SEATTLE GENETICS INC /WA
Form 10-K
March 13, 2009
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

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

21823 30th Drive SE

Bothell, WA 98021

(Address of principal executive offices, including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of class	**Name of each exchange on which registered**
Common Stock, par value $0.001	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES x NO ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ¨ NO x

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 x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large accelerated filer ¨ Accelerated filer x
Non-accelerated filer ¨ (Do not check if smaller reporting company) Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ¨ NO x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $516 million as of the last business day of the registrant s most recently completed second fiscal quarter, based upon the closing sale price on The NASDAQ Global Market reported for such date. Excludes an aggregate of 18,324,699 shares of the registrant s common stock held as of such date by officers, directors and stockholders that the registrant has concluded are or were affiliates of the registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

There were 85,613,588 shares of the registrant s Common Stock issued and outstanding as of March 12, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the registrant s definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the Registrant s 2009 Annual Meeting of Stockholders.

Table of Contents

SEATTLE GENETICS, INC.

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2008

TABLE OF CONTENTS

Table of Contents

PART I

This Annual Report on Form 10-K 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. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including those relating to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, expect, plan, anticipate, project, believe, estimate, predict, potential, intend or continue, the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading Item 1A Risk Factors. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Item 1. Business.

Overview

Seattle Genetics is a clinical stage biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer and autoimmune disease. We initiated a pivotal trial of our lead product candidate, SGN-35, during the first quarter of 2009 for patients with relapsed or refractory Hodgkin lymphoma under a special protocol assessment, or SPA, with the U.S. Food and Drug Administration, or FDA. SGN-35 is empowered by our proprietary antibody-drug conjugate, or ADC, technology comprising highly potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. In addition, we have three other product candidates in ongoing clinical trials: dacetuzumab (SGN-40), lintuzumab (SGN-33) and SGN-70. Dacetuzumab is being developed under a worldwide collaboration with Genentech, Inc.

We have collaborations for our ADC technology with a number of leading biotechnology and pharmaceutical companies, including Genentech, Inc., Bayer Pharmaceuticals Corporation, CuraGen Corporation, Progenics Pharmaceuticals, Inc., Daiichi Sankyo Co., Ltd. and MedImmune, Inc., a subsidiary of AstraZeneca, Inc., as well as an ADC co-development agreement with Agensys, Inc., a subsidiary of Astellas Pharma, Inc.

Monoclonal Antibodies for Cancer Therapy

Antibodies are proteins released by the immune system s B-cells, a type of white blood cell, in response to the presence of a foreign entity in the body, such as a virus or bacteria, or in some abnormal cases, during an autoimmune response. B-cells collectively produce millions of different kinds of antibodies, which have slightly different characteristics that enable them to bind to specific molecular targets. Once bound to the specific target, the antibody may neutralize the target cell directly or recruit other parts of the immune system to neutralize the target cell. Antibodies that have identical molecular structures and bind to a specific target are called monoclonal antibodies. The inherent selectivity of monoclonal antibodies makes them ideally suited for targeting specific cells, such as cancer cells, while bypassing most normal tissue.

There are an increasing number of antibody-based products that have been approved for the treatment of cancer. These include six engineered monoclonal antibodies (Rituxan®, Herceptin®, Campath®, Avastin®, Erbitux® and Vectibix®), two radionuclide-conjugated monoclonal antibodies (Zevalin® and Bexxar®) and an

Table of Contents

antibody-drug conjugate (Mylotarg®). Together, these nine products generated worldwide sales of more than $20 billion in 2008. Additionally, there are many monoclonal antibodies in preclinical and clinical development that are likely to increase the number of monoclonal antibody-based commercial products in the future.

Cancer is the second most common cause of death in the United States, resulting in over 565,000 deaths annually. The American Cancer Society estimated that more than 1.4 million new cases of cancer were diagnosed in the United States during 2008. The World Health Organization estimates that more than 11 million people worldwide are diagnosed with cancer each year, a rate that is expected to increase to an estimated 15 million people annually by the year 2030. Cancer causes nearly eight million deaths worldwide each year and, according to the National Cancer Institute, approximately 35 percent of people with cancer will die within five years from being diagnosed.

Our Monoclonal Antibody Technologies

Our pipeline of monoclonal antibody-based product candidates utilizes two technologies to maximize antitumor activity and reduce toxicity. The first technology is the use of genetic engineering to produce monoclonal antibodies that have intrinsic antitumor activity with lowered risk of adverse events or autoimmune response. The second technology involves attaching a highly potent cytotoxic drug to an antibody, which delivers and releases the drug inside the tumor cell. The resulting hybrid molecule is called an antibody-drug conjugate, or ADC. We also evaluate the use of our monoclonal antibodies and ADCs in combination with conventional chemotherapy, which may result in increased antitumor activity.

Engineered Monoclonal Antibodies

Our antibodies are genetically engineered to reduce non-human protein sequences, thereby lowering the potential for patients to develop a neutralizing immune response to the antibody and extending the duration of their use in therapy. Our monoclonal antibody engineering activities are primarily focused on developing humanized monoclonal antibodies. We have substantial expertise in humanizing antibodies and have non-exclusive licenses to PDL BioPharma s antibody humanization patents. Through our ADC co-development agreement with Agensys, we also have the opportunity to co-develop ADCs incorporating fully-human antibodies.

Some monoclonal antibodies have intrinsic antitumor activity and can kill cancer cells on their own either by directly sending a cell-killing signal, by activating an immune response that leads to cell death and/or by inhibiting the growth of cancer cells. These antibodies can be effective in tumor regression and have the advantage of low systemic toxicity. For example, antibodies targeted to antigens such as CD20 (Rituxan®), HER2 (Herceptin®), CD52 (Campath®), VEGF (Avastin®) and EGFR (Erbitux®) can kill tumor cells in this manner. Dacetuzumab, lintuzumab and SGN-70 also fall into this category of engineered antibodies that have intrinsic antitumor activity without conjugation to a drug.

Antibody-Drug Conjugates (ADCs)

ADCs are monoclonal antibodies that are linked to potent cell-killing drugs. Our ADCs utilize monoclonal antibodies that internalize within target cells upon binding to their cell-surface receptors. The environment inside the cell causes the cell-killing drug to be released from the monoclonal antibody, allowing it to have the desired effect. A key component of our ADC is the linker that attaches the drug to the monoclonal antibody until internalized within the target cell where the drug is released, thereby minimizing toxicity to normal tissues. Our ADCs use auristatins which are highly potent cell-killing drugs. In contrast to natural product drugs that are often more difficult to produce and link to antibodies, our drug-linkers are synthetically produced and readily scaleable. SGN-35, SGN-75, AGS-5 ADC, the ADC we are co-developing

with Agensys and SGN-19A, utilize our proprietary, auristatin-based ADC technology. We own or hold exclusive or partially-exclusive licenses to multiple issued patents and patent applications covering our ADC technology. We continue to evaluate new linkers and potent, cell-killing drugs for use in our ADC programs.

Table of Contents

Our Strategy

Our strategy is to become a leading developer and marketer of monoclonal antibody-based therapies for cancer and autoimmune diseases. Key elements of our strategy are to:

Advance our Four Lead Clinical Programs towards Regulatory Approval and Commercialization. Our primary goal is to advance our four lead clinical product candidates, SGN-35, dacetuzumab, lintuzumab and SGN-70, through clinical trials to regulatory approval and commercialization. During 2008, we continued to expand our clinical group and to broaden our relationships with experts in hematology and oncology at leading cancer centers in the United States and Europe to support aggressive advancement of our ongoing and planned clinical trials. In early 2009, we advanced SGN-35 into a pivotal trial for Hodgkin lymphoma under an SPA with the FDA. We have also gained strong internal expertise in our development and regulatory groups and entered into key relationships with scientific advisors, research organizations and contract manufacturers to supplement our internal efforts.

Enter into Strategic Collaborations to Generate Capital and Supplement our Internal Resources. We enter into collaborations at appropriate stages in our drug development process to broaden and accelerate clinical trials and commercialization of our product candidates. Collaborations can generate significant capital, supplement our own internal expertise in key areas such as manufacturing, regulatory affairs and clinical development and provide us with access to our collaborators marketing, sales and distribution capabilities. When establishing strategic collaborations, we seek strong financial terms and endeavor to retain significant product rights, such as our dacetuzumab collaboration with Genentech.

Maintain a Strong Product Candidate Pipeline by Advancing our Preclinical Programs towards Clinical Trials. We believe that it is important to maintain a diverse pipeline of antibody-based product candidates to sustain our future growth. To accomplish this, we currently have three lead preclinical programs, SGN-75, AGS-5 ADC and SGN-19A. These programs could result in additional Investigational New Drug, or IND, filings during the next several years. We also have an ADC co-development agreement with Agensys that provides us with the opportunity to co-develop an additional ADC targeting solid tumors.

Continue to Leverage our Industry-Leading ADC Technology. We have developed proprietary ADC technology designed to empower monoclonal antibodies. We are currently developing multiple product candidates that employ our ADC technology, including SGN-35, SGN-75 and several other preclinical programs. We also license our ADC technology to leading biotechnology and pharmaceutical companies to generate near-term revenue and funding, as well as potential future milestones and royalties. Presently, we have active ADC collaborations with Genentech, Bayer, CuraGen, Progenics, MedImmune, Daiichi-Sankyo and Agensys. Our technology licensing deals have generated approximately $70 million as of December 31, 2008 through a combination of upfront and research support fees, milestones and equity purchases.

Ensure Future Growth of our Pipeline through Internal Research Efforts and Strategic In-Licensing. We have internal research programs directed towards identifying novel antigen targets and monoclonal antibodies, creating new antibody engineering techniques and developing new classes of stable linkers and potent, cell-killing drugs for our ADC technology. In addition, we supplement these internal efforts through ongoing initiatives to identify product candidates, products and technologies to in-license from biotechnology and pharmaceutical companies and academic institutions. We have entered into such license agreements with Bristol-Myers Squibb, PDL BioPharma, Facet Biotech Corporation, the University of Miami, Arizona State University, Mabtech AB and CLB Research and Development, among others.

Table of Contents

Product Candidate Development Pipeline

The following table summarizes our product candidate development pipeline:

Product Candidate	Description	Commercial Rights	Status
SGN-35	Anti-CD30 ADC	Seattle Genetics	Pivotal single agent trial ongoing in relapsed or refractory Hodgkin lymphoma
			Phase II single agent trial ongoing in relapsed or refractory anaplastic large cell lymphoma, or ALCL
			Phase I single agent, weekly dosing trial ongoing in Hodgkin lymphoma and CD30-positive T-cell lymphomas
Dacetuzumab (SGN-40)	Humanized anti-CD40 antibody	Genentech (We have an option to co-promote in the United States)	Randomized phase IIb Rituxan and ifosfamide, carboplatin and etoposide, or ICE, chemotherapy combination trial ongoing in diffuse large B-cell lymphoma, or DLBCL
			Phase Ib Rituxan/Gemzar combination trial ongoing in DLBCL
			Phase Ib Rituxan combination trial ongoing in follicular and marginal zone non-Hodgkin lymphoma
			Phase Ib Revlimid combination trial ongoing in multiple myeloma
			Phase Ib Velcade combination trial ongoing in multiple myeloma
Lintuzumab (SGN-33)	Humanized anti-CD33 antibody	Seattle Genetics	Phase Ib single-agent trial ongoing in acute myeloid leukemia, or AML and myelodysplastic syndromes, or MDS; enrollment completed and data expected in 2009
			Randomized phase IIb low-dose cytarabine combination trial ongoing in AML; enrollment completed and data expected in the first half of 2010
			Phase Ib Revlimid® combination trial ongoing in MDS
SGN-70	Humanized anti-CD70 antibody	Seattle Genetics	Phase I trial ongoing for autoimmune disease
SGN-75	Anti-CD70 ADC	Seattle Genetics	IND filing planned in 2009 for CD70-positive hematologic malignancies and solid tumors
AGS-5ADC	Anti-AGS-5 ADC	50:50 co-develop-ment with Agensys, a subsidiary of Astellas Pharma	Future IND candidate for solid tumors
SGN-19A	Anti-CD19 ADC	Seattle Genetics	Future IND candidate for CD19-positive hematologic malignancies

Table of Contents

SGN-35

SGN-35 is an ADC composed of an anti-CD30 monoclonal antibody attached by our proprietary, enzyme-cleavable linker to a compound of the highly potent class of cell-killing drugs called auristatins. The CD30 antigen is an attractive target for cancer therapy because it is expressed on hematologic malignancies including Hodgkin lymphoma and several types of T-cell lymphoma but has limited expression on normal tissues. We are currently conducting a single-arm, open label pivotal trial of SGN-35 for patients with relapsed or refractory Hodgkin lymphoma pursuant to an SPA with the FDA. The SPA provides an agreement between the FDA and Seattle Genetics regarding the design, including size and clinical endpoints, of the pivotal trial to support an efficacy claim in a New Drug Application, or NDA. We are also planning to conduct a phase II single-arm, open label trial for patients with ALCL and are conducting a phase I dose escalation study of SGN-35 administered weekly for patients with relapsed or refractory CD30-positive malignancies, primarily Hodgkin lymphoma. We have received orphan drug designation from the FDA and the European Medicines Agency, or EMEA, for SGN-35 in Hodgkin lymphoma and ALCL, and have retained worldwide commercial rights to the program. Our goal is to submit an NDA for SGN-35 in 2011 under the accelerated approval regulations.

Market Opportunities

According to the American Cancer Society, approximately 8,200 cases of Hodgkin lymphoma were expected to be diagnosed in the United States during 2008, and an estimated 1,300 people were expected to die of the disease during 2008. An additional 2,000 to 3,000 patients per year in the United States are diagnosed with ALCL, a T-cell lymphoma that expresses the CD30 antigen. Advances made in the use of combined chemotherapy and radiotherapy for malignant lymphomas have resulted in high remission rates for front-line therapy in early stage lymphomas. However, a significant number of these patients relapse and require additional treatments including other chemotherapy regimens and autologous stem cell transplant, or ASCT. We believe there is a strong need for therapies that can maintain patients in remission prior to and after ASCT and provide a high rate of durable responses in post-ASCT relapses. According to a recognized cancer database and primary market research we conducted with physicians, we believe that there are several thousand newly relapsed or refractory lymphoma patients in the United States each year who would be potentially eligible for treatment with SGN-35, and that the United States prevalence population of these patients is approximately 10,000 individuals.

Clinical Results and Development Plan

We reported data in December 2008 at the American Society of Hematology, or ASH, annual meeting from a phase I clinical trial of SGN-35 in patients with relapsed or refractory CD30-positive hematologic malignancies, primarily Hodgkin lymphoma. This single-agent, dose-escalation study was designed to evaluate the safety, pharmacokinetic profile and antitumor activity of SGN-35 administered every three weeks, and enrolled approximately 50 patients at multiple sites in the United States. Among 28 evaluable patients with relapsed or refractory Hodgkin lymphoma or ALCL treated at doses of 1.2 milligrams per kilogram (mg/kg) and higher 54 percent achieved an objective response, including 32 percent with complete responses. Furthermore, 93 percent of these patients achieved tumor reductions and median progression-free survival was greater than six months. SGN-35 was generally well tolerated. The majority of adverse events were Grade 1 and 2, with the most common being fatigue, fever, diarrhea and nausea. We are also continuing dose escalation in an ongoing phase I clinical trial of SGN-35 administered on a weekly basis, and expect to report data from this study during 2009.

In February 2009, we initiated a pivotal, single-arm, open label trial of SGN-35 in patients with relapsed or refractory Hodgkin lymphoma pursuant to an SPA. The trial will assess efficacy and safety of single-agent SGN-35 in 100 patients with relapsed or refractory Hodgkin lymphoma who previously received autologous stem cell transplant. Patients will receive 1.8 mg/kg of SGN-35 every three weeks. The primary endpoint of the trial will be objective response rate assessed by an independent radiographic facility. Secondary endpoints include duration of response, progression-free survival, overall survival and tolerability. We plan to enroll patients at more than 30 sites in the U.S., Canada and Europe.

7

Table of Contents

We are also planning to conduct a phase II study of single-agent SGN-35 in approximately 50 patients with relapsed or refractory systemic ALCL. As of the date of this filing, 5 of 6 ALCL patients treated in our phase I trials of SGN-35 have achieved a complete response. We believe this phase II trial could provide supplementary safety and efficacy data for our SGN-35 registration package.

We are also exploring potential trial designs to facilitate moving SGN-35 toward front-line lymphoma therapy and other CD30-positive hematologic malignancies. Particular areas of patient need are elderly patients who cannot tolerate intensive front-line chemotherapy and patients who remain positron emission tomography, or PET, positive after two cycles of front-line chemotherapy. We believe that SGN-35 may also have future application in low-risk front-line Hodgkin lymphoma patients to reduce the intensity of chemotherapy regimens and therefore decrease the risk of secondary malignancies, reduce cardiac and pulmonary side effects and lower fertility impacts. We are in discussions with multiple clinical investigators and cooperative groups about additional clinical trials of SGN-35, and internal planning activities are underway to evaluate these and other life cycle management opportunities for the SGN-35 program.

We believe the reported clinical data for SGN-35 indicate the therapeutic potential of our ADC technology to empower antibodies. We previously conducted clinical trials of an unconjugated anti-CD30 monoclonal antibody, SGN-30, which is the same antibody used in SGN-35. At the ASH annual meeting in December 2005, we reported data from a phase II single agent trial of SGN-30, where the antibody alone was not sufficiently active as a single agent to demonstrate any objective responses in 35 patients with relapsed or refractory Hodgkin lymphoma treated at weekly doses up to 12 mg/kg. In contrast, SGN-35 has demonstrated multiple objective responses in a similar patient population at much lower doses with a less frequent dosing schedule.

