

**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 26, 2018

Seattle Genetics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

0-32405
(Commission
File Number)

91-1874389
(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 July 26, 2018, Seattle Genetics, Inc. issued a press release announcing financial results for its second quarter ended June 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](#) July 26, 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: July 26, 2018

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



Seattle Genetics Reports Second Quarter 2018 Financial Results

-Record ADCETRIS® (Brentuximab Vedotin) Net Sales in U.S. and Canada of \$122.4 Million in the Second Quarter-

-ADCETRIS ECHELON-2 Top-line Results Expected in Early Fourth Quarter 2018-

-Enrollment Completed in Pivotal Trial Cohort of Enfortumab Vedotin in Metastatic Urothelial Cancer; EV Top-line Results Expected in First Half of 2019-

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

BOTHELL, Wash. — July 26, 2018 — Seattle Genetics, Inc. (Nasdaq:SGEN) today reported financial results for the second quarter and six months ended June 30, 2018. The company also highlighted ADCETRIS (brentuximab vedotin) commercialization and clinical development accomplishments and progress with its late-stage clinical programs for cancer.

“Our ADCETRIS sales growth in the first full quarter following FDA approval in frontline Stage III or IV classical Hodgkin lymphoma demonstrates a strong reception from the oncology community and our ability to bring the first new treatment option to patients after more than 40 years,” said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. “Looking ahead, we expect to report top-line results from the ADCETRIS phase 3 ECHELON-2 trial in frontline CD30-expressing mature T-cell lymphomas early in the fourth quarter that could be another driver of future growth. Our late-stage clinical pipeline comprises three programs in ongoing pivotal trials, including enfortumab vedotin which is positioned for top-line data in the first half of 2019 in metastatic urothelial cancer. Our recent accomplishments and expected near-term milestones highlight our progress toward the goal of becoming a multi-product global oncology company.”

ADCETRIS Program Activities

- **ECHELON-2 Phase 3 Trial:** Seattle Genetics has narrowed its guidance and now expects to report top-line data early in the fourth quarter of 2018 from the phase 3 ECHELON-2 clinical trial in frontline CD30-expressing mature T-cell lymphoma, also known as peripheral T-cell lymphoma (PTCL).
- **ECHELON-1 Data:** Multiple posters featuring additional analyses from the ECHELON-1 trial in the treatment of patients with Stage III or IV classical Hodgkin lymphoma (HL) were presented at the 2018 American Society of Clinical Oncology Annual Meeting held in June. These analyses continued to demonstrate the clinical benefit of the ADCETRIS combination when compared with standard chemotherapy. In March 2018, the U.S. Food and Drug Administration (FDA) approved ADCETRIS in combination with chemotherapy for the treatment of adult patients with previously untreated Stage III or IV classical HL based on the positive results of the phase 3 ECHELON-1 clinical trial.

ADCETRIS is not currently approved for use in frontline PTCL.

Enfortumab Vedotin (EV) Program Activities

- **EV-201 Pivotal Trial Cohort Enrollment Completed:** Seattle Genetics and Astellas completed enrollment in the first cohort of the EV-201 pivotal trial in patients with locally advanced or metastatic urothelial cancer who previously received both a checkpoint inhibitor (PD-1/PD-L1) and a platinum-containing regimen. The companies expect to report top-line data from this cohort in the first half of 2019. Positive data in this cohort could potentially support registration under the FDA's accelerated approval pathway.
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- **EV-301 Phase 3 Trial Initiated:** Seattle Genetics and Astellas initiated a global randomized phase 3 clinical trial called EV-301 for patients with locally advanced or metastatic urothelial cancer who were previously treated with a checkpoint inhibitor (PD-1/PD-L1) and a platinum-containing regimen. EV-301, which is expected to enroll 550 patients, is intended to support global regulatory submissions for approval and serve as a confirmatory trial in the United States.

