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): April 25, 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 April 25, 2019, Seattle Genetics, Inc. issued a press release announcing financial results for its first quarter ended March 31, 2019. 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	April 25, 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: April 25, 2019

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

Exhibit 99.1

Seattle Genetics Reports First Quarter 2019 Financial Results

-ADCETRIS® (Brentuximab Vedotin) Net Sales in U.S. and Canada Were $135.0 Million in the First Quarter, an Increase of 42 Percent Over the First Quarter of 2018

-Positive Topline Results from Pivotal Trial of Enfortumab Vedotin in Locally Advanced or Metastatic Urothelial Cancer Support Planned 2019 Submission of Biologics License Application-

-Target Enrollment Reached in HER2CLIMB Pivotal Trial of Tucatinib in HER2-Positive Metastatic Breast Cancer; Topline Results Expected in 2019-

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

BOTHELL, Wash. — April 25, 2019 — Seattle Genetics, Inc. (Nasdaq:SGEN) today reported financial results for the first quarter ended March 31, 2019. The company also highlighted ADCETRIS (brentuximab vedotin) commercialization and clinical development accomplishments and progress with its late-stage clinical programs for cancer.

"In the first quarter we achieved an important milestone toward becoming a multi-product oncology company with the announcement of positive topline results from the pivotal trial of enfortumab vedotin in patients with locally advanced or metastatic urothelial cancer, and we plan to submit an application for approval to the FDA in 2019," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "We continue to execute on expanding ADCETRIS use in the two frontline indications, and maintain our 2019 net sales guidance of $610 million to $640 million in the U.S. and Canada. We have also advanced our other late-stage programs, including reaching target enrollment in the HER2CLIMB pivotal trial of tucatinib in HER2-positive metastatic breast cancer. We expect to report topline results from HER2CLIMB in 2019."

ADCETRIS and Late-Stage Pipeline Highlights

- **ADCETRIS Ex-U.S. Regulatory Activities in Frontline Hodgkin Lymphoma:** In February 2019, Takeda received approval from the European Commission to extend the marketing authorization for ADCETRIS to include ADCETRIS in combination with AVD (Adriamycin®, vinblastine and dacarbazine) in adult patients with previously untreated CD30-positive stage IV classical Hodgkin lymphoma. As a result, Seattle Genetics received a $30 million milestone payment from Takeda.
- **Enfortumab Vedotin (EV) Pivotal Trial Positive Topline Results; Data Selected for Oral Presentation at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting:** In March 2019, Seattle Genetics and Astellas announced positive topline results from the first cohort of the EV-201 clinical trial that enrolled 128 patients with locally advanced or metastatic urothelial cancer who previously received both platinum chemotherapy and a PD-1 or PD-L1 inhibitor. Results showed a 44 percent objective response rate per blinded independent central review. The duration of response was consistent with that recently reported in the previous phase 1 study (EV-101). The most common treatment-related adverse events included fatigue, alopecia, decreased appetite, rash and peripheral neuropathy. The companies plan to submit a Biologics License Application under the U.S. Food and Drug Administration's (FDA) accelerated approval pathway in 2019.
- **Tucatinib HER2CLIMB Pivotal Trial Update:** Seattle Genetics previously announced enrollment of 480 patients in the HER2CLIMB trial to enable analysis of the primary endpoint of progression-free survival (PFS), with topline data expected to be reported in 2019. In April 2019, Seattle Genetics achieved

enrollment of 120 additional patients in HER2CLIMB to reach the target enrollment of 600 patients to support the analyses of key secondary endpoints, including overall survival as well as PFS in patients with brain metastases.

- **Tisotumab Vedotin (TV) innovaTV 204 Pivotal Trial Update:** In March 2019, Seattle Genetics and Genmab completed enrollment in the innovaTV 204 pivotal trial evaluating TV in patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. The trial is designed to support a potential regulatory submission under the FDA's accelerated approval pathway.

FIRST QUARTER 2019 FINANCIAL RESULTS

Revenues: Total revenues in the first quarter ended March 31, 2019 increased to $195.2 million, compared to $140.6 million for the same period in 2018. Revenues are comprised of the following three components:

- **Net Product Sales:** ADCETRIS net sales for the U.S. and Canada in the first quarter were $135.0 million, a 42 percent increase over net sales of $95.4 million in the first quarter of 2018.
- **Royalty Revenues:** Royalty revenues in the first quarter were $15.6 million, compared to $15.7 million in the first quarter of 2018. Royalty revenues are primarily driven by sales of ADCETRIS outside the U.S. and Canada by Takeda. First quarter 2019 net sales of ADCETRIS in Takeda's territories increased over the comparable period in 2018; however, royalty revenues for the period in 2018 included additional amounts attributable to Takeda's portion of certain third-party royalty obligations that expired at the end of 2018.
- **Collaboration and License Agreement Revenues:** Amounts earned under the company’s ADCETRIS and ADC collaborations were $44.6 million in the first quarter of 2019, compared to $29.6 million for the same period in 2018. Collaboration revenues for the first quarter of 2019 included the earned portion of a $30.0 million milestone from Takeda triggered by European Commission approval of ADCETRIS in combination with AVD in adult patients with previously untreated CD30-positive stage IV classical Hodgkin lymphoma.