Dacetuzumab (SGN-40)

Dacetuzumab is a humanized monoclonal antibody that is currently in phase I and II clinical trials for non-Hodgkin lymphoma and multiple myeloma. Dacetuzumab targets the CD40 antigen, which is expressed on B-cell lineage hematologic malignancies, as well as solid tumors such as bladder, renal and ovarian cancer. We also believe dacetuzumab may have applications in the treatment of autoimmune disease. We have received orphan drug designation from the FDA for dacetuzumab in multiple myeloma and chronic lymphocytic leukemia.

In January 2007, we entered into an exclusive worldwide collaboration agreement with Genentech for the development and commercialization of dacetuzumab. Under the terms of the agreement, we received an upfront payment of $60 million, and are entitled to receive potential milestone payments exceeding $800 million and escalating double-digit royalties starting in the mid-teens on net sales of dacetuzumab. We also have an option to co-promote dacetuzumab in the United States. Genentech is responsible for funding research, development, manufacturing and commercialization costs for dacetuzumab, including reimbursing us for all costs we incur in connection with clinical and development activities we conduct for the program. Our joint development plan with Genentech for dacetuzumab includes multiple trials of dacetuzumab both as a single agent and combined with standard therapies for the treatment of patients with non-Hodgkin lymphoma or multiple myeloma. We have received a total of $20 million in milestone payments from Genentech as of December 31, 2008 under the collaboration associated with dacetuzumab clinical trial initiations.

Market Opportunities

Non-Hodgkin lymphoma. Non-Hodgkin lymphoma is the most common form of hematologic malignancy. According to the American Cancer Society, during 2008 approximately 66,100 cases of non-Hodgkin lymphoma were expected to be diagnosed in the United States and more than 19,100 people were expected to die from the disease. Advances made with combined chemotherapy and the use of Rituxan, a monoclonal antibody, have resulted in high remission rates for front-line therapy in early stage disease. However, therapeutic options for refractory or

relapsed patients are still limited, and there are significant opportunities for new treatments in this patient population, especially in aggressive lymphoma subtypes such as DLBCL.

Table of Contents

Multiple Myeloma. The American Cancer Society estimated that approximately 19,900 cases of multiple myeloma were expected to be diagnosed in the United States during 2008, and approximately 10,700 people were expected to die from the disease. Therapeutic advances in recent years, such as the approval of Velcade, Thalomid and Revlimid by the FDA have expanded the treatment options for patients with multiple myeloma. However, multiple myeloma remains an incurable disease, and current therapies have limited response duration and significant toxic side effects. Therefore, we believe that a well-tolerated, monoclonal antibody represents a substantial opportunity in this disease either as a single agent or in combination with other treatments.

Clinical Results and Development Plan

We reported phase II data from our DLBCL study at the ASH annual meeting in December 2008. In this open label, single agent study, we enrolled 46 patients who were heavily pre-treated, with a median of four prior systemic therapies. The median age of enrolled patients was 72 and patients received six doses of dacetuzumab over five weeks, with an intra-patient dose escalation up to 8 mg/kg. Objective responses were observed in four out of 38 patients evaluable for response, including two complete remissions and two partial remissions, for an overall response rate of ten percent. The duration of objective responses ranged from 78 days to greater than 271 days. Ten additional patients had stable disease and approximately one-third of all patients had reductions in tumor size. Dacetuzumab was generally well tolerated.

We also reported phase I data from our non-Hodgkin lymphoma study at the International Conference on Malignant Lymphoma held in Lugano, Switzerland. In that study, fifty patients with non-Hodgkin lymphoma were treated on the open label single-arm, dose-escalation study of SGN-40. Cohorts of patients received escalating doses of SGN-40 ranging from 2 mg/kg to 8 mg/kg. The median age was 62 years and patients had received a median of three prior therapies. Out of 48 patients treated with SGN-40 who were evaluable for response across all dose levels, six patients achieved objective responses, including one complete response and five partial responses. Thirteen patients had stable disease and 29 had progressive disease. Of the 22 patients on the trial with DLBCL, four achieved an objective response. Overall, dacetuzumab was generally well tolerated.

In collaboration with Genentech, we are conducting a broad development plan for dacetuzumab that includes five clinical trials of dacetuzumab both as a single agent and combined with standard therapies for non-Hodgkin lymphoma and multiple myeloma. These include:

Phase IIb R-ICE Combination Study. In December 2007, we initiated a phase IIb randomized, double blind, placebo-controlled combination study of Rituxan and ICE chemotherapy, or R-ICE, with or without dacetuzumab. This trial, which is named SeaGen MARINER, is expected to enroll approximately 220 relapsed or refractory DLBCL patients at more than 60 sites worldwide. Patients will receive either R-ICE plus dacetuzumab or R-ICE plus placebo. The primary endpoint of the study is complete response rate. Additional endpoints include safety, tolerability, failure-free survival and overall survival. Initiation of this study triggered a $12 million milestone payment from Genentech.

Phase Ib Rituxan/Gemzar Combination Study. In April 2008, we initiated a phase Ib combination study of dacetuzumab plus Rituxan and Gemzar in patients with relapsed or refractory DLBCL. The study will enroll up to approximately 30 patients with relapsed or refractory DLBCL at multiple cancer centers in the United States. Patients will receive escalating doses of SGN-40 in combination with Rituxan and Gemzar. The study will assess safety, pharmacokinetics and preliminary antitumor activity of the combination regimen.

Phase Ib Rituxan Combination Study. In January 2008, Genentech initiated a phase Ib combination study of dacetuzumab plus Rituxan in patients with relapsed or refractory follicular or marginal zone non-Hodgkin lymphoma. This study, which is being conducted at multiple U.S. sites, is designed to assess safety, pharmacokinetics and preliminary activity of escalating doses of dacetuzumab when combined with Rituxan®. Initiation of this study triggered a $4 million milestone payment from Genentech.

9

Table of Contents

Phase Ib Revlimid Combination Study. In November 2007, we initiated a phase Ib combination study of dacetuzumab plus Revlimid in patients with relapsed or refractory multiple myeloma. This study is expected to enroll up to approximately 40 patients at multiple sites in the United States. Patients will receive escalating doses of dacetuzumab in combination with Revlimid and weekly dexamethasone, a steroid. The study is designed to assess safety and tolerability, preliminary activity and pharmacokinetics of the combination therapy. Initiation of this study triggered a $4 million milestone payment from Genentech.

Phase Ib Velcade Combination Study. In June 2008, Genentech initiated a phase Ib combination study of dacetuzumab plus Velcade in patients with relapsed or refractory multiple myeloma. This study will enroll up to approximately 30 patients with relapsed or refractory multiple myeloma at multiple cancer centers in the United States and Europe. Patients will receive escalating doses of SGN-40 in combination with a standard dose of Velcade. The study will assess safety and tolerability of the combination, pharmacokinetics and preliminary antitumor activity of the combination regimen.

We expect to report data from the four ongoing phase Ib combination trials of dacetuzumab in non-Hodgkin lymphoma and multiple myeloma at appropriate medical conferences during 2009 and 2010. Data from the phase IIb combination trial of R-ICE and dacetuzumab in DLBCL is expected in 2010. The results from all five of these trials will be key in determining the future clinical, regulatory and commercial strategy for the dacetuzumab program.

Lintuzumab (SGN-33)

Lintuzumab is a humanized monoclonal antibody that targets the CD33 antigen, which is highly expressed on myeloid malignancies and several myeloproliferative disorders. We are currently conducting phase I and phase II clinical development of lintuzumab in patients with AML or MDS, and have received orphan drug designation from the FDA for lintuzumab in both diseases. We have retained worldwide commercial rights to lintuzumab.

Market Opportunities

Acute Myeloid Leukemia. AML, the most common type of acute leukemia in adults, results in uncontrolled growth and accumulation of malignant cells, or blasts, which fail to function normally and inhibit the production of normal blood cells. Progression of AML often leads to a deficiency of red cells, platelets and normal white cells in the blood, which can cause infections and bleeding. According to the American Cancer Society, approximately 13,300 cases of AML were expected to be diagnosed in the United States during 2008, and 8,800 people were expected to die of the disease during 2008. Approximately two-thirds of AML patients are over 60 years of age at diagnosis. Currently approved therapies for AML include chemotherapy drugs such as cytarabine, daunorubicin or mitoxantrone and an ADC, Mylotarg. However, these therapies have low cure rates, usually lead to relatively short disease remissions and can have life-threatening side effects such as severe neutropenia, especially in older patients. In addition, stem cell transplantation, which may offer a higher probability of cure, is not an option for many patients due to potential toxicity of this treatment or the absence of an appropriate stem cell donor. Median survival of older patients with AML that are unable to tolerate intensive chemotherapy is estimated at less than six months and less than 20% remain alive one year after diagnosis. As such, we believe there is a significant need for well-tolerated, targeted therapies for patients who cannot tolerate chemotherapy or stem cell transplant.

Myelodysplastic Syndromes. MDS includes a heterogeneous group of hematologic myeloid malignancies that occur when blood cells remain in an immature stage within the bone marrow and never develop into mature cells capable of performing their necessary functions. Eventually, the bone marrow may be filled with immature cells, which suppresses normal cell development. According to the American Cancer Society, 10,000 to 15,000 new cases of MDS are diagnosed annually in the United States, with this number increasing each year. Mean survival rates range from approximately six months to six years for the different stages of MDS, with

10

Table of Contents

approximately 30 percent of MDS cases eventually transforming into AML. MDS patients must often rely on blood transfusions or growth factors to manage symptoms of fatigue, bleeding and frequent infections. Many MDS patients die from complications of the disease prior to developing AML, establishing a critical unmet medical need for new therapies targeting the cause of the condition and helping to restore normal blood cell production as well as delay the onset of leukemia. Recent data with hypomethylating agents such as Vidaza® and Dacogen® have demonstrated advantages over standard chemotherapy regimens among patients with intermediate-2 and high-risk MDS. However, these therapies are associated with significant toxicities, and MDS remains an incurable disease. Consequently, there remains a strong need for additional therapies in MDS that are well-tolerated and effective in reducing patient morbidity and mortality.

Clinical Results and Development Plan

During 2008, we completed enrollment in a phase I single agent dose escalation study of lintuzumab in patients with AML or MDS who were not eligible for intensive chemotherapy or stem cell transplantation or had failed previous therapy. This study, which was conducted at multiple U.S. sites, was designed to evaluate safety, pharmacokinetic profile and antitumor activity of escalating doses of lintuzumab from 1.5 to 8 mg/kg. The preliminary data from this study was reported at the ASH annual meeting in December 2007. This study was expanded to include additional patients in a phase Ib trial and we intend to present the complete phase I data during 2009.

In February 2009, we completed enrollment in a randomized, double blind, placebo-controlled, phase IIb study of low-dose cytarabine chemotherapy with or without lintuzumab in approximately 210 patients with AML. This study enrolled newly diagnosed AML patients over 60 years old who declined or were ineligible for induction chemotherapy. Currently, a significant percentage of older AML patients do not receive treatment with any chemotherapy due to concerns of the related toxicity, and even those who do receive low-dose chemotherapy have a median survival of less than six months. The primary goal of this study is to determine whether the addition of lintuzumab prolongs survival of older AML patients who do not receive aggressive chemotherapy. In addition, the trial will evaluate whether patients receiving lintuzumab experience reduced infections, transfusion independence, fewer hospitalizations and improved quality of life. We believe there is a compelling opportunity in this patient population to combine a well-tolerated antibody with low-dose cytarabine to potentially prolong survival without meaningful added toxicity. We expect data from this study, which is event-driven, to be available in the first half of 2010.

In addition to treatment of older AML patients, we are pursuing opportunities for lintuzumab in MDS, as well as considering strategies for expanding into treatment of younger AML patients. Our phase Ib study evaluating the combination of lintuzumab and Revlimid for patients with intermediate and high-risk MDS is ongoing. Preclinical data demonstrate that Revlimid can augment the immune effector function of antibodies, which is a primary mechanism of action for lintuzumab. This study will enroll approximately 30 patients with intermediate or high-risk MDS at escalating doses of lintuzumab combined with Revlimid to evaluate both tolerability and antitumor activity. We are also considering potential combination studies of lintuzumab plus other standard therapies in MDS, such as Vidaza or Dacogen, based on recent clinical data with both drugs.

SGN-70

SGN-70 is a humanized anti-CD70 monoclonal antibody with potent effector functions. We believe that SGN-70 has significant application for the treatment of autoimmune diseases where the body s immune system malfunctions and attacks its own healthy cells. Many therapies for autoimmune diseases rely on suppressing the immune system to prevent further damage to normal tissues, but have the unwanted side effect of making the patient more susceptible to infection or cancer. The CD70 antigen is expressed on activated T- and B-cells but is absent on these cells when in a resting state. Since resting T- and B-cells make up the majority of immune cells circulating in the body, SGN-70 may be able to prevent or reduce a damaging immune response without globally suppressing the patient s immune system. We have presented preclinical data demonstrating that SGN-70 inhibits T- and B-cell functions, selectively depletes CD70-positive activated T-cells and limits expansion of CD70-

11

Table of Contents

positive lymphocytes. We are currently conducting a phase I dose escalation trial of SGN-70 to assess the safety, tolerability and pharmacokinetics of SGN-70 in healthy volunteers. We intend to amend the trial design to add patients with autoimmune disease and begin treatment in 2009.

SGN-75

SGN-75 is an ADC composed of an anti-CD70 monoclonal antibody linked to a potent auristatin compound using our proprietary ADC technology. The CD70 antigen has a broad expression profile in multiple types of cancer, including multiple myeloma, lymphoma, renal cancer, glioblastoma and several other solid tumors. We presented data at the American Association for Cancer Research annual meetings in both April 2006 and April 2007 demonstrating that CD70 has high expression in primary renal cell samples and that SGN-75 has potent antitumor activity at well-tolerated doses in preclinical models of renal cell cancer. We are planning to file an IND for SGN-75 in hematologic malignancies and solid tumors during 2009.

AGS-5 ADC

AGS-5 ADC is a preclinical ADC product candidate for the treatment of solid tumors that we are co-developing under our collaboration with Agensys, a subsidiary of Astellas Pharma. We are currently conducting preclinical studies and manufacturing activities to support a future IND filing for this program.

SGN-19A

SGN-19A is a preclinical ADC product candidate for the treatment of hematologic malignancies. It targets CD19, which is a B-cell antigen that is expressed in non-Hodgkin lymphoma, chronic lymphocytic leukemia and acute lymphocytic leukemia. We reported data at the American Association for Cancer Research-National Cancer Institute-European Organization for Research and Treatment of Cancer conference in October 2007 demonstrating that SGN-19A effectively binds to target cells with high affinity, internalizes and induces potent cancer-cell-killing activity and durable tumor regressions at low doses in multiple cancer models.

Research Programs

In addition to our pipeline of product candidates and antibody-based technologies, we have internal research programs directed towards identifying novel antigen targets and monoclonal antibodies, advancing our antibody engineering initiatives and developing new classes of stable linkers and potent, cell-killing drugs.

Novel Antigen Targets and Monoclonal Antibodies. We are actively engaged in internal efforts to identify and develop monoclonal antibodies and ADCs with novel specificities and activities against selected antigen targets. We focus on proteins that are highly expressed in cancer to identify molecules that are located on the surface of cancer cells that may serve as targets for monoclonal antibodies or ADCs. We then create and screen panels of cancer-reactive monoclonal antibodies in our laboratories to identify those with the desired specificity. We supplement

these internal efforts by evaluating opportunities to in-license targets and antibodies from academic groups and other biotechnology and pharmaceutical companies, such as our ongoing collaboration with Agensys.

Antibody Engineering. We have substantial internal expertise in antibody engineering, both for antibody humanization and engineering of antibodies to improve drug linkage sites for use with our ADC technology. By modifying the number and type of drug-linkage sites found on our antibodies, we believe that we can improve the robustness and cost-effectiveness of our manufacturing processes for conjugation of ADCs.

New Cell-Killing Drugs. We continue to study new cell-killing drugs that can be linked to antibodies, such as the auristatins that we currently use in our ADC technology. We are evaluating multiple auristatins, as well as other classes of cell-killing drugs, for potential applications as ADCs.

Research and Development Expense

Since inception, we have devoted a significant amount of resources to develop our product candidates and our antibody-based technologies. For the years ended December 31, 2008, 2007 and 2006, we recorded $110.9 million, $64.8 million and $40.1 million, respectively, in research and development expenses.

Table of Contents

Corporate Collaborations

We seek collaborations with leading biotechnology and pharmaceutical companies to advance the development and commercialization of our product candidates and to supplement our internal pipeline. We seek collaborations that will allow us to retain significant future participation in product sales through either profit-sharing or royalties paid on annual net sales. We also license our ADC technology to collaborators to empower their own antibodies. These ADC licenses benefit us in many ways, including generating revenues that partially offset expenditures on our internal research and development programs, expanding our knowledge base regarding ADCs across multiple targets and antibodies provided by our collaborators and providing us with future pipeline opportunities through co-development or opt-in rights to new ADC product candidates.

Genentech Dacetuzumab Collaboration

In January 2007, we entered into an exclusive worldwide collaboration agreement with Genentech for the development and commercialization of dacetuzumab. Under the terms of the agreement, we received an upfront payment of $60 million, and are entitled to receive potential milestone payments exceeding $800 million and escalating double-digit royalties starting in the mid-teens on annual net sales of dacetuzumab. We also have an option to co-promote dacetuzumab in the United States. Genentech is responsible for funding research, development, manufacturing and commercialization costs for dacetuzumab, including reimbursing us for all costs we incur in connection with clinical and development activities we conduct for the program. Our joint development plan with Genentech for dacetuzumab includes multiple trials of dacetuzumab both as a single agent and combined with standard therapies for the treatment of patients with non-Hodgkin lymphoma or multiple myeloma. We have received $20 million in milestone payments as of December 31, 2008 under this collaboration associated with dacetuzumab clinical trial initiations.

