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): July 16, 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))

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

Title of class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	SGEN	The Nasdaq Stock Market LLC

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 July 16, 2019, Seattle Genetics, Inc. issued a press release announcing financial results for its second quarter ended June 30, 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	July 16, 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: July 16, 2019

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

Exhibit 99.1

Seattle Genetics Reports Second Quarter 2019 Financial Results

-Record ADCETRIS® (Brentuximab Vedotin) Net Sales in U.S. and Canada of $159.0 Million in the Second Quarter, an Increase of 30 Percent Over the Second Quarter of 2018-

-Biologics License Application Submitted to FDA for Enfortumab Vedotin to Treat Advanced or Metastatic Urothelial Cancer Based on Results from the EV-201 Pivotal Trial-

-Topline Results from Tucatinib HER2CLIMB Pivotal Trial Expected in 2019-

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

BOTHELL, Wash. — July 16, 2019 — Seattle Genetics, Inc. (Nasdaq:SGEN) today reported financial results for the second quarter and six months ended June 30, 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 second quarter, we achieved record ADCETRIS net sales in the U.S. and Canada, reflecting growth in frontline CD30-expressing peripheral T-cell lymphomas as well as frontline advanced Hodgkin lymphoma," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "We are also making substantial progress with our late-stage programs, delivering on several key goals. The Biologics License Application for enfortumab vedotin was submitted to the FDA for patients with locally advanced or metastatic urothelial cancer, taking us another step closer to becoming a multi-product oncology company. Additionally, we expect to report topline data from the tucatinib pivotal trial, HER2CLIMB, in HER2-positive metastatic breast cancer later this year and from the tisotumab vedotin pivotal trial, innovaTV 204, in metastatic cervical cancer in the first half of 2020."

Program Highlights

ADCETRIS

- **Ex-U.S. Approvals for ADCETRIS in Frontline Hodgkin Lymphoma (HL):** In May 2019, ADCETRIS in combination with AVD (Adriamycin®, vinblastine and dacarbazine) was approved by Health Canada for patients with previously untreated stage IV HL. Also, in June 2019, Takeda received an additional approval for ADCETRIS in frontline HL that resulted in a $7.5 million milestone payment to Seattle Genetics.
- **Additional Analyses of ECHELON-1 and ECHELON-2 Trials Presented at 2019 American Society of Clinical Oncology (ASCO) Annual Meeting:** A three-year update of the ECHELON-1 trial continued to show superior clinical activity of ADCETRIS in combination with AVD compared to ABVD (Adriamycin, bleomycin, vinblastine and dacarbazine) in frontline stage III and IV HL. Separately, analyses of clinical trials in T-cell lymphomas, including the ECHELON-2 trial, showed that responses were observed in patients across all levels of CD30 expression.

Enfortumab Vedotin

- **Enfortumab Vedotin Biologics License Application (BLA) Submitted to FDA:** In July 2019, Seattle Genetics and Astellas Pharma, Inc. submitted a BLA to the U.S. Food and Drug Administration (FDA) for enfortumab vedotin to treat patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting. The submission is based on positive results

from the first cohort of the EV-201 clinical trial, which were recently presented in a late-breaking oral session at the 2019 ASCO Annual Meeting.

- **Broad Clinical Development Program Underway:** Seattle Genetics and Astellas are evaluating enfortumab vedotin in several ongoing trials. These include a phase 3 randomized clinical trial (EV-301) that is intended to support global registrations. A phase 1 trial (EV-103) is also underway evaluating enfortumab vedotin in earlier lines of treatment for patients with locally advanced or metastatic urothelial cancer, including in combination with pembrolizumab and/or platinum chemotherapy in newly diagnosed patients as well as patients whose cancer progressed from earlier-stage disease. The company expects to report initial data from the EV-103 trial in 2019.

