000

Building construction costs	434,924	-
Clinical trial costs	289,406	125,746
Compensation and benefits	209,681	53,038
Professional services	266,688	258,394
Other	180,129	31,520
Total	$ 2,123,884	$ 668,698

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

Forward–Looking Statements

The following discussion of our financial condition and results of operations contains forward–looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to future events or our future financial performance. In some cases, you can identify forward–looking statements by terminology such as may, will, should, expect, plan, anticipate, believe, estimate, predict, potential or continue, the negative of terms like these or other comparable terminology. These statements are only predictions. Actual events or results may differ materially. All forward–looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward–looking statements. In evaluating these statements, you should specifically consider various factors, including the risks outlined under the caption "Important Factors That May Affect Our Business, Results of Operations and Our Stock Price" set forth at the end of this Item 2 and those contained from time-to-time in our other filings with the SEC. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We focus on the discovery and development of monoclonal antibody-based drugs to treat cancer and related diseases. Our objective is to utilize our expertise in cancer and in monoclonal antibody-based technologies to advance our product pipeline and discover new product candidates. Since our inception, we have incurred substantial losses. As of September 30, 2001, we had an accumulated deficit of $28.4 million. These losses and accumulated deficit have resulted from the significant costs incurred in the development of our monoclonal antibody-based technologies, clinical trial costs of SGN-15 and SGN-10, manufacturing expenses of preclinical materials, and general and administrative costs. We expect that our losses will increase for the foreseeable future as we continue to expand our research, development, clinical trial activities and to build additional infrastructure.

We do not currently have any commercial products for sale. To date, we have generated revenues of $1.2 million from our license agreements and Small Business Innovative Research grants. In the future, we believe our revenues will consist of milestone payments, technology licensing fees and sponsored research fees under existing and future collaborative arrangements, royalties from collaborations with current and future strategic partners and commercial product sales. Because a substantial portion of our revenues for the foreseeable future will depend on achieving development and clinical milestones, our results of operations may vary substantially from year-to-year and even quarter-to-quarter.

Results of Operations

Three months ended September 30, 2001 and 2000

Revenues. Revenues increased to $70,000 for the three months ended September 30, 2001 from $27,000 for the three months ended September 30, 2000. Revenues were derived from service and reagent fees and the earned portion of a technology-licensing fee from Eos Biotechnology and from a new Small Business Innovative Research grant for the three months ended September 30, 2001. For the three months ended September 30, 2000, revenues were derived from an unrelated and separately awarded Small Business Innovative Research grant.

Research and development expenses. Research and development expenses, excluding non-cash stock–based compensation expenses, increased 293% to $5.1 million for the three months ended September 30, 2001 from $1.3 million for the three months ended September 30, 2000. This increase was principally due to contract manufacturing expenses of approximately $2.3 million, increases in rent and occupancy costs related to our new headquarters and operations facility of approximately $752,000, increases in personnel expenses and the proportionate increased usage of laboratory materials and supplies. The number of research and development personnel increased to 47 at September 30, 2001 from 32 at September 30, 2000. We anticipate that research and development expenses will continue to grow in the foreseeable future as we expand our research, development, contract manufacturing and clinical trial activities and incur the annualized costs related to our new headquarters and operations facility.

General and administrative expenses. General and administrative expenses, excluding non-cash stock–based compensation expenses, increased 71% to $787,000 for the three months ended September 30, 2001 from $459,000 for the three months ended September 30, 2000. This increase was primarily due to additional administrative personnel and other increases attributable to being a public company, including provisions for investor relations programs and directors' and officers' insurance. The number of general and administrative personnel increased to 14 at September 30, 2001 from 8 at September 30, 2000. We anticipate that general and administrative expenses will increase in the foreseeable future as the Company expands and incurs the annualized costs related to being a public company and the annualized costs related to our new headquarters and operations facility.

Non-cash stock–based compensation expense. Non-cash stock–based compensation expense increased 26% to $1.2 million for the three months ended September 30, 2001 from $971,000 for the three months ended September 30, 2000. The increase is attributable to higher levels of stock option grants, the difference between the deemed fair values as compared to the related exercise prices and reduced by a year-to-date adjustment attributable to options subject to variable accounting.

Investment income, net. Investment income increased 59% to $800,000 for the three months ended September 30, 2001 from $504,000 for the three months ended September 30, 2000. The increase was due to higher average balances of cash and cash equivalents, short-term and long-term investments and restricted

investments primarily from the net proceeds of our initial public offering on March 6, 2001.

Nine months ended September 30, 2001 and 2000

Revenues. Revenues increased to $105,000 for the nine months ended September 30, 2001 from $83,000 for the nine months ended September 30, 2000. Revenues were derived from service and reagent fees and the earned portion of a technology-licensing fee from Eos Biotechnology and a new Small Business Innovation Research grant for the nine months ended September 30, 2001. For the nine months ended September 30, 2000, revenues were derived from an unrelated and separately awarded Small Business Innovative Research grant .

Research and development expenses. Research and development expenses, excluding non-cash stock–based compensation expenses, increased 275% to $11.5 million for the nine months ended September 30, 2001 from $3.1 million for the nine months ended September 30, 2000. The increase was principally due to contract manufacturing expenses of approximately $4.8 million, increases in personnel expenses and the proportionate increased usage of laboratory materials and supplies of approximately $1.7 million, increased facility and occupancy costs of our new headquarters and operations facility and increased clinical trial expenses. We anticipate that research and development expenses will continue to grow in the foreseeable future as we expand our research, development, contract manufacturing and clinical trial activities and incur the costs related to our new headquarters and operations facility.

General and administrative expenses. General and administrative expenses, excluding non-cash stock–based compensation expenses, increased 118% to $2.3 million for the nine months ended September 30, 2001 from $1.1 million for the nine months ended September 30, 2000. This increase was primarily due to additional administrative personnel, increases in professional service fees and other increases attributable to being a public company, including provisions for investor relations programs and directors' and officers' insurance. We anticipate that general and administrative expenses will increase in the foreseeable future as the Company expands and incurs annualized costs related to being a public company and the annualized costs related to our new headquarters and operations facility.

Non-cash stock-based compensation expense. Non-cash stock-based compensation expenses increased 143% to $4.1 million for the nine months ended September 30, 2001 from $1.7 million for the nine months ended September 30, 2000. The increase is attributable to higher levels of stock option grants, the difference between the deemed fair values as compared to the related exercise prices and reduced by a year-to-date adjustment attributable to options subject to variable accounting.

Investment income, net. Investment income increased 55% to $2.3 million for the nine months ended September 30, 2001 from $1.5 million for the nine months ended September 30, 2000. The increase was due to higher average balances of cash and cash equivalents, short-term and long-term investments and restricted investments primarily from the net proceeds of our initial public offering on March 6, 2001.

Liquidity and Capital Resources

From inception through September 30, 2001, we have funded our operations with the net proceeds of $46.4 million from our initial public offering on March 6, 2001 and concurrent private placement, $37.5 million from private equity financings, $1.6 million from license agreements and government grants and approximately $4.2 million from investment income, net. At September 30, 2001, cash, cash equivalents, short-term and long-term investments totaled $59.7 million and restricted investments amounted to $1.0 million. Our cash, cash equivalents, short term and long-term investments and restricted investments are held in a variety of interest–bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, taxable municipal bonds, mortgage–backed securities, commercial paper and money market accounts.

Net cash used in operating activities for the nine months ended September 30, 2001 was $9.5 million compared to $2.8 million for the nine months ended September 30, 2000. Our net losses of $15.6 million for the nine months ended September 30, 2001 and $4.3 million for the nine months ended September 30, 2000 were adjusted for non-cash charges which were primarily related to amortization of deferred stock compensation and changes in operating assets and liabilities. Accrued liabilities as of September 30, 2001 increased primarily due to contract manufacturing obligations. We expect cash used in operating activities to increase in the future as we increase our staff headcount, expand our contract manufacturing initiatives and increase the patient enrollments of our clinical trials.

Net cash provided by investing activities for the nine months ended September 30, 2001 was $35.0 million compared to $26.7 million for the nine months ended September 30, 2000. Purchases of property and equipment were $4.9 million for the nine months ended September 30, 2001 compared to $566,000 for the nine months ended September 30, 2000. Capital expenditures for the nine months ended September 30, 2001 included leasehold improvements of approximately $3.1 million, equipment of approximately $1.1 million and furniture and fixtures of approximately $718,000 all in connection with our new headquarters and operations facility, which we moved to during August 2001. We expect that our level of capital expenditures will decrease as we are nearing completion of the final portion of our facility construction.

Net cash provided by financing activities was $47.1 million for the nine months ended September 30, 2001 compared to $3.1 million for the nine months ended September 30, 2000. Financing activities during the nine months ended September 30, 2001 included net proceeds of $44.4 million from our initial public offering and $2.0 million from our concurrent private placement. Financing activities during the nine months ended September 30, 2000 consisted primarily of $2.5 million from the collection of subscriptions receivable and $500,000 from the sale of additional Series B convertible preferred stock.

We expect to incur substantial costs as we continue to develop and commercialize our product candidates. We anticipate that our rate of spending will accelerate as the result of the increased costs and expenses associated with clinical trials, regulatory approvals and commercialization of our product candidates.

We believe that our current cash and investment balances will be sufficient to enable us to meet our anticipated expenditures and operating requirements for at least the next 24 months. However, we may need to sell additional equity or debt securities or obtain additional credit arrangements prior to that time. Additional financing may not be available on favorable terms or at all. If we are unable to raise additional funds should we need them, we may be required to delay, reduce or eliminate some of our development programs and some of our clinical trials, which may adversely affect our business and

operations.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Financial Instruments and for Hedging Activities" (SFAS No. 133), which provides a comprehensive and consistent standard for the recognition and measurement for derivatives and hedging activities. SFAS No. 133 became effective for fiscal years beginning after June 15, 2000. The adoption of SFAS No. 133 did not have a material impact on the Company's financial position or results of operations.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 141, "Business Combinations" (SFAS No. 141). SFAS No. 141 addresses financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, "Business Combinations" and SFAS No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises." SFAS No. 141 requires that all business combinations be accounted for by the purchase method. The provisions of this Statement apply to all business combinations initiated after June 30, 2001. Management believes the adoption of this Statement will not impact the Company's financial position or results of operations.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets" (SFAS No. 142). SFAS No. 142 addresses financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, "Intangible Assets." SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets should be accounted for in the financial statements upon their acquisition. The Statement also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. The provisions of this Statement are required to be applied starting with fiscal years beginning after December 15, 2001. Management believes the adoption of this Statement will not impact the Company's financial position or results of operations.

In July 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 143, "Accounting for Asset Retirement Obligations" (SFAS No. 143). SFAS No.143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development, and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The provisions of SFAS No. 143 will be effective for fiscal years beginning after June 15, 2002, however early application is permitted. Management believes the adoption of this Statement will not impact the Company's financial position or results of operations.

