

**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 **March 31, 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**

SEATTLE GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

91-1874389

(I.R.S. Employer Identification No.)

22215 26th Avenue SE, Suite 3000

Bothell, Washington 98021

(Address of principal executive offices, including zip code)

(425) 489-4990

(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 (1)

(1)

The registrant has been subject to the filing requirements of the Securities Exchange Act of 1934 since the effective date of its Registration Statement on Form S-1 (March 6, 2001) and has filed all such reports since the effective date.

As of April 30, 2001, there were 29,278,801 shares of the registrant's Common Stock outstanding.

Seattle Genetics, Inc.

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PART I. FINANCIAL INFORMATION**Item 1. Financial Statements.**

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

	March 31, 2001	December 31, 2000
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	\$ 54,353,910	\$ 2,618,986
Short-term investments	17,248,954	21,711,460
Interest receivable	227,349	279,070
Prepaid expenses and other current assets	509,700	759,339
	<u>72,339,913</u>	<u>25,368,855</u>
Total current assets	72,339,913	25,368,855
Property and equipment, net	943,687	894,304
Other assets	189,419	189,419
Restricted investments	1,474,809	3,421,247
	<u>1,474,809</u>	<u>3,421,247</u>
Total assets	<u>\$ 74,947,828</u>	<u>\$ 29,873,825</u>
Liabilities, Mandatorily Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		

Current liabilities		
Accounts payable	\$ 853,730	\$ 141,992
Accrued liabilities	1,555,462	668,698
	<hr/>	<hr/>
Total current liabilities	2,409,192	810,690
	<hr/>	<hr/>
Commitments and contingencies		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, 0 issued		
Mandatorily redeemable convertible preferred stock, \$0.001 par value, 17,450,000 (2000) shares authorized:		
Series A convertible preferred stock, 7,000,000 designated, 6,950,000 shares issued and outstanding (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)		
Common stock, \$0.001 par value, 100,000,000 shares authorized, 29,276,989 and 4,581,077 issued and outstanding, respectively	29,277	4,581
Additional paid-in capital	98,629,178	14,798,044
Notes receivable from stockholders	(405,288)	(408,384)
Deferred stock compensation	(8,828,247)	(10,193,778)
Accumulated other comprehensive income	122,178	69,196
Deficit accumulated during the development stage	(17,008,462)	(12,762,531)
	<hr/>	<hr/>
Total stockholders' equity (deficit)	72,538,636	(8,492,872)
	<hr/>	<hr/>
Total liabilities, mandatorily redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 74,947,828	\$ 29,873,825
	<hr/>	<hr/>

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 March 31,		Cumulative from inception (January 1, 1998) to March 31, 2001
	2001	2000	
Revenues			
License agreements	\$ —	\$ —	\$ 1,000,000
Government grants	—	20,158	98,632
	<hr/>	<hr/>	<hr/>
Total revenues	—	20,158	1,098,632
Expenses			
Research and development (excludes non-cash stock-based compensation expense of \$512,244, \$94,098 and \$1,951,173, respectively)	2,855,999	796,074	11,603,452
General and administrative (excludes non-cash stock-based compensation expense of \$730,127, \$231,416 and \$3,502,037, respectively)	725,322	272,876	4,127,633
Non-cash stock-based compensation expense	1,242,371	325,514	5,453,210
	<hr/>	<hr/>	<hr/>
Total operating expenses	4,823,692	1,394,464	21,184,295
	<hr/>	<hr/>	<hr/>
Loss from operations	(4,823,692)	(1,374,306)	(20,085,663)
Investment income, net	577,761	468,111	3,077,201

Net loss	(4,245,931)	(906,195)	\$ (17,008,462)
Accretion on mandatorily redeemable preferred stock	(3,295)	(4,694)	
Net loss attributable to common stockholders	\$ (4,249,226)	\$ (910,889)	
Basic and diluted net loss per share	\$ (0.46)	\$ (0.30)	
Weighted-average shares used in computing basic and diluted net loss per share	9,279,630	3,031,853	