We initially licensed our anti-CD40 antibody program to Genentech in June 1999. In March 2003, we entered into license agreements with Genentech providing for the return to us of the rights relating to the anti-CD40 antibody program, including an antibody that became our dacetuzumab product candidate, as well as a license under Genentech s Cabilly patent covering the recombinant expression of antibodies. As part of that license, we also received material from Genentech for use in our phase I clinical trials of dacetuzumab.

ADC Collaborations

We have active collaborations with six companies to allow them to use our proprietary ADC technology with their monoclonal antibodies:

Daiichi Sankyo. In July 2008, we entered into an ADC collaboration with Daiichi Sankyo Co., Ltd. Under the terms of the multi-year agreement, we received a $4 million upfront fee for an exclusive license to our technology for a single antigen found on multiple types of solid tumors. Daiichi Sankyo is paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting products. Daiichi Sankyo is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

Progenics. In June 2005, we entered into an ADC collaboration with PSMA Development Company, which is now a wholly-owned subsidiary of Progenics. Under the terms of the multi-year agreement, we received a $2 million upfront fee for an exclusive license to our technology for the PSMA antigen, which is highly expressed on prostate cancer as well as tumor vasculature in multiple solid tumor types. Progenics is paying

service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting products. Progenics is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration. Progenics initiated a clinical trial for the PSMA-ADC during 2008 for which we received a milestone payment.

MedImmune. In April 2005, we entered into an ADC collaboration with MedImmune, which is now a wholly-owned subsidiary of AstraZeneca. Under the terms of the multi-year agreement, MedImmune paid us a

Table of Contents

$2 million upfront fee for an exclusive license to our technology for a single antigen. In October 2007, MedImmune paid us an additional $1.5 million fee for an exclusive license to a second antigen. MedImmune is paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting products. MedImmune is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

Bayer. In September 2004, we entered into an ADC collaboration with Bayer. Under the terms of the multi-year agreement, Bayer paid us a $2 million upfront fee for an exclusive license to our technology for a single antigen. In May 2008, Bayer paid us an additional fee to amend the collaboration agreement and expand the research conducted pursuant to the collaboration. Bayer is also paying service and reagent fees and has agreed to make milestone payments and pay royalties on net sales of any resulting products. Bayer is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration.

CuraGen. In June 2004, we entered into an ADC collaboration with CuraGen. Under the terms of the multi-year agreement, CuraGen paid us a $2 million upfront fee for an exclusive license to our technology for a single antigen. In February 2005, CuraGen paid us an additional fee for an exclusive license to a second antigen. CuraGen is also paying service and reagent fees and has agreed to make milestone payments to us, certain of which milestone payments have been made in connection with the initiation of phase I and II trials of its ADC product candidate, CR011-ADC, and CuraGen has further agreed to pay royalties to us on net sales of any resulting ADC products. CuraGen is responsible for all costs associated with the development, manufacturing and marketing of any ADC products generated as a result of this collaboration. CuraGen is currently conducting phase II clinical development of CR011-ADC for the treatment of metastatic melanoma and breast cancer.

Genentech. In April 2002, we entered into an ADC collaboration with Genentech. Upon entering into the multi-year agreement, Genentech paid us a $2.5 upfront fee and purchased $3.5 million of our common stock. We have subsequently expanded this collaboration on several occasions to include additional antigens, including in December 2003 when Genentech paid us a $3 million fee and purchased an additional $7 million of our common stock, in November 2004 when Genentech paid us a $1.6 million fee and in March 2007 when Genentech paid us a $4.5 million fee to extend the research term of the license. In June 2008, Genentech paid us a milestone in connection with the filing of an IND for one of its ADC product candidates. Genentech has also agreed to pay progress-dependent milestone payments and royalties on net sales of any resulting products. Genentech is responsible for research, product development, manufacturing and commercialization of any products resulting from the collaboration. Over the past several years, Genentech has paid us fees and milestone payments based on achievement of a preclinical milestone and assistance with process development and manufacturing to support IND-enabling studies and potential future clinical trials of multiple ADC product candidates.

Agensys Co-Development Agreement

Agensys. In January 2007, we entered into an agreement with Agensys, a wholly-owned subsidiary of Astellas Pharma, to jointly research, develop and commercialize ADCs for cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Agensys to proprietary cancer targets. Under the terms of the multi-year agreement, we and Agensys will jointly screen and select ADC product candidates to an initial target, AGS-5, co-fund all preclinical and clinical development and share equally in any profits. Agensys will also conduct further preclinical studies aimed at identifying ADC product candidates to up to three additional targets. We have the right to exercise a co-development option for one of these additional ADC product candidates in connection with the initial IND filing for these additional ADC product candidates. Agensys has the right to develop and commercialize the other two ADCs product candidates on its own, subject to paying us fees, milestones and royalties. Either party may opt out of co-development and profit-sharing in return for receiving milestones and royalties from the continuing party. We and Agensys are currently collaborating on preclinical development of AGS-5 ADC for the treatment of solid tumors.

Table of Contents

License Agreements

We have in-licensed antibodies, targets and enabling technologies from pharmaceutical and biotechnology companies and academic institutions for use in our pipeline programs and ADC technologies, including the following:

Bristol-Myers Squibb. In March 1998, we obtained rights to some of our technologies and product candidates, portions of which are exclusive, through a license agreement with Bristol-Myers Squibb Corporation. Through this license, we secured rights to monoclonal antibody-based cancer targeting technologies, including patents, monoclonal antibodies, chemical linkers, a ribosome-inactivating protein and enabling technologies. Under the terms of the license agreement, we are required to pay royalties on net sales of future products incorporating technology licensed from Bristol-Myers Squibb.

PDL BioPharma. In January 2004, as part of the expansion of our then-existing ADC collaboration, PDL BioPharma, Inc. granted us one license and options for two additional licenses under PDL s antibody humanization patents. We used the initial antibody humanization license for our dacetuzumab product candidate, which we subsequently sublicensed to Genentech in January 2007 as part of our dacetuzumab collaboration. Under the terms of the license agreements, we are required to pay annual maintenance fees and royalties on net sales of products using PDL s humanization technology.

Facet Biotech Corporation. In April 2005, we in-licensed an anti-CD33 program from PDL, which is the basis for lintuzumab. In December 2008, Facet Biotech Corporation spun out of PDL with Facet being assigned all of PDL s rights and interest in the lintuzumab license, as well as its rights in our ADC collaboration with PDL. We paid PDL an upfront fee and have agreed to pay progress-dependent milestones and royalties on net sales of anti-CD33 products incorporating technology in-licensed, which includes an antibody humanization license for the CD33 antigen. As part of the agreement, we also agreed to reduce the royalties payable by Facet to us with respect to one target under the ADC collaboration. We and Facet have also granted each other a co-development option for second generation anti-CD33 antibodies with improved therapeutic characteristics developed by either party.

CMC ICOS Biologics, Inc. In October 2000, we entered into a license agreement with ICOS Corporation, now a wholly-owned subsidiary of Eli Lilly, for non-exclusive rights to use ICOS CHEF expression system. In December 2007, CMC Biologics A/S acquired the biologics manufacturing site and all related intellectual property of ICOS from Eli Lilly, including the rights to the CHEF expression system. We use this system to manufacture the antibody components of SGN-35, SGN-30, SGN-70 and SGN-75 and we may also use it for other monoclonal antibodies in the future. Under the terms of this agreement, we are required to make progress-dependent milestone payments and pay royalties on net sales of products manufactured using the CHEF expression system to CMC ICOS Biologics.

University of Miami. In September 1999, we entered into an exclusive license agreement with the University of Miami, Florida, covering an anti-CD30 monoclonal antibody that is the basis for SGN-30 and the antibody component of SGN-35. Under the terms of this license, we made an upfront payment and are required to pay annual maintenance fees, progress-dependent milestone payments and royalties on net sales of products incorporating technology licensed from the University of Miami.

Mabtech AB. In June 1998, we obtained exclusive, worldwide rights to a monoclonal antibody targeting the CD40 antigen, which is the basis for dacetuzumab, from Mabtech AB, located in Sweden. Under the terms of this license, we made an up-front payment, are required to make a progress-dependent milestone payments and pay royalties on net sales of products incorporating technology licensed from Mabtech.

CLB-Research and Development. Pursuant to a license agreement we entered into in July 2001, we obtained an exclusive license to specific monoclonal antibodies that target cancer and autoimmune disease

Table of Contents

targets from CLB-Research and Development, a division of Sanquin Blood Supply Foundation, located in the Netherlands. One of these antibodies is the basis for SGN-70 and the antibody component of SGN-75. Under the terms of this agreement, we have made upfront and option exercise payments and are required to make progress-dependent milestone payments and pay royalties on net sales of products incorporating technology licensed from CLB-Research and Development.

Arizona State University. In February 2000, we entered into a license agreement with Arizona State University for a worldwide, exclusive license to the cell-killing agent Auristatin E. We subsequently amended this agreement in August 2004. Under the terms of the amended agreement, we are required to pay annual maintenance fees to Arizona State University until expiration of their patents covering Auristatin E. We are not, however, required to pay any progress-dependent milestone payments or royalties on net sales of products incorporating the auristatins currently used in our ADC technology, and thus we do not expect to pay any milestones or royalties to Arizona State University with respect to products employing our current ADC technology.

Patents and Proprietary Technology

We seek appropriate patent protection for our proprietary technologies by filing patent applications in the United States and other countries. As of December 31, 2008, we owned approximately 175 United States and corresponding foreign patents and patent applications and held exclusive or partially exclusive licenses to over 15 United States and corresponding foreign patents and patent applications.

Our patents and patent applications are directed to product candidates, monoclonal antibodies, ADC product candidates, our ADC technology and other antibody-based and/or enabling technologies. Although we believe our patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our corporate collaborators may not be able to develop patentable products or processes or obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue. In the event of issuance, the patents may not be sufficient to protect the proprietary technology owned by or licensed to us or our corporate collaborators. Our or our corporate collaborators current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. Our patents may be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid or unenforceable under U.S. or foreign laws or they may be infringed by third parties. The costs of defending our patents or enforcing our proprietary rights in litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us or our collaborators. Our or our collaborators patents may also be circumvented which may allow third parties to use similar technologies without a license from us or our collaborators.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. A number of pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned, optioned by or licensed to us or to our corporate collaborators. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our or our corporate collaborators ability to make, use or sell any products.

We also rely on trade secrets and proprietary know-how, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we shall own all inventions conceived by the individual in the course of rendering services to us. Our agreements with commercial collaborators require them to have a similar policy and agreements with their employees, consultants

16

Table of Contents

and advisors. Our policy and agreements and those of our collaborators may not sufficiently protect our confidential information, or third parties may independently develop equivalent information.

Government Regulation

Our product candidates are subject to extensive regulation by numerous governmental authorities, principally the FDA, as well as numerous state and foreign agencies. We need to obtain approval of our product candidates from the FDA before we can begin marketing them in the United States. Similar approvals are also required in other countries.

Product development and approval within this regulatory framework is uncertain, can take many years and requires the expenditure of substantial resources. The nature and extent of the governmental review process for our product candidates will vary, depending on the regulatory categorization of particular product candidates and various other factors.

The necessary steps before a new biopharmaceutical product may be sold in the United States ordinarily include:

- preclinical laboratory and animal tests;
- submission to the FDA of an IND which must become effective before clinical trials may commence;
- completion of adequate and well controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a marketing authorization application;
- FDA pre-approval inspection of manufacturing facilities for current Good Manufacturing Practices, or GMP, compliance and FDA inspection of select clinical trial sites for Good Clinical Practice, or GCP, compliance; and
- FDA review and approval of the marketing authorization application and product label prior to any commercial sale.

Clinical trials generally are conducted in three sequential phases that may overlap. In phase I, the initial introduction of the product into humans, the product is tested to assess safety, metabolism, pharmacokinetics and pharmacological actions associated with increasing doses. Phase II usually involves trials in a limited patient population to determine the efficacy of the potential product for specific, targeted indications, determine dosage tolerance and optimum dosage and further identify possible adverse reactions and safety risks. Phase III, or pivotal, trials are undertaken to evaluate further clinical efficacy in comparison to standard therapies within a broader patient population, generally at geographically dispersed clinical sites. Phase I, phase II or phase III testing may not be completed successfully within any specific period of time, if at all, with respect to any of our product candidates. Similarly, suggestions of safety or efficacy in earlier stage trials do not necessarily predict findings of safety and effectiveness in subsequent trials. Furthermore, the FDA, an institutional review board or we may suspend a clinical trial at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical trials are subject to central registration requirements, such as on www.clinicaltrials.gov.

The results of preclinical studies, pharmaceutical development and clinical trials are submitted to the FDA in the form of an NDA or a biologics license application, or BLA, for approval of the manufacture, marketing and commercial shipment of the pharmaceutical product. The submission of an NDA or BLA is required to be accompanied by a substantial User Fee, with few exceptions or waivers. The testing and approval process is likely to require substantial time, effort and resources, and there can be no assurance that any approval will be granted on a timely basis, if at all. The FDA may deny review of an application or not approve an application if applicable regulatory criteria are not satisfied, require additional testing or information, or require risk management programs and post-market testing and surveillance to monitor the safety or efficacy of the product. In addition, after marketing approval is granted, the FDA may require post-marketing clinical trials, which

Table of Contents

typically entail extensive patient monitoring and may result in restricted marketing of an approved product for an extended period of time. Also, after marketing approval, comprehensive federal and state regulatory compliance obligations exist for the manufacture, labeling, distribution, advertising, promotion and pricing of pharmaceutical products. Failure to comply with ongoing regulatory obligations can result in warning letters, product seizures, criminal penalties, and withdrawal of approved products, among other enforcement remedies.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to cancer and autoimmune disease therapy. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs.

We expect that competition among products approved for sale will be based, among other things, on efficacy, reliability, product safety, price and patent position. Our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

- advance our technology platforms;
- license additional technology;
- maintain a proprietary position in our technologies and products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel; and
- enter into corporate partnerships.

We are aware of specific companies that have technologies that may be competitive with ours, including Wyeth, ImmunoGen and Medarex, all of which have antibody-drug conjugate technology. Wyeth markets the antibody-drug conjugate Mylotarg for patients with acute myeloid leukemia, which targets the same antigen as our lintuzumab product candidate. ImmunoGen has several antibody-drug conjugates in development that may compete with our product candidates if approved for commercial sale. ImmunoGen has also established partnerships with other pharmaceutical and biotechnology companies to allow those other companies to utilize ImmunoGen s technology, including Sanofi-Aventis

and Genentech. In addition, Medarex has developed its own technology for linking antibodies to cytotoxic payloads. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates. For example, Novartis is developing an anti-CD40 antibody, Medarex has anti-CD30 and anti-CD70 antibody programs, MedImmune has an anti-CD19 program and Xencor has anti-CD30 and anti-CD40 antibody programs that may be competitive with our product candidates if approved for commercial sale. In addition, many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer and autoimmune diseases that our product candidates are designed and being developed to treat. These include antibodies such as Genentech s Rituxan, proteosome inhibitors such as Millennium s Velcade, immunomodulatory agents such as Celgene s Revlimid, small molecule drugs such as Bayer s/Onyx s Nexavar, and a variety of cytotoxic drugs such as Genzyme s Clolar, Celgene s Vidaza, Eisai s Dacogen and Cephalon s Treanda.

Table of Contents

Manufacturing

We rely on corporate collaborators and contract manufacturing organizations to supply drug product for our IND-enabling studies and clinical trials. For dacetuzumab, Genentech has assumed manufacturing responsibility under our collaboration, and we also have an ongoing manufacturing agreement with Abbott Laboratories to supplement our clinical and potential future commercial supplies. For lintuzumab, we have contracted with Laureate Pharma for clinical drug supply. For the monoclonal antibody used in SGN-35, we have contracted with Abbott Laboratories for clinical and potential future commercial supplies. We have also contracted with Laureate Pharma to manufacture the antibody component of SGN-70 and SGN-75 to enable clinical trials. For our ADC technology, several contract manufacturers, including Albany Molecular and Sigma Aldrich Fine Chemicals, or SAFC, perform drug-linker manufacturing and several other contract manufacturers, including Piramal Healthcare, perform conjugation of the drug-linker to the antibody. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including vialing and storage of our product candidates.

We believe that our existing supplies of drug product and our contract manufacturing relationships with Abbott Laboratories, Laureate Pharma, Albany Molecular, SAFC, Piramal and our other existing and potential contract manufacturers with whom we are in discussions, will be sufficient to accommodate clinical trials through phase II, and in some cases into phase III, trials of our current product candidates. We are in the process of establishing our commercial supply chain for SGN-35 to position us for a potential 2011 NDA submission and 2012 commercial launch. However, we may need to obtain additional manufacturing arrangements or increase our own manufacturing capability to meet our future commercial needs, both of which would require significant capital investment. We may also enter into collaborations with pharmaceutical or larger biotechnology companies to enhance the manufacturing capabilities for our product candidates.

Employees

As of December 31, 2008, we had 261 employees. Of these employees, 218 are engaged in or support research, development and clinical activities and 43 are in administrative and business related positions. Each of our employees has signed confidentiality and inventions assignment agreements and none are covered by a collective bargaining agreement. We have never experienced employment-related work stoppages and consider our employee relations to be good.