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" (SFAS No. 144). This Statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This Statement supersedes FASB Statement No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business. The provisions of SFAS No.144 will be effective for fiscal years beginning after December 15, 2001. Management believes the adoption of this Statement will not impact the Company's financial position or results of operations.

Important Factors That May Affect Our Business, Results of Operations and Our Stock Price

You should carefully consider the risks described below, together with all of the other information included in this quarterly report on Form 10-Q and the information incorporated by reference herein. If we do not effectively address the risks we face, our business will suffer and we may never achieve or sustain profitability. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

This quarterly report on Form 10-Q also contains forward–looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward looking statements as a result of factors that are described below and elsewhere in this quarterly report on Form 10-Q.

We have a history of net losses. We expect to continue to incur net losses and may not achieve or maintain profitability for some time. Our limited operating history may make it difficult to evaluate our business and an investment in our common stock.

We are a development stage company incorporated in July 1997 and have a limited operating history upon which an investor may evaluate our operations and future prospects. We have incurred net losses since our inception, including net losses of approximately $7.8 million for the year ended December 31, 2000 and approximately $15.6 million for the nine months ended September 30, 2001. As of September 30, 2001, we had an accumulated deficit of approximately $28.4 million. We expect to make substantial expenditures to further develop and commercialize our product candidates and expect that our rate of spending will accelerate as the result of the increased costs and expenses associated with clinical trials, regulatory approvals and commercialization of our potential products. In the near term, we expect revenues to be derived from milestone payments and sponsored research fees under existing and possible future collaborative arrangements and National Institutes of Health grants. However, our revenue and profit potential is unproven and our limited operating history makes our future operating results difficult to predict.

Our product candidates are at an early stage of development and if we are not able to successfully develop and commercialize them, we may not generate sufficient revenues to continue our business operations.

All of our product candidates are in early stages of development. Significant further research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. Much of our efforts and expenditures over the next few years will be devoted to SGN-15, SGN-10, SGN-14, SGN-30, SGN-17/19, a novel BR96 monoclonal antibody-drug conjugate and a novel SGN-30 monoclonal antibody-drug conjugate. These are our only product candidates in preclinical development, clinical trials or in collaboration with others at the present time. We

have no drugs that have received regulatory approval for commercial sale.

Our ability to commercialize our product candidates depends on first receiving FDA approval. The future commercial success of these product candidates will depend upon their acceptance by physicians, patients and other key decision–makers as therapeutic and cost-effective alternatives to currently available products. If we fail to gain approval from the FDA or to produce a commercially successful product, we may not be able to earn sufficient revenues to continue as a going concern.

We may continue to need significant amounts of additional capital which may not be available to us.

Since our inception, we have used approximately $17.7 million of cash in operating activities and approximately $6.1 million of cash to purchase property and equipment. We expect capital outlays and operating expenditures to significantly increase over the next several years as we hire additional employees and expand our infrastructure and preclinical development and clinical trial activities. We believe that our existing cash and investment securities, milestone payments and research grants, will be sufficient to fund our operations for at least the next two years. However, changes in our business may occur that would consume available capital resources sooner than we expect. If adequate funds are not available to us, we will be required to delay, reduce the scope of or eliminate one or more of our development programs. We do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to our stockholders or us. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

Clinical trials for our product candidates are expensive, time consuming and their outcome is uncertain.

Before we can obtain regulatory approval for the commercial sale of any product candidate that we wish to develop, we are required to complete preclinical development and extensive clinical trials in humans to demonstrate its safety and efficacy. Each of these trials requires the investment of substantial expense and time. We are currently conducting a total of six clinical trials of our two most advanced product candidates, and expect to commence additional trials of these and other product candidates. There are numerous factors that could delay each of these clinical trials or prevent us from completing these trials successfully.

Success in preclinical and early clinical trials does not ensure that large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause it to be redone or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be redone or terminated.

The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by the FDA or another regulatory authority varies significantly. To date, we have limited clinical data and have seen evidence of gastrointestinal toxicity with SGN-15 and SGN-10. Future trials may not show sufficient safety or efficacy to obtain the requisite regulatory approval for these product candidates or any other potential product candidates. Because SGN-15, SGN-10, SGN-14, SGN-30, SGN-17/19, a novel BR96 monoclonal antibody-drug conjugate and a novel SGN-30 monoclonal antibody-drug conjugate, are our only product candidates in clinical trials or preclinical development at the present time, any delays or difficulties we encounter may impact our ability to generate revenue and cause our stock price to decline significantly.

We may choose to, or may be required to, delay, suspend, repeat or terminate our clinical trials if patient enrollment cannot be achieved on a timely basis or if the trials are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's guidelines and are subject to oversight by the FDA and institutional review boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under the FDA's Good Manufacturing Practices, and may require large numbers of test patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. We depend on medical institutions to conduct our clinical trials and to the extent they fail to enroll a sufficient number of patients for our clinical trials or are delayed for a significant time in achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

In addition, we or the FDA might delay or halt our clinical trials of a product candidate for various reasons, including: deficiencies in the conduct of the clinical trials; the product candidate may have unforeseen adverse side effects; the time required to determine whether the product candidate is effective may be longer than expected; fatalities arising during a clinical trial due to medical problems that may not be related to clinical trial treatments; the product candidate may not appear to be more effective than current therapies; insufficient patient enrollment in the clinical trials; the quality or stability of the product candidate may fall below acceptable standards; or we may not be able to produce sufficient quantities of the product candidate to complete the trials.

Furthermore, the process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive and uncertain. It can vary substantially, based on the type, complexity and novelty of the product involved. Accordingly, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval, which could reduce or eliminate our revenue and delay or terminate the potential commercialization of our product candidates.

We currently rely on third–party manufacturers and other third parties for production of our drug products and our dependence on these manufacturers and other third parties may impair the development of our product candidates.

We do not currently have the ability to manufacture drug products that we need to conduct our clinical trials. For our two product candidates in

clinical trials, SGN-10 and SGN-15, we rely on drug products that were produced and vialed by Bristol–Myers Squibb and contract manufacturers retained by Bristol–Myers Squibb. We have contracted with ICOS Corporation to develop cell lines expressing the SGN-30 product candidate, to manufacture preclinical and clinical supplies of SGN-30 and to manufacture clinical supplies of monoclonal antibody chimeric BR96, the monoclonal antibody used in the drug candidate SGN-15. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including vialing and storage of these product candidates.

For the foreseeable future, we will continue to rely on contract manufacturers and other third parties to produce, vial and store sufficient quantities of our product candidates for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be unable to continue development and production of our product candidates.

Contract manufacturers have a limited number of facilities in which our product candidates can be produced. We currently rely on contract manufacturers to produce our product candidates under FDA Good Manufacturing Practices to meet acceptable standards for our clinical trials. Such standards may change, affecting the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials. Contract manufacturers may not perform or may discontinue their business for the time required by us to successfully produce and market our product candidates.

In some circumstances we rely on collaborators to assist in the research and development activities necessary for the commercialization of our product candidates. If we are not able to locate suitable collaborators or if our collaborators do not perform as expected, we may not be able to commercialize our product candidates.

We intend to continue to establish alliances with third party collaborators to develop and market our current and future product candidates. We may not be able to locate third party collaborators to develop and market other product candidates and we may lack the capital and resources necessary to develop all our product candidates alone. If our collaborators do not prioritize and commit substantial resources to programs associated with our product candidates, we may be unable to commercialize our product candidates, which would limit our ability to generate revenue and become profitable.

We have a license agreement with Genentech pursuant to which they are developing our lead CD40 targeted drug, SGN-14, to treat patients with hematologic malignancies or other types of cancer. Genentech is also responsible for gaining final approval through the required U.S. and international regulatory authorities to ultimately market the product. At any time, Genentech may terminate the agreement for any reason and return the rights to the CD40 program to us. If Genentech decides not to proceed and we fail to locate a substitute partner, we may not have sufficient capital resources to continue funding the project.

If we are unable to protect our proprietary technology, trade secrets or know-how, we may not be able to operate our business profitably. Similarly, if we fail to sustain and further build our intellectual property rights, competitors may be able to develop competing therapies.

Our success depends, in part, on our ability to maintain protection for our products and technologies under the patent laws or other intellectual property laws of the United States, France, Germany, Japan, United Kingdom and Italy, as well as other countries. We have filed several patent applications with the U.S. Patent and Trademark Office for our technologies which are currently pending. We also have exclusive rights to certain issued U.S. patents, and foreign counterpart patents and patent applications in the countries listed above, relating to our monoclonal antibody–based technology. Our rights to these patents are derived from worldwide licenses from Bristol–Myers Squibb, Arizona State University, National Institutes of Health and Enzon, among others. In addition, we have licensed or optioned rights to pending U.S. patent applications and foreign counterpart patents and patent applications to third parties. The standards which the U.S. Patent and Trademark Office uses to grant patents are not always applied predictably or uniformly and can change. Consequently, the pending patent applications may not be allowed; and if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents may not contain claims that will permit us to stop competitors from using similar technology. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, the protection, if any, given by our patents if we attempt to enforce them or if they are challenged in court is uncertain. In addition, we rely on certain proprietary trade secrets and know-how. We have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach the agreements or that our competitors may independently develop or otherwise discover our trade secrets.

We may incur substantial costs and lose important rights as a result of litigation or other proceedings relating to patent and other intellectual property rights.

The defense and prosecution of intellectual property rights, U.S. Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the United States and elsewhere involve complex legal and factual questions. These proceedings are costly and time-consuming.

If we become involved in any litigation, interference or other administrative proceedings, we will incur substantial expense and it will divert the efforts of our technical and management personnel. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially reasonable terms, if at all. We may be restricted or prevented from developing and commercializing our product candidates in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

If we lose our key personnel or are unable to attract and retain additional qualified personnel, our future growth and ability to compete would suffer.

We are highly dependent on the efforts and abilities of the principal members of our managerial and scientific staff, particularly Dr. H. Perry Fell

our Chief Executive Officer and Dr. Clay B. Siegall our President and Chief Scientific Officer. We have key person insurance in the amount of $1.0 million each, however, the sum recovered under such insurance policies may not fully compensate us for any loss of their services. Additionally, we have several scientific personnel with significant and unique expertise in monoclonal antibodies and related technologies. The loss of the services of principal members of our managerial or scientific staff may prevent us from achieving our business objectives.

The competition for qualified personnel in the biotechnology field is intense, and we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our products successfully, we will be required to expand our workforce, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing management personnel. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. To the extent we are not able to attract and retain these individuals on favorable terms, our business may be harmed.