The accompanying notes are an integral part of these financial statements

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

	Three months ended March 31,		Cumulative from inception (January 1, 1998) to March 31, 2001
	2001	2000	
Cash flows from operating activities			
Net loss	\$ (4,245,931)	\$ (906,195)	\$ (17,008,462)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization of deferred compensation	1,242,371	325,514	5,406,190
Depreciation	78,606	26,161	424,314
Realized loss on sale of securities	3,652	—	10,399
Amortization/accretion on investments	(13,442)	—	(63,156)
Common stock bonus provided to employees	—	—	47,020
Change in operating assets and liabilities			
Interest receivable	51,721	—	(227,349)
Prepaid expenses and other assets	(307,124)	(62,672)	(699,118)
Accounts payable	711,739	84,256	853,731
Accrued liabilities	886,764	(2,720)	1,555,462
Net cash used in operating activities	(1,591,644)	(535,656)	(9,700,969)
Cash flows from investing activities			
Purchases of investments	(1,048,916)	—	(31,157,875)
Proceeds from sale and maturities of investments	7,520,633	—	12,609,047
Purchase of property and equipment	(127,990)	(156,388)	(1,368,002)
Net cash provided by (used in) investing activities	6,343,727	(156,388)	(19,916,830)
Cash flows from financing activities			
Net proceeds from issuance of common stock	46,979,745	75	46,443,261
Net proceeds from issuance of Series A preferred stock	—	—	6,907,052
Proceeds from subscription receivable	3,096	2,545,001	2,548,097
Net proceeds from issuance of Series B preferred stock	—	240,480	28,073,299
Book overdraft	—	101,086	—
Net cash provided by financing activities	46,982,841	2,886,642	83,971,709
Net increase in cash and cash equivalents	51,734,924	2,194,598	54,353,910

Cash and cash equivalents, at beginning of period	2,618,986	30,362,568	—
Cash and cash equivalents, at end of period	\$ 54,353,910	\$ 32,557,166	\$ 54,353,910

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

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

Seattle Genetics, Inc.
(a development stage company)
Statement of Stockholders' Equity (Deficit)
(Unaudited)

	Common stock		Additional paid-in capital	Notes receivable from stockholders	Deferred stock compensation	Accumulated Other Comprehensive Gain (Loss)	Deficit accumulated during the development stage	Total Stockholders' Equity (Deficit)
	Shares	Amount						
Balances at December 31, 2000	4,581,077	\$ 4,581	\$ 14,798,044	\$ (408,384)	\$ (10,193,778)	\$ 69,196	\$ (12,762,531)	\$ (8,492,872)
Stock option exercises	23,126	23	2,765	—	—	—	—	2,788
Collection of notes receivable from stockholders	—	—	—	3,096	—	—	—	3,096
Conversion of preferred stock to common stock	17,387,072	17,387	37,541,915	—	—	—	—	37,559,302
Initial public offering (net of issuance costs of \$1,289,803)	7,285,714	7,286	46,412,909	—	—	—	—	46,420,195
Deferred stock compensation related to grants of stock options	—	—	(123,160)	—	123,160	—	—	—
Amortization of deferred stock compensation	—	—	—	—	1,242,371	—	—	1,242,371
Accretion on mandatorily redeemable preferred stock	—	—	(3,295)	—	—	—	—	(3,295)
Unrealized gain on short-term investments	—	—	—	—	—	52,982	—	52,982
Net loss	—	—	—	—	—	—	(4,245,931)	(4,245,931)
Comprehensive loss	—	—	—	—	—	—	—	(4,192,949)
Balances at March 31, 2001	29,276,989	\$ 29,277	\$ 98,629,178	\$ (405,288)	\$ (8,828,247)	\$ 122,178	\$ (17,008,462)	\$ 72,538,636

The accompanying notes are an integral part of the 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. (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 adjustment 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 of 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

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. Initial Public Offering of Common Stock

On March 7, 2001, the Company completed an initial public offering of its common stock pursuant to a registration statement on Form S-1 that was declared effective by the Securities and Exchange Commission 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 offering included a \$2 million investment, or 285,714 shares, purchased directly by Genentech, Inc. The gross proceeds of the shares offered and sold were \$49.0 million. Expenses related to the offering, including underwriters' discounts and commissions of \$3.3 million, were \$4.6 million.

Concurrent with the closing of the initial public offering, the Company sold 285,714 shares of common stock to Medarex, Inc. in a private placement at the initial public offering price of \$7.00 per share, which generated cash proceeds of \$2.0 million. In addition, concurrent with the closing of the initial public offering, 17,387,072 shares of convertible preferred stock were converted to an equivalent number of shares of common stock.