Tucatinib

- **Tucatinib HER2CLIMB Pivotal Trial Data Expected in 2019:** The company previously announced enrollment of 480 patients in the HER2CLIMB pivotal trial of tucatinib in HER2-positive metastatic breast cancer to enable analysis of the primary endpoint of progression-free survival (PFS). Topline data are expected to be reported in 2019.

Tisotumab Vedotin

- **Tisotumab Vedotin innovaTV 204 Pivotal Trial Data Expected in 2020:** Seattle Genetics and Genmab previously reported the completion of enrollment in the innovaTV 204 pivotal trial of tisotumab vedotin in patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. Topline data from the trial are expected in the first half of 2020.

Other Recent Activities

- **Collaborator ADC Progress:** In June 2019, the FDA approved Polivy™ (polatuzumab vedotin-piiq) an antibody-drug conjugate (ADC) targeting CD79b that utilizes Seattle Genetics' technology. Polivy was developed and will be commercialized by Genentech, a member of the Roche Group. As a result, Seattle Genetics will receive a $5.0 million milestone payment and is eligible to receive royalties on worldwide net sales.
- **Robin Taylor, Ph.D., Appointed Chief Commercial Officer:** Dr. Taylor brings 18 years of biotechnology and pharmaceutical company experience in the commercialization of oncology drugs, including significant marketing, launch and global product strategy roles at both Genentech/Roche and AstraZeneca. He contributed to several leading global brands, including Tecentriq® (atezolizumab), Alecensa® (alectinib), Avastin® (bevacizumab) and Herceptin® (trastuzumab).

SECOND QUARTER AND SIX-MONTHS 2019 FINANCIAL RESULTS

Revenues: Total revenues in the second quarter and six-month periods ended June 30, 2019 increased to $218.4 million and $413.6 million, respectively, compared to $170.2 million and $310.8 million for the same periods in 2018. Revenues are comprised of the following three components:

- **Net Product Sales:** ADCETRIS net sales for the U.S. and Canada in the second quarter were $159.0 million, a 30 percent increase over net sales of $122.4 million in the second quarter of 2018. ADCETRIS net sales for the U.S. and Canada were $294.0 million for the year-to-date in 2019, a 35 percent increase over net sales of $217.8 million for the same period in 2018.
- **Royalty Revenues:** Royalty revenues in the second quarter were $23.3 million, compared to $20.6 million in the second quarter of 2018. Royalty revenues were $39.0 million for the year-to-date in 2019, compared to $36.2 million for the same period in 2018. Royalty revenues are primarily driven by sales of ADCETRIS outside the U.S. and Canada by Takeda, which increased for the periods in 2019 compared to the same periods in 2018.
- **Collaboration and License Agreement Revenues:** Amounts earned under the company's ADCETRIS and ADC collaborations increased to $36.1 million in the second quarter of 2019, compared to $27.2 million for the same period in 2018. Collaboration revenues were $80.7 million for the year-to-date in 2019, compared

to $56.7 million for the same period in 2018. Collaboration revenues included the earned portion of $12.5 million and $42.5 million for milestones achieved in the second quarter of 2019 and first half of 2019, respectively. These milestones were based on Takeda's additional approvals of ADCETRIS in frontline HL and Genentech's FDA approval of Polivy.

Research and Development (R&D) Expenses: R&D expenses in the second quarter were $163.9 million, compared to $122.9 million in the second quarter of 2018. R&D expenses were $322.2 million for the year-to-date in 2019, compared to $275.4 million for the same period in 2018. The increases reflect additional investment in the company's late-stage pipeline including enfortumab vedotin, tucatinib and tisotumab vedotin.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses in the second quarter were $82.3 million, compared to $58.3 million in the second quarter of 2018. SG&A expenses were $162.6 million for the year-to-date in 2019, compared to $124.5 million for the same period in 2018. The increases were 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 six months of 2019 was $51.9 million, compared to $32.4 million for the same period in 2018.