Corporate Information

We were incorporated in Delaware on July 15, 1997. Our principal executive offices are located at 21823 30th Drive SE, Bothell, Washington 98021. Our telephone number is (425) 527-4000. Seattle Genetics® and are our registered trademarks in the United States. All other trademarks, tradenames and service marks included in this Annual Report on Form 10-K are the property of their respective owners.

We file electronically with the Securities and Exchange Commission our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at www.seattlegenetics.com, free of charge, through a hyperlink on our website, copies of these reports, as soon as reasonably practicable after electronically filing such reports with, or furnishing them to, the Securities and Exchange Commission. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this annual report on Form 10-K and the information incorporated by reference herein. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed.

This Annual Report on Form 10-K 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 Annual Report on Form 10-K.

Table of Contents

Risks Related to Our Business

Our near-term prospects are substantially dependent on SGN-35, our lead product candidate. If we are unable to successfully develop and obtain regulatory approval for SGN-35 for the treatment of patients with relapsed or refractory Hodgkin lymphoma, our ability to generate revenue from product sales will be significantly delayed.

We currently have no products that are approved for commercial sale. Our product candidates are in various stages of development, and significant research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals for them. A substantial portion of our efforts and expenditures over the next few years will be devoted to SGN-35, which is the subject of an ongoing pivotal clinical trial pursuant to an SPA with the FDA. Accordingly, our future prospects are substantially dependent on the successful development, regulatory approval and commercialization of SGN-35 for the treatment of patients with relapsed or refractory Hodgkin lymphoma. SGN-35 is not expected to be commercially available for this or any other indication until at least 2012, if at all. Further, the commercial success of SGN-35 will depend upon its acceptance by physicians, patients, third party payors and other key decision-makers as a therapeutic and cost-effective alternative to currently available products. In addition, the indications that we are pursuing in SGN-35 have relatively low incidence rates, including Hodgkin lymphoma and ALCL, which may limit the revenue potential of SGN-35. If we are unable to successfully develop, obtain regulatory approval for and commercialize SGN-35 for the treatment of relapsed or refractory Hodgkin lymphoma and other indications, our ability to generate revenue from product sales will be significantly delayed and our business would be materially affected and we may not be able to earn sufficient revenues to continue as a going concern.

Although we have reached agreement with the FDA on a special protocol assessment relating to our SGN-35 pivotal trial, this agreement does not guarantee any particular outcome with respect to regulatory review of the pivotal trial or with respect to regulatory approval of SGN-35.

The protocol for the SGN-35 pivotal trial was reviewed by the FDA under the SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of an NDA, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. Reaching agreement with the FDA on an SPA is not an indication of approvability and even if we believe that the data from the pivotal trial is positive, an SPA agreement is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, the pivotal trial will be adequate to demonstrate the safety and efficacy of SGN-35 for the treatment of patients with relapsed or refractory Hodgkin lymphoma, or will otherwise be sufficient to support FDA or any foreign regulatory approvals. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if we fail to comply with the agreed upon trial protocols. In addition, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the pivotal trial. As a result, we do not know how the FDA will interpret the parties respective commitments under the SPA agreement, how it will interpret the data and results from the pivotal trial, or whether SGN-35 will receive any regulatory approvals. Therefore, despite the potential benefits of the SPA agreement, significant uncertainty remains regarding the clinical development and regulatory approval process of SGN-35 for the treatment of relapsed or refractory Hodgkin lymphoma, and it is possible that we might never receive any regulatory approvals for SGN-35.

Other than SGN-35, our product candidates are at an early stage of development, and it is possible that none of our product candidates will ever become commercial products.

Other than SGN-35, our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all.

Currently, dacetuzumab, lintuzumab and

Table of Contents

SGN-70 are in clinical trials, and SGN-75, AGS-5 ADC and SGN-19A are in preclinical development. We expect that much of our effort and many of our expenditures over the next few years will be devoted to registration and commercialization activities associated with SGN-35, which may restrict or delay our ability to develop our other clinical and preclinical product candidates.

Our ability to commercialize any of our product candidates, including SGN-35, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval for any of our product candidates. Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Assuming dacetuzumab receives regulatory approval, commercial success will depend in large part on Genentech s commercialization efforts. The degree of commercial success of any approved product will depend on a number of factors, including:

establishment and demonstration of clinical efficacy and safety;

cost-effectiveness of the product;

the product s potential advantage over alternative treatment methods;

whether the product can be produced in commercial quantities at acceptable costs; and

marketing and distribution support for the product.

We do not expect any of our current product candidates to be commercially available until at least 2012, if at all. If we fail to gain marketing approval from the FDA or to develop a commercially successful product, we may not be able to earn sufficient revenues to continue as a going concern and we will not be successful.

If we or our collaborators are not able to obtain required regulatory approvals, we or our collaborators will not be able to commercialize our product candidates, our ability to generate revenue will be materially impaired and our business will not be successful.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our collaborators are permitted to market our product candidates in the United States or foreign countries until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we or our collaborators may never receive regulatory approval for the commercial sale of any of our product candidates. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured, and we have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. Further, the FDA has substantial discretion in the approval process, and when or whether regulatory approval will be obtained for any product candidate we develop. In this regard, even if we believe the data collected from clinical trials of our product candidates are promising, such data, including data from our pivotal trial of SGN-35, may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from preclinical studies and clinical trials. Regulatory agencies also may approve a product candidate for fewer conditions than requested or may grant approval subject to the performance of post-approval studies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, 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 regulatory approval, which could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

Table of Contents

If we or our collaborators receive regulatory approval for our product candidates, we will also be subject to ongoing FDA obligations and oversight, including adverse event reporting requirements, marketing restrictions and potential post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. The FDA s policies may also change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to civil and criminal penalties, we may not be permitted to market our products and our business could suffer. Any delay in or failure to receive or maintain regulatory approval for any of our product candidates could harm our business and prevent us from ever generating meaningful revenues or achieving profitability.

We and our collaborators will need to obtain regulatory approval from authorities in foreign countries to market our product candidates in those countries. Neither we nor our collaborative partners have filed for regulatory approval to market our product candidates in any foreign jurisdictions. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we or our collaborative partners fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical studies and clinical trials, that the product candidate is safe and effective in humans. Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals. The clinical data from our phase I trials of SGN-35 are limited and we have only recently initiated our SGN-35 pivotal trial, the results of which will be blinded to us until completion of the trial. In addition, we still only have limited data from our phase I and II clinical trials of dacetuzumab and lintuzumab and our phase I trial of SGN-70. Phase I and phase II clinical trials are not primarily designed to test the efficacy of a product candidate but rather are designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate s side effects at various doses and dosing schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. The pivotal trial of SGN-35 will require 100 patients and we believe that any clinical trial designed to test the efficacy of dacetuzumab, lintuzumab or SGN-70, whether phase II or phase III, will likely involve a large number of patients to achieve statistical significance and will be expensive. As a result, we may conduct lengthy and expensive clinical trials of SGN-35, dacetuzumab, lintuzumab or SGN-75, only to learn that the product candidate is not an effective treatment or is not superior to existing approved therapies or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate.

Clinical trials for our product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcome is uncertain.

We are currently conducting one pivotal trial under an SPA with the FDA for SGN-35, and multiple phase I and phase II clinical trials of our other clinical product candidates, and we expect to commence additional trials of these and other product candidates in the future. Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site, and shortages of available drug supply. 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

22

Table of Contents

new treatments. In addition, future and ongoing dacetuzumab clinical trials will be coordinated with Genentech, which may delay the commencement or affect the continuation or completion of these trials. We have experienced enrollment-related delays in our current and previous clinical trials and will likely experience similar delays in our future trials, particularly as we attempt to significantly increase patient size as may be required for phase III studies. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials and to the extent they fail to enroll 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 conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with foreign currency transactions insofar as we might desire to use U.S. dollars to make contract payments denominated in the foreign currency where the trial is being conducted.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under GMP and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events 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;
- the quality or stability of the product candidate may fall below acceptable standards;
- our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;

our inability to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or

our inability to retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies, which often occurs in later-stage clinical trials. For example, we are conducting phase II clinical trials with both dacetuzumab and lintuzumab combined with other therapies, including chemotherapy, and may experience unexpected adverse events as a result of these combinations. In addition, clinical results are

Table of Contents

frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events, including patient fatalities that may be attributable to our product candidates, during a clinical trial could cause it to be redone or terminated.

In some circumstances we rely on collaborators to assist in the research and development of our product candidates, as well as to utilize our ADC technology. If we are not able to locate suitable collaborators or if our collaborators do not perform as expected, it may affect our ability to commercialize our product candidates and/or generate revenues through technology licensing.

We have established and intend to continue to establish collaborations with third-parties to develop and market some of our current and future product candidates. We entered into an exclusive worldwide collaboration agreement with Genentech in January 2007 for the development and commercialization of our dacetuzumab product candidate. We also have active ADC collaborations with Genentech, Bayer, CuraGen, Progenics, MedImmune and Daiichi Sankyo, and an ADC co-development agreement with Agensys.

Under certain conditions, our collaborators may terminate their agreements with us and discontinue use of our technologies. In addition, we cannot control the amount and timing of resources our collaborators may devote to products incorporating our technology. Moreover, our relationships with our collaborators divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. Our collaborators may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators. Even if our collaborators continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Our collaborators may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. If any of our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. On March 12, 2009, Genentech and Roche agreed to the acquisition of all of the outstanding shares of Genentech by Roche, that were not already held by Roche, and although we are not aware of any changes to our dacetuzumab collaboration as a result of the acquisition of Genentech by Roche, we are uncertain what effect this acquisition will have on our dacetuzumab collaboration. In particular, Genentech and/or Roche may terminate the dacetuzumab collaboration at its election and if Genentech and/or Roche determines to terminate the dacetuzumab collaboration, we would not receive milestone payments or royalties for development or sale of dacetuzumab. As a result of such termination, we would have to engage another collaborator to complete the dacetuzumab development process or complete the process ourselves internally, either of which could significantly delay the development process and increase our costs. In turn, this could significantly harm our financial position, adversely affect our stock price and require us to incur all the costs of developing and commercializing dacetuzumab, which are now being funded by Genentech. Furthermore, 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. In the future, we may not be able to locate third party collaborators to develop and market our product candidates and we may lack the capital and resources necessary to develop all our product candidates alone.

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 commercialize our product candidates that may be approved for commercial sale.

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 any of our product candidates that may be approved for commercial sale, except for dacetuzumab for which Genentech and/or its licensees will lead the sales and marketing efforts while we retain an ability to co-promote that product in the United States. If we are unable to establish sales and marketing capabilities or successful

24

Table of Contents

distribution relationships with biotechnology or pharmaceutical companies, we may fail to realize the full sales potential of some of our product candidates. Even if we are able to establish distribution agreements with biotechnology or pharmaceutical companies, we generally would not have control over the resources or degree of effort that any of these third parties may devote to our collaborations, and if they fail to devote sufficient time and resources to our the marketing of our product candidates, or if their performance is substandard, it will adversely affect the sale of our product candidates.

Moreover, 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. Significant changes in the U.S. healthcare system are intended in the near future, including the potential for increased use of cost-effectiveness measures and the possibility of generic biologics. 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. Similarly, even if we do receive reimbursement, the target market for any approved products may be small or the focus of intense competition and we may not realize an appropriate return on our investment in research and product development.

We depend on a small number of collaborators for most of our current revenue. The loss of any one of these collaborators could result in a substantial decline in our revenue.

We have collaborations with a limited number of companies. To date, almost all of our revenue has resulted from payments made under agreements with our corporate collaborators, and we expect that most of our future revenue will continue to come from corporate collaborations until the approval and commercialization of one or more of our product candidates and even then we may still be highly dependent on a collaborator for the approved product. For example, if dacetuzumab receives regulatory approval, our revenues will still be dependent on Genentech s ability to market the approved product. The failure of our collaborators to perform their obligations under their agreements with us, including paying license or technology fees, milestone payments or royalties, could have a material adverse effect on our financial performance. In addition, a significant portion of revenue received from our corporate collaborators is derived from research and material supply fees, and a decision by any of our corporate collaborators to conduct more research and development activities themselves could significantly reduce the revenue received from these collaborations. Payments under our existing and future collaboration agreements are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

We currently rely on third-party manufacturers and other third parties 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 internal ability to manufacture the drug products that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our drug products. For the monoclonal antibody used in SGN-35, we have contracted with Abbott Laboratories for clinical and potential future commercial supplies. For dacetuzumab, we have also contracted with Abbott Laboratories for clinical and potential future commercial supplies. Decisions on future dacetuzumab drug supply will be made jointly by us and Genentech through our collaboration. For lintuzumab, we received clinical-grade material from PDL BioPharma to support phase I trials and entered into a contract manufacturing arrangement with Laureate Pharma to provide later-stage clinical supplies, including for our ongoing phase IIb trial. We have also contracted with Laureate Pharma to manufacture the antibody component of SGN-70 and SGN-75 to enable future initiation of clinical trials. For our ADC technology, several contract manufacturers, including Albany Molecular and Sigma Aldrich Fine Chemicals, or SAFC, supply us with drug-linker and several other contract manufacturers perform conjugation of the drug-linker to the antibody. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including vialing and storage of our product candidates. For the foreseeable future, we expect to 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

25

Table of Contents

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 required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. In addition, we depend on outside vendors for the supply of raw materials used to produce our product candidates. If the third party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

Although we are currently establishing our for commercial scale supply chain for SGN-35, we do not yet have agreements for the supply of our product candidates in quantities sufficient for commercial sale and may not be able to establish or maintain commercial manufacturing arrangements on commercially reasonable terms. Securing commercial quantities of our product candidates from contract manufacturers will require us to commit significant capital and resources. We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties. In addition, contract manufacturers have a limited number of facilities in which our product candidates can be produced and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

Our contract manufacturers are required to produce our clinical product candidates under GMP in order to meet acceptable standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our product candidates. We and our contract manufacturers are subject to periodic unannounced inspection by the FDA and corresponding state and foreign authorities to ensure strict compliance with GMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer s compliance with these regulations and standards. Any difficulties or delays in our contractors manufacturing and supply of product candidates or any failure of our contractors to maintain compliance with the applicable regulations and standards could increase our costs, cause us to lose revenue make us postpone or cancel clinical trials, or cause our products to be recalled or withdrawn.

The FDA requires that we demonstrate structural and functional comparability between the same product candidates manufactured by different organizations. Because we have used or intend to use multiple sources to manufacture many of our product candidates, we will need to conduct comparability studies to assess whether manufacturing changes have affected the product safety, identity, purity or potency of any recently manufactured product candidate compared to the product candidate used in prior clinical trials. If we are unable to demonstrate comparability, the FDA could require us to conduct additional clinical trials, which would be expensive and may significantly delay our clinical progress and the possible commercialization of such product candidates. Similarly, if we believe there may be comparability issues with any one of our product candidates, we may postpone or suspend manufacture of the product candidate to conduct further process development of such product candidate in order to alleviate such product comparability concerns, which may significantly delay the clinical progress of such product candidate or increase its manufacturing costs.

We rely on third parties to provide services in connection with our preclinical and clinical development programs. The inadequate performance by or loss of any of these service providers could affect our product candidate development.

Several third parties provide services in connection with our preclinical and clinical development programs, including *in vitro* and *in vivo* studies, assay and reagent development, immunohistochemistry, toxicology, pharmacokinetics and other outsourced activities. If these service providers do not adequately perform the services for which we have contracted or cease to continue operations and we are not able to quickly find a replacement provider or we lose information or items associated with our product candidates, our development programs may be delayed.

26

Table of Contents

Our ADC technology has not been incorporated into a commercial product and is still at a relatively early stage of development.

Our ADC technology, utilizing proprietary stable linkers and highly potent cell-killing drugs, has not been incorporated into a commercial product and is still at a relatively early stage of development. This ADC technology is used in our SGN-35, SGN-75, AGS-5 ADC and SGN-19A product candidates and is the basis of our collaborations with Genentech, Bayer, CuraGen, Progenics, MedImmune, Daiichi Sankyo and Agensys. We and our corporate collaborators are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although we, CuraGen, Progenics and Genentech have initiated clinical trials of ADC product candidates, additional studies may be required before other ADC product candidates enter human clinical trials. In addition, preclinical models to study patient toxicity and anti-cancer activity of compounds are not necessarily predictive of toxicity or efficacy of these compounds in the treatment of human cancer and there may be substantially different results in clinical trials from the results obtained in preclinical studies. Any failures or setbacks in our ADC program, including adverse effects resulting from the use of this technology in humans, could have a detrimental impact on our internal product candidate pipeline and our ability to maintain and/or enter into new corporate collaborations regarding these technologies, which would negatively affect our business and financial position.

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, if at all.

We have incurred substantial net losses in each of our years of operation and, as of December 31, 2008, we had an accumulated deficit of approximately $314 million. We expect to make substantial expenditures to further develop and commercialize our product candidates, some of which are expected to be reimbursed by Genentech as part of our dacetuzumab collaboration, and anticipate that our rate of spending will accelerate as the result of the increased costs and expenses associated with research, development, clinical trials, manufacturing, regulatory approvals and commercialization of our product candidates. In the near term, we expect our revenues to be derived from technology licensing fees, sponsored research fees and milestone payments under existing and future collaborative arrangements. In the longer term, our revenues may also include royalties from collaborations with current and future strategic partners and commercial product sales if any of our product candidates are approved for commercial sale. However, our revenue and profit potential is unproven and our limited operating history makes our future operating results difficult to predict. We have never been profitable and may never achieve profitability and if we do achieve profitability, it may not be sustainable.