3. Net Loss per Share

Basic and diluted 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 March 31,	
	2001	2000
Net loss attributable to common stockholders	\$ (4,249,226)	\$ (910,889)
Basic and diluted		
Weighted-average shares used in computing basic and diluted net loss per share	9,279,630	3,031,853
Basic and diluted net loss per share	\$ (0.46)	\$ (0.30)
Antidilutive securities not included in net loss per share calculation		
Options to purchase common stock	1,462,108	664,000
Restricted shares of common stock subject to repurchase	738,543	599,167
	2,200,651	1,263,167

4. Accrued liabilities

Accrued liabilities consists of the following:

	March 31, 2001	December 31, 2000
	(Unaudited)	
Accrued professional services	\$ 446,843	\$ 258,394
Accrued license agreement	638,889	200,000
Accrued clinical trial costs	271,702	125,746
Accrued compensation and benefits	171,177	53,038
Other	26,851	31,520
	\$ 1,555,462	\$ 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 1993 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, the section entitled Risk Factors set forth in our prospectus dated March 6, 2001 filed with the Securities and Exchange Commission 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 March 31, 2001, we had an accumulated deficit of \$17.0 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, and 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 \$1.0 million from our license agreement with Genentech, Inc. and \$99,000 from a Small Business Innovative Research grant. In the future, we believe our revenues will consist of milestone payments and sponsored research fees under existing and future collaborative arrangements, royalties from collaborations with strategic current and future 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 March 31, 2001 and 2000

Revenues. We had no revenues for the three months ended March 31, 2001 compared to \$20,000 for the three months ended March 31, 2000, which represents revenue from a Small Business Innovative Research grant awarded to us for the study of monoclonal antibody-based therapies.

Research and development expenses. Research and development expenses, excluding non-cash stock-based compensation expenses, increased 259%, from \$796,000 for the three months ended March 31, 2000 to \$2,856,000 for the three months ended March 31, 2001. The increase of \$2.1 million was principally due to an increase in contract manufacturing expenses of approximately \$1.0 million, increases in clinical trial expenses, personnel expenses and the related increased usage of laboratory

materials and supplies. We anticipate that research and development expenses will continue to grow in the foreseeable future as we expand our research, development and clinical trial activities.

General and administrative expenses. General and administrative expenses, excluding non-cash stock-based compensation expenses, increased 166%, from \$273,000 for the three months ended March 31, 2000 to \$725,000 for the three months ended March 31, 2001. This increase was primarily due to additional administrative personnel and increases in professional service fees. We anticipate that general and administrative expenses will increase in the foreseeable future as we support the company's growth and incur the annualized costs related to being a public company.

Non-cash stock-based compensation expense. Non-cash stock-based compensation expenses increased 282%, from \$325,000 for the three months ended March 31, 2000 to \$1.2 million for the three months ended March 31, 2001. The increase is attributable to increasing levels of stock option grants, the difference between the deemed fair value as compared to the related exercise prices and reduced by an adjustment attributable to options subject to variable accounting.

Investment income, net. Investment income increased 23%, from \$468,000 for the three months ended March 31, 2000 to \$578,000 for the three months ended March 31, 2001. The increase was due to higher average balances of cash, cash equivalents and short-term investments and restricted investments primarily from the net proceeds of our initial public offering.

Liquidity And Capital Resources

From inception through March 31, 2001, we have funded our operations with the net proceeds of \$46.4 million from our initial public offering and concurrent private placement, \$37.5 million from private equity financings, \$1.0 million from a license agreement with Genentech, \$3.1 million from investment income, net, and \$99,000 from a Small Business Innovative Research grant. At March 31, 2001, cash, cash equivalents and short-term investments totaled \$71.6 million and restricted investments amounted to \$1.5 million. Our cash, cash equivalents, short 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, municipal bonds, mortgage-backed securities, commercial paper and money market accounts.

In December 2000, we entered into a ten-year lease for a new headquarters and operations facility. In connection with this lease, we initially pledged \$3.4 million of our investments as collateral for certain obligations of the lease. Based on the lease terms, in March 2001, we decreased the pledged amount to \$1.5 million based upon our net worth.

Net cash used in operating activities for the three months ended March 31, 2001 was \$1.6 million and for the three months ended March 31, 2000 was \$536,000. Our net loss of \$4.2 million for the three months ended March 31, 2001 included non-cash charges of \$1.3 million primarily related to amortization of deferred stock compensation. In addition, accounts payable and accrued liabilities increased by a total of \$1.6 million due primarily to a contract manufacturing obligation and capital expenditures related to new office and laboratory space. Our net loss of \$906,000 for the three months ended March 31, 2000 included non-cash charges of \$352,000 related primarily to amortization of deferred stock compensation. We expect cash used in operating activities to increase in the future as we fund our preclinical development, clinical trials and commercialization activities of our product candidates.

