Seagen®

2022 Annual Report

Improving Lives: Innovative Targeted Cancer Therapeutics with ADCs at our Core

GLORIA, RESEARCH ASSOCIATE, PHARMACEUTICAL SCIENCES

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____
Commission file number: 0-32405

SEAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**91-1874389**
(State or other Jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

21823 30th Drive SE, Bothell, WA 98021
(Address of principal executive offices, including zip code)
Registrant's telephone number, including area code: **(425) 527-4000**

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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Smaller reporting 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $24.2 billion as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price on The Nasdaq Global Select Market reported for such date. Excludes an aggregate of 47,705,501 shares of the registrant's Common Stock held as of such date by officers, directors and stockholders that the registrant has concluded are or were affiliates of the registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

There were 186,789,367 shares of the registrant's Common Stock issued and outstanding as of February 10, 2023.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the registrant's 2023 Annual Meeting of Stockholders.

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"Seagen," "we," "us" and "our" as used in this Annual Report on Form 10-K refer to Seagen Inc. and its subsidiaries.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "could", "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements, except as required by law. Any or all of our forward-looking statements in this document may turn out to be incorrect. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Item 1A—Risk Factors." We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading "Item 1A—Risk Factors", below. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties.

- Our success depends on our ability to effectively commercialize our products. If we and our collaborators are unable to effectively commercialize our products and to expand their utilization, our ability to generate significant revenue and our prospects for profitability will be adversely affected.
- Our success also depends on our ability to obtain regulatory approvals for our product candidates and for our current products in additional territories, as well as our ability to expand the labeled indications of use for our current products. Our inability to do so could have a material adverse effect on our business, results of operations, financial condition and growth prospects.
- Reports of adverse events or safety concerns involving our products or product candidates could delay or prevent us from obtaining or maintaining regulatory approvals or could negatively impact sales of our products or the prospects for our product candidates.
- Clinical trials and product development are expensive, time consuming and uncertain, may take longer than we expect and may not be successful. Our failure to effectively advance our development programs in a timely manner or at all could have a material adverse effect on our business, results of operations, financial condition and growth prospects.
- The successful commercialization of our products will depend, in part, on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.
- The successful commercialization of our products will also depend, in part, on the acceptance of our products by the medical community, patients and third-party payors.
- Any failures or setbacks in our antibody-drug conjugate, or ADC, development program or our other platform technologies could negatively affect our business and financial position.
- We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

- Our products and any future approved products remain subject to extensive ongoing regulatory obligations and oversight, including post-approval requirements, that could result in penalties and significant additional expense and could negatively impact our and our collaborators' ability to commercialize our current and any future approved products.
- Healthcare law and policy changes may negatively impact our business, including by decreasing the prices that we and our collaborators receive for our products.
- We are subject to various state, federal and international laws and regulations, including healthcare, data privacy and information security laws and regulations, that may impact our business and could subject us to significant fines and penalties or other negative consequences.
- Our collaborators and licensees may not perform as expected, which may negatively affect our ability to develop and commercialize our products and product candidates and/or generate revenues through technology licensing, and may otherwise negatively affect our business.
- We currently rely on third-party manufacturers and other third parties for production of our drug products, and our dependence on these third parties may impair the continued development and commercialization of our products and product candidates.
- If we are unable to enforce our intellectual property rights or if we fail to sustain and further procure additional intellectual property rights, we may not be able to successfully commercialize our products or any future products and competitors may be able to develop competing therapies.
- We and our collaborators rely on license agreements for certain aspects of our products and product candidates and technologies such as our ADC technology. Failure to maintain these license agreements or to secure any required new licenses could prevent us from continuing to develop and commercialize our products and product candidates.
- We have been and may in the future be subject to litigation, which could result in substantial expenses and damages and may divert management's time and attention from our business.
- The evolving effects of the COVID-19 pandemic and associated global economic instability could have further adverse effects on our business, including our commercialization efforts, supply chain, regulatory activities, clinical development activities and other business operations.
- If we are unable to manage our growth, our business, results of operations, financial condition and growth prospects may be adversely affected.
- Risks associated with our expanding operations in countries outside the U.S. could materially adversely affect our business.
- Our operating results are difficult to predict and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.
- We have a history of net losses. We expect to continue to incur net losses and may not achieve future sustained profitability for some time, if at all.
- Our stock price is volatile and our shares may suffer a decline in value.
- Our existing stockholders have significant control of our management and affairs.

PART I

Item 1. Business

Overview

Seagen is a biotechnology company that develops and commercializes targeted therapies to treat cancer. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of certain CD30-expressing lymphomas, PADCEV®, or enfortumab vedotin-ejfv, for the treatment of certain metastatic urothelial cancers, TUKYSA®, or tucatinib, for the treatment of certain metastatic HER2-positive breast and colorectal cancers, and TIVDAK®, or tisotumab vedotin-tftv, for the treatment of certain metastatic cervical cancers. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients. Many of our programs, including ADCETRIS, PADCEV and TIVDAK, are based on our ADC technology that utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells.

Our strategy is to become a leading global oncology company developing and marketing targeted therapies for cancer. Key elements of our strategy are to maximize the potential of our approved medicines through successful commercial execution, expand the number of patients eligible to receive our medicines by securing approvals of our commercial products in other countries, conduct clinical trials designed to support additional labels for our products, and develop new first-in-class or best-in-class medicines. We seek to commercialize our products either on our own as we expand our operations globally or through commercial partnerships. We are deploying our internal research, clinical, development, regulatory and manufacturing expertise to advance and expand our deep pipeline of drug candidates aimed at gaining new product approvals. We conduct internal research directed at identifying novel antigen targets, monoclonal antibodies and other targeting molecules, creating new antibody engineering techniques and developing new classes of stable linkers and cell-killing agents in support of our continued ADC innovation. In addition, we supplement these internal efforts by acquiring or in-licensing products, product candidates and technologies from biotechnology and pharmaceutical companies and academic institutions.

Our Medicines

Our approved medicines include the following:

Product*	Therapeutic Area	U.S. Approved Indication
ADCETRIS® brentuximab vedotin | for injection	**Hodgkin Lymphoma**	Previously untreated Stage III/IV classical Hodgkin lymphoma, or cHL, in combination with doxorubicin, vinblastine and dacarbazine cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation, or auto-HSCT, consolidation cHL after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates Pediatric patients 2 years and older with previously untreated high risk cHL, in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide
	T-cell Lymphoma	Previously untreated systemic anaplastic large cell lymphoma, or sALCL, or other CD30-expressing peripheral T-cell lymphoma, or PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin and prednisone sALCL after failure of at least one prior multi-agent chemotherapy regimen Primary cutaneous anaplastic large cell lymphoma, or pcALCL, or CD30-expressing mycosis fungoides who have received prior systemic therapy
PADCEV® enfortumab vedotin-ejfv Injection for IV infusion 20 mg & 30 mg vials	**Urothelial Cancer**	Locally advanced or metastatic urothelial cancer for patients who: • have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy, or • are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.
TUKYSA® tucatinib 50 mg | 150 mg tablets	**Breast Cancer**	In combination with trastuzumab and capecitabine for the treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.
	Colorectal Caner	In combination with trastuzumab for adult patients with *RAS* wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.
tivdak® tisotumab vedotin-tftv for injection 40 mg	**Cervical Cancer**	Recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

**PADCEV, TUKYSA and TIVDAK are only indicated for use in adults.*

ADCETRIS®

ADCETRIS is an ADC targeting CD30, which is a protein located on the surface of cells and highly expressed in Hodgkin lymphoma, certain T-cell lymphomas as well as other cancers. ADCETRIS first received U.S. Food and Drug Administration, or FDA, approval in 2011 and is now approved in a total of seven indications to treat Hodgkin lymphoma and certain T-cell lymphomas in various settings, including as frontline therapy for both adult and pediatric patients.

The most recent approval was granted in November 2022 for the treatment of pediatric patients two years and older with previously untreated high risk classical Hodgkin lymphoma, in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide.

ADCETRIS has received approval in more than 75 countries worldwide. We commercialize ADCETRIS in the U.S. and its territories and in Canada, and we collaborate with an affiliate of Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize ADCETRIS on a global basis. Under this collaboration, Takeda has commercial rights in the rest of the world and pays us a royalty. Takeda has received regulatory approvals for ADCETRIS as monotherapy or in combination with other agents in various settings for the treatment of patients with Hodgkin lymphoma or CD30-positive T-cell lymphomas in Europe and many countries throughout the rest of the world and is pursuing additional regulatory approvals.

PADCEV®

PADCEV is an ADC targeting Nectin-4, a protein expressed on the surface of cells and highly expressed in bladder cancer as well as other cancers. PADCEV was granted accelerated approval by the FDA in December 2019 for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1 or PD-L1 inhibitor and a platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery in the locally advanced or metastatic setting. FDA approval of PADCEV was supported by data from a single-arm pivotal phase 2 clinical trial called EV-201.

In July 2021, the FDA converted PADCEV's accelerated approval to regular approval in the U.S., in addition to granting regular approval for a new indication for adult patients with locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy. The conversion to regular approval was supported by the pivotal phase 3 clinical trial called EV-301 and the expanded indication was supported by data from the second cohort in the EV-201 trial. The FDA reviewed the application for regular approval under the Oncology Center of Excellence's, or OCE's, Real Time Oncology Review, or RTOR, pilot program.

In April 2022, the European Commission, or EC, approved PADCEV as monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a PD-1/L1 inhibitor. The approval is applicable in the European Union member states, as well as Iceland, Norway and Liechtenstein.

PADCEV is also approved in other countries, including Brazil, Canada, Japan, Great Britain and Switzerland, in previously treated metastatic urothelial cancer.

PADCEV is being co-developed and jointly commercialized with Astellas Pharma, Inc., or Astellas. In the U.S., we and Astellas are jointly promoting PADCEV. We record net sales of PADCEV in the U.S. and are responsible for all U.S. distribution activities. We and Astellas each bear the costs of our own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S., and equally share in any profits realized in the U.S. Outside the U.S., we have commercialization rights in all other countries in North and South America, and Astellas has commercialization rights in the rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively equally share in costs incurred and any profits realized in all of these markets. Cost and profit sharing in Canada, the United Kingdom, Germany, France, Spain and Italy are based on product sales and costs of commercialization. In the remaining markets, the commercializing party is responsible for bearing the costs and paying the other party a royalty rate applied to net sales of the product based on a rate intended to approximate an equal profit share for both parties.

TUKYSA®

TUKYSA is an oral, small molecule tyrosine kinase inhibitor that is highly selective for HER2, a growth factor receptor overexpressed in certain cancers. HER2 mediates cell growth, differentiation and survival. Tumors that over-express HER2 are generally more aggressive and historically have been associated with poor overall survival, compared with HER2-negative cancers. In April 2020, TUKYSA received approval from the FDA in combination with trastuzumab and capecitabine for the treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. FDA approval of TUKYSA was supported by data from the HER2CLIMB trial.

The application for approval was reviewed under the FDA's RTOR pilot program. We also participated in the Project Orbis initiative of the FDA OCE, which provides a framework for concurrent submission and review of oncology products among international partners. Under this program, we have received approval in the U.S., Canada, Australia, Singapore, and Switzerland. In February 2021, the EC granted marketing authorization for TUKYSA in combination with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive locally advanced or metastatic breast cancer who have received at least two prior anti-HER2 treatment regimens. This approval is valid in all countries of the European Union as well as Norway, Liechtenstein, Iceland and Northern Ireland. In Europe, we have begun marketing TUKYSA in Austria, France, Germany and Switzerland. Additionally, in February 2021, the UK Medicines and Healthcare products Regulatory Agency, granted a Great Britain marketing authorization for TUKYSA.

In January 2023, TUKYSA received accelerated approval in combination with trastuzumab for adult patients with *RAS* wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy. The approval was based on tumor response rate and durability of response from the phase 2 MOUNTAINEER clinical trial. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

We are responsible for commercializing TUKYSA in the U.S., Canada and Europe. In September 2020, we entered into a license and collaboration agreement, or the TUKYSA Agreement, with Merck & Co., Inc., or Merck, pursuant to which we granted exclusive rights to Merck to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. The collaboration is intended to accelerate global availability of TUKYSA.

TIVDAK®

TIVDAK is an ADC targeting tissue factor, a protein expressed on the surface of cells that has increased levels of expression on multiple solid tumors. The FDA granted accelerated approval of TIVDAK in September 2021 for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. FDA approval was supported by data from the innovaTV 204 trial where it was evaluated in patients with recurrent or metastatic cervical cancer who had received no more than two prior systemic regimens in the recurrent or metastatic setting, including at least one prior platinum-based chemotherapy regimen. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

TIVDAK is being co-developed with Genmab A/S, or Genmab, under an agreement in which the companies equally share all costs and profits for the product. Under a joint commercialization agreement, we and Genmab co-promote TIVDAK in the U.S., and we record net sales of TIVDAK in the U.S. and are responsible for leading U.S. distribution activities. The companies will each maintain 50% of the sales representatives and medical science liaisons, equally share those and certain other costs associated with commercializing TIVDAK in the U.S., and equally share in any profits realized in the U.S. Outside the U.S., we have commercialization rights in the rest of the world except for Japan, where Genmab has commercialization rights, and certain territories where Zai Lab has commercialization rights, as further described below. In Europe, China, and Japan, we and Genmab will equally share 50% of the costs associated with commercializing TIVDAK as well as any profits realized in these markets. In markets outside the U.S. other than Europe, China, and Japan, aside from certain costs specified in the agreement, we will be solely responsible for all costs associated with commercializing TIVDAK, and will pay Genmab a royalty based on a percentage of aggregate net sales.

In September 2022, we announced an exclusive collaboration and license agreement with Zai Lab for the development and commercialization of TIVDAK in mainland China, Hong Kong, Macau, and Taiwan. Under the terms of the agreement, we received an upfront fee of $30 million in October 2022, and are entitled to receive potential development, regulatory, and commercial milestone payments, and tiered royalties on net sales of TIVDAK in the Zai Lab territory. Based on our existing collaboration with Genmab, the upfront payment, milestone payments, and royalties will be equally shared with Genmab.

Our Clinical Development Pipeline

The following table summarizes the key clinical trials of ADCETRIS, PADCEV, TUKYSA and TIVDAK:

Product	Tumor Type	Setting	Trial Name / Description	Development Status
ADCETRIS (brentuximab vedotin)	Diffuse large B-cell lymphoma	R/R	ECHELON-3: In combination with lenalidomide and rituximab	Phase 3*
	Hodgkin lymphoma	1L	SGN35-027 -Part C: In combination with nivolumab, doxorubicin and dacarbazine	Phase 2
	Hodgkin lymphoma (pediatrics)	R/R	CheckMate 744: In combination with nivolumab[1]	Phase 2
	Peripheral T-cell lymphoma (< 10% CD30 expression)	1L	SGN35-032: In combination with cyclophosphamide, doxorubicin and prednisone	Phase 2
	Metastatic solid tumors	R/R	SGN35-033: In combination with pembrolizumab | post PD-1 inhibitor treatment	Phase 2
PADCEV (enfortumab vedotin-ejfv)[2]	Locally advanced or metastatic urothelial cancer	1L	EV-302: In combination with pembrolizumab vs chemotherapy alone	Phase 3*
		1L/2L	EV-103: Monotherapy and in combination with pembrolizumab	Phase 2*
	Muscle invasive bladder cancer	P	EV-303/KEYNOTE-905: In combination with pembrolizumab | cisplatin-ineligible	Phase 3*
		P	EV-304/KEYNOTE-B15: In combination with pembrolizumab | cisplatin-eligible	Phase 3*
		P	EV-103: Monotherapy and in combination with pembrolizumab	Phase 2
	Non-muscle invasive bladder cancer	BCGU	EV-104: intravesical	Phase 1
	Locally advanced or metastatic solid tumors	2L+	EV-202: Monotherapy	Phase 2
TUKYSA (tucatinib)	HER2+ metastatic breast cancer	1L/2L	HER2CLIMB-02: In combination with T-DM1	Phase 3*
	High risk HER2+ breast cancer	ADJ	COMPASSHER2 RD[4]: In combination with T-DM1	Phase 3*
	HER2+ metastatic breast cancer	1L maintenance	HER2CLIMB-05: In combination with trastuzumab and pertuzumab	Phase 3*
	HER2+ metastatic breast cancer	2L+	HER2CLIMB-04: In combination with trastuzumab deruxtecan	Phase 2
	HER2+ metastatic colorectal cancer	1L	MOUNTAINEER-03: In combination with trastuzumab and mFOLFOX6	Phase 3*
	Metastatic solid tumors HER2 alterations	2L	TUC-019: In combination trastuzumab**	Phase 2
	HER2+ gastric cancer	1L	TUC-024: In combination with trastuzumab and oxaliplatin	Phase 1
TIVDAK (tisotumab vedotin-tftv)[3]	Metastatic/recurrent cervical cancer	2L/3L	innovaTV 301: Monotherapy	Phase 3*
		1L/2L	innovaTV 205: In combination with other anti-cancer agents	Phase 1/2
	Metastatic solid tumors	R/R	innovaTV 207: Monotherapy or in combination	Phase 2

1L: front/first-line 2L:second-line R/R:relapsed or refractory ADJ = adjuvant P = perioperative BCGU= BCG unresponsive
* indicates registrational intent
**HR-positive metastatic breast cancer also in combination with fulvestrant

1. Clinical collaboration with Bristol-Myers Squibb
2. 50:50 co-development and commercial collaboration with Astellas
3. 50:50 co-development and commercial collaboration with Genmab
4. Conducted in collaboration with Alliance for Clinical Trials in Oncology and National Cancer Institute (NCI)

The table below lists select clinical trials of our development candidates.

Product Candidates	Tumor Type	Setting	Trial Name / Description	Development Status
Disitamab Vedotin	HER2-expressing metastatic urothelial cancer	2L/3L	Monotherapy	Phase 2
Ladiratuzumab Vedotin[1]	Metastatic triple-negative breast cancer	1L	In combination with pembrolizumab	Phase 2
	Metastatic solid tumors	R/R	Monotherapy	Phase 2
	Metastatic breast cancer	R/R	Monotherapy	Phase 1
SGN-ALPV	Solid tumors	R/R	Monotherapy	Phase 1
SGN-BB228	Solid Tumors	R/R	Monotherapy	Phase 1
SGN-B6A	Solid tumors	R/R	Monotherapy	Phase 1
SGN-B7H4V	Solid tumors	R/R	Monotherapy	Phase 1
SGN-STNV	Solid tumors	R/R	Monotherapy	Phase 1
SGN-PDL1V	Solid tumors	R/R	Monotherapy	Phase 1
SEA-CD70	MDS / AML	R/R	Monotherapy	Phase 1
SEA-TGT	Solid tumors and lymphoma	R/R	Monotherapy or in combination with sasanlimab	Phase 1

1L: front/first-line 2L:second-line 3L: third-line R/R:relapsed or refractory
1. 50:50 co-development and commercial collaboration with Merck

Clinical Development and Regulatory Status

ADCETRIS (brentuximab vedotin)

Beyond our current labeled indications, we are evaluating ADCETRIS as monotherapy and in combination with other agents in ongoing trials, including several potentially registration-enabling trials such as the phase 3 ECHELON-3 clinical trial in relapsed or refractory diffuse large B-cell lymphoma. We expect to report initial data in solid tumors in the first half of 2023. In addition to our corporate-sponsored trials, there are numerous investigator-sponsored trials of ADCETRIS in the United States. The investigator-sponsored trials include the use of ADCETRIS in a number of malignant hematologic indications and in solid tumors.

In February 2022, we announced that the phase 3 ECHELON-1 clinical trial demonstrated a statistically significant improvement in overall survival, or OS, (p=0.009) in patients with previously untreated advanced Hodgkin lymphoma following treatment with ADCETRIS in combination with chemotherapy. With approximately six years median follow up, patients receiving ADCETRIS plus doxorubicin, vinblastine, and dacarbazine (A+AVD) in the frontline setting had a 41 percent reduction in the risk of death (HR 0.59; [95% CI: 0.396 to 0.879]) compared with patients receiving doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD). The safety profile of ADCETRIS was consistent with previous studies and no new safety events were observed.

In July 2022, these results were published in the New England Journal of Medicine. In September 2022, based on these data, we submitted a supplemental Biologics License Application, or sBLA, to the FDA for review. The FDA established a Prescription Drug User Fee Act, or PDUFA, target action date of June 29, 2023. Also, in September 2022, based on the overall survival benefit of ADCETRIS in combination with chemotherapy that was demonstrated in the ECHELON-1 trial, the National Comprehensive Cancer Network®, or NCCN, Clinical Practice Guidelines in Oncology, or NCCN Guidelines®, were updated elevating the ADCETRIS combination to Category 1, Preferred treatment option for adults with previously untreated Stage III or IV Hodgkin lymphoma with no known neuropathy. Category 1, Preferred is the highest recommendation by NCCN, indicating that based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

In June 2022, we announced results from a phase 3 clinical trial conducted by the Children's Oncology Group evaluating ADCETRIS in children and young adults with high-risk, previously untreated classical Hodgkin lymphoma. The trial showed ADCETRIS in combination with standard of care showed a clinically meaningful and statistically significant 59% reduction in the risk of disease progression or relapse, second malignancy or death and achieved superior event-free survival compared to the current standard of care. ADCETRIS in combination with AVE-PC was well tolerated with a manageable safety profile in pediatric patients. Grade 3+ adverse events recorded, including febrile neutropenia, were comparable across both arms and consistent with the known dose-intensive chemotherapy regimen. Grade 2+ peripheral neuropathy rates were similar across both arms. Based on these data, we submitted an sBLA to the FDA for review. The sBLA was granted Priority Review and in November 2022 the FDA approved the application. The

approval resulted in a grant of pediatric exclusivity, which extends the period of U.S. market exclusivity for ADCETRIS by an additional six months.

