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): February 7, 2019

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On February 7, 2019, Seattle Genetics, Inc. issued a press release announcing financial results for its fourth quarter and year ended December 31, 2018. A copy of the press release is furnished herewith as Exhibit 99.1.

The information furnished with this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1	Press Release of Seattle Genetics, Inc. dated	February 7, 2019

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: February 7, 2019

By: /s/ Clay B. Siegall

Clay B. Siegall

President and Chief Executive Officer

Exhibit 99.1

Seattle Genetics Reports Fourth Quarter and Full Year 2018 Financial Results

-ADCETRIS® (Brentuximab Vedotin) Net Sales in U.S. and Canada of $476.9 Million in 2018, Including $132.1 Million in the Fourth Quarter-

-ADCETRIS Approved by FDA in Combination with Chemotherapy for Frontline CD30-Expressing PTCL-

-Top-line Data from Enfortumab Vedotin Pivotal Trial in Metastatic Urothelial Cancer Expected in the First Quarter of 2019-

-Conference Call Today at 4:30 p.m. ET-

BOTHELL, Wash. — February 7, 2019 — Seattle Genetics, Inc. (Nasdaq:SGEN) today reported financial results for the fourth quarter and year ended December 31, 2018. The company also highlighted ADCETRIS (brentuximab vedotin) commercialization and clinical development accomplishments and progress with its late-stage clinical programs for cancer.

"During 2018, we received FDA approval for two ADCETRIS frontline indications, a major accomplishment that significantly expands the number of patients eligible to benefit from treatment. These approvals for frontline advanced Hodgkin lymphoma and CD30-expressing peripheral T-cell lymphoma (PTCL) were based on phase 3 data showing superior efficacy of the ADCETRIS-containing regimens compared to combination chemotherapy agents that have been used for decades," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "Additionally, we made progress in 2018 with our late-stage clinical programs, leading to important anticipated milestones this year. Notably, we expect to report top-line data in the first quarter of 2019 from the pivotal trial of enfortumab vedotin in metastatic urothelial cancer and to report top-line data later in the year from the pivotal trial of tucatinib in HER2-positive metastatic breast cancer. Taken together, we are positioned to establish ADCETRIS as the standard of care in the frontline setting in both advanced Hodgkin lymphoma and CD30-expressing PTCL, and realize our vision of becoming a company with multiple oncology products addressing unmet medical needs."

ADCETRIS Program Highlights

- **New Indication for CD30-Expressing Frontline PTCL:** In November 2018, the U.S. Food and Drug Administration (FDA) approved ADCETRIS in combination with chemotherapy for adults with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified. The approval is based on the successful outcome of the ECHELON-2 phase 3 clinical trial. The FDA granted Breakthrough Therapy Designation in this setting and reviewed the application under the Real-Time Oncology Review Pilot Program leading to approval less than two weeks after submission of the supplemental Biologics License Application (BLA).
- **New Indication in Canada:** Health Canada approved ADCETRIS for the treatment of adult patients with primary cutaneous ALCL or CD30-expressing mycosis fungoides who have had prior systemic therapy.
- **Multiple Abstracts at ASH:** In addition to the presentation of ECHELON-2 data, which were also simultaneously published in *The Lancet*, ADCETRIS was featured in more than 30 data presentations at the 60th American Society of Hematology (ASH) annual meeting from both corporate and investigator-led

clinical trials. The trials highlighted the potential application of ADCETRIS as monotherapy and as part of combination regimens in a range of CD30-expressing lymphomas.

Enfortumab Vedotin (EV) Program Highlights

- **EV-201 Pivotal Trial Data in First Quarter 2019:** Seattle Genetics and Astellas expect to report top-line data in the first quarter of 2019 from the ongoing EV-201 pivotal trial evaluating EV in patients with locally advanced or metastatic urothelial cancer who previously received both platinum chemotherapy and a checkpoint inhibitor (PD-1 or PD-L1). Data from this trial could serve as the basis for a BLA submission under the FDA's accelerated approval pathway.
- **Multiple Trials Enrolling:** Seattle Genetics and Astellas continue enrollment in the global randomized phase 3 clinical trial called EV-301 for patients with locally advanced or metastatic urothelial cancer who were previously treated with a PD-1 or PD-L1 inhibitor and a platinum-containing regimen. EV-301 is intended to support global regulatory submissions for approval and serve as a confirmatory trial in the United States. Additionally, enrollment is ongoing in the phase 1 trial called EV-103 in earlier lines of locally advanced or metastatic urothelial cancer, including first-line, evaluating EV in combination with pembrolizumab and/or platinum agents.