Net cash provided by investing activities for the three months ended March 31, 2001 was \$6.3 million, which included \$6.5 million of proceeds from sale and maturities of short-term investments and restricted investments, net of purchases of short-term and restricted investments, as well as \$128,000 for capital expenditures. Net cash used in investing activities for the three months ended March 31, 2000 was \$156,000 for capital expenditures. In December 2000, the Company entered

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into an operating lease for 63,900 square feet of office and laboratory space commencing in June 2001. We expect that our level of capital expenditures will increase in the future as we complete a build-out of this space and relocate our headquarters to this new facility, which is anticipated during the summer 2001.

Net cash provided by financing activities was \$47.0 million for the three months ended March 31, 2001 compared to \$2.9 million for the three months ended March 31, 2000. Financing activities included net proceeds of \$44.4 million from our initial public offering and \$2.0 million from our concurrent private placement. Prepaid public offering costs of \$557,000 were applied to the net proceeds of our initial public offering in the three months ended March 31, 2001. Financing activities during the three months ended March 31, 2000 consisted primarily of \$2.5 million from the collection of subscriptions receivable and \$240,000 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 balances, together with the net proceeds from the initial public offering of our common stock and the proceeds of the concurrent private placement will be sufficient to enable us to meet our anticipated expenditures for at least the next 24 months, including, among other things:

- preclinical research and development activities;
- contract manufacturing activities;
- clinical trial activities; and
- general corporate purposes, including capital expenditures and working capital to fund anticipated operating losses.

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.

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, or SFAS 133, which provides a comprehensive and consistent standard for the

recognition and measurement for derivatives and hedging activities. SFAS 133 became effective for fiscal years beginning after June 15, 2000. The adoption of SFAS 133 did not have a material impact on 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."

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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. 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 \$4.2 million for the three months ended March 31, 2001. As of March 31, 2001, we had an accumulated deficit of approximately \$17.0 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. 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 or clinical trials. We have no drugs that have received regulatory approval for commercial sale. We expect that none of our product candidates will be commercially available in the near term.

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.

We have consumed limited amounts of cash to date but 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.

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Clinical trials for our product candidates are expensive and 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 will be 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 five 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 and 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, novel BR96 monoclonal antibody-drug conjugate and 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, suspend, repeat or terminate our clinical trials if they 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. Clinical trials may be suspended by the FDA at any time if the FDA finds deficiencies in the conduct of these trials or it is believed that these trials expose patients to unacceptable health risks.

In addition, we or the FDA might delay or halt our clinical trials of a product candidate for various reasons, including: 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; 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 our revenue and delay or terminate the potential commercialization of our product candidates.

We currently rely on third-party manufacturers for production of our drug products and our dependence on these manufacturers 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-15 and SGN-10, we rely on drug products that were produced and vialled by Bristol-Myers Squibb and contract manufacturers retained by Bristol-Myers Squibb. For the foreseeable future, we will continue to rely on contract manufacturers to produce sufficient quantities of our product candidates for use in our clinical trials. If our contract manufacturers fail to deliver the required quantities of 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 our collaborators do not perform as expected, we may not be able to commercialize our product candidates.

We intend to continue to develop 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 five 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 and Arizona State University. In addition, we have licensed or optioned rights to pending U.S. patent

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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 to 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.

Because of the specialized nature of our business, the termination of relationships with our key management and scientific personnel or our inability to recruit and retain additional personnel could prevent us from developing our technologies, conducting clinical trials and obtaining financing.

Since our formation, Dr. H. Perry Fell and Dr. Clay B. Siegall have played a significant role in our research efforts. Dr. Fell is Chief Executive Officer and a director of our company and Dr. Siegall is President, Chief Scientific Officer and a director of our company. We are highly dependent on these two individuals, and they have played a critical role in our research and development programs, raising financing and conducting clinical trials. Currently, we have no employment agreements with Dr. Fell or Dr. Siegall. We have obtained key person insurance for Dr. Fell and Dr. Siegall 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 either of these two key members of our company or these scientific personnel 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

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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 and more experience. 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.