In December 2022, results were presented from two parts of a phase 2 trial (SGN35-027) evaluating ADCETRIS in combination with the PD-1 inhibitor nivolumab and standard chemotherapy agents doxorubicin and dacarbazine (AN+AD) for the frontline treatment of patients with classical Hodgkin lymphoma. Part B of the trial evaluated patients with advanced-stage disease, and Part C evaluated patients with early-stage disease. Results for Part B demonstrated a complete response, or CR, rate of 88% and an overall response rate, or ORR, of 93% as well as an estimated 12-month progression-free survival, or PFS, rate of 95% (median follow-up 17.2 months) Results for Part C demonstrated a CR rate of 92% and an ORR of 95% in patients and follow up is ongoing and PFS results are not yet available. The data showed that the combination was well-tolerated, with no new safety signals observed.

PADCEV (enfortumab vedotin-ejfv)

In addition to jurisdictions where PADCEV is currently approved, applications are under review for approval in the previously treated metastatic urothelial cancer setting in other countries. In collaboration with Astellas we are conducting or planning to conduct clinical trials across the spectrum of bladder cancer including ongoing trials in frontline metastatic urothelial cancer and muscle invasive bladder cancer. We are planning to conduct a trial in non-muscle invasive bladder cancer. In addition, we are conducting a trial in a range of other solid tumors.

PADCEV is being investigated in first-line metastatic urothelial cancer and earlier stages of bladder cancer. We and Astellas are conducting a phase 1b/2 clinical trial, called EV-103, that is a multi-cohort, open-label trial of PADCEV alone or in combination with other agents. The trial is evaluating safety, tolerability and activity in locally advanced and first- and second-line metastatic urothelial cancer, and was expanded to include muscle invasive bladder cancer, or MIBC.

In February 2020, based on the positive initial results of the dose escalation/Cohort A of the EV-103 trial, the FDA granted Breakthrough Therapy designation for PADCEV in combination with Merck's anti-PD-1 therapy pembrolizumab for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are unable to receive cisplatin-based chemotherapy in the first-line setting. In April 2020, we announced that, based on discussions with the FDA, data from the randomized Cohort K in the EV-103 trial, along with other data from the EV-103 trial, could potentially support registration under the FDA's accelerated approval pathway. The primary endpoint is confirmed ORR. In October 2021, we completed enrollment in Cohort K.

In July 2022, we and Astellas announced positive topline results from the phase 1b/2 EV-103 clinical trial Cohort K evaluating PADCEV in combination with pembrolizumab as first-line treatment in patients with unresectable locally advanced or metastatic urothelial cancer who are ineligible to receive cisplatin-based chemotherapy. In September 2022, the data were presented at the European Society for Medical Oncology Congress. In patients treated with PADCEV and pembrolizumab, results demonstrated a 64.5% confirmed ORR (95% CI: 52.7 to 75.1) per blinded independent central review, or BICR, the primary endpoint of Cohort K, with 10.5% of patients experiencing a complete response and 53.9% of patients experiencing a partial response. In the trial, 97.1% of assessable patients had tumor reduction. The median duration of response, or DOR, per BICR was not reached (95% CI: 10.25 months to NR). All-grade treatment-related adverse events, or TRAEs, of special interest for PADCEV in combination with pembrolizumab were skin reactions (67.1%), peripheral neuropathy (60.5%), ocular disorders (dry eye, blurred vision, and corneal disorders) (26.3%), hyperglycemia (14.5%), and infusion-related reactions (3.9%). Pembrolizumab adverse events of special interest were consistent with previously observed safety data from monotherapy with the exception of severe skin reactions. Cohort K also included a monotherapy arm in which patients were treated with PADCEV alone (n=73), though this study was not designed to support a formal comparison between the two arms. Results showed a 45.2% confirmed ORR (95% CI: 33.5 to 57.3) per RECIST v1.1 by BICR, with 4.1% of patients experiencing a complete response and 41.1% of patients experiencing a partial response. The median DOR was 13.2 months (95% CI: 6.14 to 15.97) per RECIST v1.1 by BICR. All-grade TRAEs of special interest for PADCEV were peripheral neuropathy (54.8%), skin reactions (45.2%), ocular disorders (dry eye, blurred vision, and corneal disorders) (28.8%), hyperglycemia (11.0%), and infusion-related reactions (5.5%). TRAEs of any grade that occurred in more than 20% of patients treated with PADCEV alone or in combination with pembrolizumab were fatigue, peripheral sensory neuropathy, alopecia, rash maculo-papular, pruritus, dysgeusia, weight decreased, diarrhea, decreased appetite, nausea, and dry eye. Overall, the results are generally consistent with previously reported efficacy and safety results of EV-103 dose escalation/Cohort A. In October 2022, an sBLA based on

the data was submitted under the FDA's Accelerated Approval Program. In December 2022, the sBLA was granted Priority Review with a PDUFA target action date of April 21, 2023.

In addition to the potential accelerated approval pathway based on the EV-103 trial, we are conducting a global, registrational phase 3 clinical trial, called EV-302, in frontline metastatic urothelial cancer in collaboration with Astellas and Merck. We, Astellas and Merck are jointly funding EV-302 and the trial is being conducted by us. EV-302 is an open-label, randomized phase 3 clinical trial evaluating the combination of PADCEV and pembrolizumab versus chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial cancer. The trial includes metastatic urothelial cancer patients who are either eligible or ineligible for cisplatin-based chemotherapy. The trial has dual primary endpoints of PFS and OS and is intended to support global regulatory submissions and potentially serve as a confirmatory trial if accelerated approval is granted based on EV-103. In November 2022, we completed enrollment in the EV-302 trial. For this trial, we have initiated an extension study in China which continues to enroll. Based on study assumptions we estimate we could report topline data by the end of 2023.

In April 2020, we and Astellas entered into an agreement with Merck to evaluate PADCEV in MIBC. Merck has amended its ongoing phase 3 KEYNOTE-905/EV-303 registrational trial in cisplatin-ineligible patients with MIBC to include an arm evaluating PADCEV in combination with pembrolizumab. In October 2020, we and Astellas entered into an agreement with Merck to evaluate PADCEV in combination with pembrolizumab in a phase 3 clinical trial, called KEYNOTE-B15/EV-304, to be conducted by Merck in cisplatin-eligible patients with MIBC. This trial was initiated in the first quarter of 2021.

In January 2022, we enrolled the first patient in a phase 1 clinical trial, called EV-104, evaluating PADCEV in patients with BCG unresponsive non-muscle invasive bladder cancer.

In January 2020, we and Astellas also initiated a phase 2 clinical trial, called EV-202, to evaluate PADCEV monotherapy in solid tumors that have high-levels of Nectin-4 expression, including non-small cell lung, head and neck, gastric/esophageal and breast cancers. Astellas is conducting the trial and has obtained topline results in some cohorts. We and Astellas will be reviewing the results and discussing future direction. We expect to report initial data from the trial in the first half of 2023.

TUKYSA (tucatinib)

We are conducting a broad clinical development program for TUKYSA including ongoing and planned trials in earlier lines of breast cancer and in other HER2-positive cancers. The positive results of the HER2CLIMB trial served as the basis for approval in the U.S., Canada, the European Union as well as other countries. Merck is co-funding a portion of the TUKYSA global development plan.

In December 2021, we presented new data at the San Antonio Breast Cancer Symposium from exploratory analyses from the pivotal HER2CLIMB trial showing that improvement in OS was maintained after an additional 15.6 months of follow-up when TUKYSA was combined with trastuzumab and capecitabine in patients with HER2-positive metastatic breast cancer who had stable or active brain metastases. After a median follow-up of 29.6 months, the TUKYSA regimen improved OS for patients with brain metastases by 9.1 months compared to trastuzumab and capecitabine alone (21.6 months vs. 12.5 months) (HR: 0.60; [95% CI: 0.44, 0.81]). The benefit extended to patients with active or stable brain metastases.

In October 2019, we initiated a phase 3 randomized trial, called HER2CLIMB-02, evaluating TUKYSA versus placebo, each in combination with T-DM1, for patients with unresectable locally advanced or metastatic HER2-positive breast cancer, including those with brain metastases, who have had prior treatment with a taxane and trastuzumab. In June 2022, we completed enrollment in the HER2CLIMB-02 trial and expect to report topline data in the first half of 2023. For this trial, we have initiated an extension study in China which continues to enroll.

We are supporting a U.S. cooperative group, the Alliance for Clinical Trials in Oncology, that is conducting a phase 3 randomized trial, called CompassHER2 RD, which is evaluating TUKYSA in combination with T-DM1 in the adjuvant setting for patients with high-risk, HER2-positive breast cancer.

We are also conducting a phase 2 clinical trial, called HER2CLIMB-04, evaluating TUKYSA in combination with trastuzumab deruxtecan in previously treated locally-advanced or metastatic HER2-positive breast cancer.

We have also initiated a phase 3 clinical trial, called HER2CLIMB-05, evaluating TUKYSA compared to placebo in combination with trastuzumab and pertuzumab in the frontline maintenance setting for patients with metastatic HER2-positive breast cancer.

We have conducted a pivotal phase 2 clinical trial, called MOUNTAINEER, evaluating TUKYSA in combination with trastuzumab in patients with HER2-positive, RAS wild-type metastatic colorectal cancer after treatment with first- and second-line standard-of-care therapies. In July 2022, we presented positive results from the MOUNTAINEER trial investigating TUKYSA in combination with trastuzumab in patients with previously treated HER2-positive metastatic colorectal cancer at the European Society for Medical Oncology World Congress on Gastrointestinal Cancer. The combination of TUKYSA and trastuzumab was generally well-tolerated with durable responses in patients assigned to receive the combination demonstrating a 38.1% confirmed response rate after a median duration of follow-up of 20.7 months. In these patients, the median DOR was 12.4 months. The most common (greater than or equal to 20%) treatment-emergent adverse events, or TEAEs, in patients assigned to receive tucatinib and trastuzumab were diarrhea (Grade 1 or 2: 60.5%, Grade 3: 3.5%), fatigue (Grade 1 or 2: 41.9%, Grade 3: 2.3%), nausea (Grade 1 or 2: 34.9%) and infusion-related reaction (Grade 1 or 2: 20.9%). In January 2023, the FDA granted accelerated approval in combination with trastuzumab for adult patients with *RAS* wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

In addition, we are conducting a phase 3 clinical trial, called MOUNTAINEER-03, in combination with trastuzumab and mFOLFOX6 in first-line HER2-positive metastatic colorectal cancer, which is intended to serve as a confirmatory trial and potentially support future global regulatory submissions. We have also initiated a phase 1b trial evaluating TUKYSA in combination with trastuzumab and oxaliplatin based chemotherapy in first-line HER2-positive unresectable or metastatic colorectal, gastric, esophageal and gallbladder cancers.

TIVDAK (tisotumab vedotin-tftv)

In collaboration with Genmab, we are developing TIVDAK for metastatic cervical cancer and are evaluating it as a potential therapy in other solid tumors. The FDA granted accelerated approval of TIVDAK in September 2021 for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. In December 2022, the NCCN Guidelines were updated elevating TIVDAK to a Category 2A Preferred Regimen for second-line or subsequent recurrent or metastatic cervical cancer.

In January 2021, we and Genmab initiated a phase 3 clinical trial, called innovaTV 301, to evaluate TIVDAK compared to chemotherapy in patients with recurrent or metastatic cervical cancer who have received one or two prior lines of therapy. innovaTV 301 is intended to support global regulatory applications for potential approvals in regions where innovaTV 204 does not support approval and to serve as a confirmatory trial in the U.S.

We are also conducting a phase 2 clinical trial, called innovaTV 205, evaluating TIVDAK as monotherapy and in combination with certain other anti-cancer agents for first- and second-line treatment of patients with recurrent or advanced cervical cancer. In September 2021, interim results were presented at the European Society for Medical Oncology Annual Congress from two cohorts of the phase 1b/2 innovaTV 205 trial, evaluating TIVDAK as combination therapy for recurrent or metastatic cervical cancer. Both combinations showed encouraging, durable anti-tumor activity and demonstrated a manageable and acceptable safety profile. Additionally, in June 2022, we announced interim data from the innovaTV 205 trial, which included data evaluating TIVDAK in combination with pembrolizumab in patients with recurrent or metastatic cervical cancer who have not received prior systemic therapy. This combination cohort enrolled 33 patients with recurrent or metastatic cervical cancer who had not received any prior systemic therapy. At the time of data cutoff, the confirmed objective response rate among 32 evaluable patients was 41% with 16% of patients achieving complete responses and 25% of patients achieving partial responses. Median DOR was not reached with median follow-up of 18.8 months. In this cohort, the most common TEAEs were alopecia (61%), diarrhea (55%), epistaxis (49%), conjunctivitis (45%), and nausea (46%). We expect to report additional data in the second half of 2023.

We are conducting a phase 2 clinical trial, called innovaTV 207, for patients with relapsed, locally advanced or metastatic solid tumors. In February 2022, initial data from the innovaTV 207 phase 2 trial of TIVDAK in solid tumors was presented at the Multidisciplinary Head and Neck Cancers Symposium. The results demonstrated a manageable safety profile and promising preliminary antitumor activity in patients with squamous cell carcinoma of the head and

neck with 16 percent of patients (95% CI: 5.5 to 33.7) achieving the primary endpoint of confirmed objective response rate per investigator. We expect to report updated data in the first half of 2023.

Disitamab vedotin

Effective in September 2021, we and RemeGen entered into an exclusive license agreement to develop and commercialize disitamab vedotin, a novel HER2-targeted ADC, which has shown anti-tumor activity in several solid tumor types across a spectrum of HER2 levels, including urothelial, gastric and breast cancer, in all countries outside of RemeGen's territory of Asia, excluding Japan and Singapore. We have a broad clinical development program planned including an ongoing phase 2 clinical trial evaluating disitamab vedotin as monotherapy in previously treated HER2-expressing metastatic urothelial cancer and a phase 3 clinical trial evaluating disitamab vedotin in combination with pembrolizumab in first-line treatment for HER2-expressing metastatic urothelial cancer that is expected to initiate in 2023.

Ladiratuzumab vedotin

We are developing ladiratuzumab vedotin, or LV, an ADC targeting LIV-1, which is currently being evaluated in phase 1 and phase 2 clinical trials both as monotherapy and in combination with other agents for patients with metastatic breast cancer and select solid tumors with high LIV-1 expression. We expect to report initial data in solid tumors in the second half of 2023. In September 2020, we and Merck entered into a license and collaboration agreement, or the LV Agreement, under which the companies will jointly develop and share future costs and profits worldwide for LV.

Other clinical and early-stage product candidates

We are advancing a pipeline of early-stage clinical candidates as well as multiple preclinical and research-stage programs that employ our proprietary technologies. We advanced several product candidates into clinical development since the beginning of 2021, and we plan to submit additional Investigational New Drug applications, or INDs, to the FDA in 2023.

In November 2022, we reported interim phase 1 monotherapy results for SGN-B6A at the Society for Immunotherapy of Cancer’s, or SITC's, Annual Meeting. In the study, dose escalation cohorts enrolled 79 participants with metastatic or unresectable solid tumors, whose disease had relapsed or was refractory to standard of care therapies and had not previously received an MMAE-containing agent or agent targeting integrin beta-6. Participants had received a median of 3 lines of therapy for metastatic disease prior to enrollment in the study. SGN-B6A demonstrated a manageable and tolerable safety profile at the explored dose levels and schedules. Intermittent dosing schedules (2Q3W, 2Q4W) are being evaluated further. The initial anti-tumor activity observed in heavily pre-treated patients is encouraging and has triggered expansion cohorts in NSCLC, HNSCC, and ESCC, which are currently ongoing. We expect to report durability data in the first half of 2023.

We are also developing SGN-B7H4V, an ADC which we are evaluating in a phase 1 clinical trial in certain solid tumors including breast, endometrial and ovarian cancer. We expect to report initial data in the second half of 2023.

In September 2022, we entered into an agreement with LAVA Therapeutics N.V., or LAVA, to develop and commercialize LAVA-1223, also known as SGN-EGFRd2, a preclinical gamma delta bispecific T-cell engager for EGFR-expressing solid tumors. We received an exclusive global license for SGN-EGFRd2 and the opportunity to exclusively negotiate rights to apply LAVA's proprietary Gammabody™ platform on up to two additional tumor targets. We paid LAVA a $50 million upfront fee in October 2022 and have also agreed to pay LAVA up to approximately $650 million in potential development, regulatory and commercial milestones, as well as royalties ranging from the single digits to the mid-teens on future sales of any licensed products. We are targeting filing an IND for SGN-EFGRd2 in 2023.

In March 2022, we entered into a collaboration with Sanofi to develop and potentially commercialize multiple novel ADCs. The agreement is an exclusive collaboration that will utilize Sanofi's proprietary monoclonal antibody technology and our proprietary ADC technology for up to three cancer targets. The initial ADC is targeting CEACAM5, a protein highly expressed in certain tumor types such as colorectal, gastric, pancreatic and lung cancer. We are targeting filing an IND for the initial ADC in 2023.

In January 2023, we enrolled the first patient was dosed in a phase 1 trial of SGN-BB228, a CD228x4-1BB bispecific molecule, in advanced melanoma and other solid tumors.

Our Antibody-Drug Conjugate (ADC) Technology

ADCETRIS, PADCEV, TIVDAK and many product candidates in our clinical-stage pipeline utilize our ADC technology. ADCs are monoclonal antibodies that are linked to cytotoxic, or cell-killing, agents. Our ADCs utilize monoclonal antibodies that internalize within target cells after binding to a specified cell-surface receptor. Enzymes present inside the cell catalyze the release of the cytotoxic agent from the monoclonal antibody, which then results in the desired activity, specific killing of the target cell.

A key component of our ADCs are the linkers that attach the cell-killing agent to the monoclonal antibody. The drug linkers are designed to deliver the cytotoxic agent to tumors by virtue of the monoclonal antibody binding to the intended cell surface receptor on the target cell. The cytotoxic agent is released when the ADC internalizes within the target cell, resulting in cell killing. This targeted delivery of the cell-killing agent is intended to maximize delivery of the cytotoxic agent to targeted cells while minimizing toxicity to normal tissues. Our most advanced ADCs, including ADCETRIS, PADCEV, TIVDAK, disitamab vedotin, and ladiratuzumab vedotin, use our proprietary auristatin-based ADC technology. Auristatins are microtubule disrupting agents. In contrast to natural products that are often more difficult to produce and link to antibodies, the cytotoxic drugs used in our ADCs are synthetically produced and are readily scalable for manufacturing. This technology is also the basis of our ADC collaborations. We own or hold exclusive or partially-exclusive licenses to multiple issued patents and patent applications covering our ADC technology. We continue to evaluate new linkers, antibody formats and cell-killing agents for use in our ADC programs.

Our Sugar-Engineered Antibody (SEA) Technology

Our proprietary SEA technology is a method to selectively reduce fucose incorporation in monoclonal antibodies as they are produced in cell line-based manufacturing. Our preclinical data show that this results in increased binding to innate immune effector cells and enhanced potency in antibody dependent cellular cytotoxicity, or ADCC, in tumor cells. We believe this enhancement in ADCC activity may provide improved anti-tumor activity. Our SEA technology is a novel approach to modify the activity of monoclonal antibodies that is complementary to our ADC technology.

A key feature of our SEA technology is that no genetic modification of the antibody-producing cell line is necessary and standard cell culture conditions can be used while maintaining the underlying manufacturing processes, yields and product quality. We believe the SEA approach may be simpler and more cost-effective to implement as compared to existing technologies for enhancing antibody effector function, most of which require development of new cell lines.

We have product candidates that are being evaluated in phase 1 clinical trials that utilize our SEA technology including SEA-TGT and SEA-CD70. These agents are targeted at a variety of cancer types.

Other Technologies

In addition, we utilize other technologies designed to maximize antitumor activity and reduce toxicity of antibody-based therapies. Genetic engineering enables us to produce antibodies that are optimized for their intended uses. For ADCs, we screen and select antibodies that bind to antigens that are differentially expressed on tumor cells versus vital normal tissues, rapidly internalized within target cells and have potent anti-tumor activity in preclinical models. For our SEA technology we produce antibodies that demonstrate potent anti-tumor activities by virtue of ADCC, or through additional immune stimulatory mechanisms that are triggered by the enhanced binding potency to innate immune cells. Our ADCs utilize native or engineered conjugation sites to optimize drug attachment. In some cases, we evaluate the use of our monoclonal antibodies and ADCs in combination with conventional chemotherapy and other anticancer agents, which may result in increased antitumor activity.

Research Programs

In addition to our pipeline of current product candidates and technologies, we have internal research programs directed toward developing new classes of potent anti-tumor and immune stimulatory agents and new ADC linkers, the identification of novel drug targets and monoclonal antibodies, and advancing our antibody engineering initiatives.

New Tumor Cell-Killing Agents. We continue to identify and study new agents with anti-tumor mechanisms of action that will provide pipeline diversity and complement the auristatins that we currently use in our ADC technology. We also seek to develop new drugs that are designed to activate the host immune system by targeting key immune stimulatory pathways that can mediate innate or adaptive anti-tumor immune responses.

New Drug Linkers. We are conducting research with the intent to develop new ADC linkers that are designed to provide the appropriate stability in the bloodstream and drug release characteristics to effectively target cancer cells and improved cancer cell selectivity and tolerability.