We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapy. Some of these companies have commenced clinical trials of antibody products or have successfully commercialized antibody products. Many of these companies are developing products for the same disease indications as we are. Some of these competitors have received regulatory approval or are developing or testing product candidates that do or may in the future compete directly with our product candidates. For example, Genentech, IDEC Pharmaceuticals and American Home Products market products that may compete with ours. Other potential competitors include large, fully integrated pharmaceutical companies and more established biotechnology companies, which have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. Also, academic institutions, government agencies and other public and private research organizations conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing. It is possible that these competitors will succeed in developing technologies that are more effective than those being developed by us or that would render our technology obsolete or noncompetitive.

If our competitors develop superior products, manufacturing capability or marketing expertise, our business may fail.

Our business may fail because we face intense competition from major pharmaceutical companies and specialized biotechnology companies engaged in the development of other products directed at cancer. Many of our competitors have greater financial and human resources expertise and more experience in the commercialization of product candidates. Our competitors may, among other things: develop safer or more effective products; implement more effective approaches to sales and marketing; develop less costly products; obtain quicker regulatory approval; have access to more manufacturing capacity; form more advantageous strategic alliances; or establish superior proprietary positions.

In addition, if we receive regulatory approvals, we may compete with well-established, FDA approved therapies that have generated substantial sales over a number of years. We anticipate that we will face increased competition in the future as new companies enter our market and scientific developments surrounding other cancer therapies continue to accelerate.

We have no experience in commercializing products on our own and to the extent we do not develop this ability or contract with a third–party to assist us, we may not be able to successfully sell our product candidates. Additionally, if the market does not accept our products or if reform in the healthcare industry does not provide adequate reimbursement for our products, we may not be able to generate sufficient revenues to maintain our business.

We do not have a sales and marketing force and may not be able to develop this capacity. If we are unable to establish sales and marketing capabilities, we will need to enter into sales and marketing agreements to market our products in the United States. For sales outside the United States, we plan to enter into third–party arrangements. In these foreign markets, if we are unable to establish successful distribution relationships with pharmaceutical companies, we may fail to realize the full sales potential of our product candidates.

Additionally, our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved product candidate will depend on a number of factors, including: establishment and demonstration of clinical efficacy and safety; cost-effectiveness of a product; its potential advantage over alternative treatment methods; and marketing and distribution support for the product.

In addition, government health administrative authorities, private health insurers and other organizations are increasingly challenging both the need for and the price of new medical products and services. Consequently, uncertainty exists as to the reimbursement status of newly approved therapeutics and diagnostics. For these and other reasons, physicians, patients, third–party payors and the medical community may not accept and utilize any product candidates that we develop and even if they do, reimbursement may not be available for our products to enable us to maintain price levels sufficient to realize an appropriate return on our investment in research and product development.

We face product liability risks and may not be able to obtain adequate insurance to protect us against losses.

We currently have no products that are available for commercial sale. However, the current use of any of our product candidates in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made directly by consumers and healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products.

We may experience financial losses in the future due to product liability claims. We have obtained limited product liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for product candidates in development. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Our existing stockholders have significant control of our management and affairs, which they could exercise against your best interests.

Our executive officers and directors and greater than 5% stockholders, together with entities that may be deemed affiliates of or related to such persons or entities, beneficially own approximately 70% of our outstanding common stock. As a result, these stockholders, acting together, may be able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquiror from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

We may engage in future acquisitions that dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may make additional acquisitions of businesses, products or technologies in the future. No assurance can be given as to our ability to successfully integrate additional businesses, products, technologies or personnel that might have been acquired or may be acquired in the future, and our failure to do so could significantly affect our business and operating results. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow as quickly as possible or obtain access to technology or products that may be important to the development of our business.

Anti-takeover provisions could make it more difficult for a third party to acquire us.

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders. The rights of the holders of common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of Seattle Genetics without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. Further, certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Seattle Genetics, which could have an adverse effect on the market price of our stock. In addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state anti-takeover laws in Washington related to corporate takeovers may prevent or delay a change of control of Seattle Genetics.

Item 3. Quantitative and Qualitative Disclosure of Market Risk

In accordance with our policy, we do not use derivative financial instruments in our investment portfolio. We invest in high quality interest-bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, taxable municipal bonds, mortgage-backed securities, commercial paper and money market accounts. Such securities are subject to interest rate risk and will rise and fall in value if market interest rates change, however, we do not expect any material loss from such interest rate changes and therefore believe that our potential interest rate exposure is not material.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 2. Changes in Securities.

None.

(d) Use of Proceeds from Sale of Registered Securities

The Company's Registration Statement under the Securities Act of 1933 (File No. 333-50266) was declared effective by the SEC on March 6, 2001. All 7,000,000 shares of common stock offered in the final prospectus were sold at a price per share of $7.00. The aggregate gross proceeds of the shares offered and sold were $49.0 million which resulted in net proceeds to Seattle Genetics of approximately $44.4 million after deducting underwriting discounts and commissions and other offering expenses of $4.6 million. From the effective date of the offering through September 30, 2001, Seattle Genetics has used approximately $12.7 million of the proceeds in preclinical research and development activities, clinical trials, contract manufacturing, purchase of property and equipment and general corporate purposes. The remainder of the net proceeds from the offering are invested in a variety of high quality interest-bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, taxable municipal bonds, mortgage-backed securities, commercial paper and money market accounts in investments.

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

None.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits:

Exhibit Number

3.1* Amended and Restated Certificate of Incorporation of the Registrant

3.2* Bylaws of the Registrant

4.1* Form of Stock Certificate

4.2* Amended and Restated Investors Rights Agreement dated December 22, 2000 by and among the Registrant and certain holders of the Registrant's capital stock.

10.1† Contract Manufacturing Agreement dated August 1, 2001 between Seattle Genetics, Inc. and ICOS Corporation.

10.2 Seattle Genetics, Inc. 2001 Executive Performance Plan

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* Previously filed as an exhibit to Registrant's registration statement on Form S-1, File No. 333-50266, originally filed with the Securities and Exchange Commission on November 20, 2000, as subsequently amended, and incorporated herein by reference.

† Confidential treatment requested.

(b) Reports on Form 8-K:

The Company did not file any reports on Form 8-K during the three months ended September 30, 2001.

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.

. Seattle Genetics, Inc

By: /s/ TIM CARROLL
Tim Carroll
Chief Financial Officer
(Principal Financial Officer and Authorized Officer)

Date: November 9, 2001

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CONTRACT MANUFACTURING AGREEMENT

This CONTRACT MANUFACTURING AGREEMENT (the "Agreement") is entered into as of August 1, 2001 (the "Effective Date"), by and between ICOS Corporation ("ICOS"), a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 22021 20th Avenue S E, Bothell, WA98021 USA and Seattle Genetics, Inc. ("SGI"), a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 22215 26th Avenue S.E., Suite 3000, Bothell, WA98021.

RECITALS

WHEREAS, ICOS is in the business of manufacturing and testing pharmaceutical products; and

WHEREAS, SGI is the proprietor of a certain hybridoma that produce the monoclonal antibody chimeric BR96 (cBR96) and other material described in Appendix B; and

WHEREAS, ICOS has expertise in the development, evaluation and production of monoclonal antibodies for therapeutic use using cell lines; and

WHEREAS, subject to the terms and conditions set forth in this Agreement, SGI wishes to have ICOS manufacture for SGI a pre-commercial pharmaceutical Product (hereinafter defined); and

WHEREAS, subject to the terms and conditions set forth in this Agreement, ICOS wishes to manufacture Product for SGI.

NOW, THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Definitions

For purposes of this Agreement, the following terms will have the meanings set forth below:

1.1 "Affiliates" means, with respect to any Person, another Person that, directly or indirectly, controls, is controlled by or is under common control with such Person. The term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise. The direct or indirect ownership of at least fifty percent (50%) or, if smaller, the maximum allowed by applicable law, of the voting securities of a business entity or of an interest in the assets, profits or earnings of a Person shall be deemed to constitute "control" of the Person.

1.2 "Applicable Laws" means all ordinances, rules and regulations of any kind whatsoever of any governmental or regulatory authority, including, without limitation, the FDCA, that are applicable with respect to the context in which the term is used.

1.3 "Audit" means a review by SGI or their appointed representatives (such representatives to be reasonably acceptable to ICOS) of processes, procedures and documents of ICOS that are used or maintained by ICOS to provide the Services.

1.4 "Calendar Quarter" means the three-month period ending on March 31, June 30, September 30 or December 31. The initial Calendar Quarter will be deemed to begin on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 of such same year.

1.5 "Calendar Year" means the twelve (12) month period ending on December 31. The initial Calendar Year will be deemed to begin on the Effective Date and end on December 31 of such same year.

1.6 "Cell Line" means a hybridoma expressing cBR96 antibody as described in Appendix B, and will be used to provide the Services herein.

1.7 "cGMP" means Good Manufacturing Practices and General Biologics Products Standards as promulgated under the US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610).

1.8 "Damages" means any and all reasonable costs, losses, claims, actions, liabilities, fines, penalties, costs and expenses, court costs, and reasonable fees and disbursements of counsel, consultants and expert witnesses incurred by a party hereto (including interest which may be imposed in connection therewith).

1.9 "FDA" means the United States Food and Drug Administration, any comparable agency in any Foreign Jurisdiction, and any successor agency or entity to any of the foregoing that may be established hereafter.

1.10 "FDCA" means the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 *et seq.*).

1.11 "FAS" means the delivery term Free Along Side, meaning that ICOS has fulfilled its obligation to deliver when it has made the object of delivery available at its premises to SGI or SGI's agent (or to SGI's carrier). For the avoidance of doubt, unless otherwise agreed in writing, ICOS is not responsible for loading the object of delivery on to the vehicle provided by SGI or SGI's agent (or to ICOS's nominated carrier) or for any risk of loss during shipment.

1.12 "Foreign Jurisdiction" means any jurisdiction, not governed by the United States or any political subdivision thereof, as agreed upon by the parties.

1.13 "ICOS Know-How" means unpatented and/or unpatentable technical information, including ideas, concepts, inventions, discoveries, data, designs, formulas, specifications, procedures for experiments and tests and other protocols, results of experimentation and testing, fermentation and purification techniques, and assay protocols owned by ICOS as of the Effective Date which may be necessary for the performance of the Services. All ICOS Know-How shall be Confidential Information of ICOS.

1.14 "Manufacturing Specifications" means the specifications for manufacturing the Product. Prior to the initiation of the first cGMP manufacturing run, an Appendix C-1 signed by both parties setting forth the initial Manufacturing Specifications shall be appended to this Agreement and shall contain at a minimum a collection of documents containing certain specifications, procedures, assay methods (QC Release Tests), personnel contacts and any other information as may be needed and agreed by the parties relating to the manufacture of Product by ICOS for SGI. This Appendix C-1 shall also contain a statement to be agreed and acknowledged by ICOS and SGI that SGI adopts the initial Manufacturing Specifications as its own specification in conformance with Clause 6.7 herein. Any changes or additions to the Manufacturing Specifications shall be made by the written agreement of ICOS and SGI.

