FORM 8-K

Current report filing

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SEATTLE GENETICS INC /WA

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Mailing Address
21823 30TH DRIVE SE
SUITE
BOTHELL WA 98021

Business Address
21823 30TH DRIVE SE
SUITE
BOTHELL WA 98021
4255274000

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

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 26, 2009

Seattle Genetics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**0-32405**	**91-1874389**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On January 26, 2009, Seattle Genetics, Inc. issued a press release announcing that SGN-35, an antibody-drug conjugate, has been granted orphan drug designation by the European Medicines Agency (EMEA) for the treatment of Hodgkin lymphoma and anaplastic large cell lymphoma (ALCL) and by the U.S. Food and Drug Administration (FDA) for the treatment of ALCL. The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release of Seattle Genetics, Inc. dated January 26, 2009

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 hereunto duly authorized.

SEATTLE GENETICS, INC.

Date: January 26, 2009

By: /s/ Clay B. Siegall
Clay B. Siegall
President and Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release of Seattle Genetics, Inc. dated January 26, 2009

Exhibit 99.1

Seattle Genetics Receives Orphan Drug Designations for SGN-35 in the United States and Europe

Bothell, WA – January 26, 2009 – Seattle Genetics, Inc. (Nasdaq: SGEN) announced today that SGN-35 has been granted orphan drug designation by the European Medicines Agency (EMEA) for the treatment of Hodgkin lymphoma and anaplastic large cell lymphoma (ALCL) and by the U.S. Food and Drug Administration (FDA) for the treatment of ALCL. These designations are in addition to the SGN-35 orphan drug designation for Hodgkin lymphoma previously received from the FDA. The company plans to initiate a pivotal trial of SGN-35 for Hodgkin lymphoma and a phase II clinical trial for ALCL during the first quarter of 2009.

"These orphan drug designations support our global development strategy for SGN-35 and assist in achieving our goal of providing improved therapies for patients with Hodgkin lymphoma and ALCL," said Thomas C. Reynolds, Chief Medical Officer of Seattle Genetics. "Our clinical experience to date with SGN-35 has demonstrated its potential to induce objective responses, including complete remissions, in relapsed or refractory Hodgkin lymphoma and ALCL where limited treatment options exist. This activity paired with a favorable tolerability profile supports our plans to initiate a pivotal trial of SGN-35 this quarter under a special protocol assessment (SPA)."

FDA orphan drug designation is intended to encourage companies to develop therapies for the treatment of diseases that affect fewer than 200,000 individuals in the United States. This designation will provide Seattle Genetics with seven years of marketing exclusivity for each indication, Hodgkin lymphoma and ALCL, if SGN-35 is approved by the FDA in such indication. Prior to FDA approval, orphan designation by the FDA provides the opportunity to obtain grant funding to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential waiver of the FDA' s application user fee.

Similarly, the EMEA' s Orphan Medicinal Product Designation is designed to promote the development of drugs that may provide significant benefit to patients suffering from rare, life-threatening diseases. This designation will provide ten years of marketing exclusivity if the product candidate is approved for marketing for the designated orphan indication in the European Union. It also provides special incentives for sponsors, including eligibility for protocol assistance and possible exemptions or reductions in certain regulatory fees during development or at the time of application for marketing approval.

SGN-35 is an antibody-drug conjugate (ADC) comprising an anti-CD30 monoclonal antibody attached by an enzyme cleavable linker to a potent, synthetic drug payload, monomethyl auristatin E (MMAE), using Seattle Genetics' proprietary technology. The ADC is designed to be stable in the bloodstream, but to release MMAE upon internalization into CD30-expressing tumor cells, resulting in a targeted cell-killing effect.

Seattle Genetics reported data from a phase I dose-escalation clinical trial of SGN-35 in December 2008 at the American Society of Hematology annual meeting. Among 28 evaluable patients with relapsed or refractory Hodgkin lymphoma or ALCL treated at doses of 1.2 milligrams per kilogram and higher administered every three weeks, 54 percent achieved an objective response, including 32 percent with complete responses. SGN-35 was generally well tolerated. The company is also continuing dose escalation in an ongoing phase I clinical trial of SGN-35 administered on a weekly basis, and expects to report data from this study during 2009.

About Seattle Genetics

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. The company is planning to initiate a pivotal trial of its lead product candidate, SGN-35, in the first quarter of 2009 under an SPA with the FDA. SGN-35 is empowered by Seattle Genetics' proprietary antibody-drug conjugate (ADC) technology comprising highly potent synthetic drugs and stable linkers for attaching the drugs to monoclonal antibodies. In addition, Seattle Genetics has 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. Seattle Genetics has collaborations for its 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. More information can be found at www.seattlegenetics.com.

Certain of the statements made in this press release are forward looking. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Specifically, statements regarding planned clinical trials, potential regulatory approvals and marketing exclusivity, and the potential therapeutic benefit of SGN-35 are forward looking and actual results may differ materially from these statements for various reasons. Factors that may cause such a difference include delays in the initiation and/or completion of the clinical trials of SGN-35 in Hodgkin lymphoma and ALCL, whether caused by competition, adverse events, patient enrollment rates, regulatory issues or other factors; that the clinical trials of SGN-35 in Hodgkin lymphoma and ALCL may not demonstrate that SGN-35 is both safe and effective; that data from our phase I clinical trials of SGN-35 may not necessarily be indicative of the subsequent clinical trial results of SGN-35 in Hodgkin lymphoma and ALCL; and that the safety and/or efficacy results of the clinical trials of SGN-35 in Hodgkin lymphoma and ALCL will not support an application for marketing approval in the European Union, the United States or any other country. More information about the risks and uncertainties faced by Seattle Genetics is contained in the company' s filings with the Securities and Exchange Commission. Seattle Genetics disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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CONTACT:

Peggy Pinkston
Corporate Communications
(425) 527-4160
ppinkston@seagen.com