Novel Monoclonal Antibodies and Antigen Targets. We are actively engaged in internal efforts to identify and develop monoclonal antibodies, and other therapeutic molecules, to target tumor antigens and important tumor or immune pathways. For ADCs, we focus on drug targets that are highly expressed on the surface of cancer cells that have the appropriate expression, distribution and internalization properties that make them desirable as monoclonal antibody or ADC targets. We may then create and screen panels of cancer-reactive monoclonal antibodies in our laboratories to identify those with the desired specificity and optimized drug delivery properties. Additionally, we identify targets that play key roles in anti-tumor innate or adaptive immune responses and identify antibodies and other therapeutic molecules to stimulate an anti-tumor immune response. We supplement these internal efforts by evaluating opportunities to in-license targets and antibodies from academic groups and other biotechnology and pharmaceutical companies, such as our ongoing collaborations with Astellas and Genmab.

Antibody Engineering. We have substantial internal expertise in antibody engineering including humanization, binding affinity optimization, enhancement of immunological function by blocking fucosylation, as well as engineering antibodies to improve drug linkage sites for use with our ADC technology. By modifying the number and type of drug-linkage sites found on our antibodies, we believe that we can improve ADC drug properties and the cost-effectiveness of our manufacturing processes for conjugation of ADCs.

Corporate Collaborations

We enter into collaborations with pharmaceutical and biotechnology companies to advance the development and commercialization of our product candidates and to supplement our internal pipeline. We seek collaborations that will allow us to retain significant future participation in product sales through either profit-sharing or royalties paid on net sales. We also have licensed our technologies to collaborators to be developed with their own antibodies. These collaborations benefit us in many ways, including generating cash flow and revenues that partially offset expenditures on our internal research and development programs, expanding our knowledge base regarding ADCs across multiple targets and antibodies provided by our collaborators and providing us with future pipeline opportunities through co-development or opt-in rights to new product candidates.

Takeda ADCETRIS Collaboration

We have an agreement with Takeda for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We have commercial rights for ADCETRIS in the U.S. and its territories and in Canada. Takeda has commercial rights in the rest of the world. Under the collaboration, we and Takeda can each conduct development activities and equally co-fund the cost of certain mutually agreed development activities.

As of December 31, 2022, we had achieved milestone payments totaling $157.5 million related to regulatory and commercial progress by Takeda. As of December 31, 2022, total future potential milestone payments to us under this collaboration could total up to $77.0 million, based on achievement of development and regulatory milestones. In addition, we recognize royalty revenues based on a percentage of Takeda's net sales of ADCETRIS in its licensed territories, with percentages ranging from the mid-teens to the mid-twenties based on annual net sales tiers.

Either party may terminate the collaboration agreement if the other party materially breaches the agreement and such breach remains uncured. Takeda may terminate the collaboration agreement for any reason upon prior written notice to us and we may terminate the collaboration agreement in certain circumstances. The collaboration agreement can also be terminated by mutual written consent of the parties. If neither party terminates the collaboration agreement, then the agreement automatically terminates on the expiration of all payment obligations.

Astellas PADCEV Collaboration

We have a collaboration agreement with Agensys, Inc., which subsequently became an affiliate of Astellas, to jointly research, develop and commercialize ADCs for the treatment of several types of cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Astellas to proprietary cancer targets. Under this collaboration, we and Astellas are equally co-funding all development costs for PADCEV.

In 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of PADCEV:

- In the U.S., we and Astellas jointly promote PADCEV. We record sales of PADCEV in the U.S. and are responsible for all U.S. distribution activities. The companies each bear the costs of their own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S., and equally share in any profits realized in the U.S.
- Outside the U.S., we have commercialization rights in all countries in North and South America, and Astellas has commercialization rights in the rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively equally share in costs incurred and any profits realized in all of these markets. Cost and profit sharing in Canada, the United Kingdom, Germany, France, Spain and Italy are based on product sales and costs of commercialization. In the remaining markets, the commercializing party is responsible for bearing costs and paying the other party a royalty rate applied to net sales of the product based on a rate intended to approximate an equal profit share for both parties.

Astellas or its affiliates are responsible for overseeing the initial manufacturing supply chain for PADCEV for development and commercial use. However, we are responsible for packaging and labeling in countries in which we sell PADCEV. In addition, we are in the process of establishing a second source manufacturing supply chain, through a combination of internal manufacturing capacity and third parties. In this regard, our manufacturing facility in Bothell, Washington is used to support commercial production of PADCEV antibody.

Either party may terminate the collaboration agreement if the other party becomes insolvent or the other party materially breaches the agreement and such breach remains uncured. Subject to certain restrictions, either party may terminate the collaboration agreement for any reason upon prior written notice to the other party. The collaboration agreement can also be terminated by mutual written consent of the parties. If neither party exercises its option to terminate the collaboration agreement, then the agreement will automatically terminate on the later of the expiration of all payment obligations pursuant to the collaboration agreement, or the day upon which we and Astellas cease to develop and commercialize products under the agreement.

Either party may terminate the joint commercialization agreement if the other party becomes insolvent. The joint commercialization agreement expires on a country-by-country basis upon complete cessation of the commercialization, launch and selling of PADCEV in that country.

Either party may also opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. In addition, either party may opt out of co-development and profit-sharing for PADCEV on a country-by-country basis, in return for receiving royalties pursuant to the collaboration agreement from the continuing party with respect to that country.

Merck TUKYSA Collaboration

In September 2020, we entered into the TUKYSA Agreement with Merck. Under the TUKYSA Agreement, we granted Merck exclusive rights to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Merck is responsible for marketing applications for approval in its territory, supported by the positive results from the HER2CLIMB clinical trial. We retained commercial rights in, and will record sales in, the U.S., Canada and Europe. Merck also agreed to co-fund a portion of the TUKYSA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers. We will continue to lead ongoing TUKYSA global development operational execution. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. Under the TUKYSA Agreement, we are responsible for supplying Merck with TUKYSA for the purpose of clinical development and commercialization. We received an upfront cash payment from Merck of $125.0 million and also received $85.0 million in prepaid research and development funding to be applied to Merck's global development cost sharing obligations. We are eligible to receive progress-dependent milestone payments of up to $65.0 million, and are entitled to receive tiered royalties on sales of TUKYSA by Merck that begin in the low twenty percent range and escalate based on sales volume by Merck in its territory. We owe Array Biopharma Inc., or Array, an affiliate of Pfizer, a portion of any non-royalty payments received from sublicensing TUKYSA rights, as well as a low double-digit royalty based on net sales of TUKYSA by us, and will owe a single-digit royalty based on net sales of TUKYSA by Merck in its territories.

Genmab TIVDAK Collaborations

We have a collaboration agreement with Genmab to develop and commercialize ADCs targeting tissue factor, under which we previously exercised a co-development option for TIVDAK. Under this collaboration, we and Genmab are co-funding all development costs for TIVDAK.

In October 2020, we and Genmab entered into a joint commercialization agreement to govern the global commercialization of TIVDAK:

- In the U.S., we and Genmab co-promote TIVDAK. We record sales of TIVDAK in the U.S. and are responsible for leading U.S. distribution activities. The companies are each responsible for maintaining 50% of the sales representatives and medical science liaisons, equally share those and certain other costs associated with commercializing TIVDAK in the U.S., and equally share in any profits realized in the U.S.
- Outside the U.S., we have commercialization rights in the rest of the world except for Japan, where Genmab has commercialization rights, and certain territories where Zai Lab has commercialization rights, as further described below. In Europe, China, and Japan, we and Genmab will equally share 50% of the costs associated with commercializing TIVDAK as well as any profits realized in these markets. In markets outside the U.S. other than Europe, China, and Japan, aside from certain costs specified in the agreement, we will be solely responsible for all costs associated with commercializing TIVDAK, and will pay Genmab a royalty based on a percentage of aggregate net sales ranging from the mid-teens to mid-twenties.

Under the joint commercialization agreement, we are responsible for overseeing the clinical and commercial manufacturing of TIVDAK. Either party may terminate the collaboration agreement or the joint commercialization agreement if the other party becomes insolvent or materially breaches the applicable agreement and such breach remains uncured. In addition, either party may terminate the collaboration agreement if such party's patent rights subject to the agreement are challenged by the other party or its sublicensees. Either party may also opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. The opt out provisions of the collaboration agreement may also be applied to the joint commercialization agreement. In addition, Genmab may elect to opt out of co-promotion of TIVDAK in the United States by providing us with prior written notice.

In September 2022, we announced an exclusive collaboration and license agreement with Zai Lab for the development and commercialization of TIVDAK in mainland China, Hong Kong, Macau, and Taiwan. Under the terms of the agreement, we received an upfront payment of $30.0 million in October 2022 which was recorded in collaboration revenue for the year ended December 31, 2022, and are entitled to receive potential future development, regulatory, and commercial milestone payments, and tiered royalties on net sales of TIVDAK in the Zai Lab territory. Based on our existing collaboration with Genmab, the upfront payment, milestone payments, and royalties will be shared on a 50:50 basis with Genmab.

RemeGen Disitamab Vedotin License Agreement

Effective in September 2021, we and RemeGen entered into an exclusive worldwide licensing agreement to develop and commercialize disitamab vedotin, a novel HER2-targeted ADC. Under the terms of the agreement, we made a $200.0 million upfront payment to obtain exclusive license rights to disitamab vedotin for global development and commercialization, outside of RemeGen's territory. RemeGen retains development and commercialization rights for Asia, excluding Japan and Singapore. We will lead global development and RemeGen will fund and operationalize the portion of global clinical trials attributable to its territory. RemeGen will also be responsible for all clinical development and regulatory submissions specific to its territory. We will pay RemeGen up to $195.0 million in potential milestone payments across multiple indications and products based upon the achievement of specified development goals, and up to $2.2 billion in potential milestone payments based on the achievement of specified regulatory and commercialization goals. RemeGen will be entitled to a tiered, high single digit to mid-teen percentage royalty based on net sales of disitamab vedotin in our territory.

The agreement will remain in effect, unless earlier terminated, until the expiration, on a country-by-country and product-by-product basis, of the applicable royalty term, at which point the license for such product shall become fully paid-up, royalty-free, perpetual, irrevocable and non-exclusive in such country. The agreement also contains customary provisions for termination including by us for convenience, by either party in the event of breach of the agreement, subject to cure, upon a challenge of a party's licensed patents or upon the other party's bankruptcy. RemeGen has standard reversion rights in connection with certain early termination events.

Merck LV Collaboration

In September 2020, we entered into the LV Agreement with a subsidiary of Merck. Under the terms of the LV Agreement, we granted Merck a co-exclusive worldwide development and commercialization license for LV and agreed to jointly develop and commercialize LV on a worldwide basis. We received an upfront cash payment of $600.0 million, and we are eligible to receive up to $850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional $1.8 billion in milestone payments upon the achievement of specified annual global net sales thresholds. Each company is responsible for 50% of global costs to develop and commercialize LV and will receive 50% of potential future profits. We will lead regulatory and distribution activities, and will record sales, in the United States and Canada. Merck will lead regulatory activities in Europe, and we will lead distribution activities and record sales in Europe. We and Merck will co-commercialize LV in the United States and Europe. Merck will lead regulatory, promotion and distribution activities, and will record sales, in countries outside of the United States, Canada and Europe.

The LV Agreement will remain in effect, unless earlier terminated, until LV is no longer being developed or commercialized under the LV Agreement. The LV Agreement also contains customary provisions for termination by Merck for convenience, and by either party, including in the event of breach of the LV Agreement, subject to cure, or upon a challenge of such party's licensed patents or upon the other party's bankruptcy, subject, in each case, to customary reversion rights.

In connection with the LV Agreement, we entered into a stock purchase agreement with Merck in September 2020, referred to as the Purchase Agreement, pursuant to which we agreed to issue and sell, and Merck agreed to purchase 5,000,000 newly-issued shares of our common stock, at a purchase price of $200 per share, for an aggregate purchase price of $1.0 billion. We closed the transactions contemplated by the Purchase Agreement in October 2020.

ADC License Agreements

We have license agreements for our ADC technology with a number of biotechnology and pharmaceutical companies. Under these agreements, which we have entered into in the ordinary course of business, we have granted research and commercial licenses to use our technology, most often in conjunction with the licensee's technology. In certain agreements, we also have agreed to conduct limited development activities and to provide other materials, supplies, and services to our licensees during a specified term of the agreement. We typically receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. We also are entitled to receive royalties on net sales of any resulting products incorporating our ADC technology. Our licensees are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these agreements, which includes the achievement of the potential milestones.

In 2019, Genentech received accelerated approval from the FDA for Polivy™ (polatuzumab vedotin-piic), an ADC that uses our technology, to treat patients with relapsed or refractory diffuse large B-cell lymphoma. In August 2020, GSK plc, or GSK, received accelerated approval from the FDA and conditional marketing authorization from the EC for Blenrep™ (belantamab mafodotin-blmf), an ADC developed by GSK that uses our technology, for treatment of patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor and an immunomodulatory agent. Under our ADC license agreements with Genentech and an affiliate of GSK, these events triggered milestone payments to us and we are also entitled to receive royalties on net sales of Polivy and Blenrep worldwide. In November 2022, GSK announced that it had initiated the process for withdrawal of U.S. marketing authorization for Blenrep following a request by the FDA. The product candidates being developed under our other ADC license agreements are at various stages of clinical and preclinical development. Our ability to generate meaningful future revenues from our other ADC license agreements will largely depend on products that incorporate our technologies entering late-stage clinical development, and receiving marketing approval from the FDA and subsequently being commercialized, if any.

In-license Agreements

We have in-licensed antibodies, targets and enabling technologies from pharmaceutical and biotechnology companies and academic institutions for use in our pipeline programs and ADC technology, including the following:

- Array BioPharma, Inc. We are a party to a license agreement with Array, which was acquired by Pfizer in July 2019. Pursuant to the license agreement, Array has granted us an exclusive license to develop, manufacture and commercialize TUKYSA. We will pay Array a portion of any non-royalty payments received from sublicensing TUKYSA rights, including non-royalty payments received from Merck pursuant to the TUKYSA Agreement. Array is also entitled to receive a low double-digit royalty based on net sales of TUKYSA by us and a single-digit royalty based on any net sales of TUKYSA by our sublicensees, including Merck. The term of the license agreement expires on a country-by-country basis upon the later of the expiration of the last valid claim covering TUKYSA within that country or 10 years after the first commercial sale of TUKYSA within that country. We and Array each have the right to terminate the license agreement prior to its expiration for insolvency or material breach, subject to cure and dispute resolution provisions.
- Other Licenses. Under the terms of in-license agreements related to our pipeline programs, we would potentially owe development, regulatory, and sales-based milestones, and royalties on net sales of certain approved products.

Patents and Proprietary Technology

Our owned and licensed patents and patent applications are directed to ADCETRIS, PADCEV, TUKYSA, TIVDAK, our product candidates, monoclonal antibodies, our ADC and SEA technologies and other antibody-based and/or enabling technologies. We commonly seek patent claims directed to compositions of matter, including antibodies, ADCs, and drug-linkers containing highly potent cell-killing agents, as well as methods of using such compositions. When appropriate, we also seek claims to related technologies, such as methods of using certain sugar analogs utilized in our SEA technology. For each of our products and product candidates, we have filed or expect to file multiple patent applications. We maintain patents and prosecute applications worldwide for technologies that we have out-licensed, such as our ADC technology. Similarly, for partnered products and product candidates, such as ADCETRIS, PADCEV, TUKYSA, TIVDAK, disitamab vedotin and LV, we seek to work closely with our development partners to coordinate patent efforts, including patent application filings, prosecution, term extension, defense and enforcement. As our products and product candidates advance through research and development, we seek to diligently identify and protect new inventions, such as combination therapies, improvements to methods of manufacturing, and methods of treatment. We also work closely with our scientific personnel to identify and protect new inventions that could eventually add to our development pipeline.

We own or have rights to the following patents relating to our products and our pipeline (in addition to certain patents covering our early-stage product candidates):

- For ADCETRIS and our related ADC technology, we own thirteen patents in the United States and Europe that will expire between 2023 and 2031.

- For PADCEV and our related ADC technology, we own, co-own or have licensed rights to fourteen patents in the United States and Europe that will expire between 2023 and 2031. Of these patents, we own or co-own twelve patents and have licensed rights to two patents.
- For TUKYSA, we own or have licensed rights to eleven patents in the United States and Europe that will expire between 2024 and 2038. Of these patents, we own one patent and have licensed rights to ten patents.
- For TIVDAK and our related ADC technology, we own or have licensed rights to ten patents in the United States and Europe that will expire between 2023 and 2036. Of these patents, we own four patents and have licensed rights to six patents.
- For disitamab vedotin and our related ADC technology, we own or have licensed rights to seven patents in the United States and Europe that will expire between 2023 and 2034. Of these patents, we own four patents and have licensed rights to three patents.
- For LV and our related ADC technology, we own or have licensed rights to eight patents in the United States and Europe that will expire between 2023 and 2032. Of these patents, we own seven patents and have licensed rights to one patent.

The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage as determined by the patent office or courts in the country, and the availability of legal remedies in the country. The list above does not identify all patents that may be related to our products and product candidates. For example, in addition to the listed patents, we have patents on platform technologies (that relate to certain general classes of products or methods), as well as patents that relate to methods of using, manufacturing or administering a product or product candidate, that may confer additional patent protection. We also have pending patent applications that may give rise to new patents related to one or more of these agents.

The information in the above list is based on our current assessment of patents that we own, co-own or control or have licensed. The information is subject to revision, for example, in the event of changes in the law or legal rulings affecting our patents or if we become aware of new information. Significant legal issues remain unresolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets outside the U.S. We expect that litigation will likely be necessary to determine the term, validity, enforceability, and/or scope of certain of our patents and other proprietary rights. An adverse decision or ruling with respect to one or more of our patents could result in the loss of patent protection for a product and, in turn, the introduction of competitor products or follow-on biologics to the market earlier than anticipated, and could force us to either obtain third-party licenses at a material cost or cease using a technology or commercializing a product.

Patents expire, on a country by country basis, at various times depending on various factors, including the filing date of the corresponding patent application(s), the availability of patent term extension and supplemental protection certificates and requirements for terminal disclaimers. Although we believe our owned and licensed patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our corporate collaborators may not be able to develop patentable products or processes or obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue. In the event of issuance, the patents may not be sufficient to protect the proprietary technology owned by or licensed to us or our corporate collaborators. Our or our collaborators' current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. In addition, changes to patent laws in the United States or in other countries may limit our ability to defend or enforce our patents, or may apply retroactively to affect the term and/or scope of our patents. Our patents have been and may in the future be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid, not infringed or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we are or may be from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law and administrative tribunals, such as in U.S. Patent and Trademark Office inter partes review or reexamination proceedings, foreign opposition proceedings or related legal and administrative proceedings in the United States and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings or litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us or our collaborators. Our and our collaborators' patents may also be circumvented, which may allow third parties to use similar technologies without a license from us or our collaborators.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. Organizations such as pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned or licensed to us or to our collaborators. In addition, we are monitoring the progress of multiple pending patent applications of other organizations that, if granted, may require us to license or challenge their validity or enforceability in order to continue commercializing our products or to commercialize our product candidates. Our challenges to patents of other organizations may not be successful, which may affect our ability to commercialize our products and product candidates. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our or our collaborators' ability to make, use or sell our products and product candidates.

We require our scientific personnel to maintain laboratory notebooks and other research records in accordance with our policies, which are designed to strengthen and support our intellectual property protection. In addition to our patented intellectual property, we also rely on trade secrets and other proprietary information, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a proprietary information and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we will own all inventions conceived or reduced to practice by the individual in the course of rendering services to us. Our policy and agreements and those of our collaborators may not sufficiently protect our confidential information, or third parties may independently develop equivalent information.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, pre-market approval, manufacture, marketing and distribution of biopharmaceutical products. These agencies and other regulatory agencies regulate research and development activities and the testing, approval, manufacture, quality control, safety, efficacy, labeling, storage, distribution, import, export, recordkeeping, pricing, advertising and promotion of products and product candidates. Failure to comply with applicable FDA or other requirements may result in Warning Letters, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market. The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. We must obtain approval of our product candidates from the FDA before we can begin marketing them in the United States. Similar approvals are also required in other countries.

Product development and approval within this regulatory framework is uncertain, can take many years and requires the expenditure of substantial resources. The necessary steps before a new biopharmaceutical product may be sold in the United States ordinarily include:

- preclinical in vitro and in vivo tests, some of which must comply with Good Laboratory Practices, or GLP;
- submission to the FDA of an IND which must become effective before clinical trials may commence, and which must be updated periodically as new information is obtained and at least annually with a report on development;
- development of a drug formulation and manufacture of the drug for clinical trials, and commercial sale, if approved;
- completion of adequate and well controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a Biologics License Application, or BLA, or a New Drug Application, or NDA, which must be accompanied by a substantial user fee unless the fee is waived;
- FDA pre-approval inspection of manufacturing facilities for current Good Manufacturing Practices, or GMP, compliance and FDA inspection of select clinical trial sites and/or trial sponsors for Good Clinical Practice, or GCP, compliance; and
- FDA review and approval of the BLA or NDA, which includes the product prescribing information, prior to any commercial sale.

Clinical Trials Regulation in the U.S.

The results of preclinical tests (which include laboratory evaluation as well as preclinical GLP studies to evaluate toxicity) for a particular product candidate, together with related manufacturing information and analytical data, and a clinical protocol are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. New clinical trial protocols can be submitted to the existing IND during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP regulations and regulations for informed consent and privacy of individually-identifiable information.

Clinical trials generally are conducted in three sequential phases that may overlap or in some instances, be skipped. In phase 1, the initial introduction of the product into humans, the product candidate is tested to assess safety, metabolism, pharmacokinetics and pharmacological actions associated with increasing doses. Phase 2 usually involves trials in a limited patient population to evaluate the efficacy of the potential product for specific, targeted indications, determine dosage tolerance and optimum dosage and further identify possible adverse reactions and safety risks. Phase 3 and pivotal trials are undertaken to evaluate further clinical efficacy and safety often in comparison to standard therapies within a broader patient population, generally at geographically dispersed clinical sites. Phase 4, or post-marketing, trials may be required as a condition of commercial approval by the FDA and may also be voluntarily initiated by us or our collaborators. Testing may not be completed successfully within any specific period of time, if at all, with respect to any of our product candidates. Similarly, suggestions of safety, tolerability or efficacy in earlier stage trials do not necessarily predict findings of safety and efficacy in subsequent trials. Furthermore, the FDA, an IRB, or we may suspend a clinical trial at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical trials are subject to central registration and results reporting requirements, such as on www.clinicaltrials.gov.