1.15 "NDA" means New Drug Application or any comparable application required by a Foreign Jurisdiction filed for the Product by SGI with the FDA and all subsequent submissions, supplements or amendments related thereto.

1.16 "Person" means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any governmental authority or any other entity or organization.

1.17 "Price" means the price specified in Appendix E for the Services.

1.18 "Process" means the process for the production of the Product from the Cell Line using the Manufacturing Specifications, including any improvements thereto from time to time made as a result of the Services.

1.19 "Product" means a monoclonal antibody derived from the Cell Line manufactured through ICOS's use of the Process.

1.20 "Product Specifications" means the product specifications listed under the column "Acceptance Criteria" as listed in Appendix C.

1.21 "Services" means all or any part of the services to be provided by ICOS (or any permitted subcontractor) for the benefit of SGI pursuant to this Agreement as further described in Appendix A.

1.22 "SGI-Patent Rights" means all patents and patent applications of any kind throughout the world relating to the Process which from time to time SGI is the owner of or is entitled to use.

1.23 "SGI Information" means all confidential and proprietary technical information not in the public domain relating to the Cell Line, the Process and the Product, from time to time supplied by SGI to ICOS, or arranged by SGI to be supplied by a third party (such as a prior manufacturer) to ICOS.

1.24 "SGI Know-How" means all information relating to the Process known to SGI from time to time other than confidential SGI Information and information in the public domain.

1.25 "SGI Materials" means the Materials supplied by SGI to ICOS (if any) and identified as such by Appendix B hereto.

1.26 "SGI Technology" means all of SGI's Patent Rights, SGI Know-How and SGI Information necessary to manufacture the Product.

1.27 "SGI Tests" means the tests to be carried out on the Product immediately following receipt of the Product by SGI, particulars of which are set out in Appendix C.

1.28 "Terms of Payment" means the terms of payment specified in Appendix E.

1.29 "Testing Laboratories" means any third party instructed by ICOS to carry out tests on the Cell Line or the Product.

1.30 "United States" means the fifty (50) states, the District of Columbia and all of the territories of the United States of America.

2. Supply by SGI

2.1 Prior to or immediately following the Effective Date of this Agreement SGI shall supply to ICOS SGI Information necessary for ICOS to perform the Services. SGI shall also provide to ICOS on an ongoing basis throughout the term of this Agreement full details of any hazards relating to SGI Materials and Cell Line, including with respect to their storage and use. On review of this SGI Information and details SGI Materials shall be provided to ICOS at ICOS's request when ICOS has satisfactorily determined that SGI Materials do not pose a hazard to ICOS. SGI shall assist ICOS in making such determination, but in no way be responsible for deciding the safety of the SGI Materials to ICOS's facilities. All property rights in the SGI Information, SGI Technology and/or SGI Materials supplied to ICOS shall remain vested in SGI.

2.2 SGI hereby grants ICOS the non-exclusive right to use the SGI Materials, SGI Information, SGI Know-How and SGI Technology for the sole purpose of providing the Services. ICOS hereby undertakes not to use SGI Materials, SGI Information, SGI Know-how or SGI Technology (or any part thereof) for any other purpose.

2.3 ICOS shall:

2.3.1 at all times use all reasonable efforts to keep the SGI Materials secure and safe from loss or damage but in no case in a lesser manner than ICOS stores its own material of similar nature;

2.3.2 not transfer to a third party any part of the SGI Materials or the Product, except for the purpose of any tests at the Testing Laboratories, provided, that, SGI is given prior notification or if SGI has given prior written consent to such transfer; and

2.3.3 provide that such Testing Laboratories are subject to obligations of confidence materially in the form of those obligations of confidence imposed on ICOS under this Agreement.

2.4 SGI warrants to ICOS that SGI is and shall at all times throughout the duration of this Agreement remain entitled to supply the SGI Materials, SGI Information and SGI Know-How to ICOS for the performance of the Services.

2.5 SGI warrants that the use by ICOS of SGI Materials, SGI Information and SGI Know-How for the Services will not infringe or is not alleged to infringe any rights (including, without limitation, any intellectual or other proprietary rights) vested in any third party.

2.6 SGI shall indemnify, defend and hold harmless ICOS against any loss, damage, costs and expenses of any nature (including court costs and legal fees incurred by ICOS or ordered as payable by ICOS), whether or not foreseeable or in the contemplation of ICOS or SGI, that ICOS may suffer as a result of any third party claims, suits or actions arising out of or incidental to (a) any breach of the warranties given in Clauses 2.4 and 2.5 above, (b) the distribution or use of the Product, except to the extent such loss, damage, costs and expenses are caused by ICOS's gross negligence or willful misconduct, or (c) any claims by third parties alleging ICOS's use of the Cell Line, SGI Materials, SGI Information, SGI Know-How, or the Manufacturing Specifications infringes any rights (including, without limitation, any intellectual or other proprietary rights) vested in any third party (whether or not SGI knew or should have known about such alleged infringement) except to the extent ICOS infringes any rights of any third parties by application of its production techniques while performing the Services unless such application or production technique has been developed as part of the Services. For the purposes of Clauses 2.6 and 2.7, the term, production technique(s), is limited to all and any physical arrangement and use of plant and equipment in the provision of Services.

2.7 ICOS shall indemnify, defend and hold harmless SGI against any loss, damage, costs and expenses of any nature (including court costs and legal fees incurred by SGI or ordered as payable by SGI), whether or not foreseeable or in the contemplation of SGI or ICOS, that SGI may suffer as a result of any third party claims, suits or actions arising from ICOS's performance of the Services except to the extent the loss or damage is a result of (a) SGI's negligence or willful misconduct or (b) ICOS's use of an application or production technique that has been developed as part of the Services for SGI or is supplied by SGI. For the avoidance of doubt where ICOS's application or production techniques, existed prior to the effective date of this Agreement, are not developed as part of the Services hereto and whether or not included in the Manufacturing Specifications, then they are covered by ICOS's undertaking of indemnity and hold harmless.

2.8 Notwithstanding the above, ICOS shall be at liberty to use SGI Information as it sees fit in providing the Services subject to nondisclosure pursuant to Section 7.

2.9 The obligations of each party under this Section 2 shall survive the termination of this Agreement for whatever reason.

3. Provision of the Services

3.1 ICOS shall diligently perform the Services as provided in Appendix A and shall use all reasonable commercial efforts to achieve the estimated schedules, specifications and amounts of Product. Furthermore, ICOS shall keep SGI regularly informed of any changes to the estimated schedules for performance of the Services and provide a monthly report, in a form agreed by the parties.

3.2 With respect to all services provided by ICOS from time to time that are agreed upon by the Parties but are outside the scope of the Services ("Additional Services"), SGI shall pay to ICOS [*]. ICOS will invoice SGI monthly for all Additional Services performed, with each such invoice containing a reference to the services performed and the personnel used. All such invoices will be payable under the terms described in Section 5.

[*] Confidential Treatment Requested

3.3 Due to the unpredictable nature of the biological processes involved in the Services, the schedules set down for the performance of the Services (including, without limitation, the dates for production and delivery of Product) set out in Appendix D are estimates only.

3.4 In the event that ICOS is unable to, or notifies SGI, in writing, that it is unable, for any reason, except events of Force Majeure where Clause 9.1 of this Agreement shall be applicable, to supply one cGMP clinical production run of Product by [*]; and a second cGMP clinical production run of Product by [*], SGI may at its discretion, seek to manufacture or have manufactured by a third party designated by SGI that quantity of the Products required by SGI that ICOS is unable to supply. Provided however, that prior to manufacture of Product by a third party, SGI and ICOS negotiate in good faith the supply of undelivered Product by ICOS to SGI at a future date agreed upon by the parties. If the parties cannot agree on a time period for delivery of Product and SGI determines to manufacture or have manufactured by a third party such Products, ICOS will supply SGI and/or any such third party all reasonably available information and data, and a non-exclusive, royalty free license to all ICOS Know-How, if any, required to manufacture the Product in accordance with the Manufacturing Specifications, which license shall be for the sole purpose of permitting SGI or its designee to manufacture the Product.
[*] Confidential Treatment Requested

3.5 Delivery of Product shall be FAS ICOS's premises. Risk in and title to Product shall pass on delivery. Transportation of Product, whether or not under any arrangements made by ICOS on behalf of SGI, shall be made at the sole risk and expense of SGI. In the case where SGI accepts ICOS Product tests (QC Release Tests) and shipment is to be made to a third party, “delivery” for the purposes of risk in and title to Product, shall occur upon the signed acceptance of ICOS Product tests(QC Release Tests) by SGI but which shall occur no later than ICOS's delivery of the Product FAS ICOS's premises. Unless otherwise agreed between the parties in writing, ICOS will tender delivery to SGI upon completion of all QA and QC tests approximately six (6) to eight (8) weeks following completion of manufacture.

3.6 Unless otherwise agreed, ICOS shall package and label Product for FAS delivery in accordance with its standard operating procedures. It shall be the responsibility of SGI to provide prior written notice to ICOS of any special packaging and labeling requirements for Product. All additional costs and expenses (including reasonable profit) of whatever nature incurred by ICOS in complying with such special requirements shall be charged to SGI in addition to the Price.

3.7 Upon completion of the Services, or as soon thereafter as can be mutually agreed, ICOS will deliver to SGI a cell bank, generated by ICOS, comprised of the Cell Line and used to provide the Services herein.

3.8 Joint Communication on Manufacturing: ICOS and SGI shall communicate and cooperate on a regular basis during the provision of Services herein and in the event that the parties observe the need for a regular and active committee, such body shall be established and meet regularly to discuss and communicate the progress of the Services.

3.9 As soon as practicable after execution of this Agreement, the parties will develop and agree upon a Quality Understanding document, the format and content of which is to be agreed upon by the parties from time to time during the term of this Agreement. The agreed upon Quality Understanding will be attached as Appendix F to this Agreement.

4. SGI Tests and Return Procedures

4.1 Except where SGI has accepted ICOS Product testsand provided written notice to ICOS of such acceptance, promptly following delivery of Product, SGI shall carry out SGI Tests. If SGI Tests show that the Product fails to meet Product Specifications due to ICOS failing to meet its obligations hereunder, SGI shall give ICOS written notice thereof as soon as practicable but in no case later than [*] days from the date SGI takes delivery of the Product and shall return such Product to ICOS's premises for further testing. In the absence of such written notice Product shall be deemed to have been accepted by SGI as meeting Product Specifications. If ICOS agrees that Product returned to ICOS fails to meet Product Specifications, and such failure is not due (in whole or in part) to acts or omissions of SGI or any third party after delivery of such Product to SGI, ICOS shall at SGI's discretion replace such Product at its own cost and expense. ICOS shall be entitled to consider its other obligations and its commercial commitments to third parties in the timing of such replacement. SGI acknowledges that there may, therefore, be a delay in the timing of the replacement of such Product; provided, however, that such delay shall not exceed [*] from date of return to ICOS.
[*] Confidential Treatment Requested

FOR THE AVOIDANCE OF DOUBT, WHERE THE SPECIFICATION HAS NOT BEEN AGREED BY THE PARTIES HERETO ICOS SHALL BE OBLIGED ONLY TO USE ITS REASONABLE ENDEAVOURS TO PRODUCE PRODUCT THAT MEETS DRAFT PRODUCT SPECIFICATIONS.