Research and Development (R&D) Expenses: R&D expenses in the first quarter were $158.3 million, compared to $152.5 million in the first quarter of 2018. The increase reflects additional investment in the company's late-stage pipeline including EV, tucatinib and TV.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses in the first quarter were $80.3 million, compared to $66.2 million in the first quarter of 2018. The increase was primarily attributed to costs to support commercialization efforts related to frontline ADCETRIS indications, the company's late-stage programs and higher infrastructure costs to support the company's continued growth.

Non-cash, share-based compensation cost for the first three months of 2019 was $25.7 million, compared to $16.8 million for the same period in 2018.

Net Loss

Net loss for the first quarter of 2019 was $13.3 million, or $0.08 per diluted share, compared to a net loss of $111.7 million, or $0.73 per diluted share, for the first quarter of 2018. Net loss in the first quarter of 2019 included a non-cash net investment gain of $38.1 million associated with Seattle Genetics’ common stock holdings in Immunomedics, which are marked-to-market.

Cash and Investments

As of March 31, 2019, cash and investments were $418.3 million. In addition, the company held stock investments, primarily in Immunomedics common stock, valued at $151.9 million.

2019 FINANCIAL OUTLOOK

The company's 2019 financial guidance is detailed below, including updates to its expectations for R&D and SG&A expenses driven primarily by positive results from the EV-201 pivotal trial.

	Current	Previous
Revenues		
ADCETRIS net product sales	$610 million to $640 million	Unchanged
Collaboration and license agreement revenues	$95 million to $110 million	Unchanged
Royalty revenues	$85 million to $90 million	Unchanged
Operating Expenses and other costs		
R&D expenses	$650 million to $700 million	$600 million to $650 million
SG&A expenses	$300 million to $335 million	$280 million to $310 million
Cost of sales	5 percent to 6 percent	Unchanged
Cost of royalty revenues	Low single-digit percent on ex-US sales	Unchanged
Non-cash costs (primarily attributable to share based compensation)	$135 million to $145 million	Unchanged

Conference Call Details

Seattle Genetics' management will host a conference call and webcast with supporting slides to discuss its first quarter 2019 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 6169352. A replay of the live event and supporting slides will be available 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 6169352. The telephone replay will be available until 5:00 p.m. PT on April 29, 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 including to submit a Biologics License Application for enfortumab vedotin under the U.S. Food and Drug Administration's (FDA) accelerated approval pathway and to report topline data for tucatinib for the HER2CLIMB trial in 2019; anticipated activities related to the company's planned and ongoing clinical trials, including clinical trial enrollment and data availability and the expected timing thereof; 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; the company's anticipation to become a multi-product oncology company; 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, revenues, expenses, costs, 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, 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 Annual Report on Form 10-K for the year ended December 31, 2018 filed 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 except as required by applicable law.

CONTACTS:

Investors:	Media:
Peggy Pinkston	Monique Greer
425-527-4160	425-527-4641
ppinkston@seagen.com	mgreer@seagen.com

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

	Three Months Ended March 31,	
	2019	**2018**
Revenues:		
Net product sales	$ 135,001	$ 95,357
Collaboration and license agreement revenues	44,578	29,559
Royalty revenues	15,620	15,674
Total revenues	195,199	140,590
Costs and expenses:		
Cost of sales	7,911	10,358
Cost of royalty revenues	2,389	5,377
Research and development	158,265	152,502
Selling, general and administrative	80,271	66,182
Total costs and expenses	248,836	234,419
Loss from operations	(53,637)	(93,829)
Investment and other income (loss), net	40,308	(17,886)
Net loss	$ (13,329)	$ (111,715)
Net loss per share - basic and diluted	$ (0.08)	$ (0.73)
Shares used in computation of per share amounts - basic and diluted	160,657	152,049

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

	March 31, 2019	**December 31, 2018**
Assets		
Cash, cash equivalents and investments	$ 418,295	$ 459,866
Other assets	1,174,309	1,043,463
Total assets	$ 1,592,604	$ 1,503,329
Liabilities and Stockholders' Equity		
Accounts payable and accrued liabilities	$ 180,959	$ 191,472
Deferred revenue and long-term liabilities	98,234	37,914
Stockholders' equity	1,313,411	1,273,943
Total liabilities and stockholders' equity	$ 1,592,604	$ 1,503,329