Approval Process in the U.S.

The results of preclinical studies, pharmaceutical development and clinical trials, together with information on a product's chemistry, manufacturing, and controls, are submitted to the FDA, in the form of a BLA or NDA, for approval of the manufacture, marketing and commercial shipment of the pharmaceutical product. Data from clinical trials are not always conclusive and the FDA and other regulatory agencies may interpret data differently than we or our collaborators interpret data. The FDA may also convene an Advisory Committee of external advisors to answer questions regarding the approvability and labeling of an application. The FDA is not obligated to follow the Advisory Committee's recommendation. The submission of a BLA or NDA is required to be accompanied by a substantial user fee, with few exceptions or waivers. The user fee is administered under the PDUFA, which sets goals for the timeliness of the FDA's review. A standard review period is twelve months from submission of an original application, while priority review is eight months from submission of an original application. The testing and approval process is likely to require substantial time, effort and resources, and there can be no assurance that any approval will be granted on a timely basis, if at all. The FDA may deny review of an application by refusing to file the application, not approve an application by issuing a complete response letter, or require additional testing or information. Any approval that a product does receive may be more restricted than anticipated. For example, regulatory authorities may approve a product for fewer indications or narrower indications than requested. Further, regulatory agencies may impose post-market testing, safety monitoring, educational requirements or risk evaluation and mitigation strategies.

Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval from the FDA upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA requires, as a condition for accelerated approval, pre-approval of promotional materials.

Once an approval is issued, the FDA may require safety-related labeling changes or withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require further testing of an approved product, including phase 4 clinical trials, and surveillance programs to monitor the safety of the approved product, and the FDA has the power to prevent or limit further marketing of the approved product based on the results of these post-marketing programs or other information.

Post-Approval Regulations in the U.S.

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacture, labeling, distribution, advertising, promotion, recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion, and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA.

Manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including current Good Manufacturing Practices, or cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form FDA 483 and Warning Letters that could cause us to modify certain activities. A Form FDA 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidance. Failure to adequately and promptly correct the observation(s) can result in further regulatory enforcement action. In addition to Form FDA 483 notices and Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, not approve our products, require us to recall a product from distribution or withdraw approval of the BLA or NDA for that product. Failure to comply with ongoing regulatory obligations can result in delay of approval or Warning Letters, product seizures, criminal penalties, and withdrawal of approved products, among other enforcement remedies.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet, and off-label promotion. While physicians may prescribe products for off-label uses, manufacturers may only promote products for the approved indications and in accordance with the provisions of the approved label. The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing entities to correct deviations from FDA standards, and state and federal civil and criminal investigations and prosecutions.

FDA Regulation of Companion Diagnostics

Certain of our products and product candidates may rely upon in vitro companion diagnostics for use in selecting the patients that we believe will respond to our therapeutics. If safe and effective use of a therapeutic product depends on an in vitro diagnostic, the FDA generally will require approval or clearance of a reproducible, validated diagnostic test to be used with our therapeutic product at the same time that FDA approves the therapeutic product. The review of these in vitro companion diagnostics in conjunction with the review of our cancer treatments involves coordination of review by the FDA's Center for Drug Evaluation and Research and by the FDA's Center for Devices and Radiological Health. The FDA's premarket approval, or PMA, process is costly, lengthy, and uncertain. The receipt and timing of PMA approval may have a significant effect on the receipt and timing of any future commercial approvals for our products and product candidates. Human diagnostic products are subject to pervasive and ongoing regulatory obligations, including the submission of medical device reports, adherence to the Quality Systems Regulation, recordkeeping and product labeling, as enforced by the FDA and comparable state authorities.

The FDA's approval of ADCETRIS in the frontline PTCL indication included a post-marketing commitment to develop a clinically validated in vitro diagnostic device for the selection of patients with CD30-expressing PTCL, not including sALCL, for treatment with ADCETRIS in this indication. We and Takeda have a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana is working to develop, manufacture and commercialize a companion diagnostic test to measure CD30 expression levels in tissue specimens.

Regulations Outside of the United States

In addition to regulations in the U.S., we and our collaborators are and will be subject to regulations of other countries governing clinical trials, manufacturing, distribution, sales and promotion of our products. We must obtain approval by the regulatory authorities of countries or other economic areas outside of the U.S. before we can commence clinical trials in those countries and approval of the regulators of such countries or economic areas before we may market products in those countries or areas. For example, to commercialize TUKYSA in Europe, we need to comply with applicable European regulations. The approval requirements and processes can vary greatly, and the time required may be longer or shorter than that required for FDA approval. Requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from place to place.

Clinical Trials Regulation in Europe

In the EU, pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials with investigation of medicinal product(s) in the EU has been implemented through national legislation of the EU member states. Under this system, an applicant must obtain approval from the national competent authority of an EU member state in which the clinical trial with investigation of medicinal product(s) is to be conducted, or in multiple member states if the clinical trial with investigation of medicinal product(s) is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee for each site has issued a favorable opinion. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the individual EU member states and further detailed in applicable guidance documents. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which was set to replace the Clinical Trials Directive 2001/20/EC. The new Clinical Trials Regulation (EU) No 536/2014 came into effect in January 2022 with a three-year transition period in which clinical trial sponsors must use the new Clinical Trials Regulation (EU) No 536/2014 submission pathway beginning January 31, 2023 for new clinical trial applications, and must have transitioned any trials approved under the Clinical Trials Directive 2001/20/EC that continue running to the new Clinical Trials Regulation (EU) No 536/2014 beginning January 31, 2025. The new regulation, which is directly applicable in all EU member states, aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications.

In Vitro Diagnostic Medical Regulation in Europe and Combined Trials

In the EU, pursuant to the currently applicable In Vitro Diagnostic medical Regulation 2017/746, which replaces Directive 98/79/EC as of May 26, 2022, a system for the approval of combined trials, with a simultaneous investigation of a medicinal product (a clinical trial authorized under Clinical Trials Directive 2001/20/EC or Clinical Trials Regulation (EU) No 536/2014) and an in vitro diagnostic (clinical performance study), has been implemented. Under this system, while the clinical module of the EUDAMED database (a unique device identification system for medical devices) is not yet available, an applicant must obtain an additional approval from the national competent authority of an EU member state in which a clinical trial with medical purpose of an assay that fulfills the definition of an in vitro diagnostic according to the regulation is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial with medical purpose of an assay that fulfills the definition of an in vitro diagnostic according to the regulation at a specific study site after the independent ethics committee for each site has issued an additional favorable opinion. The additional and separate trial application must be accompanied by a clinical performance study protocol with supporting information prescribed by Regulation 2017/746, corresponding national laws of the individual EU member states and further detailed in applicable guidance documents.

Marketing Authorization Regulation in Europe

In the European Economic Area, which is comprised of the 27 member states of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization through one of the following procedures: centralized, mutual recognition, and decentralized. Under the centralized procedure, a single marketing authorization application is submitted to the CHMP, which then makes a recommendation to the EC. The EC makes the final determination on whether to approve the application. The centralized procedure is compulsory for the approval, among others, of human medicines containing a new active substance to treat cancer. The mutual recognition and decentralized procedures provide for mutual recognition of individual national approval decisions and are available for products that are not subject to the mandatory scope of the centralized procedure. The U.K., following its exit from the EU and EEA, and Switzerland conduct separate regulatory reviews of new drug applications.

For the EMA, an application designated as standard review typically lasts approximately twelve to fourteen months depending on the length of time sponsors take to address EMA questions. An accelerated assessment procedure is applicable to marketing authorization applications for medicinal products that are expected to be of major public health interest. For applications that receive accelerated assessment designation and are able to remain on this timeline, the review may last approximately seven months depending on the length of time sponsors take to address EMA questions. It is not unusual, however, for applications that receive accelerated assessment designation to revert to standard review if, for example, the EMA has determined that the significance of the questions that the company needs to address would be more appropriate under the standard review timelines. At the end of the review period, EMA will issue an opinion either in support of granting a marketing authorization (positive opinion) or recommending refusal of a marketing authorization (negative opinion). In the event of a negative opinion, the company may request a re-examination of the application. The initial marketing authorization granted in the EU is valid for five years. Once renewed, the authorization will be valid for an unlimited period, unless the national competent authority or the EC decides on justified grounds to proceed with one additional five-year renewal. The renewal of a marketing authorization is subject to a re-evaluation of the risk-benefit balance of the product by the national competent authorities or the EMA.

Post-approval Regulation in Europe

In countries where we receive regulatory approvals, we are subject to a variety of post-authorization regulations, including with respect to post-marketing authorization studies, product manufacturing, advertising and promotion, distribution, and safety reporting.

Various requirements apply to the manufacturing and placing of medicinal products on the EU market. The manufacturing of medicinal products in the EU requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, or APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution which are granted by the competent authorities of the individual EU member states. Marketing authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU member states' requirements applicable to the manufacturing of medicinal products.

The advertising and promotion of medicinal products are subject to EU member states' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, legislation adopted by individual EU member states may apply to the advertising and promotion of medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our future products and impose limitations on promotional activities with healthcare professionals.

The holder of an EU marketing authorization for a medicinal product must also comply with the EU's pharmacovigilance legislation, which includes requirements for conducting pharmacovigilance surveillance, or the assessment and monitoring of the safety of medicinal products. The EMA reviews periodic safety update reports submitted by marketing authorization holders. If the EMA has concerns that the risk-benefit profile of a product has changed, it can adopt an opinion advising that the existing marketing authorization for the product be amended. The agency can also require that the marketing authorization holder conducts post-authorization safety studies. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

Healthcare Regulation

U.S. federal and state healthcare laws and regulations are also applicable to our business. If we fail to comply with these laws, we could face substantial penalties and our business, results of operations, financial condition and growth prospects could be adversely affected. The healthcare laws and regulations that may affect our operations include, without limitation, anti-kickback and false claims laws, regulations prohibiting off-label promotion activities, and transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively PPACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. PPACA also codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. In addition, a criminal conviction for violation of the federal Anti-Kickback Statute requires mandatory exclusion from participation in federal healthcare programs.

The federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from, or approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government.

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. In recent years, private whistleblowers have also pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of off-label promotion. If we are found to have promoted an approved product for off-label uses, we may be subject to significant liability, including significant civil and administrative financial penalties and other remedies as well as criminal penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company's sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements, deferred prosecution agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Like the Anti-Kickback Statute, PPACA amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal transparency requirements under the Physician Payments Sunshine Act, created under PPACA and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to annually report information related to certain payments or other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures," as adjusted for inflation. Covered manufacturers are required to submit reports on aggregate payment data to the Secretary of the U.S. Department of Health and Human Services on an annual basis.

Many states have similar statutes or regulations to the above federal laws and regulations that may be broader in scope than the aforementioned federal versions and apply regardless of payor, and many of which differ from each other in significant ways and may not have the same effect, further complicating compliance efforts. Additionally, our business operations in jurisdictions outside the United States, including Canada and the EU, subject us to additional laws and regulations.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations were found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including significant criminal, civil and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, administrative burdens, imprisonment, diminished profits and future earnings, exclusion from government healthcare reimbursement programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and/or the curtailment or restructuring of our operations.

Anti-Corruption Legislation

We are also subject to numerous other laws and regulations that are not specific to the healthcare industry. For instance, the U.S. Foreign Corrupt Practices Act, or FCPA, generally prohibits paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, governmental staff members, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. In Europe, national anti-corruption laws prohibit giving, offering, or promising bribes to any person, including foreign government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. Various European anti-corruption laws have broad extraterritorial reach and therefore we may be subject to those laws even if we do not have an established entity in those countries and we may be held liable for bribes given, offered or promised to any person, including private persons, by employees and persons associated with us in order to obtain or retain business or a business advantage. As we continue to expand our footprint and activities internationally, our exposure to compliance risks under the FCPA and other similar laws will likewise increase.

Privacy and Security Laws

There are also numerous privacy and data protection laws to which we are currently, and/or may in the future, be subject. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data security and breach notification laws, personal data privacy laws, and consumer protection laws. The laws are not consistent, and states frequently amend existing laws, requiring attention to constantly changing regulatory requirements. For example, the California Consumer Privacy Act, or CCPA, became effective on January 1, 2020, and the California Privacy Rights Act, or CPRA, took effect January 1, 2023. The CPRA significantly modifies the CCPA, including by expanding individual rights, especially with respect to certain sensitive personal information. We may also be subject to additional U.S. state privacy regulations in the future. In addition, at the federal level, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations impose additional obligations on certain types of individuals and entities with respect to the security, privacy and transmission of individually identifiable health information.

EU member countries and other jurisdictions, including Switzerland, the United Kingdom and Canada, have also adopted data protection laws and regulations which impose significant compliance obligations. For example, the EU's General Data Protection Regulation, or GDPR, imposes a range of requirements relating to the collection, use, handling and protection of personal data. Violations of the GDPR can result in significant penalties, including potential fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The GDPR has increased our responsibility and potential liability in relation to all types of personal data that we process or that is processed on our behalf, including data from clinical trials, employees, collaborators and vendors. In addition, local data protection authorities can have different interpretations of the GDPR, leading to compliance challenges as a result of potential inconsistencies amongst various EU member states.

Among other requirements, the GDPR regulates transfers of personal data to countries that have not been found to provide adequate protection to such personal data, including the U.S. This includes transfers between us and our subsidiaries. In July 2020, the Court of Justice of the EU, or the CJEU, invalidated one of the primary safeguards enabling U.S. companies to import personal information from Europe, the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the EC's Standard Contractual Clauses, or SCCs, provide sufficient protection for personal data transfers without analyzing each transfer and implementing supplementary measures to protect the data. As a result of the CJEU's decision, the EC issued new SCCs in June 2021 that repeal and replace the previous clauses. Following recommendations from the European Data Protection Board, we review personal data transfers from the EU and add the new SCCs and supplementary measures, when required. Since local data protection authorities can interpret GDPR and the CJEU's decision differently, there is no definitive set of controls that can ensure GDPR compliance across our business operations. In addition, authorities in Switzerland and the United Kingdom, whose data protection laws are similar to those of the EU followed the EU's approach and CJEU decision. Additional compliance efforts may be needed to respond to evolving regulatory guidance. If our compliance solutions are found to be insufficient, we could face substantial fines under European data protection laws as well as injunctions against processing and/or transferring personal information from Europe. The inability to import personal information from Europe could restrict our clinical trial activities in Europe, limit our ability to collaborate with contract research organizations, service providers, contractors and other companies subject to European data protection laws, interfere with our ability to hire employees in Europe and require us to increase our data processing capabilities in Europe at significant expense.

In addition, we may be subject to other foreign data privacy and security laws. For example, China's Personal Information Protection Law, or PIPL, which took effect in November 2021, imposes various requirements related to personal information processing, similar to the GDPR and CCPA. In particular, the PIPL sets out personal information localization requirements, along with rules regarding the transfer of personal information outside of China. Such transfers may require assessment and/or approval by China's Cyberspace Administration, certification by professional institutions or entering into contracts with and supervising overseas recipients. Violations of the PIPL may lead to an administrative fine of up to RMB 50 million or 5% of turnover in the last year.

Any failure or alleged failure to comply with legal or contractual obligations, policies and industry standards relating to personal information, and any incident resulting in the unauthorized access to, or acquisition, release or transfer of, personal information, may result in governmental investigations or enforcement actions, litigation, fines, penalties, damage to our reputation and other adverse consequences. In addition, we expect that laws, regulations, policies and industry standards relating to privacy and data protection will continue to evolve. These changes may require us to modify our practices and may increase our costs of doing business. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these standards, even if no personal information is compromised, we may incur significant fines or experience a significant increase in costs.

Coverage and Reimbursement

Sales of our current and any future approved products will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Patients who are prescribed treatment for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients and providers are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Pharmaceutical products are typically reimbursed based on FDA labeled indications, recognized compendia listings, available medical literature, evidence of favorable clinical outcomes, determination of medical necessity and cost effectiveness.

Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product candidates is individual to each insurer, can vary based on provider contract, and will be affected by state and federal laws providing for reimbursement formulas based on acquisition cost. Third-party payors continue to work diligently to control their spending on prescription drugs and medical service. The containment of healthcare costs has become a priority of the U.S. government and abroad, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and the governments of other countries have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net sales and negatively impact our operating results. Payors, commercial and public, in the U.S. and abroad, must review the therapeutic value of our products before extending coverage under their plans to reimburse our products. If third-party payors do not find a product to be of therapeutic value, they may not cover it or, if they do, they may do so at an insufficient level of payment. Further, in the event that our product candidates rely upon in vitro companion diagnostics for use in selecting the patients that we believe will respond to our therapeutics, we or our collaborators may be required to obtain coverage and reimbursement separate and apart from the coverage and reimbursement we may seek for our product candidates.

Many of the patients in the U.S. who seek treatment with our products may be eligible for Medicare or Medicaid benefits. The Medicare and Medicaid programs are administered by the Centers for Medicare and Medicaid Services, or CMS, and coverage and reimbursement for products and services under these programs are subject to changes in CMS regulations and interpretive policy determinations, in addition to statutory changes made by Congress. For example, PPACA increased the mandated Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, expanded the rebate to Medicaid managed care utilization and increased the types of entities eligible for the federal 340B drug discount program. Federal budget decisions have reduced Medicare payment rates, and future budget decisions may reduce Medicare payment rates again. In addition, as a condition of federal funds being made available to cover our products under Medicaid, we are required to participate in the Medicaid drug rebate program. The rebate amount under this program varies by quarter, and is based on pricing data we report to CMS. In addition, because we participate in the Medicaid drug rebate program, we must make our products available to authorized users of the Federal Supply Schedule of the General Services Administration. This requires compliance with additional laws and requirements, including offering our products at a reduced price to federal agencies including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and the Indian Health Service. We are also required to offer discounted pricing to certain eligible not for profit entities that are eligible for 340B pricing under the Public Health Services Act. Participation in these programs requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial criminal, civil and/or administrative penalties, as well as administrative burdens and exclusion from or contract termination regarding these programs. The terms of these government programs could change in the future which may increase the discounts or rebates we are required to offer, possibly reducing the revenue derived from sales of our products to these entities.

Policies governing drug pricing vary widely from country to country. In many European countries, authorities regulate the pricing of a pharmaceutical product at launch or subsequent to launch through direct price controls such as international reference pricing. In addition, in many European countries, pharmaceutical products are funded largely by the national healthcare systems. As a result, patients are unlikely to use a pharmaceutical product that is not reimbursed by the national authorities. There can be no assurance as to the pricing and/or level of reimbursement that may be available for our products in countries with pricing and reimbursement policies in place at the national level.

Health Technology Assessment, or HTA, of pharmaceutical products is becoming an increasingly common part of the pricing and reimbursement procedures in EU member states. The HTA process, which is governed by the national laws of the applicable country, aims to measure the added value of a new health technology compared to existing ones by assessing its public health impact, therapeutic impact and economic and societal impact in the context and setting of the individual country's national healthcare system. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost and cost-effectiveness of individual pharmaceutical products in comparison to the local standard of care, as well as their potential implications for the healthcare system. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these pharmaceutical products by the competent authorities of individual EU member states. Pursuant to Directive 2011/24/EU, a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization between EU member states of the criteria taken into account in the conduct of HTA and their impact on pricing and reimbursement decisions.

Healthcare Reform

PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affected the pharmaceutical industry. PPACA has, among other things, expanded and increased industry rebates for products covered under Medicaid programs and changed the coverage requirements under the Medicare Part D program. In order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. The required PHS discount on a given product is calculated based on the Average Manufacturers Price, or AMP, and Medicaid rebate amounts reported by the manufacturer. PPACA expanded the types of entities eligible to receive discounted PHS pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted PHS pricing on orphan drugs when used for the orphan indication. In addition, as PHS drug pricing is determined based on AMP and Medicaid rebate data, revisions, including the AMP rule, to the Medicaid rebate formula and AMP definition described above could cause the required PHS discount to increase.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers, which went into effect in April 2013 and, due to subsequent legislative action, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a temporary cut in the amount of the reduction from April 1 through June 30 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023.

As described above in "Coverage and Reimbursement", federal and state legislatures, governments in countries outside the U.S., health agencies and third-party payors continue to focus on containing the cost of healthcare. Legislative and regulatory changes and increasing pressure from social sources are likely to further influence the manner in which our products are priced, prescribed, purchased and reimbursed. For example, the federal government has implemented reforms to government healthcare programs in the U.S., including changes to the methods for, and amounts of, Medicare reimbursement and changes to the Medicaid Drug Rebate Program. In March 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In November 2021, President Biden signed the Infrastructure Investment and Jobs Act, which included changes to the Medicare Part B program requiring rebates for some discarded drug products that are expected to increase future rebates for ADCETRIS, TIVDAK and possibly PADCEV with an implementation date in the first quarter of 2023. The Biden administration also announced an Executive Order that includes initiatives to support the implementation of Canadian drug importation and reduce drug prices. In response to President Biden's Executive Order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future.

Inflation Reduction Act

On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated “maximum fair price” under the law; (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize drug price increases that outpace inflation; and (iii) redesigns the Medicare Part D program, increasing manufacturer rebates within the catastrophic coverage phase. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively beginning in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry.