Tucatinib Program Activities

- **HER2CLIMB Pivotal Trial:** Enrollment is ongoing in the tucatinib HER2CLIMB randomized pivotal trial for patients with HER2-positive (HER2+) metastatic breast cancer who have been previously treated with HER2-targeted agents, including patients with or without brain metastases. Results from a phase 1b trial that support the HER2CLIMB trial were recently published in *The Lancet Oncology*. The company continues to expect to complete enrollment of HER2CLIMB in 2019.
- **Expansion of Tucatinib Clinical Program:** Seattle Genetics is evaluating opportunities to expand the development of tucatinib in earlier lines of HER2+ metastatic breast cancer based on the results of a separate phase 1b clinical trial of tucatinib that were recently published in *JAMA Oncology*. The company is also considering development opportunities for tucatinib in the treatment of other HER2+ solid tumors such as colorectal and gastric cancer.

Tisotumab Vedotin (TV) Program Activities

- **Metastatic Cervical Cancer Trial Initiated:** Seattle Genetics and Genmab initiated a phase 2 trial called innovaTV 204 in patients with recurrent and/or metastatic cervical cancer who have relapsed or progressed after standard of care treatment. The trial will enroll approximately 100 patients and is intended to potentially support registration under the FDA's accelerated approval pathway.
- **Solid Tumor Trial Initiated:** Seattle Genetics and Genmab initiated a phase 2 clinical trial called innovaTV 207 in several types of solid tumors. The trial is intended to inform a potential broad development program.

Other Recent Activities

- **ADC Collaborator Milestones:** Seattle Genetics earned milestone payments totaling \$17.0 million under its antibody-drug conjugate (ADC) technology collaborations with AbbVie, Genmab and GlaxoSmithKline, triggered by clinical progress with programs using its technology.
- **Roger Dansey, M.D., Appointed Chief Medical Officer:** Dr. Dansey has extensive experience in cancer drug development, most recently at Merck Inc. where he was Therapeutic Area Head for Late Stage Oncology, and led the registration efforts for KEYTRUDA® (pembrolizumab) across multiple tumor types.

Second Quarter and Six Months 2018 Financial Results

Total revenues in the second quarter and six month periods ended June 30, 2018 increased to \$170.2 million and \$310.8 million, respectively, compared to \$108.2 million and \$217.4 million for the same periods in 2017. Revenues included:

- ADCETRIS net sales for the U.S. and Canada in the second quarter of \$122.4 million, a 65 percent increase over net sales of \$74.3 million in the second quarter of 2017. ADCETRIS net sales for the U.S. and Canada were \$217.8 million for the year-to-date in 2018, a 51 percent increase over net sales of \$144.7 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 or IV Hodgkin lymphoma in March 2018.
 - Royalty revenues in the second quarter of \$20.6 million, compared to \$12.4 million in the second quarter of 2017. Royalty revenues were \$36.2 million for the year-to-date in 2018, compared to \$29.4 million for the same period in 2017. Royalty revenues are primarily driven by sales of ADCETRIS outside the U.S. and Canada by Takeda.
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- Amounts earned under the company's ADCETRIS and ADC collaborations totaling \$27.2 million in the second quarter and \$56.7 million for the first six months of 2018, compared to \$21.5 million and \$43.3 million, respectively, for the same periods in 2017. Collaboration revenues for the second quarter included \$17.0 million in product development milestones achieved under the company's ADC collaborations.

Total costs and expenses for the second quarter of 2018 were \$200.5 million, compared to \$167.5 million for the second quarter of 2017. For the first six months of 2018, total costs and expenses were \$434.9 million, compared to \$335.9 million for the same period in 2017. Costs and expenses included:

- Research and development expenses in the second quarter of \$122.9 million, compared to \$114.4 million in the second quarter of 2017. Research and development expenses were \$275.4 million for the year-to-date in 2018, compared to \$232.6 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 expenses in the second quarter of \$58.3 million, compared to \$40.7 million in the second quarter of 2017. Selling, general and administrative expenses were \$124.5 million for the year-to-date in 2018, compared to \$79.1 million for the same period 2017. The increase for the year-to-date period was primarily due to transaction costs associated with the acquisition of Cascadian Therapeutics and costs to support the launch of ADCETRIS in frontline Hodgkin lymphoma.

Non-cash, share-based compensation cost for the first six months of 2018 was \$32.4 million, compared to \$32.0 million for the same period in 2017.