4.2 If there is any dispute concerning whether Product returned to ICOS fails to meet Product Specifications or whether such failure is due (in whole or in part) to acts or omissions of SGI or any third party after delivery of such Product to SGI, such dispute shall be referred for decision to an independent expert (acting as an expert and not as an arbitrator) to be appointed by agreement between ICOS and SGI.

The costs of such independent expert shall be borne by the parties equally; provided that the party that is determined to be incorrect in the dispute shall be responsible for all such costs and shall indemnify the correct party for its share of the costs incurred. The decision of such independent expert shall be in writing and shall be binding on both ICOS and SGI.

4.3 In the event that the parties hereto agree that a shipment or batch of Product fails to meet Product Specifications as a result

of ICOS failing to meet its obligations hereunder, the entire shipment or batch of Product that failed to meet Product Specifications shall either be returned to ICOS or destroyed, at ICOS's option.

4.4 The provisions of Clauses 4.1 and 4.2 shall be the sole remedies available to SGI in respect of Product that fails to meet Product Specifications.

5. Price and Terms of Payment

5.1 SGI shall pay the Price in accordance with the Terms of Payment all as specified in Appendix E.

5.2 Unless otherwise indicated in writing by ICOS, all prices and charges are exclusive of State Sales Tax or of any other applicable taxes, levies, duties and fees of whatever nature imposed by or under the authority of any government or public authority, which shall be paid by SGI (other than taxes on ICOS's income). All invoices are strictly net and payment must be made within thirty (30) days of date of invoice. Payment shall be made without deduction, deferment, set-off, lien or counterclaim of any nature.

5.3 In default of payment on due date interest shall accrue on a day to day basis with effect from the date which is [*] after the due date for payment on any amount overdue at the lower of [*] or the maximum rate allowable under Washington law.

[*] Confidential Treatment Requested

6. Warranty and Limitation of Liability

6.1 ICOS warrants that:

6.1.1 the Services shall be performed in accordance with Clause 3.1; and

6.1.2 the Product shall meet Product Specifications, except where the Product Specifications has not been agreed between the parties hereto in which case ICOS shall be obliged only to use its reasonable commercial efforts to produce Product that meets draft Product Specifications.

6.1.3 the Product delivered to SGI pursuant to this Agreement shall conform to the Product Specifications and that such Product shall (i) be free from defects in material and workmanship, (ii) be manufactured in accordance with cGMP and (iii) be manufactured in accordance with Appendix C hereof.

6.2 Clause 6.1 is in lieu of all conditions, warranties and statements in respect of the Services and/or the Product whether expressed or implied by statute, custom of the trade or otherwise (including but without limitation any such condition, warranty or statement relating to the description or quality of the Product, its fitness for a particular purpose or use under any conditions whether or not known to ICOS) and any such condition, warranty or statement is hereby excluded. ICOS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY ICOS. IN NO EVENT SHALL ICOS BE LIABLE FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

6.3 Without prejudice or modification to the terms of Clauses 6.1 and 6.2 the liability of ICOS to SGI, its permitted assigns and successors in interest, for any loss suffered by SGI or its permitted assigns and successors in interest, arising as a direct result of a breach of this Agreement, or of any other liability, including without limitation, misrepresentation and negligence (whether active, passive or imputed), arising out of this Agreement and Services provided thereunder, including without limitation the production and/or supply of the Product, shall be limited to the payment of damages which shall not exceed in US Dollars THE PRICE FOR SERVICES PAID BY SGI UNDER THE AGREEMENT; provided, however, if and to the extent such damages are caused by ICOS's willful or intentional breach of this Agreement or willful or intentional misconduct in the performance of the Services, then the damage limitation in this Clause 6.3 shall not apply.

6.4 ICOS shall in no event be liable for the following loss or damage howsoever caused (even if foreseeable or in the contemplation of ICOS or SGI):

6.4.1 loss of profits, business or revenue suffered by SGI or any other person who may be subrogated to, or assigned rights in the loss or damage; or

6.4.2 special, indirect or consequential loss, whether suffered by SGI or any other person.

6.5 SGI shall indemnify, defend and hold harmless and maintain ICOS indemnified and held harmless against all Damages in respect of:

6.5.1 any product liability in respect of Product, except for ICOS's obligations to indemnify in Clause 2.7 above; and

6.5.2 any negligent (active, passive or imputed), gross negligence or intentional act or omission of SGI in relation to the use, processing, storage or sale of the Product.

6.6 SGI represents and warrants that unless already expressly agreed in a written and executed document immediately prior to

the initiation of the first cGMP manufacturing run, SGI will adopt the initial Manufacturing Specifications as its own specification. Any changes or additions to the Manufacturing Specifications shall be made with the written approval of SGI.

6.7 The obligations of SGI under this Section 6 shall survive the termination for whatever reason of this Agreement.

7. Confidentiality

7.1 Each party agrees to keep the other party's Confidential Information (as defined in Clause 7.3) strictly confidential and to respect the other's proprietary rights therein and not at any time for any reason whatsoever to disclose or use the other party's Confidential Information for any purpose other than as expressly provided herein.

7.2 SGI and ICOS shall each ensure that all their respective employees, consultants and contractors having access to confidential ICOS Know-How or confidential SGI Information, SGI Know-How, SGI Materials, or SGI Technology shall be subject to the same obligations of confidence as the principals pursuant to Clause 7.1 and shall be subject to written confidentiality agreements in support of such obligations.

7.3 For purposes of this Agreement, "Confidential Information" means any business or technical information, trade secrets, know-how, techniques, data or other information, disclosed by the disclosing party to the receiving party in writing or that is disclosed orally and confirmed in writing as confidential within forty-five (45) days following such disclosure. The parties agree that SGI 's Confidential Information includes, without limitation, the SGI Information, SGI Materials, SGI Trade-Secrets and SGI Technology. The parties further agree that ICOS's Confidential Information includes, without limitation, ICOS Know-How.

7.4 The obligations of confidence referred to in this Section 7 shall not extend to any Confidential Information that:

7.4.1 is or becomes generally available to the public otherwise than by reason of a breach by the recipient party of the provisions of this Section 7;

7.4.2 is lawfully known to the recipient party prior to its receipt from the other;

7.4.3 is subsequently disclosed to the recipient party without being made subject to an obligation of confidence by a third party that does not have a prior obligation of confidence to SGI or ICOS, as the case may be; or

7.4.4 which may be required to be disclosed under any statutory, regulatory or similar legislative requirement, subject to the imposition of obligations of confidentiality to the extent allowed and provided further that each party shall, unless prohibited by law, use reasonable efforts to notify the other party of such compelled disclosure prior to such disclosure in order to seek injunctive or any other relief provided in law or equity; or

7.4.5 is independently developed by the recipient party without reliance on the Confidential Information of the disclosing party as shown by its written records.

7.5 SGI acknowledges that:

7.5.1 ICOS Know-How is vested in ICOS; and

7.5.2 Except as provided herein, SGI shall not at any time have any right, title, license or interest in or to ICOS Know-How or any other intellectual property rights relating to the Process which are vested in ICOS or to which ICOS is otherwise entitled.

7.6 ICOS acknowledges that:

7.6.1 SGI Information, SGI Materials, SGI Technology, SGI Know-How and SGI-Patent Rights are vested in SGI; and

7.6.2 except as provided herein ICOS shall not at any time have any right, title, license or interest in or to SGI Technology or any other intellectual property rights vested in SGI or to which SGI is entitled.

7.7 The obligations of ICOS and SGI under this Section 7 shall survive the termination of this Agreement for whatever reason.

8. Termination

8.1 If, on or before [*], it becomes apparent to ICOS that after using its commercially reasonable efforts (or such higher standard as may be required under this Agreement), it will be unable to meet the Product Specifications, ICOS may immediately terminate this Agreement upon written notice to SGI (which written notice will be delivered to SGI promptly upon ICOS determining that it will be unable to meet the Product Specification, but in no event later than [*]). Upon such termination, SGI shall pay to ICOS a termination sum calculated by reference to all the Services performed by ICOS (as demonstrated by signed timesheets in so far as they are applicable) and all expenses reasonably incurred by ICOS in giving effect to such termination, including the costs of terminating any commitments entered into under this Agreement such termination sum not to exceed [*], and SGI shall have the right to third party manufacture as set forth in Section 3.4 and 8.5.3. Provided, however, that if the termination sum is less than the amount of any advance payments made by SGI against the performance of the Services a payment in sum equal to the residue of such advance payments shall be made to SGI

[*] Confidential Treatment Requested

8.2 Except as provided for in Section 8.1, if it becomes apparent to either ICOS or SGI at any stage in the provision of the Services that it will not be possible to complete the Services for scientific or technical reasons, a sixty (60) day period shall be allowed for discussion to resolve such problems.

If such problems are not resolved at the end of such sixty (60) day period, ICOS and SGI shall each have the right to terminate this Agreement. In the event of such termination, SGI shall pay to ICOS a termination sum calculated by reference to all the Services performed by ICOS prior to such termination (including a pro rata proportion (as demonstrated by signed timesheets in so far as they are applicable) of the Price for any stage of the Services which is in process at the date of termination) and all expenses reasonably incurred by ICOS in giving effect to such termination, including the costs of terminating any commitments entered into under this Agreement, such termination sum not to exceed the Price. Provided however, that if the termination sum is less than the amount of any advance payments made by SGI against the performance of the Services a payment in sum equal to the residue of such advance payments shall be made to SGI.

8.3 SGI shall be entitled to terminate this Agreement at any time for any reason by [*] days' notice to ICOS in writing providing that the termination sum set forth in Clause 8.3.1 or 8.3.2, as applicable, has been paid.
[*] Confidential Treatment Requested

In the event SGI serves written notice to terminate this Agreement, which notice is expressly to be given pursuant to this Clause 8.3, SGI shall:

8.3.1 pay to ICOS a termination sum calculated by reference to all the Services performed by ICOS prior to such termination (including a pro rata proportion (as demonstrated by signed timesheets in so far as they are applicable) of the Price for any stage of the Services which is in process at the date of termination) and all expenses reasonably incurred by ICOS in giving effect to such termination, including the costs of terminating any commitments entered into under this Agreement such termination sum not to exceed the Price plus any changes. Provided however, that if the termination sum is less than the amount of any advance payments made by SGI against the performance of the Services a payment in sum equal to the residue of such advance payments shall be made to SGI; and

8.3.2 pay to ICOS a sum equal to the full Price less all amounts already paid to ICOS for the Services.

