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): October 25, 2018

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 October 25, 2018, Seattle Genetics, Inc. issued a press release announcing financial results for its third quarter ended September 30, 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	October 25, 2018

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: October 25, 2018

By: /s/ Clay B. Siegall

Clay B. Siegall

President and Chief Executive Officer

Exhibit 99.1

Seattle Genetics Reports Third Quarter 2018 Financial Results

-ADCETRIS® (Brentuximab Vedotin) Net Sales in U.S. and Canada of $127.0 Million in the Third Quarter-

-Positive Top-line Data from ADCETRIS Phase 3 ECHELON-2 Trial in Frontline PTCL; Supplemental BLA Planned for November 2018; Full Data to be Presented at ASH Annual Meeting-

-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. — October 25, 2018 — Seattle Genetics, Inc. (Nasdaq:SGEN) today reported financial results for the third quarter and nine months ended September 30, 2018. The company also highlighted ADCETRIS (brentuximab vedotin) commercialization and clinical development accomplishments and progress with its late-stage clinical programs for cancer.

"ADCETRIS net sales during the third quarter and year-to-date increased by more than 50 percent over the same periods in 2017, as we continue to expand into the frontline Hodgkin lymphoma setting following FDA approval earlier this year. In addition, we recently reported positive top-line results from the phase 3 ECHELON-2 trial in frontline peripheral T-cell lymphoma, including a statistically significant improvement in overall survival for the ADCETRIS regimen," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "We plan to submit an application for approval to the FDA in November and look forward to highlighting results from ECHELON-2 at the American Society of Hematology Annual Meeting in December. Our late-stage programs continue to progress, and we believe they have the potential to transform Seattle Genetics into a multi-product oncology company. We now plan to report top-line results from the pivotal trial of enfortumab vedotin in metastatic urothelial cancer in the first quarter of 2019. Additionally, we expect to complete enrollment of 480 patients in the HER2CLIMB pivotal trial of tucatinib in metastatic breast cancer in early 2019 to support analysis of the primary endpoint."

ADCETRIS Program Highlights

- **Positive ECHELON-2 Phase 3 Results:** Seattle Genetics and its partner Takeda Pharmaceutical Company Limited (Takeda) reported positive top-line results from the ECHELON-2 phase 3 clinical trial in frontline CD30-expressing peripheral T-cell lymphoma (PTCL). The trial demonstrated a statistically significant improvement in the primary endpoint of progression-free survival (PFS) of ADCETRIS in combination with CHP (cyclophosphamide, doxorubicin, prednisone) versus the control arm, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone). The ADCETRIS plus CHP arm also demonstrated superior overall survival, a key secondary endpoint, compared to CHOP. The safety profile of ADCETRIS plus CHP in the ECHELON-2 trial was comparable to CHOP and consistent with the established safety profile of ADCETRIS in combination with chemotherapy. Additional data will be presented at the 60th Annual Meeting of the American Society of Hematology (ASH), taking place December 1-4, 2018, in San Diego, Calif.

- **ECHELON-2 U.S. Regulatory Submission:** Seattle Genetics expects to submit in November 2018 a supplemental Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for approval of ADCETRIS plus CHP in frontline CD30-expressing PTCL. Takeda plans to submit the results to regulatory authorities for approval in its territories.
- **Ex-U.S. Regulatory Activities in Frontline Hodgkin Lymphoma:** Takeda received approval in Japan for ADCETRIS in combination with doxorubicin, vinblastine and dacarbazine (AVD) as a frontline treatment option for CD30-positive Hodgkin lymphoma patients. The approval was based on the positive outcome from the ECHELON-1 phase 3 trial. As a result, Seattle Genetics received a $10 million milestone payment from Takeda. In addition, Takeda submitted applications for approval of ADCETRIS in combination with AVD in previously untreated Hodgkin lymphoma to several other regulatory authorities, including the European Medicines Agency.
- **Multiple Presentations at ISHL:** ADCETRIS will be featured in several presentations at the 11th International Symposium on Hodgkin Lymphoma (ISHL), including data from the ECHELON-1 phase 3 trial and interim results from ongoing studies of ADCETRIS plus Opdivo® (nivolumab) in frontline or relapsed Hodgkin lymphoma.
- **Strong Presence Expected at ASH:** In addition to data from the ECHELON-2 phase 3 trial, the company expects ADCETRIS will be featured in more than 30 abstracts at the ASH 2018 Annual Meeting.

ADCETRIS is not currently approved for use in frontline PTCL or in combination with nivolumab.