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

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees and support our preclinical development, manufacturing and clinical trial activities, as well as position our product candidates, specifically SGN-35, for potential regulatory approval and commercial sale. Although some of these expenditures are expected to be reimbursed by Genentech as part of our dacetuzumab collaboration, we will continue to need significant amounts of additional capital. We may seek additional funding through public or private financings, including equity financings, and through other means, such as collaborations and license agreements. However, the global credit markets and the financial services industry have recently been experiencing a period of unusual volatility and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. government. These events have generally made equity and debt financing more difficult to obtain. As a result of these recent events and other factors, we do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. 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, which may adversely affect our business and operations. Our future capital requirements will depend upon a number of factors, including:

- the time and costs involved in obtaining regulatory approvals, including the preparation for product commercialization;

27

Table of Contents

- the size, complexity, timing, and number of clinical programs;
- our receipt of milestone-based payments or other revenue from our collaborations or license arrangements, including reimbursements for expenses pursuant to our dacetuzumab collaboration with Genentech;
- the ability to manufacture sufficient drug supply to complete clinical trials;
- progress with clinical trials;
- the costs associated with acquisitions or licenses of additional products, including licenses we may need to commercialize our products;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the potential costs associated with state and federal taxes;
- the timing and cost of milestone payment obligations as our product candidates progress towards commercialization; and
- competing technological and market developments.

In addition, changes in our business may occur that would consume available capital resources sooner than we expect. 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.

We rely on license agreements for certain aspects of our product candidates and technology. Failure to maintain these license agreements or to secure any required new licenses could prevent us from developing or commercializing our product candidates and technology.

We have entered into agreements with third-party commercial and academic institutions to license technology for use in our product candidates and ADC technology. Currently, we have license agreements with Bristol-Myers Squibb, Arizona State University, Genentech, PDL BioPharma, Facet Biotech, CLB Research and Development, CMC ICOS Biologics, Mabtech AB, and the University of Miami, among others. Some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our product candidates. In addition, continued development and commercialization of our product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

If we are unable to enforce our intellectual property rights, we may not be able to commercialize our product candidates. 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 obtaining and maintaining patent protection and successfully defending these patents against third party challenges in the United States and other countries. We own multiple U.S. and foreign patents and pending patent applications for our technologies. We also have rights to issued U.S. patents, patent applications, and their foreign counterparts, relating to our monoclonal antibody and drug-based technologies. Our rights to these patents and patent applications are derived in part from worldwide licenses from Bristol-Myers Squibb, Arizona State University and Facet Biotech, among others. In addition, we have licensed our U.S. and foreign patents and patent applications to third parties.

Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. In particular, the U.S. Patent and Trademark Office issued

Table of Contents

revised regulations affecting prosecution before that office, and various pieces of legislation, including patent reform acts, have been introduced or discussed in the U.S. Senate and Congress in the past few years. If implemented, or following final resolution of pending legislation, these new regulations or legislation could, among other things, restrict our ability to prosecute applications in the U.S. Patent and Trademark Office, limit the number of patent claims in applications that we have previously filed or intend to file, and may lower the threshold required for competitors to challenge our patents in the U.S. Patent and Trademark Office after they have been granted.

The standards that the U.S. Patent and Trademark Office and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our 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 we currently own or obtain in the future 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 may evolve, 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.

We rely on trade secrets and other proprietary information where we believe patent protection is not appropriate or obtainable. However, trade secrets and other proprietary information are difficult to protect. 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 or other proprietary information.

Our research collaborators may publish data and information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

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.

We may face potential patent infringement suits by companies that own or control patents for products similar to our product candidates or suits alleging infringement of such companies other intellectual property. Because patent applications can take many years to publish, there may be currently pending applications of which we are unaware that may later result in issued patents that affect the commercial development of our product candidates. In addition, we are monitoring the progress of multiple pending patent applications of other companies that, if granted, may require us to license or challenge their validity upon commercialization of our product candidates.

The defense and enforcement of intellectual property rights in a court of law, U.S. Patent and Trademark Office interference or reexamination proceedings, foreign opposition 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 limit the scope of intellectual property protection for our proprietary technologies, 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 senior management. Additionally, we have scientific personnel with significant and unique expertise in monoclonal antibodies, ADCs

Table of Contents

and related technologies. The loss of the services of any one of the principal members of our managerial or scientific staff may prevent us from achieving our business objectives.

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial 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, 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 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 many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapy or that are otherwise developing various approaches to cancer and autoimmune disease therapy. Some of these competitors have successfully commercialized antibody products or are developing or testing product candidates that do or may in the future compete directly with our product candidates. For example, we believe that companies including Genentech, Amgen, Bayer, ImmunoGen, Biogen IDEC, Celgene, Cephalon, Genzyme, Medarex, Eisai, Millennium, Novartis and Wyeth are developing and/or marketing products or technologies that may compete with ours, and some of these companies, including Wyeth, ImmunoGen and Medarex, have antibody-drug conjugate technology. Other potential competitors include large, fully integrated pharmaceutical companies and more established biotechnology companies that 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 our product candidates or that would render our technology obsolete or noncompetitive. 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 face product liability risks and may not be able to obtain adequate insurance to protect us against losses.

We currently have no products that have been approved for commercial sale. However, the current and future use of our product candidates by us and our corporate collaborators 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

Table of Contents

consumers or 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 general commercial liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against all 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 operations involve hazardous materials and are subject to environmental, health and safety controls and regulations.

We are subject to environmental, health and safety laws and regulations, including those governing the use of hazardous materials, and we spend considerable time complying with such laws and regulations. Our business activities involve the controlled use of hazardous materials and although we take precautions to prevent accidental contamination or injury from these materials, we cannot completely eliminate the risk of using these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may materially harm our business, financial condition and results of operations.

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

We actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring complementary products, technologies or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation of operations and products, retention of key employees, diversion of our management s attention and uncertainties in our ability to maintain key business relationships of the acquired entities. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Legislative actions, potential new accounting pronouncements and higher insurance costs are likely to impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and may occur again in the future and as a result we may be required to make changes in our accounting policies. Those changes could adversely affect our reported revenues, future profitability or financial position. Compliance with new regulations regarding corporate governance and public disclosure may result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from science and business activities to compliance activities.

Current global credit and financial market conditions may negatively impact or impair the value of our current portfolio of cash equivalents, short-term investments or auction rate securities and our ability to fund our planned operations.

Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments and subject to investment guidelines allowing for investments in government and agency securities, high-grade corporate bonds, taxable municipal bonds, mortgage-backed securities, auction rate securities, or ARS, commercial paper and money market accounts. As a result of the current adverse global credit and financial market conditions, investments in some financial instruments, such as mortgage-backed securities and ARS, may pose risks arising

Table of Contents

from liquidity and credit concerns. For example, as of December 31, 2008 we held ARS valued at $13.4 million that have failed at auction and are currently illiquid. As of the date of this filing, the failed ARS carried ratings ranging from BBB+ to BBB- by Standard & Poor s and ranging from A to BBB by Fitch. Given that further deterioration in the global credit and financial markets is a possibility, no assurance can be made that further downgrades, losses, failed auctions or other significant deterioration in the fair value of our cash equivalents, short-term or long-term investments or ARS will not occur. If any such further downgrades, losses, failed auctions or other significant deteriorations occur, it may negatively impact or impair our current portfolio of cash equivalents, short-term or long-term investments or ARS and our ability to fund our planned operations. Further, unless and until the current global credit and financial market crisis has been sufficiently resolved, it may be difficult for us to liquidate our investments prior to their maturity without incurring a loss.

Risks Related to Our Stock

Our stock price is volatile and our shares may suffer a decline in value.

The market price of our stock has in the past been, and is likely to continue in the future to be, very volatile. During the fourth quarter of 2008, our closing stock price fluctuated between $7.67 and $11.04 per share. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock may be subject to substantial volatility in response to many risk factors listed in this section, and others beyond our control, including:

- announcements regarding the results of discovery efforts and preclinical and clinical activities by us or our competitors, specifically the results of our pivotal trial of SGN-35;
- termination of or changes in our existing corporate partnerships or licensing arrangements, especially our dacetuzumab collaboration with Genentech;
- establishment of new corporate partnering or licensing arrangements by us or our competitors;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory authorities with respect to our product candidates, our clinical trials or our regulatory filings;
- our ability to raise capital;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- developments or disputes concerning our proprietary rights;
- issuance of new or changed analysts reports and recommendations regarding us or our competitors;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

changes in government regulations; and

economic or other external factors.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. Recently, the financial markets have faced almost unprecedented turmoil, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management s attention and resources, which could result in delays of our clinical trials or commercialization efforts.

Table of Contents

Our existing stockholders have significant control of our management and affairs.

Our executive officers and directors and holders of greater than five percent of our outstanding voting stock, together with entities that may be deemed affiliates of, or related to, such persons or entities, beneficially owned approximately 40 percent of our voting power as of March 12, 2009. 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 acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

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 Delaware and Washington related to corporate takeovers may prevent or delay a change of control of Seattle Genetics.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our headquarters are in Bothell, Washington, where we lease approximately 63,900 square feet. We entered into the lease for this facility in December 2000 and use it for laboratory, discovery, research and development and general and administrative purposes. On July 1, 2008, we entered into a lease amendment to extend and modify the terms of this lease. The lease amendment provides for a reduction in the current base rent, an extension of the lease term to June 2018 and a reduction in level of security pledged by us under the lease. We are also entitled to receive a tenant improvement allowance which will be used to offset the cost of improvements to be made to the facility to accommodate our growth. We have two renewal options of five years each and the option to terminate the lease effective June 2013 or June 2015 upon providing notice of our intent to accelerate the termination date of the lease and payment of a termination fee.

In June 2007, we entered into an operating lease for approximately 25,000 square feet of additional office space. The lease expires in June 2018 with two extension options, the first option for three years and the second option period for seven years. The lease allows for options to

terminate the lease effective June 2011 or June 2014. In July 2008, we amended this lease to include an additional 25,000 square feet of office space under the same terms as the original lease.

Item 3. Legal Proceedings.

We are not a party to any material legal proceedings.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2008.

Table of Contents

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Price Range of Our Common Stock

Our common stock is traded on The NASDAQ Global Market under the symbol SGEN. As of March 12, 2009, there were 85,613,588 shares of our common stock outstanding, which were held by approximately 127 holders of record of our common stock. On March 12, 2009, the closing price of our common stock as reported by The NASDAQ Global Market was $8.82 per share.

Our common stock has been quoted on The NASDAQ Global Market under the symbol SGEN since our initial public offering on March 6, 2001. The following table sets forth, for the periods indicated, the reported high and low sales prices per share of our common stock as reported by The NASDAQ Global Market:

	High	Low
2007		
First Quarter	$ 9.52	$ 5.14
Second Quarter	11.43	8.04
Third Quarter	12.12	8.53
Fourth Quarter	13.44	9.70
2008		
First Quarter	$ 11.98	$ 7.20
Second Quarter	10.80	8.18
Third Quarter	13.40	7.80
Fourth Quarter	11.10	6.81
2009		
First Quarter (prior to March 12, 2009)	$ 10.78	$ 7.00

Dividend Policy

We have not paid any cash dividends on our common stock since our inception. We do not intend to pay any cash dividends in the foreseeable future, but intend to retain all earnings, if any, for use in our business operations.

Sales of Unregistered Securities and Issuer Repurchases of Securities

Other than sales disclosed in previous quarterly reports on Form 10-Q or current reports on Form 8-K, we did not make any unregistered sales of shares of our common stock in 2008. In addition, we did not repurchase any of our equity securities during the fourth quarter of 2008.

34

Table of Contents

Stock Performance Graph

We show below the cumulative total return to our stockholders during the period from December 31, 2003 through December 31, 2008 in comparison to the cumulative return on the Nasdaq Pharmaceutical Index, the Nasdaq Composite Index and the Nasdaq Biotechnology Index during that same period. The results assume that $100 was invested on December 31, 2003 in our common stock and each of the indexes listed above, including reinvestment of dividends, if any.

	Years ended					
	12/03	12/04	12/05	12/06	12/07	12/08
Seattle Genetics, Inc.	**100.00**	**76.11**	**55.01**	**62.12**	**132.87**	**104.20**
NASDAQ Composite	**100.00**	**110.06**	**112.92**	**126.61**	**138.33**	**80.65**
NASDAQ Pharmaceutical	**100.00**	**110.37**	**112.07**	**115.01**	**106.58**	**97.41**
NASDAQ Biotechnology	**100.00**	**112.17**	**130.53**	**130.05**	**132.24**	**122.10**

This information under Stock Performance Graph is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of Seattle Genetics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K and irrespective of any general incorporation language in those filings.

Table of Contents

Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with our consolidated financial statements and notes to our consolidated financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations contained elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2008, 2007 and 2006 and Consolidated Balance Sheet data as of December 31, 2008 and 2007 have been derived from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. The selected Consolidated Statements of Operations data for the years ended December 31, 2005 and 2004 and Consolidated Balance Sheet data as of December 31, 2006, 2005 and 2004 have been derived from our audited financial statements that are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues	$ 35,236	$ 22,420	$ 10,005	$ 9,757	$ 6,701
Operating Expenses:					
Research and development	110,944	64,828	40,136	34,683	37,208
General and administrative	16,078	13,237	10,074	7,145	7,161
Loss from operations	(91,786)	(55,645)	(40,205)	(32,071)	(37,668)
Investment income, net	6,285	6,713	4,190	2,638	2,229
Net loss	(85,501)	(48,932)	(36,015)	(29,433)	(35,439)
Non-cash preferred stock deemed dividend					(36,558)
Net loss attributable to common stockholders	$ (85,501)	$ (48,932)	$ (36,015)	$ (29,433)	$ (71,997)
Basic and diluted net loss per share attributable to common stockholders	$ (1.09)	$ (0.80)	$ (0.74)	$ (0.70)	$ (1.80)
Weighted-average shares used in computing basic and diluted net loss per share	78,724	61,293	48,659	42,238	39,985

	December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investment securities	$ 160,708	$ 129,584	$ 86,573	$ 79,207	$ 105,898
Working capital	70,496	90,003	76,880	33,048	30,233
Total assets	187,717	148,530	97,695	90,019	119,109
Stockholders equity	79,018	53,986	88,234	75,458	103,833

Table of Contents

Item 7. 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. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including those relating to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may, might, will, should, expect, plan, anticipate, project, believe, estimate, predict, potential, intend or continue, the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. 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. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading Item 1A Risk Factors. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a clinical stage biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer and autoimmune disease. We initiated a pivotal trial of our lead product candidate, SGN-35, during the first quarter of 2009 for patients with relapsed or refractory Hodgkin lymphoma under a SPA with the FDA. SGN-35 is empowered by our proprietary ADC technology comprising highly potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. In addition, we have three other product candidates in ongoing clinical trials: dacetuzumab, lintuzumab and SGN-70. Dacetuzumab is being developed under a worldwide collaboration with Genentech.

We have collaborations for our ADC technology with a number of leading biotechnology and pharmaceutical companies, including Genentech, Bayer, CuraGen, Progenics, Daiichi Sankyo and MedImmune, a subsidiary of AstraZeneca, as well as an ADC co-development agreement with Agensys, a subsidiary of Astellas Pharma.

We do not currently have any commercial products for sale. While certain of our product candidates are advancing into later stages of development, such as SGN-35, significant further research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. As of December 31, 2008, we had an accumulated deficit of $314.0 million. Over the next several years, we expect that we will incur substantial expenses, primarily the result of activities related to the potential regulatory approval and commercialization of SGN-35, including preparation for commercial manufacturing. We will also continue to invest in research, development and manufacturing and move towards potential commercialization of our other product candidates. Our commitment of resources to the approval and commercialization activities for SGN-35 and the research and continued development and potential commercialization of our other product candidates will require substantial additional funds and resources and our operating expenses will also likely increase as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization. We expect that a substantial portion of our revenues for the next several years will be the result of amortization of payments already received and expected to be received from Genentech under our dacetuzumab collaboration agreement. Until such time as we have commercialized a product candidate, our revenues will also depend on the achievement of development and clinical milestones under our existing

37

Table of Contents

collaboration and license agreements, particularly our dacetuzumab collaboration with Genentech, as well as entering into new collaboration and license agreements. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and you should not rely on them as indicative of our future performance.

Critical Accounting Policies

The preparation of financial statements in accordance with generally accepted accounting principles requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. We believe the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition. Many of our agreements contain multiple revenue elements including upfront payments, license fees, milestone payments, royalties, maintenance fees and payments received for the delivery of supplies or services provided. Each agreement may contain some or all of these elements. The assessment of multiple element arrangements requires judgment in order to determine the appropriate point in time, or period of time, that revenue should be recognized.

Revenue recognition is predicated upon persuasive evidence of an agreement existing, delivery of materials occurring or services being rendered, fees being fixed or determinable and collectibility being reasonably assured. When contracts require us to perform activities that represent substantive continuing obligations and fair value cannot be determined, revenue is recognized over the service period using either a time-based or an activity-based proportional performance model as appropriate in the circumstance. Where activities represent the culmination of a separate earnings process and verifiable evidence of the fair value of each element can be established, revenue is recognized as the activities are completed. When verifiable evidence of fair value cannot be established for each undelivered element, revenue is deferred until all elements have been delivered or until verifiable evidence of the fair value for any undelivered element can be determined.