The IRA also includes various tax provisions, including an excise tax on stock repurchases, expanded tax credits for clean energy incentives, and a corporate alternative minimum tax that generally applies to U.S. corporations with average adjusted financial statement income over a three year period in excess of $1 billion. The Company does not expect these tax provision to materially impact its financial statements.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies and intense competition. Many third parties compete with us in developing various approaches to treating cancer. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

With respect to ADCETRIS, there are several other FDA approved drugs for its approved indications. Bristol-Myers Squibb's, or BMS's nivolumab and Merck's pembrolizumab are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Acrotech Biopharma's pralatrexate and belinostat are approved for relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, among other T-cell lymphomas. BMS's romidepsin is approved for cutaneous T-cell lymphoma. Kyowa Kirin's mogamulizumab is approved for adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome. The competition ADCETRIS faces from these and other therapies is intensifying. Additionally, Merck conducted a phase 3 clinical trial in relapsed or refractory classical Hodgkin lymphoma comparing pembrolizumab to ADCETRIS. An interim analysis of this clinical trial demonstrated a statistically significant improvement in progression-free survival for pembrolizumab compared with ADCETRIS, resulting in a label expansion to an earlier line of therapy, and pembrolizumab is now competing with ADCETRIS in this indication. We are also aware of multiple investigational agents currently being studied that, if successful, may compete with ADCETRIS in the future, such as camidanlumab tesirine, which is in a phase 2 study in relapsed/refractory classical Hodgkin lymphoma. Nivolumab, with or without chemotherapy, in a phase 2 investigator-initiated trial, has demonstrated significant objective response rate in the salvage setting. In the frontline classical Hodgkin lymphoma setting, nivolumab in combination with chemotherapy and pembrolizumab in combination with chemotherapy are each being studied and if proven beneficial, could compete with ADCETRIS in that setting. Data have also been presented on several developing technologies, including bispecific antibodies and CAR modified T-cell therapies that may compete with ADCETRIS in the future. Further, there are many competing approaches used in the treatment of patients in ADCETRIS' approved indications, including autologous hematopoietic stem cell transplant, allogeneic hematopoietic stem cell transplant and chemotherapy, in addition to clinical trials with experimental agents.

With respect to PADCEV, other treatments in pretreated metastatic urothelial cancer include sacituzumab govitecan (a Trop-2-directed antibody and topoisomerase inhibitor conjugate), checkpoint inhibitor monotherapy, generic chemotherapy and, for patients with select FGFR genetic alterations, Janssen's erdafitinib. Front line metastatic urothelial cancer was traditionally treated with chemotherapy alone but is evolving to include checkpoint inhibitors for cisplatin-ineligible patients with high PD-L1 expression in addition to patients who are ineligible for platinum therapy. Avelumab is used for frontline maintenance therapy, and several trials of investigational agents in combination with chemotherapy or other novel agents are ongoing. Continued development of PD-(L)1 targeted therapies across early-stage bladder cancer and in metastatic bladder cancer in frontline combinations with chemotherapy, in frontline maintenance, and in pretreated disease, could potentially impact PADCEV usage and enrollment in PADCEV clinical trials.

With respect to TUKYSA, there are multiple marketed products which target HER2, including the antibodies trastuzumab and pertuzumab and the antibody drug conjugate T-DM1. In addition, lapatinib is an EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer, and neratinib is an irreversible pan-HER kinase inhibitor indicated for extended adjuvant treatment and treatment of metastatic breast cancer in patients who received two or more prior anti-HER2-based regimens. Daiichi Sankyo and AstraZeneca have fam-trastuzumab deruxtecan-nxki, which was approved by the FDA for patients who have received one or more prior anti-HER2-based regimens in the metastatic breast cancer setting and in the HER2-positive gastric cancer setting post-trastuzumab-based therapy. The agent was also granted conditional marketing authorization by the EMA for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens. We believe that the sequence of therapies patients receive for HER2-positive breast cancer is likely to continue to change in both the U.S. and EU, with greater fam-trastuzumab deruxtecan-nxki use in second line. This has resulted and is expected to continue to result in increased competition for TUKYSA, which is approved by the FDA for patients who have received one or more prior anti-HER2-based regimens in the metastatic breast cancer setting, including in patients with brain metastases. MacroGenics has a HER2 targeted, Fc-optimized antibody, margetuximab, which is approved by the FDA for patients who have received at least two previous anti-HER2 regimens. Additionally, Byondis released results from a pivotal trial of its antibody drug conjugate, SYD985, in metastatic breast cancer patients treated with multiple anti-HER2-based regimens and the FDA accepted a regulatory submission based on these results with a target action date in May 2023. Fam-trastuzumab deruxtecan-nxki is also recommended by NCCN for use as part of a combination therapy in HER2-positive metastatic colorectal cancer.

With respect to TIVDAK, Merck's pembrolizumab is approved by the FDA and EC in first line in combination with chemotherapy, with or without bevacizumab, for the treatment of recurrent or metastatic cervical cancer whose tumors express PD-L1 and is approved by the FDA in second line as a monotherapy for recurrent or metastatic cervical cancer patients with disease progression on or after chemotherapy in patients whose tumors express PD-L1. In September 2022, pembrolizumab was approved in Japan as first-line therapy in combination with chemotherapy, with or without bevacizumab, for patients with recurrent or metastatic cervical cancer who are not amenable to curative treatment. We are also aware of other companies that currently have products in development for the treatment of late-stage cervical cancer which could be competitive with TIVDAK, including Agenus, BMS, Iovance Biotherapeutics, Merck, Regeneron Pharmaceuticals, Sanofi and Roche. Cemiplimab is being reviewed in several countries outside the U.S. for the treatment of patients with recurrent or metastatic cervical cancer following progression on platinum-based chemotherapy. A supplemental Biologics License Application for cemiplimab was withdrawn in the U.S. in January 2022. Cemiplimab received Canadian approval in March 2022, EC approval in November 2022 and Japanese approval in December 2022, which will likely impact the potential future opportunity for TIVDAK in that geography.

Many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer that our product candidates are designed and being developed to treat. In addition, we are aware of a number of other companies that have ADC and other technologies that may be competitive with ours. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates. In addition, our ADC collaborators may develop compounds utilizing our technology that may compete with product candidates that we are developing.

The risk of biosimilar or generic challenges has also been increasing in our industry. In the U.S. and the EU, after a period of exclusivity for an innovator's approved biological product or branded drug has passed, there are abbreviated pathways for approval of biosimilar products or generic drugs. For example, in the U.S., the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" or "biosimilar" to or "interchangeable" with an FDA approved biological product. This pathway allows competitors to reference the FDA's prior approvals regarding innovative biological products and data submitted with a BLA to obtain approval of a biosimilar application twelve years after the time of approval of the innovative biological product. The twelve-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the twelve-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. The twelve-year exclusivity only assures that another company cannot rely on the FDA's prior approvals in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. Similarly, in the EU, the EC has granted marketing authorizations for biosimilars pursuant to a set of general and product class-specific guidelines. In addition, it is not possible to predict changes in law that might reduce regulatory exclusivity. As a result, and due to uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that biosimilar, interchangeable or generic versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

It is also possible that our competitors will succeed in developing technologies that are more effective than our products and product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar, interchangeable or generic products for our products and product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of our products and product candidates.

With respect to our current and potential future product candidates, we believe that our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

- advance our technology platforms;
- license additional technology;
- complete clinical trials which position our products for regulatory and commercial success;
- maintain a proprietary position in our technologies and products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel;
- commercialize effectively;
- obtain reimbursement for our products in approved indications;
- comply with applicable laws, regulations and regulatory requirements and restrictions with respect to the commercialization of our products, including with respect to any changed or increased regulatory restrictions; and
- enter into additional collaborations to advance the development and commercialization of our product candidates.

Manufacturing

We own a biologics manufacturing facility located in Bothell, Washington, which we use to support certain clinical and commercial supply needs, and have signed a lease to a facility currently being constructed in Everett, Washington, which will be used for future manufacturing capability. However, we rely and expect to continue to rely on collaborators, contract manufacturers and other third parties to produce and store sufficient quantities of drug product for both our clinical and commercial programs. While we believe that the existing supplies of our products and our collaborators' contract manufacturing relationships will be sufficient to accommodate current clinical and commercial needs, we or our collaborators may need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs, which could require additional capital investment or cause delays.

ADCETRIS

We rely on contract manufacturing organizations to supply ADCETRIS for commercial sale and for our clinical trials. For the monoclonal antibody used in ADCETRIS, we have contracted with AbbVie Inc., or AbbVie, for commercial and clinical supplies. We have multiple contract manufacturers for commercial and clinical supplies of the drug linker used in ADCETRIS, conjugating the drug linker to the antibody and producing ADCETRIS drug product. In addition, we rely on other third parties to supply the raw materials used to produce ADCETRIS, and to perform additional steps in the manufacturing process, including storage and distribution of ADCETRIS and our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, store and distribute sufficient quantities of ADCETRIS for commercial sale and for use in our clinical trials.

AbbVie. In 2004, we entered into a development and supply agreement with AbbVie (formerly a part of Abbott Laboratories) to manufacture developmental, clinical and commercial quantities of anti-CD30 monoclonal antibody, which is a component of ADCETRIS. The agreement generally provides for the supply by AbbVie and the purchase by us of such anti-CD30 monoclonal antibody. Under terms of the supply agreement, we may purchase a portion of our required anti-CD30 monoclonal antibody from a second source third-party supplier. We are required to make a minimum annual purchase. The anti-CD30 monoclonal antibody is purchased by us based upon a rolling forecast. The supply agreement will continue until 2025 with an automatic one-year term extension unless either party provides written termination notice to the other party. Either party has the right to terminate the supply agreement if the other party materially breaches its obligations thereunder.

PADCEV

Astellas or its affiliates are responsible for overseeing the initial manufacturing supply chain for PADCEV for development and commercial use. However, we are responsible for packaging and labeling in countries in which we sell PADCEV. In addition, we are in the process of establishing a second source manufacturing supply chain, through a combination of internal manufacturing capacity and third parties. In this regard, our manufacturing facility in Bothell, Washington is used to support commercial production of PADCEV antibody. For the foreseeable future, we expect to continue to rely on third parties to produce, store and distribute sufficient quantities of PADCEV for commercial sale and for use in our clinical trials.

TUKYSA

With respect to TUKYSA, we rely on multiple contract manufacturers and other third parties to perform manufacturing services for us, including Sterling Pharma Solutions Limited, or Sterling, for production of the starting materials for TUKYSA, Esteve Quimica, S.A., or Esteve, to produce the active pharmaceutical ingredient and Hovione FarmaCiencia SA, or Hovione, to complete spray drying. We have multiple contract manufacturers to produce the tablets for TUKYSA. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce and store sufficient quantities of TUKYSA. We have limited prior experience as an organization manufacturing TUKYSA and small molecule drug products generally, and we have relatively new working relationships with many of the third-party manufacturers involved in TUKYSA manufacture.

Sterling. We have a commercial supply agreement with Sterling to manufacture starting materials for TUKYSA. The agreement provides that we will purchase starting materials pursuant to rolling forecasts and will purchase a minimum percentage of our requirements for the starting materials from Sterling. The agreement will remain in effect until 2025, after which it will continue automatically for up to two additional years subject to termination by either party giving written notice to the other party. Either party has the right to terminate the agreement if the other party commits any breach of the agreement and does not remedy, make a bona fide attempt to remedy or enter into negotiations to resolve, the breach after notice to do so, if capable of remedy.

Esteve. Our commercial supply agreement with Esteve provides that we will order the active pharmaceutical ingredient for TUKYSA pursuant to rolling forecasts and will purchase a minimum percentage of our requirements for the active pharmaceutical ingredient from Esteve. The agreement will remain in effect until 2025, subject to termination by us giving written notice to Esteve, after which it will automatically renew subject to termination by either party by giving written notice to the other party. Either party has the right to terminate the agreement if the other party fails to cure a material breach.

Hovione. We have a commercial supply agreement with Hovione to manufacture the tucatinib spray-dried dispersion or drug product intermediate for TUKYSA. The agreement provides that we will order pursuant to rolling forecasts and will purchase a minimum percentage of our requirements from Hovione. The agreement will remain in effect until 2026, followed by successive automatic two-year renewals. Either party may terminate the agreement by written notice prior to commencement of the applicable renewal term. In addition, either party has the right to terminate the agreement if the other party breaches the agreement and does not remedy the breach after written notice or if the occurrence of a force majeure event prevents the other party from performing its obligations under the agreement.

TIVDAK

We also rely on multiple contract manufacturers and other third parties to perform manufacturing services for us with respect to TIVDAK. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce and store sufficient quantities of TIVDAK.

Our Product Candidates

We also rely on multiple contract manufacturers and other third parties to perform manufacturing services for us with respect to our product candidates.

Commercial Operations

We have allocated commercial resources, including sales, marketing, supply chain management and reimbursement capabilities, to commercialize ADCETRIS and PADCEV in the U.S. and Canada, TUKYSA in the U.S., Europe and Canada, and TIVDAK in the U.S. We believe the markets for our products in their approved indications are addressable with a targeted sales and marketing organization. We intend to continue promoting our products in our territories for their current indications and any additional indications we may obtain in the future. Astellas jointly commercializes PADCEV with us in the U.S. In addition, Genmab jointly commercializes TIVDAK with us in the U.S.

In the U.S., we sell ADCETRIS, PADCEV, TUKYSA, and TIVDAK through a limited number of specialty distributors. Three of our major distributors, together with entities under their common control—AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation—each accounted for 10% or more of our total net product sales in 2022, 2021 and 2020. Healthcare providers purchase ADCETRIS, PADCEV, TUKYSA, and TIVDAK through these specialty distributors and the product is drop shipped directly to the healthcare provider. In addition to specialty distributors, we also sell TUKYSA to a limited number of specialty pharmacies.

ADCETRIS, PADCEV and TIVDAK are infused products and generally shipped directly to healthcare providers and facilities for administration to patients. TUKYSA is an oral product ordered by prescription and typically dispensed to patients by the network specialty pharmacies, at physician in-office dispensing sites, or by hospital/Integrated Delivery Network pharmacies.

In Europe, we have allocated commercial resources, including sales, marketing, supply chain management, and reimbursement capabilities to enable and execute launches across key markets in Europe. Hospitals in Europe can purchase TUKYSA directly from Seagen or indirectly from wholesale distributors. In European countries where we have not established our own sales force, TUKYSA can be accessed through distribution partners.

Human Capital Resources

As of December 31, 2022, we had 3,256 employees. Of these employees, 2,027 were engaged in or support research, clinical, and supply chain management activities, 616 were in administrative and business-related positions, and 613 were in sales and marketing. We consider our employee relations to be good. The Compensation and Management Development Committee of our Board of Directors is responsible for, among other things, reviewing and discussing with management our human capital management practices and policies, including diversity and inclusion initiatives.

Diversity, Equity and Inclusion

We believe that fostering diversity, equity, and inclusion, or DEI, is a key element to discovering, developing, and bringing transformative therapies to patients with cancer. As of the end of 2022, 58% of our global workforce and 41% of our leadership (at the executive director level and above) were female. In addition, as of the end of 2022, 36% of our U.S. workforce and 32% of our U.S. leadership (at the executive director level and above) were racially or ethnically diverse. We strive to build a workforce representative of the people we serve and to nurture an inclusive culture where all voices are welcomed, heard, and respected. In 2022, we continued initiatives to further build our capacity to meet our DEI goals. We have five employee resource networks and a DEI executive council that help us work towards achieving our DEI goals.

Recruiting and Retention

We believe that we have been successful in attracting and retaining talented personnel to support our expanding business, though competition for personnel in our industry is intense. We monitor recruiting efforts using a variety of metrics such as internal placement rates, cycle times, cost per hire, information on the retention of business-critical hires (such as medical directors and executives), and the percentage of budgeted openings filled on time and on budget. We also track voluntary and involuntary turnover rates for the company as a whole, for business-critical talent and by gender, race or ethnicity, time in role and job level.

Compensation and Benefits

We offer competitive pay and benefits designed to attract and retain exceptional talent and drive company performance. In setting appropriate compensation levels, we look at the average base pay rate for each position based on market data. At the time of our last completed annual compensation review, effective February 2022, for regular employees who were eligible for a pay increase, the average ratio of base pay to this market rate was 100%. We also offer an annual cash incentive program, a sales incentive program and an equity incentive plan that we use to provide long-term equity incentives broadly throughout the organization. These programs are designed to assist in attracting, retaining and motivating employees and promoting the creation of long-term value for stockholders.

Our standard employee benefits in the U.S. include paid and unpaid leaves, medical, dental and vision insurance coverage, a 401(k) plan, short- and long-term disability, life insurance, flexible spending accounts and an employee stock purchase plan. We also offer a variety of voluntary benefits that allow employees to select options that meet their needs, including telehealth, an employee assistance program, backup childcare, adoption assistance, a travel solution for nursing mothers, education assistance, fitness reimbursements, and wellness programs. We benchmark our benefits program against others in our industry on an annual basis.

Succession Planning and Leadership Development

We establish retention plans for our executives and other business-critical talent and review their total compensation and unvested equity annually. Succession, development, and retention plans for our executive officers are reviewed at the board level. The Compensation and Management Development Committee is responsible for, among other things, discussing succession and development planning for our chief executive officer and other executives with our Board of Directors. In addition, we hold company-wide talent-planning reviews both at the executive and departmental levels. To help accelerate the development of leaders across the company, we have established the Seagen Leadership Academy, a program that provides training, leadership opportunities, mentorship and support to high-potential talent at the director level and above.

COVID-19

We are continuing to monitor the impact of the evolving effects of the COVID-19 pandemic on our business. We have maintained a cross-functional COVID-19 working group, which meets periodically to discuss policies and protocols, strategic planning, business continuity, and other matters relating to the pandemic. We are continuing to take proactive steps designed to protect the health and safety of our workforce, patients, and healthcare professionals, and to continue our business operations so we can advance our goal of bringing important medicines to patients. Earlier in the pandemic, we instituted a mandatory work-from-home policy for employees who could perform their jobs offsite, but continued our essential research, manufacturing, and laboratory activities on site. We have since allowed additional employees who have been fully vaccinated to return to the office. We maintain a number of precautionary measures designed to protect our on-site employees, such as enhanced facilities cleaning, contact tracing and making testing available.

We believe that the measures we have implemented are appropriate and are helping to reduce transmission of COVID-19, and we will continue to monitor conditions and related guidance from governmental authorities and adjust our activities as appropriate. For information regarding the impacts related to the COVID-19 pandemic on our ability and the ability of our collaborators to effectively market, sell and distribute our products and to develop our products and product candidates, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview—Outlook" in Part II Item 7 of this Annual Report on Form 10-K.

Corporate Information

We were incorporated in Delaware on July 15, 1997, as Seattle Genetics, Inc. In October 2020, we changed our corporate name from Seattle Genetics, Inc. to Seagen Inc., reflecting the global expansion of our operations. Our principal executive offices are located at 21823 30th Drive SE, Bothell, Washington 98021. Our telephone number is (425) 527-4000, and our website address is www.seagen.com. Seagen, the Seagen logo, ADCETRIS, TIVDAK and TUKYSA are our registered trademarks in the United States. PADCEV is a U.S. registered trademark jointly owned by us and Agensys, Inc. All other trademarks, tradenames and service marks included in this Annual Report on Form 10-K are the property of their respective owners.

We file electronically with the Securities and Exchange Commission, or SEC, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at www.seagen.com, free of charge, through a hyperlink on our website, copies of these reports, as soon as reasonably practicable after electronically filing such reports with, or furnishing them to, the SEC. Information found on, or accessible through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K. In addition, the SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results and financial condition could be seriously harmed. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Products, Product Candidates and Research and Development

Our success depends on our ability to effectively commercialize our products. If we and our collaborators are unable to effectively commercialize our products and to expand their utilization, our ability to generate significant revenue and our prospects for profitability will be adversely affected.

Our ability to generate revenue from product sales and our prospects for profitability are substantially dependent on our and our collaborators' ability to effectively commercialize our products and expand their utilization. We may not be able to fully realize the commercial potential of our products, and/or commercial sales of our products may be lower than our projections, for a number of reasons, including:

- we and our collaborators may be unable to effectively launch, market and commercialize our products, including in any new markets or in any new indications;
- we and our collaborators may not be able to establish or demonstrate to the medical community the efficacy, safety and value of our products and their potential advantages compared to existing and future therapeutics in their approved indications;
- we and our collaborators may not be able to obtain and maintain regulatory and other required governmental approvals to market our products in any additional territories or for any additional indications;
- new competitive therapies in the approved indications for our products have been approved by regulatory authorities or may be approved or submitted to regulatory authorities for approval in the near term;
- there may continue to be new adverse results, adverse events or safety concerns reported in connection with the use of our products, including in clinical trials;
- there may be additional changes to the labeling for our products that further restrict how we market and sell our products, including as a result of data collected from clinical trials and/or as a result of the use of our products;
- the incidence rate of new patients or the duration of therapy in the approved indications for our products may be lower than our projections;
- we may experience further or more severe negative impacts related to the COVID-19 pandemic, including potential future impacts on cancer diagnosis rates;
- negative impacts related to global economic instability and inflationary pressures;
- we may encounter challenges in joint decision making and joint execution with our collaborators that adversely affect product sales;
- co-promotion arrangements, such as the joint commercialization of PADCEV with Astellas in the U.S. and the joint commercialization of TIVDAK with Genmab in the U.S., may not be successful;

- our products may be impacted by adverse reimbursement and coverage policies from government and private payors such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators, or may be subject to pricing pressures enacted by industry organizations or state and federal governments, including as a result of increased scrutiny over pharmaceutical pricing, the cost of alternative treatment options or otherwise;
- we and our collaborators may not be able to obtain favorable pricing and reimbursement approvals in additional territories in a timely manner or at all;
- physicians may be reluctant to prescribe our products due to side effects associated with their use or until longer term efficacy and safety data exist;
- regulatory restrictions may change or increase;
- we and our collaborators may not have adequate financial or other resources to effectively commercialize our products; and
- we and our collaborators may not be able to accurately predict demand for our products and obtain adequate commercial supplies of our products to meet demand at an acceptable cost.