8.4 ICOS and SGI may each terminate this Agreement by notice in writing to the other upon the occurrence of any of the following events:

8.4.1 if the other commits a breach of this Agreement which (in the case of a breach capable of remedy) is not remedied within sixty (60) days of the receipt by the other of written notice identifying the breach with specificity and requiring its remedy; provided, however, if the breach is as a result of nonpayment of any amounts owing, the breaching party must remedy the breach within [*] days after receiving such written notice; or
[*] Confidential Treatment Requested

8.4.2 if the other ceases for any reason to carry on business or convenes a meeting of its creditors or has a receiver or manager appointed in respect of all or any part of its assets or is the subject of an application for an administration order or of any proposal for a voluntary arrangement or enters into liquidation (whether compulsorily or voluntarily) or undergoes any analogous act or proceedings under foreign law; provided, however, either party may merge with or into another equity pursuant to which the obligations of this Agreement will be assumed or effect the sale of all its assets or substantially all of its assets pursuant to which the acquiring party will assume such party's obligations under this Agreement without notice to or waiver by the other party.

8.5 Upon the termination of this Agreement for whatever reason:

8.5.1 ICOS shall promptly return all SGI Information to SGI and shall dispose of or return to SGI, SGI Materials and any materials therefrom, as directed by SGI;

8.5.2 SGI shall promptly return to ICOS all ICOS Know-How it has received from ICOS;

8.5.3 SGI shall not thereafter use or exploit the ICOS Know-How in any way whatsoever for production by SGI, or production by a third-party. If SGI determines to manufacture or have manufactured by a third party such Products, ICOS will give SGI and/or any such Third Party all reasonably necessary information and cooperation, and a non-exclusive, royalty free license to all ICOS Know-How, if any, required to manufacture the Product in accordance with the Manufacturing Specifications, for the sole purpose of enabling SGI or such third party to manufacture the Products in connection with the Manufacturing Specifications.

8.5.4 ICOS may thereafter use or exploit the ICOS Know-How in any way whatsoever without restriction; and

8.5.5 ICOS and SGI shall do all such acts and things and shall sign and execute all such deeds and documents as the other may reasonably require to evidence compliance with this Clause 8.5.

8.6 Termination of this Agreement for whatever reason shall not affect the accrued rights of either ICOS or SGI arising under or out of this Agreement and Sections 2, 6, 7, and 8 and any definitions in Section 1 required to interpret such surviving provisions, and all provisions which are expressly to survive this Agreement or have a continuing obligation shall remain in full force and effect.

9. Force Majeure

Neither ICOS nor SGI shall be deemed to be in default nor be liable for loss, damage, or delay in performance, when and to the extent due to causes beyond its reasonable control or from fire, strike, labor difficulties, insurrection or riot, embargo, or inability to obtain materials from usual sources, or any other unforeseeable cause or causes beyond the reasonable control and without the fault or negligence of the party so affected, or from defects or delays in the performance of its suppliers or subcontractors due to any of the foregoing enumerated causes. If ICOS is prevented or delayed in the performance of any of its obligations under this Agreement by Force Majeure and shall give written notice thereof to SGI specifying the matters constituting Force Majeure together with such evidence as ICOS reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, ICOS shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue, provided that within [*] from the date of such notice, ICOS shall provide SGI with written notice of the anticipated date of resumption of performance. In the event that the anticipated date of such resumption is greater than [*] months from the date of the original notice, SGI may invoke the remedy of third party manufacture provided in Clause 3.3 herein or terminate this Agreement.
[*] Confidential Treatment Requested

10. Governing Law, Jurisdiction and Enforceability

10.1 This Agreement shall be governed and interpreted, and all rights and obligations of the parties shall be determined, in accordance with the laws of the State of Washington and the United States of Americawithout regards to principles of conflicts of law.

10.2 No failure or delay on the part of either ICOS or SGI to exercise or enforce any rights conferred on it by this Agreement shall be construed or operate as a waiver thereof nor shall any single or partial exercise of any right, power or privilege or further exercise thereof operate so as to bar the exercise or enforcement thereof at any time or times thereafter of any other right.

10.3 The illegality or invalidity of any provision (or any part thereof) of this Agreement shall not affect the legality, validity or enforceability of the remainder of its provisions or the other parts of such provision as the case may be and this Agreement shall continue in full force and effect without such provision.

11. Miscellaneous

11.1 Neither party shall be entitled to assign, or in any way transfer the benefit and/or the duties of this Agreement without the prior written consent of the other which consent shall not be unreasonably withheld or delayed, except that either party shall be entitled without the prior written consent of the other to assign transfer, charge, subcontract, deal with or in any other manner make over the benefit and/or burden of this Agreement to an Affiliate, or to any limited liability partner or to any [*] company of which the party in question is the beneficial owner of [*] of the issued share capital thereof or to any company with which the party in question may merge or to any company to which that party may transfer its assets and undertakings.
[*] Confidential Treatment Requested

11.2 The text of any press release or other communication to be published by or in the media concerning the subject matter of this Agreement shall require the prior written approval of ICOS and SGI.

11.3 Notices. All notices, requests, demands, waivers, consents, approval or other communications to any party hereunder shall be in writing and shall be deemed to have been duly given if delivered personally to such party or sent to such party by recorded electronic transmission (facsimile) or by registered or certified mail, postage prepaid, to its address as shown below:

SGI: Seattle Genetics, Inc.
22215 26th Avenue S.E., Suite 3000
Bothell, WA 98021
Attention: H. Perry Fell

ICOS: ICOS Corporation
22021 20th Avenue S.E.
Bothell, WA 98021
Attention: Legal Department

or to such other address as the addressee may have specified in a notice duly given to the sender as provided herein. Such notice, request, demand, waiver, consent, approval or other communications will be deemed to have been given as of the date so delivered, telegraphed, telexed, or five (5) days after so mailed.

11.4 Independent Contractor. Each party shall be and shall act as the independent contractor of the other party. Neither party shall be the legal agent of the other for any purpose whatsoever and therefore has no right or authority to make or underwrite any promise, warranty or representation, to execute any contract or otherwise to assume any obligation or responsibility in the name of or on behalf of the other party, except to the extent specifically authorized in writing by the other party. Neither of the parties hereto shall be bound by or liable to any third persons for any act or for any obligation or debt incurred by the other toward such third party, except to the extent specifically agreed to in writing by the party so to be bound.

11.5 Headings. All section headings and numbering contained in this Agreement are for convenience of reference only, do not form a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement.

11.6 Entire Agreement. The Agreement, and the attached appendixes, embodies the entire understanding of ICOS and SGI and there are no promises, terms, conditions or obligations, oral or written, expressed on implied, other than those contained in this Agreement, and the attached appendixes. The terms of this Agreement shall supersede all previous agreements (if any) which may exist or have existed between ICOS and SGI relating to the Services.

11.7 Modifications. Any and all modifications or amendments to this Agreement, or any Appendix hereto, shall be binding only if made in writing and signed by both parties.

11.8 Counterparts. This Agreement may be executed simultaneously in any number of counterparts, each of which shall be deemed an original and all of which together shall constitute one in the same agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

ICOS CORPORATION	**SEATTLE GENETICS, INC.**
By: /s/Gary Wilcox	By: /s/H. Perry Fell
Name: Gary Wilcox	Name: H. Perry Fell
Title: EVP, Operations	Title: C.E.O.

APPENDIX A
Scope of Services

Assumptions

1. ICOS will make a go-no go decision on [*] with regard to the ability to meet agreed upon Product Specifications.
   [*] Confidential Treatment Requested
2. Seattle Genetics will provide the raw materials, protocols, and data as described in Appendix B.
3. ICOS will transfer the Seattle Genetics cell culture process as-is and only make modifications as necessary to facilitate process transfer to the ICOS Manufacturing facility.
4. ICOS will use historical process data provided by Seattle Genetics to guide development of the BR96 purification process.
5. At least [*] at-scale development lot and [*] cGMP clinical lots will be manufactured that are suitable for regulatory filings and human clinical trials.
   [*] Confidential Treatment Requested
6. ICOS will provide documentation summarizing development and manufacturing activities that are sufficient to support the generation of CMC sections necessary for IND filings for Phase II/III material.
7. The costs listed for process development, the development runs, and cGMP lots do not include the purchase of chromatography resins, special or non-standard cell culture media components, or storage. ICOS reserves the right to invoice Seattle Genetics for these costs, including (but not limited to):
   - Basal media (e.g. HSFM, CD Hybridoma, eRDF)
   - Yeastolate
   - Defined lipids
   - Storage of liquid media
   - Chromatography resins

1. Development

Objectives

- *Transfer the cell culture process, purification process, and product specific analytical methods from Seattle Genetics to ICOS*
- *Evaluate the cell culture and purification process at bench-scale.*
- *Adapt the process in order to make the process suitable for transfer and scale-up in the ICOS Manufacturing Plant*

1.1. Cell Culture Process Development

1.1.1. Transfer raw materials and protocols from Seattle Genetics to ICOS

- Transfer of process documentation from Seattle Genetics to ICOS Corporation
  - Data on mycoplasma and sterility tests for the cell bank
  - Process protocols and in-process specifications (media preparation, thaw, expansion, production, and harvest)
  - Raw material specifications (including vendors and catalog numbers)
  - Historical process data (e.g. bioreactor data, cell-line stability)
- Transfer a sufficient quantity of material to support experiments until such time that materials can be ordered and received by ICOS
- Transfer [*] vials each of [*] BR96 cell lines

[*] Confidential Treatment Requested

1.1.2. Preparation of prebanks

- Prepare prebanks of the primary and back-up cell line; store in two places
- Test the primary cell line pre-bank: mycoplasma, sterility, in vitro viral, MVM
- Transfer the primary cell line pre-bank to cGMP liquid nitrogen storage

1.1.3. Order raw materials

1.1.4. Evaluation of expansion media

- Evaluate growth of cells in HSFM (Bovine Transferrin) and CD Hybridoma.
- On basis of growth, productivity, regulatory impact of components in medium, and cost, Seattle Genetics and ICOS will make a joint decision on an expansion medium.

1.1.5. Establish expansion process

- Define cell growth rates and viability in chosen medium
- Establish upper and lower cell density limits
- Establish expansion process through a [*] spinner
- Demonstrate that the expansion process through a [*] spinner is reproducible.

[*] Confidential Treatment Requested

1.1.6. Establish a baseline production process in bioreactors

- Generate a preliminary process development protocol incorporating changes to the Seattle Genetics process such that the process is suitable for the ICOS process development lab.
- Evaluate production process in [*] bioreactor with automated DO, pH and temperature control.
- Assess suitability of the process for scale-up in the ICOS Manufacturing Plant.
- Evaluate feed media (preliminary work in shake flasks.)
- Verification of reproducibility of the process: at least [*] consecutive bioreactor runs that both ICOS and Seattle Genetics agree are reasonably consistent with respect to the cell growth profile, process chemistries and product titers.