Nonrefundable upfront license payments, option and maintenance fees and milestone payments:

Our collaborative agreements may include nonrefundable upfront license payments, option and maintenance fees, and payments triggered by the achievement of development milestones by the other party or by us. When we have substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using either a time-based or proportional performance-based approach. When we cannot estimate the total amount of performance obligations that are to be provided under the arrangement, a time-based method is used. Under the time-based method, revenue is recognized over the arrangement s estimated performance period based on the elapsed time compared to the total estimated performance period. When we are able to estimate the total amount of performance obligations under the arrangement, revenue is recognized using a proportional performance model. Under this approach, revenue recognition is based on costs incurred to date compared to total expected costs to be incurred over the performance period as this is considered to be representative of the delivery of service under the arrangement. Changes in estimates of total expected performance costs or service obligation time period are accounted for prospectively as a change in estimate. Under both methods, revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When we have no substantive continuing performance obligations under an arrangement, we recognize milestone payments as revenue upon achievement of the milestone event. Otherwise, milestone payments are recognized using the applicable time-based or performance-based approach for that agreement.

Research and development services:

We may also perform research and development activities on behalf of collaborative partners that are paid for by the collaborator. When no other obligation to provide services is required by us, revenue from research

Table of Contents

and development services is generally recognized as the service is provided. However, if the arrangement provides for other ongoing services by us or contains multiple delivery elements for which verifiable and objective evidence of fair value cannot be established for each element, payments for such services are recognized as revenue over the service period.

Royalties:

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured. To date, we have not received significant royalty revenues.

We generally invoice our collaborators on a monthly or quarterly basis, or upon the completion of the effort, based on the terms of each agreement. Amounts due, but not billed to a collaborator, if any, are included in accounts receivable in the accompanying consolidated balance sheets. Deferred revenue arises from payments received in advance of the culmination of the earnings process and is recognized as revenue in future periods when the applicable revenue recognition criteria have been met. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Investments. Our investments are diversified among high-credit quality debt securities in accordance with our investment policy. We classify our investments as available-for-sale, which are reported at fair market value with the related unrealized gains and losses included in accumulated other comprehensive income or loss in stockholders equity. Realized gains and losses and declines in value of investments judged to be other than temporary are included in investment income. To date, we have not deemed it necessary to record any charges related to other-than-temporary declines in the estimated fair values of our marketable debt securities. The fair value of our investments is subject to volatility. Declines in the fair value of our investments judged to be other than temporary could adversely affect our future operating results. As described below under Liquidity and capital resources we use a probability-weighted cash flow analysis to value our investment in auction rate securities, or ARS.

Accrued Expenses. As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of services performed and the associated costs incurred for such services where we have not yet been invoiced or otherwise notified of actual cost. We record these estimates in our consolidated financial statements as of each balance sheet date. Examples of estimated accrued expenses include fees due to contract research organizations and other costs in conjunction with clinical trials, fees due in conjunction with manufacturing clinical grade materials and professional service fees.

In accruing service fees, we estimate the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. In the event that we do not identify costs that have been incurred or we under or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon the facts and circumstances known to us at the time and in accordance with generally accepted accounting principles.

Research and Development. Research and development expenses consist of salaries, benefits and other headcount related costs of our research and development staff, preclinical activities, clinical trials, lab supplies, manufacturing costs for product candidates used in research and clinical trials, contract and outside service fees and facilities and overhead expenses. Research and development activities are expensed as incurred. In-licensing fees, including milestones and maintenance fees, and other costs to acquire technologies that are utilized in research and

development and that are not expected to have alternative future use are expensed when incurred.

Table of Contents

We account for our clinical trial costs by estimating the total cost to treat a patient in each clinical trial and recognize this cost, based on a variety of factors, beginning with the preparation for the clinical trial, continuing through patient accrual into the clinical trial and completion of the clinical trial. This estimated cost includes payments for clinical trial site and patient-related costs, including laboratory costs related to the conduct of the trial, and other costs. Costs associated with activities performed under research and development co-development collaborations, net of reimbursement paid to and received from, are reflected in research and development expense. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are capitalized and recognized as expense as the related goods are delivered or the related services are performed.

Share-based Compensation. We expense the fair value of share-based payment transactions in our consolidated financial statements in accordance with SFAS 123R, which we adopted in 2006 using the modified prospective application method. We use the Black-Scholes option pricing model to estimate the fair value of options on the date of grant which requires certain estimates to be made by management, including the expected forfeiture rate and expected term of the options. Management also makes decisions regarding the method of calculating the expected stock price volatility and the risk free interest rate used in the model. Fluctuations in the market that affect these estimates could have an impact on the resulting compensation cost. For additional information see Note 9 of the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K.

Income Taxes. We have net deferred tax assets which are fully offset by a valuation allowance due to our determination that it is more likely than not that the deferred assets will not be realized. We believe that a full valuation allowance is appropriate as we expect to incur operating losses for at least the next several years as we continue to pursue the development of our product candidates. In the event we were to determine that we would be able to realize our net deferred tax assets in the future, an adjustment to the deferred tax asset would be made, a portion of which would increase income (or decrease losses) in the period in which such a determination was made.

On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, investments, accrued expenses, research and development, share-based compensation and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions and conditions.

Table of Contents

Results of Operations

Years Ended December 31, 2008, 2007 and 2006

Revenues

Total revenues in 2008 increased by 57% to $35.2 million from 2007, and increased by 124% in 2007 to $22.4 million from 2006. Our revenues reflect amounts earned under our dacetuzumab collaboration agreement with Genentech entered into in January 2007, and the earned portion of technology access fees and milestone payments received under our ADC collaborations, including funded research and material supply fees. Revenues are summarized by collaborator as follows:

Collaboration and license agreement revenue by collaborator ($ in thousands)				Annual percentage change	
	2008	2007	2006	2008/2007	2007/2006
Genentech	$ 28,544	$ 17,397	$ 4,117	64%	323%
MedImmune	1,582	1,402	932	13%	50%
Bayer	1,514	852	929	78%	-8%
CuraGen	1,138	100	1,760	1,038%	-94%
Progenics	968	1,383	1,621	-30%	-15%
Daiichi Sankyo	797			NA	NA
Other collaborations	693	1,286	646	-46%	99%
Total	$ 35,236	$ 22,420	$ 10,005	57%	124%

Revenues earned under our dacetuzumab and our ADC collaborations with Genentech represented 81% of our total revenues in 2008, 78% of our total revenues in 2007 and 41% of our total revenues in 2006. Our ADC collaborations with MedImmune, Bayer, CuraGen, Daiichi Sankyo and Progenics comprised substantially all of the rest of our revenues. Our revenues are impacted by progress-dependent milestones, annual maintenance fees and reimbursement and support fees as our collaborators advance their ADC product candidates through the development process and, in the case of our dacetuzumab collaboration with Genentech, the level of development activities that we perform. We anticipate that revenues in 2009 will increase compared to 2008 primarily as a result of amounts expected to be earned under our dacetuzumab collaboration with Genentech. However, revenue may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their ADC product candidates, the level of support we provide to our collaborators, the timing of milestones achieved and our ability to enter into additional collaboration agreements. In addition, we have a significant balance in deferred revenue representing prior payments from collaborators. This deferred revenue will be recognized as revenue in the future using a time-based approach.

Genentech

We entered into an exclusive worldwide collaboration agreement with Genentech in January 2007 for the development and commercialization of dacetuzumab. Under the terms of the agreement, we received an upfront payment of $60.0 million and are entitled to receive progress-dependent milestone payments and royalties on net sales of any resulting products. In addition, dacetuzumab research and development activities that we perform are reimbursed by Genentech. We received milestone payments of $4.0 million in 2008 and $16.0 million in 2007 triggered by the initiation of dacetuzumab clinical trials. All amounts billed under the dacetuzumab collaboration agreement are deferred and recognized as

revenue over the six year development period ending February 2013 using a time-based method.

We entered into an ADC collaboration with Genentech in April 2002. In March 2007, Genentech extended the term of the collaboration to April 2010 in accordance with the terms of the agreement. In 2008, we received $1.5 million in milestones related to two IND-enabling toxicology approvals and an IND filing. In 2007, Genentech exercised an exclusive license to specific targets and extended the research term under the ADC

Table of Contents

collaboration agreement by paying a fee of $4.5 million. In addition, we receive a renewal fee and other fees as well as reimbursement payments for research and development services and materials provided to Genentech under the collaboration. These payments are deferred and recognized as revenue over the research term of the collaboration using a time-based approach. We are entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Genentech s ADC product candidates progress through development and royalties on product sales of such product candidates.

Revenues under our agreements with Genentech increased by $11.1 million, or 64%, in 2008 from 2007, and increased by $13.3 million, or 323%, in 2007 from 2006. The increase in both periods was primarily due to amounts earned under our dacetuzumab collaboration agreement. A substantial portion of our deferred revenue balance, which totaled $91.3 million as of December 31, 2008, relates to our dacetuzumab collaboration with Genentech and will be recognized into revenue through February 2013 commensurate with our remaining service period commitment pursuant to the collaboration.

MedImmune

We entered into an ADC collaboration agreement with MedImmune, a wholly-owned subsidiary of AstraZeneca, in April 2005 which included an upfront technology access fee of $2.0 million. This fee was recognized as revenue over the two year research period of the collaboration. In October 2007, MedImmune exercised its option to obtain an exclusive license to a second antigen target under the existing ADC collaboration. We received a $1.5 million payment from MedImmune as a result of the option exercise which was recognized as revenue over a twelve month period commensurate with our remaining service period commitment under the agreement. Revenues under our ADC collaboration agreement with MedImmune increased by $180,000 or 13% in 2008. From 2006 to 2007, revenues increased $470,000 primarily due to increased material supply fees. We are entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as MedImmune s ADC product candidate progresses through development and royalties on product sales.

Bayer

We entered into an ADC collaboration agreement with Bayer in September 2004 which included an upfront technology access fee of $2.0 million. This fee was recognized as revenue over the initial three year research period of the collaboration which ended in 2007. In May 2008, we amended the collaboration agreement and Bayer paid an additional fee to extend the term of the collaboration for one additional year. In December 2008, Bayer paid us a preclincial milestone payment. These payments are being recognized as revenue over the extended research term. Revenues under our ADC collaboration agreement with Bayer increased by $662,000, or 78%, in 2008, primarily due to the earned portion of the collaboration extension payment. Revenues decreased by $77,000, or 8%, in 2007, reflecting completion of the recognition of the upfront technology access fee. We are entitled to receive additional progress-dependent milestones and annual maintenance fees as Bayer s ADC product candidate progresses through development and royalties on product sales.

CuraGen

We entered into an ADC collaboration agreement with CuraGen in June 2004 which included an upfront technology access fee of $2.0 million. This fee, along with additional access fees received, was recognized as revenue over the two year research period. In May 2008, we received a $1.0 million milestone payment in connection with the initiation of a phase II clinical trial by CuraGen. This milestone payment was recognized as revenue when received as we had completed our performance obligations under the collaboration. Recognition of the milestone payment was the primary cause of increased revenues from CuraGen in 2008. Revenues in 2007 decreased by $1.7 million, or 94%, due to completion, in 2006, of recognition of the upfront technology access fee. We are entitled to receive additional progress-dependent milestones, annual

maintenance fees and support fees as CuraGen s ADC product candidates progress through development and royalties on product sales.

Table of Contents

Progenics

We entered into an ADC collaboration agreement with PSMA Development Company, which is now a wholly-owned subsidiary of Progenics, in June 2005 which included an upfront technology access fee of $2.0 million. This fee was recognized as revenue over the three year research period of the collaboration. In October 2008, we received a milestone payment in connection with the initiation of a phase I clinical trial by Progenics. This milestone payment was recognized as revenue when received as we had completed our performance obligations under the collaboration. Revenues under our ADC collaboration agreement with Progenics in 2008 decreased by $415,000, or 30%, primarily due to lower revenue attributable to technology access fees, and decreased in 2007 by $238,000, or 15%, reflecting lower funded research and material supply fees. We are entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Progenics ADC product candidate progresses through development, and royalties on product sales.

Daiichi Sankyo

In July 2008, we entered into an ADC collaboration agreement with Daiichi Sankyo Co., Ltd. We received a $4.0 million upfront fee for an exclusive license to our ADC technology to a single antigen target. The upfront fee and other payments received will be recorded as revenue over the three year development term of the collaboration agreement using a time-based approach. We recognized revenues of $797,000 in 2008 associated with the earned portion of the upfront fee as well as the earned portion of materials and services supplied by us to Daiichi Sankyo under the collaboration. We are entitled to receive additional progress-dependent milestones, annual maintenance fees and support fees as Daiichi Sankyo s ADC product candidate progresses through development and royalties on product sales.

Other Collaborations

Other collaborations consist of collaborative agreements that have concluded, research agreements established to explore future business relationships and royalty payments from suppliers to which we have granted limited access to our technology under preferred provider agreements.

Research and development

Research and development expenses increased 71% to $110.9 million in 2008 from 2007, and increased 62% to $64.8 million in 2007 from 2006. Our research and development expenses are summarized as follows:

Research & development ($ in thousands)				Annual percentage change	
	2008	2007	2006	2008/2007	2007/2006
Research	$ 15,219	$ 14,915	$ 12,608	2%	18%
Development and contract manufacturing	44,397	21,810	16,885	104%	29%
Clinical	44,914	22,759	7,586	97%	200%
Share-based compensation expense	6,414	5,344	3,057	20%	75%
Total	$ 110,944	$ 64,828	$ 40,136	71%	62%

Research expenses included, among other things, personnel, occupancy and laboratory expenses associated with the discovery and identification of new monoclonal antibodies and related technologies and the development of novel classes of stable linkers and potent cell-killing drugs for our ADC program. Research expenses also included research activities associated with our product candidates, such as preclinical translational biology and *in vitro* and *in vivo* studies. Research expenses increased moderately during 2008 from 2007, and increased 18% to $14.9 million in 2007 from 2006. The increase in 2008 was related to building-related service costs and contracted costs. The increase in 2007 was primarily due to higher personnel expenses, severance costs, license fees, laboratory supply and building-related service costs.

Table of Contents

Development and contract manufacturing expenses included personnel and occupancy expenses and external contract manufacturing costs for the scale up and manufacturing of drug product for use in our clinical trials, including IND-enabling pharmacology and toxicology studies. Development and contract manufacturing expenses also included quality control and assurance activities, including storage and shipment services of our product candidates for clinical trials. Development and contract manufacturing costs increased 104% to $44.4 million in 2008 from 2007, and 29% to $21.8 million in 2007 from 2006. These increases were primarily driven by increased manufacturing activities, including manufacturing campaigns for clinical supply of SGN-35 and dacetuzumab at Abbott Laboratories during 2008, and for clinical supply of lintuzumab at Laureate Pharma in 2007. In addition, 2008 and 2007 expenses increased reflecting higher compensation costs related to an increase in staffing levels and higher pharmacology and toxicology study costs.

Clinical expenses included personnel expenses, travel, occupancy costs and external clinical trial costs including principal investigator fees, clinical site expenses, clinical research organization charges and regulatory activities associated with conducting human clinical trials. Clinical costs increased 97% to $44.9 million in 2008 from 2007, and 200% to $22.8 million in 2007 from 2006. The increases in both periods related primarily to expanded third party clinical trial costs associated with our SGN-35, dacetuzumab and lintuzumab programs, and compensation costs relating to increased staffing levels.

Share-based compensation expense included in research and development expenses reflects the non-cash charge associated with stock options and the employee stock purchase plan. The fair value of all employee share-based payments is charged to expense over the vesting period of the related share-based payment. Share-based compensation expense increased 20% to $6.4 million in 2008 from 2007, and 75% to $5.3 million in 2007 from 2006. The increase for both periods was primarily due to the higher weighted-average grant date fair value of stock options expensed in 2008 compared to 2007 and in 2007 compared to 2006. Non-cash share-based compensation expense in 2007 also included a charge for accelerated vesting of stock options for employee severance.

We utilize our employee and infrastructure resources across multiple development projects as well as our discovery and research programs directed towards identifying monoclonal antibodies and new classes of stable linkers and cell-killing drugs for our ADC program. We track human resource efforts expended on many of our programs for purposes of billing our collaborators for time incurred at agreed upon rates and for resource planning. We do not track actual costs on a project-by-project basis as it relates to our infrastructure, facility, employee and other indirect costs. We do, however, separately track significant third party costs including clinical trial costs manufacturing costs and other contracted service costs on a project-by-project basis.

The following table shows expenses incurred for preclinical study support, contract manufacturing for clinical supplies and clinical trial services provided by third parties as well as milestone payments for in-licensed technology for each of our product candidates. The table also presents unallocated costs, which consist of personnel, facilities and other indirect costs not directly allocated to development programs:

Product candidates ($ in thousands)				Annual Percentage Change		(5 years) January 1, 2004 to December 31, 2008
	2008	2007	2006	2008/2007	2007/2006	
dacetuzumab (SGN-40)	$ 4,068	$ 4,795				

Table of Contents

ENERGY FOCUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2011

(Unaudited)

NOTE 10. INCOME TAXES

At September 30, 2011, the Company has recorded a full valuation allowance against its deferred tax asset in the United States, due to uncertainties related to the Company s ability to utilize its deferred tax assets, primarily consisting of certain net operating losses carried forward. The valuation allowance is based upon the Company s estimates of taxable income by jurisdiction and the period over which its deferred tax assets will be recoverable.

NOTE 11. COMMITMENTS AND CONTINGENCIES

In August 2011, the Company and its landlord for the Solon, Ohio office, located at 32000 Aurora Road, finalized an amended and restated sublease agreement that resolved past due amounts under the lease agreement, which expired April 30, 2011, as well as the terms by which the Company and its landlord entered into an extension of the previous lease. The terms of the agreement include a reduction of the gross rent to $25,000 for the period September 1, 2010 to April 30, 2011 (the period), an extension of the lease until April 30, 2014 with a Company option to extend thereafter and a reduction in both the square footage of the premises and the gross rent per square foot to be paid from May 1, 2011 to April 30, 2014. In conjunction with the signing of the lease agreement and to satisfy past due amounts, the Company delivered an unsecured Promissory Note to the landlord. For details relating to this promissory note, please see Note 7 *Long Term Borrowings*.