Net Loss

Net loss for the second quarter of 2019 was $79.2 million, or $0.49 per diluted share, compared to net income of $76.3 million, or $0.47 per diluted share, for the second quarter of 2018. Net loss in the second quarter of 2019 included a net investment loss of $40.5 million primarily associated with Seattle Genetics' common stock holdings, which are marked-to-market, compared to a net investment gain of $106.6 million in the second quarter of 2018. For the six months ended June 30, 2019, net loss was $92.6 million, or $0.57 per share, compared to a net loss of $35.4 million, or $0.23 per share, for the six months ended June 30, 2018. Net loss for the six months ended June 30, 2018 included an investment gain of $88.7 million.

Cash and Investments

As of June 30, 2019, cash and investments were $376.1 million. In addition, the company held stock investments, primarily in Immunomedics common stock, valued at $109.2 million.

2019 FINANCIAL OUTLOOK

The company's 2019 financial guidance is detailed below, including updates to its expectations for collaboration revenues driven by recent milestones and SG&A expenses driven primarily by pre-commercialization activities for the potential launch of enfortumab vedotin in connection with the recent BLA submission.

	Current	Previous
Revenues		
ADCETRIS net product sales	$610 million to $640 million	Unchanged
Collaboration and license agreement revenues	$110 million to $125 million	$95 million to $110 million
Royalty revenues	$85 million to $90 million	Unchanged
Operating expenses and other costs		
R&D expenses	$650 million to $700 million	Unchanged
SG&A expenses	$335 million to $360 million	$300 million to $335 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 second 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 and available for replay from the Seattle Genetics website at www.seattlegenetics.com, under the Investors section. Investors may also participate in the conference call by calling 800-458-4121 (domestic) or 323-794-2093 (international). The conference ID is 3271918. A replay of the audio only will be available by calling 888-203-1112 (domestic) or 719-457-0820 (international), using conference ID 3271918. The telephone replay will be available until 5:00 p.m. PT on July 19, 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 the potential approval by the FDA of the BLA for enfortumab vedotin to treat patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting; the anticipated reporting of topline data for tucatinib for the HER2CLIMB trial in 2019 and for tisotumab vedotin for the innovaTV 204 trial in the first half of 2020; anticipated activities related to the company's planned and ongoing 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; the company's aspiration 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, market adoption by physicians or other factors. The company may also be delayed or unsuccessful 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Net product sales	$ 158,980	$ 122,443	$ 293,981	$ 217,800
Collaboration and license agreement revenues	36,130	27,179	80,708	56,738
Royalty revenues	23,337	20,551	38,957	36,225
Total revenues	218,447	170,173	413,646	310,763
Costs and expenses:				
Cost of sales	8,609	13,157	16,520	23,515
Cost of royalty revenues	2,288	6,148	4,677	11,525
Research and development	163,929	122,860	322,194	275,362
Selling, general and administrative	82,331	58,292	162,602	124,474
Total costs and expenses	257,157	200,457	505,993	434,876
Loss from operations	(38,710)	(30,284)	(92,347)	(124,113)
Investment and other income (loss), net	(40,528)	106,557	(220)	88,671
Net income (loss)	$ (79,238)	$ 76,273	$ (92,567)	$ (35,442)
Net income (loss) per share - basic	$ (0.49)	$ 0.48	$ (0.57)	$ (0.23)
Net income (loss) per share - diluted	$ (0.49)	$ 0.47	$ (0.57)	$ (0.23)
Shares used in computation of per share amounts - basic	161,436	158,381	161,049	155,525
Shares used in computation of per share amounts - diluted	161,436	163,382	161,049	155,525

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

	June 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and investments	$ 376,129	$ 459,866
Other assets	1,191,436	1,043,463
Total assets	$ 1,567,565	$ 1,503,329
Liabilities and Stockholders' Equity		
Accounts payable and accrued liabilities	$ 204,950	$ 191,472
Deferred revenue and long-term liabilities	90,789	37,914
Stockholders' equity	1,271,826	1,273,943
Total liabilities and stockholders' equity	$ 1,567,565	$ 1,503,329