Tucatinib Program Highlights

- **HER2CLIMB Pivotal Trial Data in 2019:** Seattle Genetics achieved enrollment of 480 patients in the HER2CLIMB pivotal trial to enable analysis of the primary endpoint of PFS, with top-line data expected to be reported in 2019. In addition, HER2CLIMB enrollment is continuing up to 600 patients, to support the analyses of key secondary endpoints, including overall survival as well as progression-free survival in patients with brain metastases. The company anticipates completing enrollment of the additional patients in mid-2019.

Tisotumab Vedotin (TV) Program Highlights

- **innovaTV 204 Pivotal Trial Enrollment:** Seattle Genetics and Genmab expect to complete enrollment by mid-2019 in the pivotal innovaTV 204 trial evaluating TV in patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment.
- **Broad Development Program:** Seattle Genetics and Genmab are evaluating TV in multiple ongoing or planned clinical trials, including trials in earlier-stage cervical cancer and in multiple types of other solid tumors.

Other Recent Activities

- **Initiated Phase 1 Trial of SEA-BCMA:** Seattle Genetics announced the dosing of the first patient in a phase 1 trial evaluating the safety and tolerability of SEA-BCMA in relapsed or refractory multiple myeloma. SEA-BCMA is an empowered antibody using the company's proprietary Sugar Engineered Antibody (SEA) technology designed to enhance antibody dependent cellular cytotoxicity.
- **ADC Collaborator Regulatory Submission:** In December 2018, Roche submitted regulatory applications in the U.S. and the European Union for approval of polatuzumab vedotin to treat patients with relapsed or refractory diffuse large B-cell lymphoma. Polatuzumab vedotin utilizes Seattle Genetics' proprietary antibody-drug conjugate (ADC) technology.

FOURTH QUARTER AND FULL YEAR 2018 FINANCIAL RESULTS

Revenues: Total revenues in the fourth quarter and year ended December 31, 2018 increased to $174.5 million and $654.7 million, respectively, compared to $129.6 million and $482.3 million for the same periods in 2017. Revenues are comprised of the following three components:

- **Product Revenues:** ADCETRIS net sales in the U.S. and Canada for the fourth quarter were $132.1 million, a 58 percent increase over net sales of $83.7 million in the fourth quarter of 2017. ADCETRIS net sales in the U.S. and Canada were $476.9 million for the full year in 2018, a 55 percent increase over net sales of $307.6 million for the same period in 2017. Growth over 2017 reflects ADCETRIS label

expansions in 2018, most notably in frontline Stage III and IV Hodgkin lymphoma in March 2018 and to a lesser degree in frontline CD30-expressing PTCL in November 2018.

- **Royalty Revenues:** Royalty revenues in the fourth quarter were $24.6 million, compared to $20.0 million in the fourth quarter of 2017. Royalty revenues were $83.4 million for the full year in 2018, compared to $66.1 million for the same period in 2017. Royalty revenues are primarily driven by sales of ADCETRIS outside the U.S. and Canada by Takeda.
- **Collaboration and License Agreement Revenues:** Amounts earned under the company's ADCETRIS and ADC collaborations were $17.8 million in the fourth quarter and $94.4 million for the full year in 2018, compared to $25.9 million and $108.6 million, respectively, for the same periods in 2017.

Research and Development (R&D) Expenses: R&D expenses in the fourth quarter were $149.8 million, compared to $110.5 million in the fourth quarter of 2017. R&D expenses were $565.3 million for the full year in 2018, compared to $456.7 million for the same period in 2017. The increase in 2018 reflects increased investment in the company's late-stage pipeline and technology acquisition costs in the first quarter of 2018.