Our ability to grow our product sales in future periods is also dependent on price increases, and we periodically increase the price of our products. Price increases on our products, as well as negative publicity regarding drug pricing and increases in drug prices generally, whether on our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of, and sales of, our products. In any event, we cannot assure you that price increases we have taken or may take in the future will not negatively affect our future product sales.

If we and our collaborators are unable to successfully commercialize our products or if sales of a product do not reach the levels we expect, then our business, results of operation, financial condition and growth prospects could be adversely affected.

Our success also depends on our ability to obtain regulatory approvals for our product candidates and for our current products in additional territories, as well as our ability to expand the labeled indications of use for our current products. Our inability to do so could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

We and our collaborators are required to obtain marketing approvals from applicable regulatory authorities in order to market our products or to expand the labeled indications of use for our current marketed products. However, regulatory review is a lengthy and expensive process, and approval is highly uncertain.

The U.S. Food and Drug Administration, or FDA, and other regulatory agencies have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained. Clinical trial data are subject to differing interpretations. Even if we believe data are promising, regulatory authorities may disagree and may require additional data, limit the scope of the approval or deny approval altogether. For example, although we and Astellas announced positive initial results from the dose escalation/Cohort A, and positive data from Cohort K, of the EV-103 trial and the FDA accepted a supplemental Biologics License Application, or sBLA, based on these results, the FDA or its advisors may disagree with our interpretation of the data from this trial. We cannot be certain the sBLA submitted for PADCEV in October 2022 will be approved in a timely manner or at all. It is possible that PADCEV may never be approved for use in any first-line setting or any other additional indications. In addition, the approval of a product candidate by one regulatory agency does not mean that other regulatory agencies will also approve such product candidate.

Any approval that a product does receive may be more restricted than anticipated. For example, regulatory authorities may approve a product for fewer indications or narrower indications than requested. Further, regulatory agencies may impose post-marketing testing, safety monitoring, educational requirements or risk evaluation and mitigation strategies, or REMS. Regulatory authorities may also fail to approve the facilities or processes used to manufacture a product candidate or the dosing or delivery methods.

The regulatory review process may also take significantly longer than expected, which may delay or eliminate any potential revenues from sales of the affected product or product candidate. Target action dates and regulatory timelines may be subject to substantial delays. For example, although the FDA set a target action date for the sBLA we and Astellas submitted for PADCEV based on certain results from the EV-103 trial, the FDA does not always meet its target action dates. In addition, although the FDA and EMA have programs to facilitate expedited development and accelerated approval processes, these programs may not result in faster development, review or approval than conventional procedures and do not assure ultimate approval. For example, although the FDA granted Breakthrough Therapy designation to each of PADCEV and disitamab vedotin in a specified treatment setting and granted Priority Review to the sBLA we and Astellas submitted for PADCEV based on certain results from the EV-103 trial, these designations do not provide any assurance that PADCEV or disitamab vedotin will receive marketing approval in the specified settings or in any other settings in a timely manner or at all. Disruptions at the FDA and other agencies due to reduced funding levels, government shutdowns, impacts associated with the COVID-19 pandemic or other factors, may also lead to delays in the regulatory review process. These disruptions may also slow our other interactions with regulatory agencies, which may slow our other product development efforts.

If a product candidate fails to receive regulatory approvals, we will not have the anticipated revenues from that product candidate to fund our operations, and we may not recoup or receive any return on our investment in that product candidate. Similarly, if regulatory authorities do not approve product labeling that is necessary or desirable for the successful commercialization of an approved product, or if they do not approve an application to expand a product's labeled indications of use or market the product in a new territory, then our anticipated revenue from that product may be adversely affected. Any of these events could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

Even if regulatory approval is achieved, the launch of a new product or of an existing product in a new indication or territory is subject to a number of risks and uncertainties and may not be successful.

Sales of a new product and sales of an existing product in a new indication or territory are subject to significant risks and uncertainties and can be particularly difficult to predict. For example, the commercialization of TIVDAK is at an early stage and may not be successful. A proposed launch, including the launch of PADCEV and TUKYSA in countries where they have not yet launched, could also be delayed or impaired due to a variety of factors, including supply constraints, delays in arranging a commercial infrastructure, delays in obtaining or failure to obtain pricing and reimbursement approvals, or other factors. These risks could be heightened by impacts related to the COVID-19 pandemic. Delays or other difficulties due to any of these factors could negatively impact anticipated revenue from the affected product. In addition, prior to TUKYSA, we had no prior experience as an organization launching or commercializing a product outside the U.S. and Canada, which could adversely affect our ability to maximize the commercial potential of TUKYSA. If we and our collaborators are unable to successfully launch and commercialize any newly approved products and/or to successfully launch and commercialize our existing products in new indications or territories, then our business, results of operation, financial condition and growth prospects could be adversely affected.

Reports of adverse events or safety concerns involving our products or product candidates could delay or prevent us from obtaining or maintaining regulatory approvals or could negatively impact sales of our products or the prospects for our product candidates.

Reports of adverse events or safety concerns involving our products and product candidates could result in the limitation, denial or withdrawal of regulatory approval by the FDA or other regulatory authorities for any or all indications, the need to conduct additional trials, implementation of a REMS or the inclusion of unfavorable information in our product labeling and, in turn, could delay or prevent us from commercializing the applicable product or product candidate. There are no assurances that patients receiving our products will not experience serious adverse events, including fatal events, in the future, whether the serious adverse events are disclosed in the prescribing information or are newly reported. Further, there are no assurances that patients receiving our products with co-morbid diseases not previously studied, such as autoimmune diseases, will not experience new or different serious adverse events in the future.

The prescribing information for each of our products includes warnings and precautions for various toxicities and reactions, including certain fatal reactions. The prescribing information for ADCETRIS also includes a boxed warning related to the risk that JC virus infection resulting in progressive multifocal leukoencephalopathy and death can occur in patients receiving ADCETRIS. The prescribing information for PADCEV also includes a boxed warning related to the risk that severe and fatal cutaneous adverse reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, may occur in patients receiving PADCEV. The prescribing information for TIVDAK also includes a boxed warning related to the risk that ocular toxicity may occur in patients receiving TIVDAK, and the boxed warning includes requirements for ophthalmic exams at baseline, prior to each dose, and as clinically indicated, as well as premedication and eye care. We have updated the prescribing information for our products from time to time in the past, based on reports of adverse events or safety concerns, and we may be required to further update the prescribing information for our products, including boxed warnings, limitations of use, contraindications, warnings and precautions, and adverse reactions, or to implement a REMS in the future. Side effects and toxicities associated with our products, as well as the warnings, precautions and requirements listed in the prescribing information for our products, could affect the willingness of physicians to prescribe, and patients to utilize, our products and thus harm commercial sales of our products. Implementation of a REMS could advantage products that compete with ours or make it more difficult or expensive for us to distribute our products.

Likewise, reports of adverse events or safety concerns involving our products and product candidates could interrupt, delay or halt clinical trials of our products and product candidates, including the post-approval confirmatory studies that regulatory agencies have required us or our collaborators to complete. There have been serious side effects and, in some cases, deaths in clinical trials for our products and product candidates that were deemed to be treatment-related by the investigators in those trials, and additional and/or unexpected side effects may be observed in these or other trials in the future. In addition, in response to prior safety events observed in our clinical trials, including serious side effects and patient deaths, we have in the past, and may in the future, institute additional precautionary safety measures such as dosing caps and delays, enhanced monitoring for side effects, and modified patient inclusion and exclusion criteria. Additional and/or unexpected safety events could be observed in these or other trials that could delay or prevent us from advancing the clinical development of, or obtaining regulatory approvals for, our products and product candidates, could require us to alter the approved labeling of our products, may cause a trial to be redone or terminated, may affect patient recruitment or may affect the ability of enrolled patients to complete a trial. As a result, such safety events could adversely affect our business, results of operations, financial condition and growth prospects.

Clinical trials and product development are expensive, time consuming and uncertain, may take longer than we expect and may not be successful. Our failure to effectively advance our development programs in a timely manner or at all could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

Our long-term success will depend upon the successful development of new products, as well as developing our existing products for new indications. However, only a small number of development programs result in the commercialization of a product. It is possible that none of our product candidates will ever become commercial products and that none of our existing products will obtain regulatory approval in any additional indications or territories. We and our collaborators are currently conducting multiple clinical trials for our products and product candidates, and we plan to commence additional trials in the future. Each of these trials requires the investment of substantial expense and time. However, there can be no assurance that the design or conduct of these trials, or any data collected from them, will be sufficient to support advancement to the next stage of development, any regulatory approvals or commercial viability.

Many of our clinical trials were initiated based on limited data. Encouraging preclinical, preliminary or interim data, and/or positive early-stage clinical trial results do not ensure that full, larger scale, later stage or confirmatory trials will be successful or that regulatory approval will be obtained. For example, despite the positive initial results we and Astellas reported from the dose escalation/Cohort A of the EV-103 trial and the positive results we and Astellas announced from Cohort K of the EV-103 trial, we cannot be certain that PADCEV will demonstrate sufficient efficacy or a favorable safety profile in other trials, including the EV-302 trial. Many companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in late-stage clinical trials after achieving encouraging or positive results in early-stage development. We cannot be certain that we will not face similar setbacks in our ongoing or planned clinical trials, including ongoing pivotal and confirmatory trials.

There may still be important facts about the safety, efficacy, and risk versus benefit of our products and product candidates, as single agents or in combination with other agents, that are not known to us at this time and that may negatively impact our ability to develop and commercialize them. Safety events or concerns, or negative or inconclusive trial results, could adversely affect the development timeline and the regulatory approval and commercialization prospects for our products and product candidates, or cause us to cease further development of a product or product candidate, any of which may materially and adversely affect our business, results of operations, financial condition and growth prospects. In addition, we may make a strategic decision to discontinue development if, for example, we believe commercialization will be difficult relative to the standard of care or we prefer to prioritize other opportunities in our pipeline. We also face intense competition, and it is possible that a clinical trial may meet its safety and efficacy endpoints but we may choose not to advance the development of a product or product due to changes in the competitive environment.

From time to time, the commencement, continuation and completion of our clinical trials have been subject to delays, and we are likely to experience additional delays in the future. Factors that could lead to the delay, suspension, termination or need to modify clinical trials of our products and product candidates include:

- adverse medical events or side effects, including fatalities, in treated patients or other safety issues or concerns;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, Good Clinical Practice, or GCP, or study protocols;
- problems, errors or other deficiencies with respect to data collection, data processing and analysis;
- action by competent authorities to place a clinical hold or partial clinical hold on a trial or compound;
- the time required to determine efficacy may be longer than expected;
- unfavorable scientific results or insufficient data to support safety and effectiveness;
- inadequate supply or deficient quality of the applicable product or product candidate or of other materials necessary to complete the trials;
- inability to reach agreement on acceptable terms with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- delay or failure to obtain institutional review board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- decisions by competent authorities, IRBs, ethics committees, our collaborators or us, or recommendation by a data monitoring committee, to suspend or terminate a clinical trial for safety issues, futility or any other reason or to demand variations in the protocols or conduct of clinical trials;
- changes in governmental regulations or administrative actions that adversely affect the ability to continue to conduct or to complete a clinical trial;
- budgetary constraints or prohibitively high clinical trial costs;
- difficulties in identifying and enrolling patients who meet trial eligibility criteria;
- lower than anticipated retention rates for patients who have initiated a clinical trial;
- the risks and evolving effects of the COVID-19 pandemic; and
- risks related to the ongoing military conflict between Russia and Ukraine, and sanctions imposed against Russia by the international community.

Additionally, patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials, perceived side effects and the availability of alternative or new treatments. We have experienced enrollment-related delays in clinical trials in the past, and we will likely continue to experience similar delays in our current and future trials. Many of our future and ongoing clinical trials are being or will be coordinated or conducted with collaborators. If we and these collaborators fail to collaborate effectively, we may experience delays or adverse effects on the commencement, continuation or completion of these trials. In addition, our collaborators have operational control over some of the studies we conduct jointly and we do not have full visibility into these studies run by our collaborators. We also conduct clinical trials in countries outside the U.S., which may subject us to additional expenses, regulatory requirements and potential delays, as well as risks associated with different standards of medical care.

If a product candidate or a potential new indication fails at any stage of development, or if we or our collaborators otherwise discontinue development of a product candidate or indication for any reason, we will not have the anticipated revenues from that product candidate or indication to fund our operations and we may not recoup or receive any return on our investment in that product candidate or indication. Failure to effectively advance our development programs in a timely manner or at all could have a material adverse effect on our business, results of operations, financial condition and prospects.

The successful commercialization of our products will depend, in part, on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.

Successful sales of our current and any future approved products will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new products and require increasing levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of this pricing scrutiny, we cannot be sure that we and our collaborators will achieve and maintain coverage for our products and any product candidates that we or our collaborators commercialize and, if available, that the reimbursement rates will be adequate and grant access to all eligible patients. If we or our collaborators are unable to obtain and maintain coverage and adequate levels of reimbursement for our current and any future approved products that we or our collaborators commercialize, their marketability will be negatively and materially impacted. For example, we cannot be certain that third-party payors will provide coverage and adequate reimbursement for PADCEV, TUKYSA or TIVDAK based on their relative price and perceived benefits as compared to alternative treatment options or otherwise, which may materially harm our and our collaborators' ability to successfully commercialize PADCEV, TUKYSA and TIVDAK in our respective designated territories. In addition, gross-to-net deduction rates are dependent on market and site of care dynamics that may continue to evolve throughout the lifecycle of each of our products. These gross-to-net deduction rates also vary by product. We have experienced fluctuations in gross-to-net deductions in the past and may experience additional fluctuations in gross-to-net deductions for one or more of our products in the future.

In many jurisdictions, including many countries in Europe, the proposed pricing for a drug must be approved in an individual country before it may be lawfully marketed, which could delay entry of a product into a market or, if pricing is not approved, may prevent us or our collaborators from selling a product in a country where it has received regulatory approval. In European countries where TUKYSA and PADCEV have obtained regulatory approval, we will seek additional pricing and reimbursement agreements for TUKYSA, and work with Astellas to seek additional pricing and reimbursement agreements for PADCEV, in accordance with local timelines. Further, authorities in Europe have substantial discretion in the pricing and reimbursement approval process and in determining when or whether coverage will be available for a product in its initial indication or for any additional indications or in additional territories. In addition, in some cases, they may lower the price for a medicine after the price has been established. If we or our collaborators are unable to obtain favorable pricing and reimbursement approvals in the countries that represent significant potential markets, our anticipated revenue from and growth prospects for PADCEV and/or TUKYSA in those regions would be negatively affected.

Eligibility for coverage and reimbursement does not imply that payors will pay for a drug in all cases or at a rate that (i) captures the value delivered to patients, payors and the overall healthcare system; (ii) allows for continued investment in innovative treatments for cancer patients; or (iii) covers our costs, including research, development, manufacture, sale and distribution. In addition, obtaining and maintaining adequate coverage and reimbursement status is time-consuming and costly. Third-party payors may deny coverage and reimbursement status altogether for a given product, or they may cover the product but establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development or limit access to select patient populations, reducing revenue potential. Further, in the U.S., there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided is made on a payor-by-payor basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases at short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact the favorable status.

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of our current and any future approved products and the future revenues we may expect to receive from those products. Further, in the event that our product candidates rely upon in vitro companion diagnostics for use in selecting the patients that we believe will respond to our therapeutics, we or our collaborators may be required to obtain coverage and reimbursement separate and apart from the coverage and reimbursement we may seek for our product candidates. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be upheld or enacted in the future, or what effect such legislation or regulation would have on our business. Continuing negative publicity regarding pharmaceutical pricing practices and ongoing governmental and societal scrutiny create significant uncertainty regarding regulation of the healthcare industry and third-party coverage and reimbursement in the U.S. and other jurisdictions. If additional healthcare policies or reforms intended to curb healthcare costs are implemented or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical products generally, the prices that we charge for our current and any future approved products may be limited, and our revenues from sales of our current and any future approved products may be negatively impacted.

The successful commercialization of our products will also depend, in part, on the acceptance of our products by the medical community, patients and third-party payors.

The degree of market acceptance among patients, physicians, and third-party payors is important to our ability to successfully commercialize our current and any future approved products. The degree of acceptance will depend on a number of factors including the clinical benefits of our products, the effectiveness of our marketing, sales and distribution strategy and operations, the perceived advantages and relative cost, safety and efficacy of alternative treatments, and the acceptance and degree of adoption of our products by institutional treatment pathways and institutional, local, and national clinical guidelines. In the U.S., many oncology practices and healthcare providers rely on the National Comprehensive Cancer Network, or NCCN, Clinical Practice Guidelines in Oncology or other institutional practice pathways in decisions related to treatment of patients and utilization of medicines. To the extent that our current or any future approved products are not included or positioned favorably in such treatment guidelines and pathways, the full utilization potential of our products may not be reached, which may harm our ability to successfully commercialize our current or any future approved products.

Any failures or setbacks in our ADC development program or our other platform technologies could negatively affect our business and financial position.

ADCETRIS, PADCEV, TIVDAK and our ladiratuzumab vedotin and disitamab vedotin product candidates are all based on antibody-drug conjugate, or ADC, technology, which utilizes proprietary stable linkers and potent cell-killing synthetic agents. Our ADC technology is also the basis of our license agreements with AbbVie Biotechnology Ltd., Astellas, Genentech, Inc., a member of the Roche Group, or Genentech, and GlaxoSmithKline LLC and our collaboration agreements with Takeda, Astellas, Genmab, Merck and Zai Lab. Any failures or setbacks in our ADC development program or with respect to our additional proprietary technologies, including adverse effects resulting from the use of this technology in human clinical trials and/or the imposition of clinical holds on our trials of our product candidates, could have a detrimental impact on the continued commercialization of our products in their current or any potential future approved indications and on our product candidate pipeline, as well as our ability to maintain and/or enter into new corporate collaborations regarding our ADC technology, which would negatively affect our business and financial position.

We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies and intense competition. Many third parties compete with us in developing various approaches to treating cancer. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

With respect to ADCETRIS, there are several other FDA approved drugs for its approved indications. Bristol-Myers Squibb's, or BMS's, nivolumab and Merck's pembrolizumab are approved for the treatment of certain patients with relapsed or refractory classical Hodgkin lymphoma, and Acrotech Biopharma's pralatrexate and belinostat are approved for relapsed or refractory systemic anaplastic large cell lymphoma, or sALCL, among other T-cell lymphomas. BMS's romidepsin is approved for cutaneous T-cell lymphoma. Kyowa Kirin's mogamulizumab is approved for adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome. The competition ADCETRIS faces from these and other therapies is intensifying. Additionally, Merck conducted a phase 3 clinical trial in relapsed or refractory classical Hodgkin lymphoma comparing pembrolizumab to ADCETRIS. An interim analysis of this clinical trial demonstrated a statistically significant improvement in progression-free survival for pembrolizumab compared with ADCETRIS, resulting in a label expansion to an earlier line of therapy, and pembrolizumab is now competing with ADCETRIS in this indication. We are also aware of multiple investigational agents currently being studied that, if successful, may compete with ADCETRIS in the future, such as camidanlumab tesirine, which is in a phase 2 study in relapsed/refractory classical Hodgkin lymphoma. Nivolumab, with or without chemotherapy, in a phase 2 investigator initiated trial, has demonstrated significant objective response rate in the salvage setting. In the frontline classical Hodgkin lymphoma setting, nivolumab in combination with chemotherapy and pembrolizumab in combination with chemotherapy are each being studied and if proven beneficial, could compete with ADCETRIS in that setting. Data have also been presented on several developing technologies, including bispecific antibodies and CAR modified T-cell therapies that may compete with ADCETRIS in the future. Further, there are many competing approaches used in the treatment of patients in ADCETRIS' approved indications, including autologous hematopoietic stem cell transplant, allogeneic hematopoietic stem cell transplant and chemotherapy, in addition to clinical trials with experimental agents.

With respect to PADCEV, other treatments in pretreated metastatic urothelial cancer include sacituzumab govitecan (a Trop-2-directed antibody and topoisomerase inhibitor conjugate), checkpoint inhibitor monotherapy, generic chemotherapy and, for patients with select FGFR genetic alterations, Janssen's erdafitinib. Front line metastatic urothelial cancer was traditionally treated with chemotherapy alone but is evolving to include checkpoint inhibitors for cisplatin-ineligible patients with high PD-L1 expression in addition to patients who are ineligible for platinum therapy. Avelumab is used for frontline maintenance therapy, and several trials of investigational agents in combination with chemotherapy or other novel agents are ongoing. Continued development of PD-(L)1 targeted therapies across early-stage bladder cancer and in metastatic bladder cancer in frontline combinations with chemotherapy, in frontline maintenance, and in pretreated disease, could potentially impact PADCEV usage and enrollment in PADCEV clinical trials.