Enfortumab Vedotin (EV) Program Highlights

- **EV-201 Pivotal Trial Timing Update:** Seattle Genetics and Astellas now 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-L1 or PD-1). Positive data from this trial could serve as the basis for a BLA submission under the FDA's accelerated approval pathway.
- **Expanded Phase 1 Trial for First-line Metastatic Urothelial Cancer:** Seattle Genetics and Astellas are expanding the ongoing EV-103 phase 1 trial in first-line metastatic urothelial cancer. In addition to evaluating EV in combination with Keytruda® (pembrolizumab), the companies plan to evaluate EV in combination with platinum agents, which are the current first-line standard of care.

Tucatinib Program Highlights

- **HER2CLIMB Pivotal Trial Update:** Seattle Genetics expects to achieve enrollment of 480 patients in the HER2CLIMB pivotal trial for patients with HER2-positive metastatic breast cancer in early 2019 to support analysis of the primary endpoint of PFS. In addition, based on interactions with the FDA, the company intends to continue enrollment up to 600 patients to strengthen the analyses of key secondary endpoints, including PFS in patients with brain metastases and overall survival. The company anticipates completing enrollment of the additional patients in mid-2019.

Tisotumab Vedotin (TV) Program Highlights

- **Phase 1/2 Data Presented at ESMO:** Seattle Genetics and Genmab reported updated data from the cervical cancer expansion cohort of the innovaTV 201 phase 1/2 trial at the European Society for Medical Oncology 2018 Congress. The data continue to support the rationale for the ongoing potentially pivotal trial, innovaTV 204, evaluating TV as monotherapy for patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment.
- **InnovaTV 208 Phase 2 trial in Ovarian Cancer:** Seattle Genetics and Genmab plan to evaluate the safety and activity of TV as monotherapy in patients with platinum-resistant ovarian cancer. The trial is expected to begin by early 2019.

THIRD QUARTER AND NINE MONTHS 2018 FINANCIAL RESULTS

Revenues: Total revenues in the third quarter and nine month periods ended September 30, 2018 increased to $169.4 million and $480.2 million, respectively, compared to $135.3 million and $352.6 million for the same periods in 2017. Revenues are comprised of the following three components:

- **Product Revenues:** ADCETRIS net sales for the U.S. and Canada in the third quarter were $127.0 million, a 60 percent increase over net sales of $79.2 million in the third quarter of 2017. ADCETRIS net sales for the U.S. and Canada were $344.8 million for the year-to-date in 2018, a 54 percent increase over net sales of $223.8 million for the same period in 2017. Growth over 2017 reflects recent ADCETRIS label expansions, including cutaneous T-cell lymphoma subtypes in November 2017 and frontline Stage III and IV Hodgkin lymphoma in March 2018.
- **Royalty Revenues:** Royalty revenues in the third quarter were $22.7 million, compared to $16.7 million in the third quarter of 2017. Royalty revenues were $58.9 million for the year-to-date in 2018, compared to $46.0 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 $19.8 million in the third quarter and $76.5 million for the first nine months of 2018, compared to $39.4 million and $82.8 million, respectively, for the same periods in 2017. Collaboration revenues for the third quarter included the earned portion of a $10.0 million milestone from Takeda triggered by the approval of ADCETRIS in combination with AVD as a frontline treatment for CD30-positive Hodgkin lymphoma patients in Japan.

Research and Development (R&D) Expenses: R&D expenses in the third quarter were $140.2 million, compared to $113.6 million in the third quarter of 2017. R&D expenses were $415.5 million for the year-to-date in 2018, compared to $346.2 million for the same period in 2017. The increase for the year-to-date period reflects $35.0 million in upfront costs in the first quarter of 2018 related to technology licensing agreements in addition to increased investment in the company's pipeline programs.

Selling, general and administrative (SG&A) Expenses: SG&A expenses in the third quarter were $57.2 million, compared to $39.7 million in the third quarter of 2017. SG&A expenses were $181.6 million for the year-to-date in 2018, compared to $118.8 million for the same period 2017. The increase for the year-to-date period was primarily attributed to costs to support the launch of ADCETRIS in frontline Hodgkin lymphoma and transaction costs associated with the acquisition of Cascadian Therapeutics.

Non-cash, share-based compensation cost for the first nine months of 2018 was $53.2 million, compared to $47.9 million for the same period in 2017.