Selling, general and administrative (SG&A) Expenses: SG&A expenses in the fourth quarter were $79.5 million, compared to $48.5 million in the fourth quarter of 2017. The increase in SG&A expenses for the fourth quarter of 2018 was primarily driven by the rapid approval and launch of ADCETRIS for frontline CD30-expressing PTCL. SG&A expenses were $261.1 million for the full year in 2018, compared to $167.2 million for the same period in 2017. The increase for the full year in 2018 was primarily related to costs to support the launch of ADCETRIS in the frontline indications as well as transaction costs associated with the acquisition of Cascadian Therapeutics.

Cost of Sales: Cost of sales in the fourth quarter were $30.2 million, compared to $10.2 million in the fourth quarter of 2017. Cost of sales were $66.1 million for the year in 2018, compared to $34.8 million for the same period in 2017. The increases in 2018 reflect an inventory write-off of $18.1 million recorded in the fourth quarter of 2018 related to in-process production that did not meet manufacturing specifications and did not impact availability of product supply required to meet demand for ADCETRIS.

Non-cash, share-based compensation cost for the full year in 2018 was $78.9 million, compared to $63.8 million for the same period in 2017.

Net Loss: Net loss for the fourth quarter of 2018 was $119.8 million, or $0.75 per share, compared to a net loss of $59.2 million, or $0.41 per share, for the fourth quarter of 2017. Net loss in the fourth quarter of 2018 includes a net investment loss of $53.2 million primarily associated with Seattle Genetics' common stock holdings in Immunomedics, which are marked-to-market. For the full year in 2018, net loss was $222.7 million, or $1.41 per share, compared to a net loss of $125.5 million, or $0.88 per share, for the year in 2017. Net loss for the full year in 2018 includes net investment income of $13.7 million primarily associated with Seattle Genetics' common stock holdings in Immunomedics. Net loss for both the fourth quarter and the full year in 2018 included a non-cash income tax benefit of $23.7 million related to acquired intangible assets as part of the acquisition of Cascadian Therapeutics.

Cash and Investments: As of December 31, 2018, Seattle Genetics had $459.9 million in cash and investments. In addition, the company held stock investments, primarily in Immunomedics common stock, valued at $113.8 million.

2019 FINANCIAL OUTLOOK

Seattle Genetics anticipates 2019 total revenues to be in the range of $790 million to $840 million, driven by the following components:

ADCETRIS net product sales	$610 million to $640 million
Collaboration and license agreement revenues	$95 million to $110 million
Royalty revenues	$85 million to $90 million

Operating expenses and other costs are expected to be within the following ranges for the year in 2019:

R&D expenses	$600 million to $650 million
SG&A expenses	$280 million to $310 million
Cost of sales	5 percent to 6 percent
Cost of royalty revenues	Low single digit percent on ex-US sales
Non-cash costs (primarily attributable to share based compensation)	$135 million to $145 million

Conference Call Details

Seattle Genetics' management will host a conference call and webcast with supporting slides to discuss its fourth quarter and full year 2018 financial results and provide an update on business activities. The event will be held today at 1:30 p.m. Pacific Time (PT); 4:30 p.m. Eastern Time (ET). The live event and supporting slides will be simultaneously webcast on the Seattle Genetics website at www.seattlegenetics.com, under the Investors section. Investors may also participate in the conference call by calling 877-260-1479 (domestic) or 334-323-0522 (international). The conference ID is 1660553. A replay of the live event and supporting slides will be available starting on February 7, 2019 on the Seattle Genetics website at www.seattlegenetics.com, under the Investors section, for at least 30 days. A replay of the audio only will be available by calling 888-203-1112 (domestic) or 719-457-0820 (international), using conference ID 1660553. The telephone replay will be available until 5:00 p.m. PT on February 11, 2019.