In connection with the acquisition of SRC, the Company maintains a performance-related contingent obligation related to a 2.5% payout based upon the annual revenues of the acquired business over 42 months commencing January 1, 2010, and a $500,000 fee if the market price of the Company s common stock is not equal to or greater than $2.00 per share for at least twenty trading days between June 30, 2010 and June 30, 2013. The Company accrued for this potential fee at the time of the agreement. For the three and nine months ended September 30, 2011, the Company has paid $86,000 and $255,000, respectively, relating to this 2.5% payout. For the three and nine months ended September 30, 2010, the Company has paid $123,000 and $380,000, respectively.

NOTE 12. RELATED PARTY TRANSACTIONS

In November, 2009, the Company received an additional $3,344,000 in equity financing, net of expenses by selling 4,813,000 shares of common stock in a registered offering. The investment was made by numerous current Energy Focus shareholders, including two then current members of the Company s Board of Directors. The investment was made under the Company s registration statement for a $3,500,000 common stock subscription rights offering. Under the terms of the rights offering, the Company distributed, at no charge to its shareholders, transferable rights to purchase up to $3.5 million of the Company s common stock at the established subscription price per share of $0.75, which was set by the Company s Board of Directors. At the time the offering began, the Company distributed to each shareholder one transferable right for each share of common stock owned by the shareholder. Each right entitled the holder to purchase one share of the Company s common stock, par value $0.0001 per share, subject to a maximum of 4,600,000 shares to be issued in the offering. Shareholders were entitled to subscribe for shares not subscribed for by other shareholders. Among the investors were Philip E. Wolfson, a member of the Company s Board of Directors at the time of the transaction, and who invested approximately $8,000 in the aggregate. Also among the investors was Quercus, whose trustees include David Gelbaum, who was a member of the Company s Board of Directors at the time of the offering.

In the Company s subscription rights offering discussed above, an investor inadvertently purchased 1,000,000 shares of our common stock at $0.75 per share. The Company agreed to facilitate the sale of these shares to another shareholder or investor or to purchase them directly. A purchase of those shares by the Company would have severely depleted its cash-on-hand and working capital. After contacting selected shareholders and investors, the Company introduced the investor to Quercus, one of the Company s large shareholders. The Company was informed on December 30, 2009, by the investor and Quercus that Quercus had agreed to purchase those shares at $0.80 per share. At that time, the closing market price of a share of the Company s common stock was approximately $0.65 per share. To facilitate the purchase of the 1,000,000 shares by Quercus, on December 30, 2009, the Company s Board of Directors agreed with Quercus to reduce the exercise price of 1,560,062 warrants issued to Quercus, in the March 2008 private placement, to $0.01 per share upon the completion of the purchase of all

1,000,000 shares in 2010. The purchase of the 1,000,000 shares by Quercus was completed on February 20, 2010. The Company incurred a non-cash charge of $1,421,000 for the quarter ended June 30, 2010 related to the valuation of the warrants to purchase shares of the Company s common stock acquired by Quercus in the Company s March 2008 equity financing. On April 28, 2010, Quercus exercised the 2008 warrants. The Company s shareholders approved the reduction in exercise price of the above mentioned warrants at its Annual Meeting on June 16, 2010.

Table of Contents

ENERGY FOCUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2011

(Unaudited)

On December 29, 2009, and in conjunction with the acquisition of SRC, the Company entered into Letter of Credit Agreements (LOC s) with John Davenport, President of the Company, and with Quercus, for $250,000 and $300,000, respectively. Additionally, on August 11, 2011, the Company entered into a LOC with Mark Plush, the CFO of Energy Focus, for $250,000. Please refer to Note 7 *Long-Term Borrowings* for further details regarding the terms of these LOC s.

The Vice President of SRC is a minority owner in TLC as well as in Woodstone Energy, LLC (Woodstone), a Tennessee limited liability company, both of which are located in Nashville, Tennessee.

SRC renders lighting design and lighting solution services to these related parties within the scope of their ordinary business activities. Conversely, these related parties, operating as electrical subcontractors, provide installation support services to SRC as part of their normal business. For the three months ended September 30, 2011 and 2010, related party sales totaled $424,000 and $1,542,000, respectively. Related party sales for the nine months ended September 30, 2011, and 2010 totaled $1,358,000 and $5,485,000, respectively. Of these sales, the Company had $555,000 of receivables, including retainage, at September 30, 2011. Subcontractor installation support services and materials provided by related parties for the three and nine months ended September 30, 2011 was $1,176,000 and $5,049,000, respectively. For the three and nine months ended September 30, 2010, subcontractor installation support services and materials was $3,257,000 and $10,837,000, respectively. Of the support services provided, $1,427,000 was payable at September 30, 2011.

With the acquisition of SRC, the Company entered into an agreement with the seller, TLC, whereby, SRC would be guaranteed a profit percentage of 25% on certain projects which were begun prior to the acquisition or were out for bid at the time the acquisition occurred on December 31, 2009. During 2010, a significant portion of our projects were subject to this guarantee. During 2011, SRC continues to utilize TLC as an electrical subcontractor on certain projects which were not begun or were not out for bid at the time of the acquisition and, therefore, would not be subject to the guaranteed 25% gross profit percentage on these projects.

In connection with the acquisition of SRC on December 31, 2009, the Company entered into an agreement with TLC whereby a Convertible Promissory Note (Convertible Note) was issued for the principal amount of $500,000. This Convertible Note bears interest at a rate of the Wall Street Journal Prime Rate plus two percent (2%), which along with the principal, is due and payable on June 30, 2013. This Convertible Note is secured by a first-lien-position security interest in all assets of SRC. Additionally, TLC has the right to convert the principal of the Convertible Note, in whole, into 500,000 shares of the Company s common stock at any time during the period commencing on June 30, 2010 and ending on the maturity date. Additionally, as a provision to the Convertible Note, if the reported closing price of a share of the Company s common stock shall not be equal to or greater than $2.00 for at least twenty (20) trading days between June 30, 2010 and June 30, 2013, the Company shall pay TLC an additional fee of $500,000 on the maturity date.

On December 31, 2009, the Company issued to Woodstone warrants to purchase up to 600,000 shares of the Company s common stock at an exercise price of $0.65 per share, and with a term ending on December 31, 2014. The warrants become exercisable only if SRC receives from Woodstone firm contracts or purchase orders for at least $10,000,000 by June 30, 2013. The warrants vest in two tranches: 400,000 shares when contracts or purchase orders between SRC and Woodstone reach $10,000,000 and an additional 200,000 shares when contracts or purchase orders between SRC and Woodstone reach an additional $5,000,000. As of September 30, 2011, no warrants related to this issuance have vested.

The Company, in the agreement for the acquisition of SRC, provided for payment of a management fee to TLC for overhead expenses in support of up to $20,000,000 in project billings for 2010 on those projects which TLC provided installation support services. The management fee totaled $1,232,000, payable in equal monthly installments, and began January 31, 2010 and ended on December 31, 2010. Furthermore, an additional 8% management fee is payable for project billings above $20,000,000 in fiscal year 2010 and for fiscal years after December 31, 2010, where TLC provides installation support services on projects that were pending at the date of acquisition of SRC. For the fiscal year ending December 31, 2010, the Company did not exceed the $20,000,000 threshold and incurred only the $1,232,000 of management fees as stipulated in the agreement. For the three months ended September 30, 2011 and 2010, the Company incurred $75,000 and $308,000, respectively, of expense relating to this management fee. For the nine months ended September 30, 2011 and 2010, the Company incurred

$343,000 and $924,000, respectively, of expense relating to this management fee.

Table of Contents

ENERGY FOCUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2011

(Unaudited)

NOTE 13. LEGAL MATTERS

On January 29, 2010, a competitor and former supplier filed a complaint against the Company in the Court of Chancery of the State of Delaware, alleging that the Company had misused proprietary trade secrets, breached a contract, and engaged in deceptive trade practices relating to one of the Company s lighting products. The complaint sought injunctive relief and damages. The Company answered the complaint and filed a counterclaim for breach of contract. The parties settled and dismissed the case in the second quarter of 2011. In the opinion of management, neither the defense of the lawsuit nor the implementation of the settlement has had or will have an adverse effect on the Company s financial condition, cash flows, or results of operations.

NOTE 14. SUBSEQUENT EVENTS

None.

Table of Contents

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the Condensed Consolidated Financial Statements (financial statements) and related notes included elsewhere in this report and the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2010.

When used in this discussion, the words expects, anticipates, estimates, plan, and similar expressions are intended to identify forward-looking statements. These statements, which include statements as to our expected sales and gross profit margins, expected operating expenses and capital expenditure levels, our sales and marketing expenses, our general and administrative expenses, expected expenses related to compliance with the Sarbanes-Oxley Act of 2002, the adequacy of capital resources and necessity to raise additional funds, our critical accounting policies, expected benefits from our consolidation and statements regarding pending litigation are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These risks and uncertainties include, but are not limited to, those risks discussed below, as well as our ability to manage expenses, our ability to reduce manufacturing overhead and general and administrative expenses as a percentage of sales, our ability to collect on doubtful accounts receivable, our ability to increase cash balances in future quarters, the cost of enforcing or defending intellectual property, unforeseen adverse competitive, economic or other factors that may impact our cash position, risks associated with raising additional funds, and risks associated with our pending litigation. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Overview

Energy Focus, Inc. and its subsidiaries engage in the design, development, manufacturing, marketing, and installation of energy-efficient lighting systems and solutions where we serve two segments:

- product-based sales providing military, general commercial and industrial lighting and pool lighting offerings, each of which markets and sells energy-efficient lighting systems; and

- solutions-based sales providing turnkey, high-quality, energy-efficient lighting application alternatives primarily to the existing public-sector building market.

We continue to evolve our business strategy to include providing our customers with turnkey, comprehensive energy-efficient lighting solutions, which use, but are not limited to, our patented and proprietary technology. Our product-based solutions include light-emitting diode (LED), fiber optic, high-intensity discharge (HID), fluorescent tube and other highly energy-efficient lighting technologies. Typical savings related to our current technology approximates 80% in electricity costs, while providing full-spectrum light closely simulating daylight colors. Our strategy also incorporates continued investment into the research of new and emerging energy sources including, but not limited to, LED and solar energy applications.

Our development of solar technology continues through our role in the United States Government s Very High Efficiency Solar Cell (VHESC) Consortium sponsored by the Defense Advanced Research Projects Agency (DARPA). The goal of the VHESC project is to develop a 40% or greater efficient solar cell for United States military applications, which would also ultimately become available to the public for commercial application.

Results of Operations

Cash Utilization

Cash and cash equivalents were $1,890,000 at September 30, 2011 as compared to $4,107,000 at December 31, 2010. This represents a decrease in cash and cash equivalents of $2,217,000 for the nine months ended September 30, 2011. Included in cash and cash equivalents at September 30, 2011 and December 31, 2010 is $87,000 and $128,000, respectively, of restricted cash related to funds received from a grant from/for a branch of United States government. For nine months ended September 30, 2010, cash increased $1,686,000 and included $1,150,000 of cash received from the selling of a Secured Subordinated Promissory Note in the first quarter of 2010.

20

Table of Contents

Net Sales and Gross Profit

Solutions-based net sales were $2,014,000 and $7,960,000 for the three and nine months ended September 30, 2011, respectively, compared to $4,416,000 and $14,631,000 for the three and nine months ended September 30, 2010, respectively. This decrease is related to the size and number of projects which were completed in the first half of 2011 and the size and number of projects signed and started during the nine months ended September 30, 2011. Our solutions-based backlog at September 30, 2011 and 2010 was $854,000 and $3,946,000, respectively. This decrease in our backlog is a result of delays and number of signed contracts coming to realization during the first half of 2011 and available for start during the third quarter of 2011. Product-based net sales were $4,032,000 for the three months ended September 30, 2011 as compared to $4,633,000 for the three months ended September 30, 2010. Product-based net sales increased slightly to $11,739,000 for the nine months ended September 30, 2011 as compared to $11,733,000 for the nine months ended September 30, 2010.

Revenues from our products-based business include, but are not limited to, revenues recognized upon shipping, product sale at completion of installation and installation service at completion of installation. Revenues from our lighting solutions-based business include, but are not limited to, revenues recognized from long-term contracts on a percentage-of-completion basis or the fair value of certain contract deliverables. For a detailed discussion on our revenue recognition policy, see our Annual Report on Form 10-K for the year ended December 31, 2010.

Gross profit was $1,215,000 for the three months ended September 30, 2011 compared to $1,862,000 for the three months ended September 30, 2010. The gross profit margin, as a percentage of sales, was 20.1% for the three months ended September 30, 2011, as compared to 20.6% for the three months ended September 30, 2010. Reserves for excess and obsolete inventory increased $171,000 compared to the prior year s third quarter, which had a 2.8% unfavorable impact on gross profit margins for the three months ended September 30, 2011. Gross profit was $3,922,000 for the nine months ended September 30, 2011 compared to $4,825,000 for the three months ended September 30, 2010. The gross profit margin, as a percentage of sales, increased 1.6 percentage points to 19.9% for the nine months ended September 30, 2011, as compared to 18.3% for the nine months ended September 30, 2010. For the nine months ended September 30, 2011, the increase in the gross profit margin are primarily the result of slightly higher profit margins relating to our product-based net sales coupled with a reduction in manufacturing overhead costs associated with our US product-based business, which was partially offset by slightly lower margins in our solutions-based business.

Research and Development

Gross research and development income was $362,000 for the quarter ended September 30, 2011, compared to expense of $164,000 for the quarter ended September 30, 2010. For the nine months ended September 30, 2011 and 2010, gross research and development expenses were $443,000 and $566,000, respectively.

Research and development expenses include salaries, contractor and consulting fees, supplies and materials, as well as costs related to other overhead such as depreciation and facilities costs. Research and development costs are expensed as they are incurred. Our gross research and development expenses are reduced on a proportional performance basis under SBIR development contracts. During 2009, 2010 and 2011, SBIR contracts were signed totaling $4,148,000 to be reimbursed over a three-year recovery period, respectively. Of this total contract amount, $2,439,000 was billed through September 30, 2011 with the remaining $1,709,000 to be billed in the future, which will reduce gross research and development expenses. The amount of expenses incurred and accrued from SBIR government contracts was $84,000 for the quarter ended September 30, 2011, compared to $186,000 in credits for the same period in 2010. For the nine months ended September 30, 2011 and 2010, the amount of credits incurred and accrued from government contracts were $587,000 and $667,000, respectively. We are currently pursuing additional contracts through various government agencies, and anticipate being granted additional contracts in 2012.

When the government contract is for the delivery of a product or service, we recognize revenues from those government projects according to proportional performance method or actual deliveries made. Costs related to the completion of the sale are charged to cost of sales. Revenues recognized from completed deliveries were $905,000 and $939,000 for the quarters ended September 30, 2011 and 2010, respectively. Revenues recognized for the nine months ended September 30, 2011 and 2010 were $2,590,000 and $2,305,000, respectively.

Total government reimbursements are the combination of revenues and credits from government contracts. For the quarters ended September 30, 2011 and 2010, our net credits were $821,000 and $1,125,000, respectively. Net credits for the nine months ended September 30, 2011 and 2010 were $3,177,000 and $2,972,000, respectively. Net research and development income was $278,000 for the quarter ended September 30, 2011, compared to $22,000 for the same period in 2010. Net research and development income for the nine months ended September 30, 2011 was $144,000, compared to $101,000 for the same period in 2010.

21

Table of Contents

The gross and net research and development spending along with credits from government contracts is shown in the following table (in thousands):

	Three months ended		Nine months ended	
	September 30,		September 30,	
Net Research & Development Spending	2011	2010	2011	2010
Revenues	$ 905	$ 939	$ 2,590	$ 2,305
Expenses:				
Gross research and development income / (expense)	362	(164)	(443)	(566)
(Expense) / credits from government contracts	(84)	186	587	667
Net research and development income	$ 278	$ 22	$ 144	$ 101

Sales and Marketing

Sales and marketing expenses decreased 11.4% to $1,524,000 for the three months ended September 30, 2011, as compared to $1,721,000 for the three months ended September 30, 2010. The decrease was due primarily to lower commission expense. For the nine months ended September 30, 2011, sales and marketing expenses increased 4.9% to $5,095,000, as compared to $4,858,000 for the nine months ended September 30, 2010. This increase is primarily the result of an increase in sales incentive costs and costs associated with new product introduction.

General and Administrative

General and administrative expenses decreased $316,000, or 20.7%, to $1,212,000 for the three months ended September 30, 2011, as compared to $1,528,000 for the three months ended September 30, 2010. The decrease was due mainly to lower amortization expense related to intangible assets. For the nine months ended September 30, 2011, general and administrative expenses decreased $889,000, or 18.8%, to $3,834,000, as compared to $4,723,000 for the nine months ended September 30, 2010. The decreases are primarily the result of a reduction in amortization expense related to our intangible assets relating to the acquisition of SRC and a decrease in legal and accounting fees.

Valuation of Equity Instruments

In the nine months of 2011, we recognized non-cash charges of $56,000 relating to the valuation of our common stock upon the issuance of 412,000 shares to Lincoln Park Capital Partners, LLC. During the nine months of 2010, we recognized a non-cash charge of $1,421,000 related to the revaluation of warrants to purchase shares of our common stock acquired by The Quercus Trust (Quercus) in our March 2008 equity financing. In addition, we recognized non-cash charges of $329,000, primarily related to the valuation of 350,000 warrants issued to Lincoln Park Capital Partners in May, 2010 and $53,000 of non-cash charges relating to 191,000 shares of our common stock issued to LPC during the nine months ending September 30, 2011. Please refer to Note 12, *Related Party Transactions*, of our financial statements for a discussion of the transaction with Quercus.