[*] Confidential Treatment Requested

1.1.7. Harvest material provided for purification process development

1.1.8. Modifications made to the cell culture process as needed in order to optimize the process and make it suitable for transfer to the ICOS Manufacturing Plant. Possible modifications may include, but are not limited to:

- process parameter setpoints (e.g. DO, pH, agitation)
- methods of DO and pH control
- change of the feed schedules
- substitution of vendors and/or raw materials

1.1.9. Generate process description suitable for use in preparation of Manufacturing Batch Records

1.1.10. Genetic characterization of EOP and MCB cells following cGMP production runs to confirm genetic stability (assuming that methods are relatively simple to implement at ICOS as determined by ICOS).

- Southern blots
- Sequencing of antibody-encoding bulk RT-PCR

1.1.11. Prepare report describing key experimental results generated during the establishment of the cell culture production process at ICOS

1.2. Purification process development

1.2.1. Harvest hold time stability

- Assess harvest fluid stability. Testing to include, titer (by Protein A), SDS-PAGE and HPLC-SEC.
- Target maximum harvest hold time in production to be five days.

1.2.2. Protein A chromatography (ProSep A).

- Evaluate standard load and wash procedures.
- Determine resins capacity

- Evaluate low pH. Evaluate salt concentration as needed to minimize aggregation and precipitation.

1.2.3. Protein A eluate stability.

- Determine stability against aggregation with respect to pH (3.0-4.0) and time (0-3 h) and concentration.
- Define pH inactivation protocol with the above data. Target pH range of ≤ 3.7 to get robust viral clearance.

1.2.4. Ion exchange chromatography.

- Determine antibody pI.
- Evaluate relative retention Ion-Exchange resins (S-Sepharose, and DEAE-Sepharose for example) as a function of pH and NaCl concentration. For example, S-Sepharose from pH 5-7 and DEAE Sepharose from pH 7-8.5.
- Optimize binding and elution conditions.
- Determine resin capacity

1.2.5. Hydrophobic interaction chromatography (Phenyl Sepharose)

- Evaluate capacity and retention as a function of ammonium sulfate concentration.
- Optimize elution conditions for aggregate removal.

1.2.6. Evaluate stability for all in-process eluate hold times with respect to time, temperature and concentration. Testing to include HPLC-SEC, SDS-PAGE and concentration (A280)

1.2.7. Develop UF concentration/buffer exchange.

1.2.8. Evaluate viral removal filter for product passage.

1.2.9. Purification process qualification (verify reproducibility).

- Demonstrate process reproducibility by purifying cell culture process development batches
- Monitor process performance with respect to yield, product purity, and quality. SEC and SDS PAGE will be used to monitor process eluates. Yield will be determined by absorbance measurements on process eluates.

1.2.10. Analytical characterization of the antibody as described in Section 4.

1.2.11. Generate process description and report on Purification Development.

1.2.12. Evaluate process for viral inactivation using one virus.

1.3. Formulation Process Development

1.3.1. Evaluate the current buffer provided by Seattle Genetics in a -70°C freeze-thaw cycle study

1.3.2. Evaluate the current buffer provided by Seattle Genetics in an accelerated stability study at one temperature for two weeks

1.3.3. If necessary, evaluate two additional buffers in a freeze-thaw study to identify a back-up

1.3.4. Evaluate antibody using HPLC-SEC, SDS-PAGE and concentration (A280).

1.3.5. Generate report on the results of the study

1.4 Analytical and Quality Control

1.4.1. Transfer raw materials, protocols, and data from Seattle Genetics to ICOS

- Binding assay
- Transferrin assay (if necessary)
- Murine Heavy Chain ELISA
- Seattle Genetics and S2.14.19 reference standard

1.4.2. Qualify standard test methods for process and product characterization with the BR96 Antibody and modify if necessary.

2. Process Transfer and Scale-Up

Objectives

- *Manufacture Master Cell Bank*
- *Transfer the cell culture process and antibody purification process into Manufacturing Plant.*
- *Evaluate process parameters at intermediate and production scale to confirm they are comparable to results generated in the bench-scale process.*
- *Perform analytical tests on in-process samples and drug substance to confirm that the production process has been successfully scaled up.*

2.1. Intermediate Scale Development Run

2.1.1. Evaluate the cell culture process:

- Perform at least one bioreactor run at an intermediate scale.
- Assess process performance in terms of specific growth rate, maximum cell density, process chemistries, and

antibody expression.

- Compare results obtained in the intermediate scale bioreactor to those generated at the 15L scale to determine whether scale-up of the process was successful.

2.1.2. Evaluate the harvest process:

- Harvest of cell culture fluid generated in the previous step.
- Characterize the harvest fluid for antibody titer and other tests as specified in Section 4.
- Determine filter capacity required for production scale bioreactor.

2.1.3. Evaluate the purification process:

- Purify product from the harvest fluid
- Analyze in-process samples and the end product
- Compare data obtained at the intermediate scale to those obtained in process development

2.2. Production Scale Development Run

2.2.1. Evaluate cell culture process at production scale:

- Perform at least [*] bioreactor run

[*] Confidential Treatment Requested

- Assess process performance in terms of specific growth rate, maximum cell density, process chemistries and antibody expression.
- Compare results obtained in the at-scale bioreactor to those generated at the intermediate scale to determine whether scale-up of the process was successful.

2.2.2. Evaluate the harvest process at-scale:

- Harvest of cell culture fluid generated in the previous step.
- Characterize the harvest fluid for antibody titer.

2.2.3. Evaluate the purification process at-scale:

- Purify product from the harvest fluid
- Analyze in-process samples
- Comparison of data obtained at the at-scale to those obtained in the intermediate scale to determine whether scale-up of the process was successful.

2.2.4. Evaluations will be performed using draft MBRs, SOPS, and TMs

2.2.5. The process intermediates and drug substance will be tested by the methods listed in Section 4 to demonstrate the process has been successfully transferred and to characterize the product for regulatory submissions.

2.2.6. Raw materials will be released following ICOS Raw Material Quality Assurance procedures.

2.2.7. Data obtained in the production scale run will be reviewed to asses the suitability of the process for clinical manufacturing, and to make modifications to the process, if necessary, for preparation of the final drafts of the master documents

2.2.8. An interim reference standard will be made from production scale development run. This standard will be qualified and used as the reference standard for release testing of the clinical GMP lots

3. Clinical Manufacturing

Objectives

- *Perform clinical production runs.*
- *Perform in-process and drug substance testing to confirm that the process is in control and that the product from each lot meets pre-defined standards*

3.1. All clinical (cGMP) operations will be performed according to the Quality Understanding.

3.2. A [*] (approximate) Master Cell Bank (MCB) will be created from a pre-bank vial that is released for manufacturing use. The MCB will be tested according to ICH guidelines. Vials from the bank will be stored in two locations.
[*] Confidential Treatment Requested

3.3. Following the MBR which was finalized in Section 2.2, manufacture and purify [*] lots of bulk drug substance.
[*] Confidential Treatment Requested

3.4. Manufacturing processes and testing will be performed according to approved, written procedures. Master documents will be reviewed and

approved by ICOS and Seattle Genetics according to the Quality understanding.

3.5. Every effort should be made to store the harvest fluid for as minimal a time as possible. Ideally, the storage period will be at [*] for a target period of [*] days.
[*] Confidential Treatment Requested

3.6. Solutions, process intermediates, and formulated bulk product (Drug Substance) will be stored in controlled access locations under appropriate conditions as specified in the Material Specifications.

3.7. Each lot of Drug Substance will be tested by the methods described in Section 4 and as specified in the Material Specification.

3.8. Batch Disposition will be performed according to the Quality Understanding.

3.8.1. ICOS QA will review all MBRs and QC Data Sheets for completeness and accuracy.

3.8.2. ICOS QA will verify that materials used in the production process were released within expiration.

3.8.3. Deviations from ICOS procedures, MBRs, or Materials Specifications will be recorded and justified. Product impact will be assessed for all deviations and non-conforming materials.

3.8.4. ICOS will issue a Certificate of Analysis that includes all ICOS release testing results and a notice of disposition from ICOS Quality Assurance.

4. Test Methods

The test methods in the table below will be performed at the indicated process stages. The development or performance of any other assays is out-of-scope work.

	Process Development/Transfer		Production Scale (Development and Clinical)		
Method	**Process Characterization**	**Product Characterization**	**Cell Culture In-Process**	**Purification In-Process**	**Drug Substance**
Mycoplasma[1]			✓(EOP)[3]		
Sterility[1]			✓(EOP)[3]		
MMV[1]			✓(EOP)[3]		
In-vitro Viral[1]			✓(EOP)[3]		
BR96 Titer (Protein A)	✓		✓(Harvest)		
Bioburden	✓		✓(Harvest)		✓
Endotoxin	✓		✓(Harvest)	✓	✓
BR96 concentration (A_{280})	✓			✓	✓
Size Exclusion HPLC	✓	✓		✓	✓
SDS-PAGE, unreduced	✓	✓		✓	✓
SDS-PAGE, reduced	✓	✓		✓	✓
Isoelectric Focusing		✓			✓
MALDI-MS		✓			
Silver stain, unreduced		✓			✓
Silver stain, reduced		✓			✓
Appearance					✓
Osmolality					✓
PH					✓
Insulin		✓			✓
Residual Protein A EIA		✓			✓
Residual Host Cell DNA Content		✓			✓
Binding assay[2]		✓			✓
Bovine transferrin [2,4]		✓			✓
Murine IgG heavy chain[2]		✓			✓

[1] Contracted to an outside vendor

[2] Protocol and necessary reagents to be transferred from Seattle Genetics to ICOS

[3] Clinical lots only

[4] This test may be omitted if bovine transferrin is not in the process

5. Deliverables

The following items will be delivered from ICOS Corporation to Seattle Genetics

5.1. Samples from various development stages for sample retention and comparability studies. Sample requests must be made in writing at least [*] in advance of the execution of the process step.
[*] Confidential Treatment Requested
5.2. [*] lots of bulk drug substance manufactured from [*] clinical productions runs in the ICOS [*] bioreactor.
[*] Confidential Treatment Requested
5.3. ICOS will issue a Certificate of Analysis that includes all ICOS release testing results and a notice of disposition from ICOS Quality Assurance
5.4. Documentation as described in the Quality Agreement
5.5. The pre-bank and Master Cell Bank [1]
5.6. Summary reports and data describing the work completed in Sections 1, 2, and 3.
5.7. Qualified Interim Reference Standard

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[1] If desired, ICOS will retain a umber of vials in the event that at some future date Seattle Genetics would like to request additional clinical production runs

APPENDIX B
Materials to be Transferred

1. Cell Culture

1.1. [*] vials of the primary and back-up cell line which produce the BR96 antibody
[*] Confidential Treatment Requested
1.2. List of raw materials and specifications (e.g. vendor, catalog number)
1.3. Process protocols (e.g. media formulations, thaw and expansion protocol, final production tank protocol)
1.4. Historical process data (e.g. thaw and expansion data, in-process data from final production tank)
1.5. Cell-line stability data (as it becomes available)

2. Purification

2.1. List of raw materials and specifications (e.g. resin identification, column loads)
2.2. Process Protocols for the current purification process (e.g. buffer recipes, cleaning protocols)
2.3. Historical process data (e.g. yields, reproducibility, clearance of contaminants, product aggregate)
2.4. Data on product stability, especially at intermediate hold points
2.5. Reference Antibody [1] for assay development and comparability studies

3. Quality Control

3.1. Reagents and protocols for the antigen/antibody binding assay
3.2. Reagents and protocols for Murine IgG Heavy Chain Assay
3.3. Reagents and protocols for a bovine transferrin assay- if transferrin is used in the cell culture media.
3.4. Reference Antibody [1] for assay development and comparability studies

4. Formulation

4.1 List of raw materials and specifications for the final antibody formulation
4.2 Historical stability data (e.g. freeze/thaw data, stability data)
4.3 Reference Antibody [1] for comparability studies

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[1] Reference Antibody should be derived from the same cell line and process being transferred to ICOS.