With respect to TUKYSA, there are multiple marketed products which target HER2, including the antibodies trastuzumab and pertuzumab and the antibody drug conjugate T-DM1. In addition, lapatinib is an EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer, and neratinib is an irreversible pan-HER kinase inhibitor indicated for extended adjuvant treatment and treatment of metastatic breast cancer in patients who received two or more prior anti-HER2-based regimens. Daiichi Sankyo and AstraZeneca have fam-trastuzumab deruxtecan-nxki, which was approved by the FDA for patients who have received one or more prior anti-HER2-based regimens in the metastatic breast cancer setting and in the HER2-positive gastric cancer setting post-trastuzumab-based therapy. The agent was also granted conditional marketing authorization by the EMA for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens. We believe that the sequence of therapies patients receive for HER2-positive breast cancer is likely to continue to change in both the U.S. and EU, with greater fam-trastuzumab deruxtecan-nxki use in second line. This has resulted and is expected to continue to result in increased competition for TUKYSA, which is approved by the FDA for patients who have received one or more prior anti-HER2-based regimens in the metastatic breast cancer setting, including in patients with brain metastases. MacroGenics has a HER2 targeted, Fc-optimized antibody, margetuximab, which is approved by the FDA for patients who have received at least two previous anti-HER2 regimens. Additionally, Byondis released results from a pivotal trial of its antibody drug conjugate, SYD985, in metastatic breast cancer patients treated with multiple anti-HER2-based regimens and the FDA accepted a regulatory submission based on these results with a target action date in May 2023. Fam-trastuzumab deruxtecan-nxki is also recommended by NCCN for use as part of a combination therapy in HER2-positive metastatic colorectal cancer.

With respect to TIVDAK, Merck's pembrolizumab is approved by the FDA and EC in first line in combination with chemotherapy, with or without bevacizumab, for the treatment of recurrent or metastatic cervical cancer whose tumors express PD-L1 and is approved by the FDA in second line as a monotherapy for recurrent or metastatic cervical cancer patients with disease progression on or after chemotherapy in patients whose tumors express PD-L1. In September 2022, pembrolizumab was approved in Japan as first-line therapy in combination with chemotherapy, with or without bevacizumab, for patients with recurrent or metastatic cervical cancer who are not amenable to curative treatment. We are also aware of other companies that currently have products in development for the treatment of late-stage cervical cancer which could be competitive with TIVDAK, including Agenus, BMS, Iovance Biotherapeutics, Merck, Regeneron Pharmaceuticals, Sanofi and Roche. Cemiplimab is being reviewed in several countries outside the U.S. for the treatment of patients with recurrent or metastatic cervical cancer following progression on platinum-based chemotherapy. A supplemental Biologics License Application for cemiplimab was withdrawn in the U.S. in January 2022. Cemiplimab received Canadian approval in March 2022, EC approval in November 2022 and Japanese approval in December 2022, which will likely impact the potential future opportunity for TIVDAK in that geography.

Many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer that our product candidates are designed and being developed to treat. In addition, we are aware of a number of other companies that have ADC and other technologies that may be competitive with ours. We are also aware of a number of companies developing monoclonal antibodies directed at the same antigen targets or for the treatment of the same diseases as our product candidates. In addition, our ADC collaborators may develop compounds utilizing our technology that may compete with product candidates that we are developing.

The risk of biosimilar or generic challenges has also been increasing in our industry. In the U.S. and the EU, after a period of exclusivity for an innovator's approved biological product or branded drug has passed, there are abbreviated pathways for approval of biosimilar products or generic drugs. In addition, it is not possible to predict changes in law that might reduce regulatory exclusivity. As a result, and due to uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that biosimilar, interchangeable or generic versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

It is also possible that our competitors will succeed in developing technologies that are more effective than our products and product candidates or that would render our technology obsolete or noncompetitive, or will succeed in developing biosimilar, interchangeable or generic products for our products and product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of our products and product candidates.

Risks Related to Regulatory Oversight, and Other Legal Compliance Matters

Our products and any future approved products remain subject to extensive ongoing regulatory obligations and oversight, including post-approval requirements, that could result in penalties and significant additional expense and could negatively impact our and our collaborators' ability to commercialize our current and any future approved products.

Any product that has received regulatory approval remains subject to extensive ongoing obligations and continued review from applicable regulatory agencies. These obligations include, among other things, drug safety reporting and surveillance, submission of other post-marketing information and reports, pre-clearance of certain promotional materials, manufacturing processes and practices, product labeling, confirmatory or post-approval clinical research, import and export requirements and record keeping. These obligations may result in significant expense and limit our and our collaborators' ability to commercialize our current and any future approved products. Any violation of ongoing regulatory obligations could result in restrictions on the applicable product, including the withdrawal of the applicable product from the market.

If FDA approval is granted via the accelerated approval pathway or a product receives conditional marketing authorization from another comparable regulatory agency, we and our collaborators may be required to conduct a post-marketing confirmatory trial in support of full approval and to comply with other additional requirements. For example, in connection with ADCETRIS's conditional marketing authorization in relapsed Hodgkin lymphoma, relapsed cutaneous T-cell lymphoma, and both relapsed and frontline sALCL in the EU, Takeda is subject to certain post-approval requirements, including the requirement to conduct clinical trials to confirm clinical benefit. The FDA's accelerated approval of TIVDAK and of TUKYSA in its colorectal cancer indication also included requirements for confirmatory trials. An unsuccessful post-marketing study or failure to complete such a study with due diligence could result in the withdrawal of marketing approval. Post-marketing studies may also suggest unfavorable safety information that could require us to update the product's prescribing information or limit or prevent the product's widespread use. In addition, the labeling, advertising and promotion of products that have received accelerated approval from the FDA, including TUKYSA and TIVDAK, are subject to additional regulatory requirements, which entail significant expense and could negatively impact the product's commercialization. Recent legislation has given the FDA additional authority to require accountability and enforce the post-marketing requirements and commitments associated with accelerated approval.

Regulatory authorities may also impose additional post-marketing commitments, including requirements for companion diagnostics. For example, the FDA's approval of ADCETRIS in the frontline peripheral T-cell lymphoma indication included a post-marketing commitment to develop an in-vitro diagnostic device for the selection of patients with CD30-expressing PTCL, not including SALCL, for treatment with ADCETRIS in this indication. We and Takeda have a collaboration with Ventana Medical Systems, Inc., or Ventana, under which Ventana is working to develop such a diagnostic device.

We and the manufacturers of our current and any future approved products are also required, or will be required, to comply with current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products and product candidates, and these facilities are subject to ongoing regulatory inspections. In addition, any approved product, its manufacturer and the manufacturer's facilities are subject to continual regulatory review and inspections, including periodic unannounced inspections. Failure to comply with applicable FDA and other regulatory requirements may subject us to administrative or judicially imposed sanctions and other consequences, including:

- issuance of Form FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in regulatory approvals and commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us;
- refusals to permit drugs to be imported into or exported from the U.S.;
- restrictions on operations, including costly new manufacturing requirements;
- product recalls or seizures or withdrawal of the affected product from the market; and
- reputational harm.

The policies of the FDA and other regulatory agencies may change and additional laws and regulations may be enacted that could prevent or delay regulatory approval of our product candidates or of our products in any additional indications or territories, or further restrict or regulate post-approval activities. Any problems with a product or any violation of ongoing regulatory obligations could result in restrictions on the applicable product, including the withdrawal of the applicable product from the market. If we are not able to maintain regulatory compliance, we or our collaborators might not be permitted to commercialize our current or any future approved products and our business would suffer.

Healthcare law and policy changes may negatively impact our business, including by decreasing the prices that we and our collaborators receive for our products.

In recent years, there have been a number of legislative and regulatory actions and executive orders that have made reforms to the U.S. healthcare system. The implementation of certain of these policy changes has decreased our revenues and increased our costs, and federal and state legislatures, governments in countries outside the U.S., health agencies and third-party payors continue to focus on containing the cost of healthcare. Further legislative and regulatory changes, and increasing pressure from social sources, are likely to further influence the manner in which our products are priced, reimbursed, prescribed and purchased. Such additional reforms could result in further reductions in coverage and levels of reimbursement for our products, expansion of U.S. government rebate and discount programs, increases in the rebates and discounts payable under these programs, requests for additional or supplemental rebates, and additional downward pressure on the prices that we and our collaborators receive for our products.

The federal government has implemented reforms to government healthcare programs in the U.S., including changes to the methods for, and amounts of, Medicare reimbursement and changes to the Medicaid Drug Rebate Program. For example, in March 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In November 2021, President Biden signed the Infrastructure Investment and Jobs Act, which included changes to the Medicare Part B program requiring rebates for some discarded drug products that are expected to increase future rebates for ADCETRIS, TIVDAK and possibly PADCEV with an implementation date in the first quarter of 2023. The Biden administration also announced an Executive Order that includes initiatives to support the implementation of Canadian drug importation and reduce drug prices. In response to President Biden's Executive Order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law; (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize drug price increases that outpace inflation; and (iii) redesigns the Medicare Part D program, increasing manufacturer rebates within the catastrophic coverage phase. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively beginning in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future.

Some states are also considering legislation, or have passed laws, that would control the prices and coverage and reimbursement levels of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the U.S. and laws intended to impose price controls on state drug purchases.

In addition, governments in countries outside the U.S. control the costs of pharmaceuticals. Many European countries and Canada have established pricing and reimbursement policies that contain costs by referencing the price of the same or similar products in other countries. In these instances, if coverage or the level of reimbursement is reduced, limited or eliminated in one or more countries, we may be unable to obtain or maintain anticipated pricing or reimbursement in other countries or in new markets. This may create the opportunity for third-party cross-border trade or may influence our decision whether to sell a product in one or more countries, thus adversely affecting our geographic expansion plans.

It is also possible that governments may take additional action to reform the healthcare system in response to the evolving effects of the COVID-19 pandemic.

We cannot assure you as to the ultimate content, timing, or effect of future healthcare law and policy changes, nor is it possible at this time to estimate the impact of any such potential changes; however, such changes or the ultimate impact of changes could materially and adversely affect our revenue or sales of our current and or potential future products, as well as those of our collaborators.

We are subject to various state, federal and international laws and regulations, including healthcare laws and regulations, that may impact our business and could subject us to significant fines and penalties or other negative consequences.

Our operations may be directly or indirectly subject to various healthcare laws, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws, regulations prohibiting off-label promotions and federal transparency requirements. These laws may impact, among other things, the sales, marketing and education programs for our products and any future approved products. In addition, the number and complexity of healthcare laws and regulations applicable to our business continue to increase.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration not intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a criminal conviction for violation of the federal Anti-Kickback Statute requires mandatory exclusion from participation in federal healthcare programs.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false claim to, or the knowing use of false statements to obtain payment from or approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease, or conceal an obligation to pay money to the federal government. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing, promotion or other activities.

The FDA and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. In recent years, private whistleblowers have also pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of off-label promotion. If we are found to have promoted an approved product for off-label uses, we may be subject to significant liability, including significant civil and administrative financial penalties and other remedies as well as criminal penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company's sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements, deferred prosecution agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

The federal transparency requirements under the Physician Payments Sunshine Act require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to annually report information related to certain payments or other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year plus up to an aggregate of $1 million per year for "knowing failures," as adjusted for inflation.

In addition, there has been increased scrutiny of company-sponsored patient assistance programs, including co-pay assistance programs, and donations to third-party charities that provide such assistance. There has also been enhanced scrutiny by governments of reimbursement support offerings, clinical education programs and promotional speaker programs. If we or our vendors are deemed to fail to comply with laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, in connection with civil settlements related to these laws and regulations, the U.S. government has and may in the future require companies to enter into complex corporate integrity agreements that impost significant reporting and other requirements.

Other healthcare laws and regulations that may affect our ability to operate include, among others, the federal civil monetary penalties statute and the healthcare fraud provisions of the federal Health Insurance Portability and Accountability Act, or HIPAA. In addition, many states and jurisdictions outside the U.S. have similar laws and regulations, such as anti-kickback, anti-bribery and corruption, false claims and transparency, to which we are currently and/or may in the future, be subject. Additional information about these requirements is provided under "Business—Government Regulation—Healthcare Regulation" in Part I Item 1 of this Annual Report on Form 10-K.

We are also subject to numerous other laws and regulations that while not specific to the healthcare industry, do apply to the healthcare industry in important ways. For example, we are subject to antitrust regulations with respect to interactions with other participants in the markets we currently serve or may serve in the future. These antitrust laws are vigorously enforced in the U.S. and in other jurisdictions in which we operate.

In an effort to comply with applicable laws and regulations, we have implemented a compliance program designed to actively identify, prevent and mitigate risk by implementing policies and systems and promoting a culture of compliance. We also actively work to revise and evolve our compliance program in an effort to keep pace with evolving compliance risks and the growing scale of our business. However, we cannot guarantee that our compliance program will be sufficient or effective, that we will be able to integrate the operations of newly formed affiliates or acquired businesses into our compliance program effectively or on a timely basis, that our employees will comply with our policies, that our employees will notify us of any violation of our policies, that we will have the ability to take appropriate and timely corrective action in response to any such violation, or that we will make decisions and take actions that will limit or avoid liability for whistleblower claims or actions by governmental authorities. If we are found to be in violation of any of the laws and regulations described above or other applicable laws, we may be subject to penalties, including significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, administrative burdens, imprisonment, diminished profits and future earnings, exclusion from government healthcare reimbursement programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and/or the curtailment or restructuring of our operations. Any of these outcomes could have a material adverse effect on our business, results of operations, financial condition and growth prospects. Regardless of whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses. Moreover, achieving and sustaining compliance with applicable federal, state and healthcare laws outside the U.S. is costly and time-consuming for our management.

We are subject to stringent and changing obligations related to data privacy and information security. Our actual or perceived failure to comply with such obligations could lead to governmental investigations or actions, litigation, fines and penalties, a disruption of our business operations, reputational harm and other adverse business impacts.

We are subject to numerous privacy and data protection laws and regulations governing personal information, including healthcare information. In addition, the legislative and regulatory landscape for privacy and data protection continues to evolve.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data security and breach notification laws, personal data privacy laws, and consumer protection laws. The laws are not consistent, and states frequently amend existing laws, requiring attention to constantly changing regulatory requirements. For example, the California Consumer Privacy Act, or CCPA, became effective on January 1, 2020, and the California Privacy Rights Act, or CPRA, took effect January 1, 2023. The CPRA significantly modifies the CCPA, including by expanding individual rights, especially with respect to certain sensitive personal information. We may also be subject to additional U.S. state privacy regulations in the future. In addition, at the federal level, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations impose additional obligations on certain types of individuals and entities with respect to the security, privacy and transmission of individually identifiable health information.

EU member countries and other jurisdictions, including Switzerland, the United Kingdom, or the U.K., and Canada, have also adopted data protection laws and regulations which impose significant compliance obligations. For example, the EU's General Data Protection Regulation, or GDPR, imposes a range of requirements relating to the collection, use, handling and protection of personal data. Violations of the GDPR can result in significant penalties, including potential fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The GDPR has increased our responsibility and potential liability in relation to all types of personal data that we process or that is processed on our behalf, including data from clinical trials, employees, collaborators and vendors. In addition, local data protection authorities can have different interpretations of the GDPR, leading to compliance challenges as a result of potential inconsistencies amongst various EU member states.

Among other requirements, the GDPR regulates transfers of personal data to countries that have not been found to provide adequate protection to such personal data, including the U.S. This includes transfers between us and our subsidiaries. In July 2020, the Court of Justice of the EU, or the CJEU, invalidated one of the primary safeguards enabling U.S. companies to import personal information from Europe, the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the EC's Standard Contractual Clauses, or SCCs, provide sufficient protection for personal data transfers without analyzing each transfer and implementing supplementary measures to protect the data. As a result of the CJEU's decision, the EC issued new SCCs in June 2021 that repeal and replace the previous clauses. Following recommendations from the European Data Protection Board, we review personal data transfers from the EU and add the new SCCs and supplementary measures, when required. Since local data protection authorities can interpret GDPR and the CJEU's decision differently, there is no definitive set of controls that can ensure GDPR compliance across our business operations. In addition, authorities in Switzerland and the U.K., whose data protection laws are similar to those of the EU, have followed the EU's approach and CJEU decision. Additional compliance efforts may be needed to respond to evolving regulatory guidance. If our compliance solutions are found to be insufficient, we could face substantial fines under European data protection laws as well as injunctions against processing and/or transferring personal information from Europe. The inability to import personal information from Europe could restrict our clinical trial activities in Europe, limit our ability to collaborate with contract research organizations, service providers, contractors and other companies subject to European data protection laws, interfere with our ability to hire employees in Europe and require us to increase our data processing capabilities in Europe at significant expense.

In addition, we may be subject to other foreign data privacy and security laws. For example, China's Personal Information Protection Law, or PIPL, which took effect in November 2021, imposes various requirements related to personal information processing, similar to the GDPR and CCPA. In particular, the PIPL sets out personal information localization requirements, along with rules regarding the transfer of personal information outside of China. Such transfers may require assessment and/or approval by China's Cyberspace Administration, certification by professional institutions or entering into contracts with and supervising overseas recipients. Violations of the PIPL may lead to an administrative fine of up to RMB 50 million or 5% of turnover in the last year.

Any failure or alleged failure to comply with legal or contractual obligations, policies and industry standards relating to personal information, and any incident resulting in the unauthorized access to, or acquisition, release or transfer of, personal information, may result in governmental investigations or enforcement actions, litigation, fines, penalties, damage to our reputation and other adverse consequences. In addition, we expect that laws, regulations, policies and industry standards relating to privacy and data protection will continue to evolve. These changes may require us to modify our practices and may increase our costs of doing business. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these standards, even if no personal information is compromised, we may incur significant fines or experience a significant increase in costs.

Product liability and product recalls could harm our business, and we may not be able to obtain adequate insurance to protect us against product liability losses.

The testing, manufacturing, marketing, and sale of products and product candidates expose us to product liability claims. As a result, it is possible that we may be named as a defendant in product liability suits that may allege that drug products we manufactured resulted in injury to patients. While we have obtained product liability insurance, it may not provide adequate coverage against all potential liabilities. In addition, we may not be able to maintain insurance coverage on acceptable terms or at all. If a product liability claim or series of claims is brought against us, we may experience substantial financial losses, including uninsured liabilities or liabilities in excess of insured amounts, and may be required to limit further development and commercialization of our products, either of which could have a material adverse effect on our business, results of operations, financial condition and growth prospects. Additionally, product liability claims, regardless of their merits, could be costly, could divert management's attention and could adversely affect our reputation and the demand for our products.

Product recalls may be issued at our discretion, or at the discretion of government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell our products for some time and by adversely affecting our reputation.

Our operations involve hazardous materials and are subject to environmental, health and safety laws and regulations.

We are subject to environmental, health and safety laws and regulations, including those governing the use and disposal of hazardous materials, and we spend considerable time complying with such laws and regulations. Our business activities involve the controlled use of hazardous materials, and although we take precautions to prevent accidental contamination or injury from these materials, we cannot completely eliminate the risk of using these materials. In this regard, with respect to our manufacturing facility, we may incur substantial costs to comply with environmental laws and regulations and may become subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process. It is also possible that our manufacturing facility may expose us to environmental liabilities associated with historical site conditions that we are not currently aware of and did not cause. Some environmental laws impose liability for contamination on current owners or operators of affected sites, regardless of fault. In the event of an accident or environmental discharge, or new or previously unknown contamination is discovered or new cleanup obligations are otherwise imposed in connection with any of our currently or previously owned or operated facilities, we may be held liable for remediation obligations, damages or fines, which may exceed our insurance coverage and materially harm our business, financial condition and results of operations. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Related to Our Reliance on Third Parties

Our collaborators and licensees may not perform as expected, which may negatively affect our ability to develop and commercialize our products and product candidates and/or generate revenues through technology licensing, and may otherwise negatively affect our business.

We have established collaborations with third parties to develop and market each of our products and some of our current and potential future product candidates. These include our collaborations with Takeda for ADCETRIS, with Astellas for PADCEV, with Merck for TUKYSA, and with Genmab and Zai Lab for TIVDAK. We also have established clinical trial collaborations to develop certain of our products or product candidates in combination with the products or product candidates of third parties. Our dependence on these collaboration and licensing arrangements subjects us to a number of risks, including:

- we are not able to control the amount or timing of resources our collaborators and licensees devote to the development or commercialization of our programs, products or product candidates;
- the interests of our collaborators may not always be aligned with our interests, and such parties may not pursue regulatory approvals or market a product in the same manner or to the same extent that we would, which could adversely affect our revenue, or may adopt tax strategies that could have an adverse effect on our business, results of operations or financial condition;
- with respect to products or product candidates under joint control, we may encounter challenges in joint decision making and joint execution, including with respect to any joint development or commercialization plans or co-promotion activities, which may delay or otherwise harm the research, development, launch or commercialization of the applicable products and product candidates;
- disputes may arise between us and our collaborators or licensees, including with respect to the achievement and payment of milestones or ownership of rights to technology developed, that could result in litigation or arbitration;
- any failure on the part of our collaborators to comply with applicable laws, including tax laws, regulatory requirements and/or applicable contractual obligations or to fulfill any responsibilities they may have to protect and enforce any intellectual property rights underlying our products could have an adverse effect on our revenue as well as involve us in possible legal proceedings;
- any improper conduct or actions on the part of our collaborators, licensees or other third parties could subject us to civil or criminal investigations and monetary penalties and injunctions, impact the accuracy and timing of our financial reporting and/or adversely impact our ability to conduct business, our operating results and our reputation;

- business combinations or significant changes in a collaborator's business strategy may adversely affect such party's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with competing products, therapeutic approaches or technologies, either independently or in collaboration with others, including with our competitors; and
- our collaboration agreements may be terminated, breached or allowed to expire, or our collaborators may reduce the scope of our agreements with them.