Net Income (Loss)

Net loss for the third quarter of 2018 was $67.4 million, or $0.42 per diluted share, compared to net income of $50.0 million, or $0.34 per diluted share, for the third quarter of 2017. Net loss in the third quarter of 2018 includes a net investment loss of $23.8 million primarily associated with Seattle Genetics' common stock holdings in Immunomedics, which are marked-to-market. For the nine months ended September 30, 2018, net loss was $102.9 million, or $0.66 per share, compared to a net loss of $66.3 million, or $0.46 per share, for the nine months ended September 30, 2017. Net loss for the year-to-date in 2018 includes a net investment gain of $62.9 million primarily associated with Seattle Genetics' common stock holdings in Immunomedics.

Cash and Investments

As of September 30, 2018, Seattle Genetics had $485.7 million in cash and investments. In addition, the company held stock investments, primarily in Immunomedics common stock, valued at $169.4 million.

2018 FINANCIAL GUIDANCE

The company's 2018 financial guidance is detailed below.

	Current	Previous
Fourth Quarter		
ADCETRIS net product sales	$128 million to $133 million	None provided
Full Year		
ADCETRIS net product sales	$473 million to $478 million	None provided
Collaboration and license agreement revenues	$80 million to $90 million	$65 million to $75 million
Royalty revenues	$78 million to $82 million	$75 million to $80 million
R&D expenses	$555 million to $575 million	$530 million to $580 million
SG&A expenses	$240 million to $250 million	$220 million to $240 million

Conference Call Details

Seattle Genetics' management will host a conference call and webcast to discuss its third quarter 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 will be available from the Seattle Genetics website at www.seattlegenetics.com, under the Investors section, or by calling 877-260-1479 (domestic) or 334-323-0522 (international). The conference ID is 3537888. A replay of the discussion will be available on October 25, 2018 from the Seattle Genetics website or by calling 888-203-1112 (domestic) or 719-457-0820 (international), using conference ID 3537888. The telephone replay will be available until 5:00 p.m. PT on Monday, October 29, 2018.

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 2018 outlook, including anticipated fourth quarter ADCETRIS net sales and full year ADCETRIS net sales, revenues and expenses; the company's potential to achieve the noted development and regulatory milestones in 2018 and in future periods and to otherwise offer multiple transformative therapies including the submission of a supplemental Biologics License Application (BLA) to the FDA for approval of ADCETRIS in frontline CD30-expressing PTCL in November 2018; anticipated activities related to the company's planned and ongoing clinical trials, including clinical trial initiation, 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; anticipated presentations at scientific conferences; 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, unexpected adverse events or regulatory discussions or actions and the inherent uncertainty associated with the regulatory approval process. The company may also be unable to expand ADCETRIS' labeled indications due to unexpected, negative or delayed regulatory action, and that supplemental BLA submission based on ECHELON-2 may not be accepted for filing by, or ultimately approved by, the FDA in a timely manner or at all or with the requested label, and the company may be unable to complete the development of, and obtain regulatory approval for, any of its product candidates. 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 June 30, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Net product sales	$ 126,976	$ 79,177	$ 344,776	$ 223,841
Collaboration and license agreement revenues	19,786	39,444	76,524	82,779
Royalty revenues	22,662	16,670	58,887	46,025
Total revenues	169,424	135,291	480,187	352,645
Costs and expenses:				
Cost of sales	12,348	9,019	35,863	24,555
Cost of royalty revenues	5,320	5,196	16,845	13,900
Research and development	140,175	113,606	415,537	346,196
Selling, general and administrative	57,155	39,667	181,629	118,783
Total costs and expenses	214,998	167,488	649,874	503,434
Loss from operations	(45,574)	(32,197)	(169,687)	(150,789)
Investment and other income (loss), net	(21,872)	82,218	66,799	84,460
Net income (loss)	$ (67,446)	$ 50,021	$ (102,888)	$ (66,329)
Net income (loss) per share - basic	$ (0.42)	$ 0.35	$ (0.66)	$ (0.46)
Net income (loss) per share - diluted	$ (0.42)	$ 0.34	$ (0.66)	$ (0.46)
Shares used in computation of per share amounts - basic	159,304	143,357	156,799	142,876
Shares used in computation of per share amounts - diluted	159,304	148,068	156,799	142,876

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

	September 30, 2018	December 31, 2017
Assets		
Cash, cash equivalents and investments	$ 485,711	$ 413,171
Other assets	1,082,134	464,778
Total assets	$ 1,567,845	$ 877,949
Liabilities and Stockholders' Equity		
Accounts payable and accrued liabilities	$ 157,157	$ 132,672
Deferred revenue and long-term liabilities	46,167	67,708
Stockholders' equity	1,364,521	677,569
Total liabilities and stockholders' equity	$ 1,567,845	$ 877,949