APPENDIX C
Acceptance Criteria / Internal Release Specs – Drug Substance
"Product Specifications"

Unless otherwise stated, ICOS test methods will be used.

	Test	Acceptance Criteria ("Product Specifications")
Quality	Appearance (color and clarity)	Colorless, clear to slightly opalescent
	Appearance (particulates)	Report
Identity	IEF	pI range consistent with reference
	SEC HPLC	Main peak retention time consistent with reference

	SDS-PAGE (unreduced, Coomassie)	IgG band molecular weights consistent with reference
	SDS-PAGE (reduced, Coomassie)	IgG band molecular weights consistent with reference
Purity	SEC HPLC	≥ 97.0 % main peak, No single impurity > 2.0%
	SDS-PAGE (unreduced, Coomassie)	Impurity profile consistent with reference
	SDS-PAGE (reduced, Coomassie)	Impurity profile consistent with reference
	DNA Content	Report (pg DNA/mg protein)
	Murine IgG Heavy Chain[1]	Report (%)
	Protein A EIA	< 100 ppm (w/w)
	Bovine Transferrin[1, 2]	Report (ppm)
	Insulin	Report (ppm)
Potency	Protein Concentration (A280)[3]	10 ± 1 mg/mL
	Binding Assay[3]	100 ± 30% of reference
Safety	Endotoxin (LAL)[4]	< 0.33 EU/mg
	Microbial Limit (Bioburden)	< 1 (CFU/mL)
Excipient/Chemical Composition	PH	5.5 ± 0.3
	Osmolality[5]	Value[5] + 50 mOsm
Other Tests (For information only)	SDS-PAGE (unreduced, Silver)	Report
	SDS-PAGE (reduced, Silver)	Report

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[1] SGI Test to be transferred to ICOS

[2] This test may be omitted if bovine transferrin is not in the process.

[3] Extinction coefficient = 1.44.

[4] Based on a maximum human dose of [*] by parenteral administration.
[*] Confidential Treatment Requested

[5] Osmolality acceptance criteria needs to be established.

APPENDIX D
Estimate of Manufacturing Schedules

[*]

[*] Confidential Treatment Requested

APPENDIX E
Price and Payment Terms

Stage	Terms[1]	Estimated Date of Payment[2]	Total Price for Stage
Technology Transfer, and Process Development.	$[*] upon signing of the agreement[3]; $[*] at initiation of purification process development; . $[*] upon ICOS decision to proceed based on "research specifications"[4]	[*] [*] [*]	$[*]
Manufacturing Campaign (Including Mfg. Transfer and Scale-up;	$[*] at initiation of Process Transfer to Manufacturing and Scale-up stage as described in Appendix A, Section 2;	[*]	$[*]
Development run and two cGMP clinical			

production runs)[5]			
	$[*] at initiation of Development Run; $[*] at initiation of first GMP run;	[*]	
	$[*] at initiation of second GMP run;	[*]	
	$[*] at stage completion.	[*]	
Total			[*]
Option for [*] years from [*] for up to [*] additional cGMP clinical production runs[6,7].	[*] reservation fee[8]; [*] of the cost of the campaign at the start of the campaign; [*] of the cost of the campaign at the completion of the campaign.		[*] per cGMP run[9,10].

[*] Confidential Treatment Requested

1. Seattle Genetics and ICOS will mutually commit to the manufacturing campaign upon signing the agreement. As stated in Section 8.1 of the Agreement, the Agreement will terminate on [*] with no further obligation to either party if ICOS determines it is unable to meet the Product Specifications.
   [*] Confidential Treatment Requested
2. The dates listed are estimates only. The actual payment date is the date on which the applicable event occurs as stated in the "Terms" column.
3. Includes [*] non-refundable payment made in connection with the Letter of Agreement of [*].
   [*] Confidential Treatment Requested
4. Decision to proceed to cGMP production will be based on ICOS meeting certain "research specifications".
5. Seattle Genetics will bear the cost of the resins and "special or non-standard" media components (including, without limitation, storage and stocking fees) needed for the process. The cost for the "special or non-standard" basal media components (listed in Assumption 7 of Appendix A) will be less any standard ICOS basal media components removed from the process.
6. Additional production runs will be at Seattle Genetics' option. ICOS will have [*] months to start the additional cGMP campaign after payment of a reservation fee from Seattle Genetics. For ICOS planning purposes Seattle Genetics will provide a non-binding forecast on the first working day of each quarter.
   [*] Confidential Treatment Requested
7. All terms and conditions as stated in the Agreement and Appendices will apply to the additional cGMP clinical production runs.
8. The reservation fee applies to the total cost of the reserved campaign.
9. Fee for additional cGMP clinical production runs increases to $[*] per run if not reserved by the end of the Development run or the end of [*], whichever is later. The "end of the Development run" is defined as the completion of the purification process at scale as described in Appendix A, Section 2.2.4.
   [*] Confidential Treatment Requested
10. If at the end of the second cGMP clinical production run the combined yield from the [*] cGMP clinical production runs is less than [*] grams, then Seattle Genetics may have [*] working days following the completion of the following tests to reserve [*] of the [*] optional cGMP clinical production runs at a fee of $[*]: SEC HPLC, IEF, Protein concentration, the Binding Assay, and Endotoxin. The fee will be paid in two installments: [*] reservation fee; and [*] at the start of the optional cGMP clinical production run. The "end of the second cGMP clinical production run" is defined as the completion of the purification process at scale as described in Appendix A, Section 3.3.
    [*] Confidential Treatment Requested

APPENDIX F
Quality Understanding

[*]

[*] Confidential Treatment Requested

SEATTLE GENETICS, INC.

2001 Executive Performance Plan

Objective

The objective of this program is to reward and recognize members of the Company's management team for the successful attainment of corporate goals and objectives and individual performance toward meeting those goals and objectives for 2001.

Eligibility

Employees at the Associate Director level and above are eligible to participate in this program. Eligibility of other positions is subject to approval in the sole discretion of the Company's Compensation Committee of the Board of Directors. (See "Conditions" set forth below.)

Employees must be employed in an eligible position through December 1, 2001 in order to participate in the program for 2001. Employees hired or promoted into an eligible position after January 1, 2001, but prior to December 1, 2001 will be eligible to earn a pro-rated bonus payment based on their period of participation from their date of hire or eligibility through December 1, 2001. Eligible employees who change management positions during the year will be eligible to earn a pro-rated bonus payment based on time served in each eligible position. Participants must be considered an active employee on the date of bonus payout in order to be eligible for payout under the plan guidelines.

Eligible employees at the level below Vice President may also receive the Company's periodic milestone awards, which may be paid to specific departments or the Company at large in recognition for the successful accomplishment of a milestone event. All employees at the level of Vice President and above are not eligible to receive periodic milestone awards.

Program Criteria

The Board of Directors or its Compensation Committee will establish the corporate goals and objectives for the year based on recommendations from the Chief Executive Officer and President. Upon approval, these corporate goals and objectives will be communicated to all eligible program participants. Seventy-five percent (75%) of the participant's annual performance bonus will be based on the attainment of these corporate goals and objectives. Twenty-five percent (25%) of the annual performance bonus will be based on individual performance toward meeting these corporate goals and objectives.

Toward the close of the calendar year the Board of Directors will evaluate, measure and determine the success of the Company's management teams efforts toward the attainment of the corporate goals and objectives. Based on this assessment, the Compensation Committee of the Board will set the percentage of bonus that will be awarded for the corporate portion of the program.

The Chief Executive Officer and President will evaluate the contribution of each eligible participant (other than themselves) towards the attainment of the approved corporate goals and objectives for the calendar year. (The Board of Directors or the Compensation Committee will evaluate the contribution of the Chief Executive Officer and President.) Recommendations will be provided to the Compensation Committee of the Board of Directors for consideration in their determination of the individual portion of the total bonus payment to be earned by each participant based on their individual performance toward meeting the corporate goals and objectives.
Participants will need to successfully achieve at least half (50%) of their expected individual contributions toward corporate goals and objectives in order to be eligible to receive any payment under this program.

Bonus Payments

Payments will be processed in the next practical payroll cycle following the date of approval by the Board of Directors or its Compensation Committee.

Bonus payments will be based on the base pay rate of an eligible participant as of December 1, 2001. Payments will be made minus all applicable payroll deductions.

Participants whose employment terminates for any reason prior to the bonus payouts will not be eligible to receive a bonus payment

Leave of Absence

Employees on an approved leave of absence of longer than 30 days will be eligible to receive a pro-rated payout based on the number of months they were an active employee. If an employee is on an approved leave of absence on the date bonus payout is made, the employee will be eligible to receive payout, if any, upon return from the leave of absence.

Target Awards

The target awards for successful achievement of the 2001 corporate goals and objectives shall be determined by the Board, such target awards to range from 3% to 30% of base salary depending on the level of management responsibility.

Conditions

This program may be amended, modified or terminated at any time, for any reason within the sole discretion of the Compensation Committee of the Board of

Directors or by the Board of Directors itself. This may be done with or without notice to the participants. These changes may be retroactive or prospective, as determined in the sole discretion of the Compensation Committee or the Board. Additionally, this program may not be modified by any oral statement; it may only be modified in writing in a form authorized by the Compensation Committee or the Board. Also, the Compensation Committee or the Board of Directors expressly reserves the right to decide that this program should not apply due to individual circumstances. Such decision(s) will be made in the sole discretion of the Compensation Committee or the Board. Accordingly, no one should rely on this statement as a firm commitment and no one should rely on any oral statements made about any change to the program.

As a reminder, your employment with the Company is on an "at will" basis, meaning that either you or the Company may terminate your employment at any time for any reason, with or without cause or advance notice. This program sets forth the terms of the Executive Performance Plan with the Company and supersedes any prior representations or agreements, whether written or oral.