About Seattle Genetics

Seattle Genetics, Inc. is an emerging multi-product, global biotechnology company that develops and commercializes transformative therapies targeting cancer to make a meaningful difference in people's lives. ADCETRIS® (brentuximab vedotin) utilizes the company's industry-leading antibody-drug conjugate (ADC) technology and is currently approved for the treatment of multiple CD30-expressing lymphomas. Beyond ADCETRIS, the company has established a pipeline of novel targeted therapies at various stages of clinical testing, including three in ongoing pivotal trials for solid tumors. Enfortumab vedotin for metastatic urothelial cancer and tisotumab vedotin for metastatic cervical cancer utilize our proprietary ADC technology. Tucatinib, a small molecule tyrosine kinase inhibitor, is in a pivotal trial for HER2-positive metastatic breast cancer. In addition, we are leveraging our expertise in empowered antibodies to build a portfolio of proprietary immuno-oncology agents in clinical trials targeting hematologic malignancies and solid tumors. The company is headquartered in Bothell, Washington, and has a European office in Switzerland. For more information on our robust pipeline, visit www.seattlegenetics.com and follow @SeattleGenetics on Twitter.

Forward-Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the company's 2019 outlook, including anticipated 2019 revenues, costs and expenses; the company's potential to achieve the noted development and regulatory milestones in 2019 and in future periods and to establish ADCETRIS as the standard of care in the frontline setting in both advanced Hodgkin lymphoma and CD30-expressing PTCL and become a multi-product oncology company; anticipated activities related to the company's planned and ongoing clinical trials, including clinical trial enrollment and data availability and the expected timing thereof, including with respect to EV-201, HER2CLIMB and other clinical trials; the potential for the company's clinical trials to support further development, regulatory submissions and potential marketing approvals; the opportunities for, and the therapeutic and commercial potential of ADCETRIS, enfortumab vedotin, tucatinib, and tisotumab vedotin and the company's other product candidates and those of its licensees and collaborators; as well as other statements that are not historical facts. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks that the company's ADCETRIS net sales, revenue, expense, and other financial guidance may not be as expected, as well as risks and uncertainties associated with maintaining or increasing sales of ADCETRIS due to competition, unexpected adverse events, regulatory action, reimbursement, or market adoption by physicians. The company may also be delayed in its planned clinical trial initiations, the enrollment in and conduct of its clinical trials, obtaining data from clinical trials, planned regulatory submissions, and regulatory approvals in each case for a variety of

reasons including the difficulty and uncertainty of pharmaceutical product development, u, negative or disappointing clinical trial results, unexpected adverse events or regulatory discussions or actions and the inherent uncertainty associated with the regulatory approval process. More information about the risks and uncertainties faced by Seattle Genetics is contained under the caption “Risk Factors” included in the company’s periodic reports filed with the Securities and Exchange Commission, including the company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and future periodic reports filed by the company, including the company's Annual Report on Form 10-K for the year ended December 31, 2018.

CONTACTS:

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Seattle Genetics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Net product sales	$ 132,127	$ 83,721	$ 476,903	$ 307,562
Collaboration and license agreement revenues	17,833	25,853	94,357	108,632
Royalty revenues	24,553	20,031	83,440	66,056
Total revenues	174,513	129,605	654,700	482,250
Costs and expenses:				
Cost of sales	30,222	10,213	66,085	34,768
Cost of royalty revenues	5,363	5,450	22,208	19,350
Research and development	149,772	110,504	565,309	456,700
Selling, general and administrative	79,467	48,450	261,096	167,233
Total costs and expenses	264,824	174,617	914,698	678,051
Loss from operations	(90,311)	(45,012)	(259,998)	(195,801)
Investment and other income (loss), net	(53,180)	(42,131)	13,652	36,914
Loss before income taxes	(143,491)	(87,143)	(246,346)	(158,887)
Income tax benefit	23,686	27,942	23,653	33,357
Net loss	$ (119,805)	$ (59,201)	$ (222,693)	$ (125,530)
Net loss per share - basic and diluted	$ (0.75)	$ (0.41)	$ (1.41)	$ (0.88)
Shares used in computation of per share amounts - basic and diluted	160,197	144,061	157,655	143,174

Seattle Genetics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	December 31,	
	2018	2017
Assets		
Cash, cash equivalents and investments	$ 459,866	$ 413,171
Other assets	1,043,463	464,778
Total assets	$ 1,503,329	$ 877,949
Liabilities and Stockholders' Equity		
Accounts payable and accrued liabilities	$ 191,472	$ 132,672
Deferred revenue and long-term liabilities	37,914	67,708
Stockholders' equity	1,273,943	677,569
Total liabilities and stockholders' equity	$ 1,503,329	$ 877,949