Restructuring Expenses

During the three and nine months ended September 30, 2011, we did not incur any restructuring expenses. For the nine months ended September 30, 2010, we recognized restructuring expenses of $26,000, all of which was incurred during the first quarter. These expenses are associated with the relocation of our manufacturing equipment and operations from Solon, Ohio to a warehouse facility located in California.

Other Income and Expenses

We had interest income of $1,000 and interest expense of $207,000 for the three months ended September 30, 2011. For the nine months ended September 30, 2011, we had interest income of $4,000 and interest expense of $582,000. Interest income consists of interest earned on deposits. Interest expense includes interest on our long-term borrowings and contingent consideration, including any amortization of debt discounts related to these commitments. Please refer to Note 7, *Long-Term Borrowings*, of our financial statements for a more detailed discussion of our

borrowings. For the three months ended September 30, 2010, interest income was $1,000 and interest expense was $154,000. For the nine months ended September 30, 2010, interest income was $4,000 and interest expense was $404,000.

Net loss

We recorded a net loss of $1,459,000 for the three months ended September 30, 2011 compared to a net loss of $1,563,000 for the three months ended September 30, 2010, a 6.7% decrease from the same period last year. For the nine months ended September 30,

Table of Contents

2011, we recorded a net loss of $5,445,000, a 21.6% decrease compared to a net loss of $6,945,000 for the nine months ended September 30, 2010.

Liquidity and Capital Resources

Cash and Cash Equivalents

At September 30, 2011, our cash and cash equivalents were $1,890,000, including restricted cash of $87,000 relating to funds received from a grant from/for a branch of United States government, as compared to $4,107,000, including restricted cash of $128,000, at December 31, 2010, a net cash decrease of $2,217,000 for the nine months ended September 30, 2011. This compares to a net cash increase of $1,686,000 for nine months ended September 30, 2010, which included $1,150,000 of cash received from the selling of a Secured Subordinated Promissory Note.

Net Cash Used in Operating Activities

Net cash used in operating activities primarily consists of our net loss adjusted by non-cash items, including depreciation, amortization, equity valuations and stock-based compensation, as well as the effect of changes in working capital. Net cash used in operating activities was $3,043,000 for the nine months ended September 30, 2011 compared to net cash provided of $155,000 for the nine months ended September 30, 2010. This increase in cash usage is primarily the result of the timing of disbursements to subcontractors and certain vendors in support of our solutions-based business as well as expenditures incurred relating to our ongoing government contracts.

Net Cash Used in Investing Activities

Net cash used in investing activities was $213,000 for the nine months ended September 30, 2011, compared to a net cash usage of $119,000 for the nine months ended September 30, 2010. During both periods, the net cash used was primarily for the acquisition of equipment relating to our information systems.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $1,037,000 for the nine months ended September 30, 2011. The cash provided was primarily due to $407,000 of proceeds received from the issuance of 412,000 shares of our common stock to Lincoln Park Capital Fund, LLC (LPC) as described in further detail below, the issuance of a $355,000 unsecured promissory note and $250,000 received in an letter of credit agreement with our Chief Financial Officer, Mark Plush, both of which are described in further detail below under the caption Long-Term Borrowings. Net cash provided by financing activities for the nine months ended September 30, 2010 was $1,643,000 which was primarily the result of us issuing a secured subordinated note payable to EF Energy Partners.

As referenced above, on March 17, 2010, we entered into a Purchase Agreement (the Purchase Agreement) with LPC of Chicago, Illinois and issued to them 120,000 shares of our common stock. Under the Purchase Agreement, on May 31, 2010, we sold and issued to LPC, and LPC purchased from us, 360,500 shares of our common stock, together with warrants (Warrants) to purchase 350,000 shares at an exercise price of $1.20 per share, for a total consideration of $375,000. The Warrants have a term of five years, are not exercisable until December 1, 2010, and expire on December 1, 2015. Under the Purchase Agreement, LPC has also agreed to purchase up to an additional 3,650,000 shares of our common stock at our option over approximately 25 months. As often as every five (5) business days, we have the right to direct LPC to purchase a calculated number of shares as defined by the terms of the Purchase Agreement. We can suspend purchases or accelerate the number of shares to be purchased at any time. No sales of shares may occur below $1.00 per share. The purchase prices of the shares will be based on the market prices of our shares at the time of sale, as computed under the Agreement without any fixed discount. We may at any time in our sole discretion terminate the Agreement without fee, penalty, or cost upon five business dates notice. In connection with the transactions contemplated by the Purchase Agreement, we filed a Registration Statement (the Registration Statement) with the U.S. Securities & Exchange Commission (the SEC) to register under the Securities Act of 1933, as amended, the shares of common stock associated with this transaction. On July 14, 2010, we received a Notice of Effectiveness from the SEC relating to the Registration Statement. As of December 31, 2010, we sold and issued to LPC, and LPC purchased from us, a total of 705,550 shares of our common stock for a total consideration of $791,000 which was offset by expenses of $139,000. In the first nine months of 2011, we sold and issued to LPC, and LPC purchased from us, a total of 412,000 shares of our common stock for a total consideration of $407,000. Although we retain the right, in our sole discretion, to terminate the agreement without fee, penalty, or cost, we reserve the right to continue to utilize this financing activity for general corporate and working capital purposes and pursuit of our business strategy.

On May 18, 2011 we received a notification from the NASDAQ Listing Qualifications Department indicating that, for the last 30 consecutive business days, the bid price of the Company s common stock had closed below the minimum $1.00 per share requirement for continued listing on

the NASDAQ Capital Market under NASDAQ Listing Rule 5550(a)(2). The Company, in accordance with NASDAQ Listing Rule 5810(c)(3)(A), has been provided 180 calendar days, or until November 14, 2011, to regain compliance with

Table of Contents

the minimum $1.00 per share requirement. If at any time during this grace period the bid price of our common stock closes at or above $1.00 per share for a minimum of ten consecutive days, the NASDAQ Stock Market will provide us with a written confirmation of compliance and the matter will be closed.

If we do not regain compliance with Listing Rule 5550(a)(2) by November 14, 2011, the Company may be notified that its common stock is subject to delisting. At that time, the Company may appeal NASDAQ s determination to delist its common stock to a Hearings Panel.

Long-Term Borrowings

On May 27, 2009, we entered into an unsecured promissory note (the Note) with Quercus in the amount of $70,000. Under the terms of this Note, we are obligated to pay Quercus the principal sum of the Note and interest accruing at a yearly rate of 1.00% in one lump sum payment on or before June 1, 2109. We received these funds on June 9, 2009.

On December 29, 2009 and in conjunction with the acquisition of SRC, we entered into Letter of Credit Agreements (LOC s) with John Davenport, President of Energy Focus, and with Quercus, for $250,000 and $300,000, respectively. These LOC s have terms of 24 months and bear interest at a rate of 12.5% on the face amount. The LOC s are collateralized by 15% and 18%, respectively, of the capital stock of Crescent Lighting Ltd. (CLL), which in turn is based on CLL s net worth as of November 30, 2009 and are subordinated to the senior indebtedness of Energy Focus and CLL. As an incentive to enter into the LOC s, we issued five-year, detached warrants to purchase 125,000 and 150,000 shares, respectively, of common stock at an exercise price of $0.01 per share. Our shareholders approved the warrants at the Annual Meeting on June 16, 2010.

In connection with the acquisition of Stones River Companies, LLC. (SRC) on December 31, 2009, we entered into an agreement with TLC Investments, LLC (TLC), whereby a Convertible Promissory Note (Convertible Note) was issued for the principal amount of $500,000. This Convertible Note bears interest at the Wall Street Journal Prime Rate plus two percent (2%), which along with the principal, is due and payable on June 30, 2013 (maturity date). This Convertible Note is secured by a first-lien-position security interest in all assets of SRC. Additionally, TLC has the right to convert the principal of the Convertible Note, in whole, but not in part, into 500,000 shares of our common stock at any time during the period commencing on June 30, 2010 and through the maturity date. Additionally, as a provision to the Convertible Note, if the reported closing price of a share of our common stock is not equal to or greater than $2.00 for at least twenty (20) trading days between June 30, 2010 and June 30, 2013, we shall pay TLC an additional fee of $500,000 on the maturity date. We accrued for this potential fee at the time of the agreement.

On March 30, 2010, we entered into an agreement with EF Energy Partners LLC (EF Energy), an Ohio limited liability company, under which it sold to EF Energy a Secured Subordinated Promissory Note (Subordinated Note) for the principal amount of $1,150,000. We secured the full amount of this financing with a pledge of its United States gross accounts receivable and selected capital equipment. This Subordinated Note bears interest at a rate of 12.5%, which is payable quarterly, in arrears, commencing September 30, 2010. The entire outstanding principal balance of this Subordinated Note, together with all accrued interest thereon, is due and payable on March 30, 2013. Additionally, we issued to the eight investors in EF Energy five-year, detached penny warrants ($.01 per share) to purchase shares of its common stock at a rate of 0.2 warrants per dollar of financing, or 230,000 warrants, with an expiration date of March 30, 2015. We are not affiliated with EF Energy Partners.

On August 11, 2011 we entered into a Letter of Credit Agreement (LOC) with Mark Plush, our Chief Financial Officer, for $250,000. This LOC has a term of 24 months and bears interest at a rate of 12.5% on the face amount. The LOC is collateralized by the assignment of proceeds of the cash collateral on deposit with the insurance company related to our surety bonding program. This LOC is subordinated to the senior indebtedness of the Energy Focus. As an incentive to enter into the LOC, we issued five-year, detached warrants to purchase 125,000 shares of common stock at an exercise price of $0.01 per share. We did not register the offering and issuance of the warrant, or of the underlying shares of common stock, under the Securities Act of 1933, as amended, in reliance upon the exemption from registration under the Act in Section 4(2) of the Act. The purchaser of the warrants qualifies as an accredited investor under the U.S. Securities and Exchange Commission s Regulation D.

In conjunction with the signing of the lease agreement for the Solon, Ohio office building on August 1, 2011 and to satisfy past due rent amounts, we delivered an unsecured promissory note to our landlord in the amount of $676,000 which bears interest at a rate of 10% annually commencing May 1, 2011 and has a maturity date of April 30, 2014. In addition, we made a payment of approximately $121,000 on May 9, 2011, not subject to interest, and made gross rent payments of $200,000, during the period September 1, 2010 to April 30, 2011, which reduced the balance of the promissory note at inception to $355,000.

Through its United Kingdom subsidiary, we maintain a British pounds sterling-denominated bank overdraft facility with Lloyds Bank Plc, in the amount of £100,000, which was approximately $156,000 based on the exchange rate at September 30, 2011. There were no borrowings against this facility as of September 30, 2011 or December 31, 2010. This facility is renewed annually on January 1. The interest rate for this facility in

2011 is a variable interest rate equal to the Bank of England s Bank Rate, which was 0.50% at September 30, 2011, plus 3.10%. The interest rate on the facility at December 31, 2010 was 2.75%.

Table of Contents

Liquidity

Historically, we have incurred losses attributable to operational performance which have negatively impacted cash flows. Although management continues to address many of the legacy issues that have historically burdened our financial performance, we still face challenges in order to reach profitability. In order for us to attain profitability and growth, we will need to successfully address these challenges, including the continuation of cost reductions throughout the organization, execution of our marketing and sales plans for our turnkey energy-efficient lighting solutions business, execution of the $23 million U.S. Navy supply contract, the development of new technologies into sustainable product lines and continued improvements in supply chain performance.

We remain optimistic about obtaining the funding necessary to meet on-going tactical and strategic capital requirements. However, there can be no assurances that this objective will be successful. As such, we will continue to review and pursue selected external funding sources, if necessary, to execute these objectives including the following:

- obtain financing from traditional and non-traditional investment capital organizations or individuals,
- potential sale or divestiture of one or more operating units, and
- obtain funding from the sale of common stock or other equity or debt instruments.

Obtaining financing through the above-mentioned mechanisms contains risks, including:

- loans or other debt instruments may have terms and/or conditions, such as interest rate, restrictive covenants, and control or revocation provisions, which are not acceptable to management or the Board of Directors,
- the current economic environment combined with our capital constraints may prevent us from being able to obtain any debt financing,
- financing may not be available for parties interested in pursuing the acquisition of one or more of our operating units, and
- additional equity financing may not be available in the current economic environment and could lead to further dilution of shareholder value for current shareholders of record.

Critical Accounting Policies

The preparation of our financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingencies, and the reported amounts of net sales and expenses in the financial statements. Material differences may result in the amount and timing of net sales and expenses if different judgments or different estimates were utilized. Critical accounting policies, judgments, and estimates which we believe have the most significant impact on our financial statements include, but are not limited to, the establishment of reserves for accounts receivable, sales returns, inventory obsolescence, and warranty claims; the useful lives for property, equipment, and intangible assets; revenues recognized on a percentage-of-completion basis; and stock-based compensation. In addition, estimates and assumptions associated with the determination of fair value of financial instruments and evaluation of goodwill and long-lived assets for impairment requires considerable judgment. For the detailed discussion of the application of policies critical to our business operations, see our Annual Report on Form 10-K for the year ended December 31, 2010.

Recent Accounting Pronouncements

In April 2011, the Financial Accounting Standards Board (FASB) issued revisions to the accounting guidance related to troubled debt restructuring. This new guidance is effective for the first interim or annual period beginning on or after June 15, 2011 and should be applied retrospectively to the beginning of the annual period of adoption. The adoption of this new guidance did not have a material effect on the Company s consolidated results of operations, cash flows or financial position.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2011, we had British pounds sterling-denominated cash valued at $287,000 held in the United Kingdom, based on the exchange rate at that date. The balances for cash held in the United Kingdom are subject to exchange rate risk. We have a policy of maintaining cash balances in local currency unless an amount of cash is occasionally transferred in order to repay inter-company debts.

Table of Contents

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

We maintain disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the Exchange Act), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet, and management believes that they meet, reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. Any design of disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that, subject to the limitations noted above, our disclosure controls and procedures were effective to ensure that material information relating to us, including our consolidated subsidiaries, is made known to them by others within those entities, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

(b) Changes in internal control over financial reporting

There were no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter. Further, there were no other items identified in connection with our internal evaluations that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On January 29, 2010, a competitor and former supplier filed a complaint against our Company in the Court of Chancery of the State of Delaware, alleging that we had misused proprietary trade secrets, breached a contract, and engaged in deceptive trade practices relating to one of the Company s lighting products. The complaint sought injunctive relief and damages. Energy Focus answered the complaint and filed a counterclaim for breach of contract. The parties settled and dismissed the case in the second quarter of 2011. In the opinion of management, neither the defense of the lawsuit nor the implementation of the settlement has had or will have an adverse effect on our financial condition, cash flows, or results of operations.

In the ordinary course of business, we become involved in lawsuits and administrative proceedings. Some of these proceedings may result in fines, penalties or judgments which, from time to time, may have an impact on its business and financial condition. Although the outcome of such lawsuits or other proceedings cannot be predicted with certainty, we do not believe that any uninsured ultimate liabilities, individually or in the aggregate, will have a material adverse effect on its liquidity, financial position or results of operations.

ITEM 1A. RISK FACTORS

Reference is made to the Risk Factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2010 (the Annual Report). Other than the risk factor listed below, there have been no significant changes in those risk factors as set forth in the Annual Report.

Compliance with the continued listing requirements of the NASDAQ Stock Market

On May 18, 2011 the Company received a notification from the NASDAQ Listing Qualifications Department indicating that, for the last 30 consecutive business days, the bid price of the Company s common stock had closed below the minimum $1.00 per share requirement for continued listing on the NASDAQ Capital Market under NASDAQ Listing Rule 5550(a)(2). The Company, in accordance with NASDAQ Listing Rule 5810(c)(3)(A), has been provided 180 calendar days, or until November 14, 2011, to regain compliance with the minimum $1.00 per share requirement. The Company s stock has not closed at or above $1.00 per share for ten consecutive days during this 180 calendar day period. As a result, the Company expects to receive a delisting notice from the NASDAQ Listing Qualifications Department within several days from November 14, 2011. Further, as of September 30, 2011 the Company s Stockholder s equity balance is below the minimum $2.5 million of equity requirement for continued listing under NASDAQ Listing Rule 5550(b)(1). The Company is expected to receive a delisting notice from the NASDAQ Listing Qualifications Department within several days from November 14, 2011. Upon receiving the deficiency notice, the Company will have seven days to appeal NASDAQ s determination to delist its common stock to a Hearings Panel.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

The information about the August 11, 2011 letter of credit agreement contained above under the caption Long Term Borrowings and in Note 7 to the Condensed Consolidated Financial Statements in Item 1 of Part I of this report is hereby incorporated by reference into this Item 2 of Part II of this report.

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS

The exhibits listed below are filed or furnished, as the case may be, as part of this report.

Exhibit Number	Description
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Furnished herewith. As provided in Rule 406T of Regulation S-T, this information shall not be deemed filed for purposes of Section 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934 or otherwise subject to liability under those sections.

Table of Contents

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.

ENERGY FOCUS, INC.

Date: November 14, 2011

By: /s/ Joseph G. Kaveski
Joseph G. Kaveski
Chief Executive Officer

By: /s/ Mark J. Plush
Mark J. Plush
Chief Financial Officer

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Furnished herewith. As provided in Rule 406T of Regulation S-T, this information shall not be deemed filed for purposes of Section 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934 or otherwise subject to liability under those sections.