Upon the expiration of a 180 day lock-up, a substantial number of our shares of common stock will become available for sale in the public market that may cause the market price of our stock to decline.

Within 180 days after the date of our initial public offering, approximately 22,000,000 shares held by existing stockholders will become available for sale. If these stockholders sell substantial amounts of our common stock (including shares issued upon the exercise of outstanding options and warrants) in

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the public market at concentrated times, the market price of our common stock could fall. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price acceptable to us.

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 company 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, corporate obligations, 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 our marketable security investments and therefore believe that our potential interest rate exposure is not material.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 2. Changes in Securities.

(c) Recent Sales of Unregistered Securities

On March 7, 2001, concurrent with our initial public offering, we sold to Medarex 285,714 shares of our unregistered common stock at \$7.00 per share, which generated cash proceeds of approximately \$2.0 million. In issuing these securities, we relied on Section 4(2) of the Securities Act, on the basis that the transaction did not involve a public offering. Medarex represented to us that it was an accredited investor within the meaning of Rule 501 of Regulation D and was able to bear the financial risk of its investment. Medarex further represented that its intention to acquire the securities was for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities. We did not make any offer to sell the securities by means of any general solicitation or general advertising within the meaning of Rule 502 of Regulation D of the Securities Act. We intend to use the net proceeds from the private placement primarily for working capital and general corporate purposes.

In the quarter ended March 31, 2001, we issued 23,126 shares of unregistered common stock to employees pursuant to the exercise of stock options under our 1998 Stock Option Plan. These options were exercised at a weighted average exercise price of \$0.12 per share. The issuance of these securities was deemed to be exempt from registration under the Securities Act in reliance on Rule 701 and Section 4(2) of the Securities Act.

(d) Use of Proceeds from Sale of Registered Securities

On March 7, 2001, we completed an initial public offering of our common stock pursuant to a registration statement on Form S-1 (File No. 333-50266) that 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 managing underwriters of our offering were J.P. Morgan Securities Inc., CIBC World Markets Corp. and Banc of America Securities LLC. The aggregate gross proceeds of the shares offered and sold were \$49.0 million. In connection with the offering, we paid an aggregate of \$3.3 million in underwriting discounts and commissions to the underwriters. In addition, the following table sets forth the other material expenses incurred in connection with the offering:

	Amount Paid
Legal fees and expenses	\$ 384,805
Accounting fees and expenses	350,400
Printing and engraving expenses	252,070
Travel fees and miscellaneous expenses	145,071
Nasdaq National Market listing fee	95,000
Securities and Exchange Commission registration	51,524
NASD filing fee	10,933
Total	\$ 1,289,803

After deducting the underwriting discounts and commissions and the offering expenses described above, we received net proceeds from our initial public offering of approximately \$44.4 million.

As of March 31, 2001, we have invested all of the proceeds in short-term marketable securities. We intend to use the proceeds from this offering as follows:

- approximately 20-30% for preclinical research and development activities;
- approximately 20-30% for contract manufacturing activities;
- approximately 10-20% for clinical trial activities; and
- the remainder for general corporate purposes, including capital expenditures and working capital to fund anticipated operating losses.

Although we have identified certain ranges above, we have broad discretion to use the proceeds, and may also, when and if the opportunity arises, use a portion of the proceeds to acquire or invest in complimentary businesses, products or technologies. Pending such uses, we have invested the net proceeds in a variety of interest-bearing instruments, consisting of U.S. government and agency securities, high-grade U.S. corporate bonds, municipal bonds, mortgage-backed securities, commercial paper and money market accounts.

None of the net offering proceeds were paid, directly or indirectly, to: (i) directors or officers of Seattle Genetics, or their associates; (ii) persons owning ten percent or more of any class of equity securities of Seattle Genetics; or (iii) affiliates of Seattle Genetics.

Upon the closing of the initial public offering in March 2001, all outstanding shares of our preferred stock were automatically converted, on a one-for-one basis, into shares of common stock. On March 7, 2001, the Company's Certificate of Incorporation was amended to authorize 5,000,000 shares of undesignated preferred stock.

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

Effective February 2, 2001, the stockholders of Seattle Genetics, Inc. approved the following items in an action by written consent:

In connection with the closing of the Public Offering, an amendment and restatement of the Certificate of Incorporation to delete all references to the prior series of Preferred Stock, authorize undesignated Preferred Stock consisting of 5,000,000 shares and provide for

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Exhibit Number

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|------|--|
| 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. |

*

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

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