Net income for the second quarter of 2018 was \$76.3 million, or \$0.47 per diluted share, compared to a net loss of \$56.4 million, or \$0.39 per diluted share, for the second quarter of 2017. Net income in the second quarter of 2018 includes a net gain of \$105.5 million primarily associated with Seattle Genetics' common stock holdings in Immunomedics. For the six months ended June 30, 2018, net loss was \$35.4 million, or \$0.23 per share, compared to a net loss of \$116.4 million, or \$0.82 per share, for the six months ended June 30, 2017. Net loss for the year-to-date in 2018 includes a net gain of \$86.6 million primarily associated with Seattle Genetics' common stock holdings in Immunomedics.

As of June 30, 2018, Seattle Genetics had \$457.8 million in cash and investments. In addition, the company held stock in Immunomedics and Unum valued at \$208.0 million.

2018 Financial Outlook

For the third quarter of 2018, Seattle Genetics expects sales of ADCETRIS to be in the range of \$130 million to \$135 million. In addition, as a result of milestone achievements and other items that occurred in the first half of 2018, the company is increasing collaboration revenue guidance for the full year in 2018 to a range of \$65 million to \$75 million, compared to its previous guidance of \$55 million to \$65 million.

Conference Call Details

Seattle Genetics' management will host a conference call and webcast to discuss its second 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 6908320. A replay of the discussion will be available on July 26, 2018 from the Seattle Genetics website or by calling 888-203-1112 (domestic) or 719-457-0820 (international), using conference ID 6908320. The telephone replay will be available until 5:00 p.m. PT on Monday, July 30, 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 third quarter ADCETRIS net sales and full year 2018 collaboration revenues; 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; 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 ECHELON-2, 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 third quarter ADCETRIS net sales, full year 2018 collaboration revenue and other financial guidance may not be as expected, as well as risks and uncertainties associated with maintaining or increasing sales of ADCETRIS particularly in light of the company's lack of commercialization experience in additional indications for which ADCETRIS has recently and may in the future be approved for marketing. 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 data from ECHELON-2 or regulatory action, and that any 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 March 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:

Peggy Pinkston

425-527-4160

ppinkston@seagen.com

Media:

Monique Greer

425-527-4641

mgreer@seagen.com

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,	
	2018	2017	2018	2017
Revenues:				
Net product sales	\$ 122,443	\$ 74,343	\$ 217,800	\$ 144,664
Collaboration and license agreement revenues	27,179	21,505	56,738	43,335
Royalty revenues	20,551	12,375	36,225	29,355
Total revenues	170,173	108,223	310,763	217,354
Costs and expenses:				
Cost of sales	13,157	8,055	23,515	15,536
Cost of royalty revenues	6,148	4,324	11,525	8,704
Research and development	122,860	114,406	275,362	232,590
Selling, general and administrative	58,292	40,712	124,474	79,116
Total costs and expenses	200,457	167,497	434,876	335,946
Loss from operations	(30,284)	(59,274)	(124,113)	(118,592)
Investment and other income, net	106,557	2,914	88,671	2,242
Net income (loss)	\$ 76,273	\$ (56,360)	\$ (35,442)	\$ (116,350)
Net income (loss) per share - basic	\$ 0.48	\$ (0.39)	\$ (0.23)	\$ (0.82)
Net income (loss) per share - diluted	\$ 0.47	\$ (0.39)	\$ (0.23)	\$ (0.82)
Shares used in computation of per share amounts - basic	158,381	142,802	155,525	142,631
Shares used in computation of per share amounts - diluted	163,382	142,802	155,525	142,631

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

	June 30, 2018	December 31, 2017
Assets		
Cash, cash equivalents and investments	\$ 457,834	\$ 413,171
Other assets	1,123,083	464,778
Total assets	\$ 1,580,917	\$ 877,949
Liabilities and Stockholders' Equity		
Accounts payable and accrued liabilities	\$ 145,189	\$ 132,672
Deferred revenue and long-term liabilities	53,289	67,708
Stockholders' equity	1,382,439	677,569
Total liabilities and stockholders' equity	\$ 1,580,917	\$ 877,949