If our collaborative and license arrangements are not successful, then our ability to advance the development and commercialization of the applicable products and product candidates, or to otherwise generate revenue from these arrangements, will be adversely affected, and our business and business prospects may be materially harmed. If any of our collaborators terminates our collaboration or opts out of their obligations, we may have to engage another collaborator, or we may have to complete the development process and undertake commercializing the applicable product or product candidate in our collaborator's current territories ourselves. This could significantly disrupt or delay the development and commercialization of the applicable product or product candidate and substantially increase our costs. Any of these events could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

A substantial portion of our revenue results from payments made under agreements with our collaborators. The loss of any of our collaborators, changes in product development or business strategies of our collaborators, or the failure of our collaborators to perform their obligations under their agreements with us for any reason, including paying license or technology fees, milestone payments, royalties or reimbursements, could have a material adverse effect on our business, results of operations, financial condition and growth prospects. Payments under our existing and potential future collaboration agreements are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

In addition to collaboration agreements, we also have ADC license agreements that allow our licensees to use our proprietary ADC technology. Our ADC licensees conduct all research, product development, manufacturing and commercialization of any product candidates under these agreements. Any delay or termination of the development and commercialization of a licensed product or product candidate by the licensee could adversely affect our business, results of operations, financial condition and growth prospects by reducing or eliminating the potential for us to receive applicable milestones and royalties.

We currently rely on third-party manufacturers and other third parties for production of our drug products, and our dependence on these third parties may impair the continued development and commercialization of our products and product candidates.

We own a biologics manufacturing facility located in Bothell, Washington, which we use to support our clinical supply needs, as well as for commercial production of PADCEV antibody, for which the facility was recently approved by the FDA. We have also signed a lease for a site in Everett, Washington, where we are constructing a new manufacturing facility that we intend to use for future biologics manufacturing. We have made and plan to continue to make investments in these facilities with no assurance that these investments will be recouped. We may experience cost overruns, delays or other difficulties in construction, obtaining regulatory approvals and permits or in otherwise bringing the Everett facility online. In addition, we rely and expect to continue to rely on collaborators, contract manufacturers and other third parties to produce and store sufficient quantities of drug product for both our clinical and commercial programs. In some cases, we rely on contract manufacturers and other third parties that are single-source suppliers to complete steps in the manufacturing process. If any of the parties in our supply chain cease or interrupt production or otherwise fail to deliver materials, products or services on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacements or to develop our own manufacturing capabilities, we may bear costly losses or be required to delay or suspend clinical trials or otherwise delay or discontinue development, production and sale of our products. As a result, our business, results of operations, financial condition and growth prospects could be materially and adversely affected.

There are a limited number of facilities in which each of our products and product candidates can be produced. Any interruption of the operation of those facilities, due to equipment malfunction or failure, damage to the facility, natural disasters, regulatory actions, contractual disputes or other events, could result in delays, cancellation of shipments, loss of product in the manufacturing process, or a shortfall in supply. Further, we and our collaborators depend on outside vendors for the supply of raw materials used to produce our products and product candidates. If these suppliers were to cease production or otherwise fail to supply quality raw materials and we or our collaborators were unable to contract with alternative suppliers for these raw materials on acceptable terms, our ability to have our products manufactured to meet clinical and commercial requirements would be adversely affected. In addition, if any of the parties in our supply chain are adversely impacted by the evolving effects of the COVID-19 pandemic, such as staffing shortages, productions slowdowns and/or disruptions in delivery systems, there could be disruptions and delays in the manufacturing and supply of our products and product candidates.

While we believe that the existing supplies of our products and our and our collaborators' contract manufacturing relationships will be sufficient to accommodate current clinical and commercial needs, we or our collaborators may need to obtain additional manufacturing arrangements or increase manufacturing capability to meet potential future commercial needs, which could require additional capital investment or cause delays. We cannot assure you that we can enter into additional manufacturing arrangements on commercially reasonable terms or at all. Forecasting demand for a new product or for a newly-approved territory or indication for an existing product can be challenging. If demand for a product exceeds our estimates or if our commercial manufacturers are unable or unwilling to increase production capacity commensurate with demand, our commercialization of the affected product could be negatively impacted by short-term product supply challenges. Supply challenges would adversely impact our revenues and could negatively affect our relationships with patients and healthcare professionals. In addition, any failures or delays in manufacturing adequate product supplies and in putting in place or expanding our manufacturing and supply infrastructure could delay or impede our and collaborators' ability to launch and commercialize our products, including PADCEV and TUKYSA, in additional markets where they have obtained regulatory approval.

In order to obtain regulatory approval of any product candidate or regulatory approval of any product in a new jurisdiction, the suppliers for that product or product candidate must obtain approval to manufacture and supply product. In addition, the facilities utilized to manufacture the product or product candidate will be subject to pre-approval regulatory inspections. Any delay or failure in generating the chemistry, manufacturing and control data required in connection with any application for regulatory approval, or challenges in the regulatory inspection process, could negatively impact our ability to meet our anticipated regulatory submission dates, delay any approval decisions and/or negatively affect our ability to obtain regulatory approval at all. Any failure of us, our collaborators or a manufacturer to obtain approval to manufacture and supply product in a jurisdiction, or to obtain and distribute adequate supplies of the product, on a timely basis or in accordance with applicable specifications and local requirements could negatively impact our ability to successfully launch and commercialize the applicable product in that jurisdiction and to generate sales of that product at the levels we expect. We or our collaborators may also encounter difficulties in meeting the regulatory requirements applicable to the manufacturing process for these agents, in managing the additional complexity of manufacturing for a number of markets outside the U.S. or in responding to changes in the amount or timing of supply needs. Any failures or delays in meeting these requirements could substantially delay or impede our ability to obtain regulatory approvals for and to market these agents, which could negatively impact our operating results and adversely affect our business.

We are dependent upon a small number of distributors for a significant portion of our net sales, and the loss of, or significant reduction or cancellation in sales to, any one of these distributors could adversely affect our revenues and increase our costs.

We sell ADCETRIS, PADCEV and TIVDAK through a limited number of specialty distributors. Healthcare providers order ADCETRIS, PADCEV and TIVDAK through these distributors. We receive orders from distributors and generally ship product directly to the healthcare provider. We sell TUKYSA through a distribution network of specialty pharmacies, integrated delivery network hospitals and practices that dispense in the office. These distributors and distribution network partners do not set or determine demand for our products; however, our ability to effectively commercialize our products will depend, in part, on their performance. If we lost a major distributor or partner, revenue during any period of disruption could suffer and we might incur additional costs. In addition, business disruptions arising from the COVID-19 pandemic could negatively affect the ability of some of our distributors or distribution network partners to pay amounts owed to us in a timely manner or at all.

We are dependent on third parties such as contract research organizations, medical institutions and clinical investigators to assist with the design, review, management and conduct of our clinical trials and other activities.

We depend on third parties such as contract research organizations, medical institutions and clinical investigators to assist with the design, review, management and conduct of our clinical trials and other activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with regulatory requirements, GCP and study protocols. To the extent these third parties fail to successfully carry out their contractual duties or meet expected deadlines, our clinical trials and regulatory filings may be negatively impacted including possible impacts to data, results, or conclusions, increased costs, and delays to regulatory timelines, which may harm our reputation and business.

Risks Related to Intellectual Property and Litigation

If we are unable to enforce our intellectual property rights or if we fail to sustain and further procure additional intellectual property rights, we may not be able to successfully commercialize our products or any future products and competitors may be able to develop competing therapies.

Our success depends, in part, on obtaining and maintaining patent protection and successfully enforcing these patents and defending them against third-party challenges in the U.S. and other countries. We own multiple U.S. and foreign patents and pending patent applications for our technologies. We also have rights to issued U.S. patents, patent applications, and their foreign counterparts, relating to our monoclonal antibody, linker and drug-based technologies. Our rights to these patents and patent applications are derived in part from worldwide licenses from third parties.

The standards that the U.S. Patent and Trademark Office, or USPTO, and patent offices in other countries use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, patents may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our products. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. For example, the U.S. Federal Circuit Court of Appeals and the U.S. Supreme Court have modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. These changes and any future changes to the patent system in the U.S. or in other countries could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operations, financial condition and growth prospects. In addition, changes to patent laws may be applied retroactively to affect the validity, enforceability, or term of our patents. Patent protection outside the U.S. is particularly uncertain and costly. The laws of some countries may not protect our intellectual property rights to the same extent as U.S. laws, and many companies in our industry have encountered significant difficulties in protecting and defending such rights in these jurisdictions.

We rely on external agents to perform certain activities to maintain our patents. Although we carefully select and oversee these agents, the failure of an agent to properly perform these maintenance activities, whether through mistake or otherwise, could adversely affect our intellectual property rights. Additionally, if we do not control all of the intellectual property rights in-licensed to us with respect to a drug candidate and the entity that controls the intellectual property rights does not adequately protect those rights, our rights may be impaired, which may impact our ability to develop, market and commercialize the in-licensed drug candidate.

We rely on trade secrets and other proprietary information where we believe patent protection is not appropriate or obtainable. However, trade secrets and other proprietary information are difficult to protect. We have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach the agreements or that our competitors may independently develop or otherwise discover our trade secrets or other proprietary information. Our research collaborators may also publish confidential data or other restricted information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired. In addition, under proposed or adopted policies in the EU, information related to clinical trials and clinical trial data that historically were considered confidential are now increasingly subject to public disclosure. The move toward public disclosure of this information could adversely affect our business in many ways, such as by requiring the disclosure of confidential methodologies for product development, preventing us from obtaining intellectual property right protection for innovations, requiring significant resources to prevent others from violating our intellectual property rights, adding complexity to compliance with applicable data privacy regulations, and enabling competitors to use our data to gain approvals for their own products.

We may incur substantial costs and lose important rights or may not be able to continue to commercialize our products or to commercialize any of our product candidates that may be approved for commercial sale as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be required to obtain patent and other intellectual property rights from others.

We may face potential lawsuits by companies, academic institutions or others alleging infringement of their intellectual property. Due to the amount of intellectual property in our field, we cannot be certain that we do not infringe intellectual property rights of competitors or that we will not infringe intellectual property rights of competitors granted or created in the future. In addition, we are monitoring the progress of multiple pending patent applications of other organizations that, if granted, may require us to license or challenge their enforceability in order to continue commercializing our products or to commercialize our product candidates that may be approved for commercial sale. Our challenges to patents of other organizations may not be successful, which may affect our ability to commercialize our products or product candidates. If it is ultimately determined that our products infringe a third-party's intellectual property rights, we may be required to pay substantial damages, including lost profits, royalties, treble damages, attorneys' fees and costs. Even if infringement claims against us are without merit, the results may be unpredictable. In addition, defending lawsuits takes significant time, may be expensive and may divert management's attention from other business concerns. Further, we may be stopped from developing, manufacturing or selling our products unless and until we obtain a license from the owner of the relevant technology or other intellectual property rights, or we may be forced to undertake costly design-arounds, if feasible. If such a license is available at all, it may require us to pay substantial royalties or other fees.

We are or may be from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law, USPTO interference, inter partes review, or IPR, post-grant review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the U.S. and elsewhere. For example, see the risk factor below titled, "We have been and may in the future be subject to litigation, which could result in substantial expenses and damages and may divert management's time and attention from our business," for information on certain disputes with Daiichi Sanyko Co. Ltd, or Daiichi Sankyo. In addition, if we choose to go to court to stop a third party from infringing our patents, that third party has the right to ask the court to rule that these patents are invalid, not infringed and/or should not be enforced. Under the America Invents Act, a third party may also have the option to challenge the validity of certain patents at the Patent Trial and Appeal Board, or PTAB, of the USPTO whether they are accused of infringing our patents or not, and certain entities associated with hedge funds, pharmaceutical companies and other entities have challenged valuable pharmaceutical patents through the IPR process. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, there is a risk that a court will decide that these patents are not valid or not infringed or otherwise not enforceable, or that the PTAB will decide that certain patents are not valid, and that we do not have the right to stop a third party from using the patented subject matter. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators, which may also result in loss of future royalty payments. Furthermore, if such challenges to our rights are

not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing potential products, which could adversely affect our business, results of operations, financial condition and growth prospects. In addition, we may challenge the patent or other intellectual property rights of third parties and if we are unsuccessful in actions we bring against the rights of such parties, through litigation or otherwise, and it is determined that we infringe the intellectual property rights of such parties, we may be prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those rights or develop or obtain alternative technologies, any of which could harm our business.

We and our collaborators rely on license agreements for certain aspects of our products and product candidates and technologies such as our ADC technology. Failure to maintain these license agreements or to secure any required new licenses could prevent us from continuing to develop and commercialize our products and product candidates.

We have entered into agreements with third-party commercial and academic institutions to license technology for use in ADCETRIS, TUKYSA, our product candidates and technologies such as our ADC technology. These agreements include our license agreement with Array BioPharma, Inc., among others. In addition to royalty provisions and other payment obligations, some of these license agreements contain diligence and milestone-based termination provisions, in which case our failure to meet any agreed upon royalty or diligence requirements or milestones may allow the licensor to terminate the agreement. Many of our license agreements grant us exclusive licenses to the underlying technologies. In addition, Astellas has agreements to license technology for use in PADCEV. We rely on Astellas to maintain these license agreements. If Astellas fails to maintain these license agreements, if our licensors terminate our license agreements or if we or our collaborators are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our products or product candidates. Further, we have had in the past, and we or our collaborators may in the future have, disputes with our licensors, which may impact our ability to develop and commercialize our products or product candidates or require us to enter into additional licenses. An adverse result in potential future disputes with our or our collaborators' licensors may impact our ability to develop and commercialize our products and product candidates, or may require us to enter into additional licenses or to incur additional costs in litigation or settlement. In addition, continued development and commercialization of our products and product candidates will likely require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

We have been and may in the future be subject to litigation, which could result in substantial expenses and damages and may divert management's time and attention from our business.

We are engaged in multiple legal disputes with Daiichi Sankyo. We have been in a dispute with Daiichi Sankyo regarding the ownership of certain technology used by Daiichi Sankyo in its cancer drug Enhertu® (fam-trastuzumab deruxtecan-nxki) and certain product candidates. On August 12, 2022, the arbitrator in this dispute ruled in favor of Daiichi Sankyo, citing statute of limitations and disagreement with us on the interpretation of the contract. On September 14, 2022, Daiichi Sankyo submitted a petition for approximately $58 million for reimbursement of its legal fees and costs associated with the arbitration. We filed an opposition to Daiichi Sankyo's request on October 12, 2022. On November 10, 2022, we filed a motion to vacate the arbitration award in the U.S. District Court for the Western District of Washington. In addition, in October 2020, we filed a complaint in the U.S. District Court for the Eastern District of Texas to commence an action for infringement of our U.S. Patent No. 10,808,039, or the '039 Patent, by Daiichi Sankyo's importation into, offer for sale, sale, and use in the U.S. of Enhertu. Daiichi Sankyo (as well as Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP, or AstraZeneca) subsequently filed an action in the U.S. District Court for the District of Delaware seeking a declaratory judgment that Enhertu does not infringe the '039 Patent. The Delaware action has been stayed by court order. Daiichi Sankyo, Inc. and AstraZeneca also filed two petitions for post-grant review with the USPTO seeking to have claims of the '039 Patent cancelled as unpatentable. On June 24, 2021, the USPTO issued a decision denying both petitions for post-grant review. On April 7, 2022, the USPTO granted a request on rehearing and instituted two post-grant review proceedings, but on July 15, 2022, the USPTO issued a new decision denying post-grant review of the claims asserted in the patent infringement action. On February 7, 2023, in response to Daiichi Sankyo and AstraZeneca's second request for rehearing of the denial of the post-grant review to the USPTO and for Precedential Opinion Panel, or POP, review, the Precedential Opinion Panel issued an order denying the request for POP review but directing the USPTO panel evaluating the second rehearing request to make an explicit finding using its own discretion as to whether the post-grant review petition presents a "compelling" showing of invalidity as part of its ruling on the

pending second rehearing request. The panel was also directed to rule on the second rehearing request within two weeks from the POP order. On February 14, 2023, the panel decided to institute the post-grant review of the claims of the ‘039 Patent asserted in the patent infringement action. On April 8, 2022, a jury in the U.S. District Court for the Eastern District of Texas found that Daiichi Sankyo willfully infringed the asserted claims of the '039 Patent with its Enhertu product, and also found that the asserted claims were not invalid. The U.S. District Court for the Eastern District of Texas also denied Daiichi Sankyo's claim that the '039 Patent should be unenforceable under the equitable theory of prosecution laches, entered judgment in favor of us based on the jury's verdict that Daiichi Sankyo willfully infringed the '039 Patent consisting of pre-trial damages in the sum of $41.8 million, and awarded us pre- and post-trial interest and costs. We have requested a royalty in the range of 10-12% on Daiichi Sankyo's future sales of Enhertu in the United States through November 5, 2024, the current expiration date of the '039 Patent, as well as $12 million for reimbursement of our reasonable attorneys' fees. As a result of these disputes, we have incurred and will continue to incur litigation expenses. In addition, from time to time, we may become involved in other lawsuits, claims and proceedings relating to the conduct of our business, including those pertaining to the defense and enforcement of our patent or other intellectual property rights and our contractual rights.

These and other potential future litigations are subject to inherent uncertainties, and the actual costs to be incurred relating to litigations may be impacted by unknown factors. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the course of these and potential future litigations, we may be subject to additional claims and counterclaims that may result in liabilities or require us to take or refrain from certain actions, and we may not prevail. Monitoring, defending against and pursuing legal actions can be time-consuming for our management and detract from our ability to fully focus our internal resources on our business activities, which could result in delays of our clinical trials or our development and commercialization efforts. In addition, we may incur substantial legal fees and costs in connection with these and potential future litigations. Decisions adverse to our interests in these and potential future litigations could result in the payment of substantial damages, or possibly fines, or affect our intellectual property rights and could have a material adverse effect on our business, results of operations, financial condition and growth prospects. Successful challenges to our patent or other intellectual property rights could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

Risks Related to Our Operations, Managing Our Growth and Other Risks

The evolving effects of the COVID-19 pandemic and associated global economic instability could have further adverse effects on our business, including our commercialization efforts, supply chain, regulatory activities, clinical development activities and other business operations.

Our business is currently being adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic. Our ongoing increased reliance on personnel working from home may present operational and workplace culture challenges, negatively impact productivity or disrupt, delay or otherwise adversely impact our business. This could also increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. In addition, the evolving effects of the COVID-19 pandemic appear to have negatively affected our product sales in the past and could affect product sales in the future. In this regard, impacts associated with the COVID-19 pandemic appear to have led to a reduction in diagnosis rates for the ADCETRIS frontline indications earlier in the pandemic and, while we believe these diagnosis rates have returned to pre-pandemic levels, these impacts may have adversely affected diagnosis rates of other cancers, and may adversely affect rates of cancer diagnoses or patient access to healthcare settings in the future. As we resume more travel and in-person interactions after pauses earlier in the pandemic, we may subsequently decide or be forced to resume a more restrictive remote work model, whether as a result of further spikes or surges in COVID-19 infection or hospitalization rates, COVID-19 variants, government actions, restrictions at healthcare institutions, or otherwise. Future COVID-19 related restrictions could negatively impact research and development activities or sales and marketing efforts, or could present product distribution challenges.

Some of the sites participating in our clinical trials are affected by site closings, reduced capacity, staffing shortages or other effects of the COVID-19 pandemic. At some sites, we are experiencing impacts to our ability to monitor patients, activate sites, screen and enroll patients, complete site monitoring and manage samples. The extent of the impact on a particular clinical trial depends on the current stage of activities at a given site, for example study start up

versus post-enrollment, and the number of impacted sites participating in that trial. Impacts on diagnosis rates associated with the COVID-19 pandemic may also negatively impact enrollment. While we do not at this time anticipate the need to revise our publicly reported projected clinical milestone dates as a result of the effects of the COVID-19 pandemic, there may continue to be adverse impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability. Due to the suspension of data monitoring activities at sites that do not currently allow remote monitoring, as well as impacts on the ability to monitor patients, maintain patient treatment according to the trial protocols and manage samples, there is also the potential for negative impacts on data quality. While we are actively utilizing digital monitoring measures and other mitigations designed to prevent negative data quality impacts, if there were in fact a negative impact on data quality, we or our collaborators could be required to repeat, extend the duration of, or increase the size of clinical trials, which could significantly delay potential commercialization and require greater expenditures. We expect that similar factors will impact clinical studies operationalized by our collaborators.

The effects of the COVID-19 pandemic have increased market volatility and could result in a significant long-term disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, economic instability resulting from the effects of the COVID-19 pandemic could materially affect our business and the value of our common stock.

The extent to which the evolving effects of the COVID-19 pandemic (or any future pandemic) impact our business will depend on future developments that are highly uncertain, such as virus variants that may prove to be especially contagious or virulent, the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of vaccine programs and other actions taken to contain and treat the disease. Accordingly, we do not yet know the full extent of potential effects from the pandemic. However, these effects could materially and adversely affect our business, results of operations, financial condition and growth prospects. In addition, the evolving effects of the COVID-19 pandemic may also heighten many of the other risks described elsewhere in this "Risk Factors" section. It is also possible that future global pandemics could occur and materially and adversely affect our business, results of operations, financial condition and growth prospects.

If we are unable to manage our growth, our business, results of operations, financial condition and growth prospects may be adversely affected.

We have experienced and expect to continue to experience significant growth in the number of our employees and in the scope and complexity of our operations. This rapid growth and additional complexity places significant demands on our management and other personnel, our operational and financial resources and our third party suppliers. Our current and planned personnel, operational and financial systems, procedures, controls and suppliers may not be adequate to support our growth, and we may experience operating inefficiencies, delays, control deficiencies, compliance issues or other problems. In addition, we may not be able to achieve any necessary growth objectives in a timely or cost-effective manner, or at all, and may not realize a positive return on our investment. If we are unable to manage our growth effectively, our business, results of operations, financial condition and growth prospects may be adversely affected.

Risks associated with our expanding operations in countries outside the U.S. could materially adversely affect our business.

We have operations outside the U.S., and we plan to continue expanding our operations internationally. Consequently, we are, and will increasingly be, subject to risks and complexities related to operating internationally, including:

- the increased complexity and costs inherent in managing international operations, including in geographically disparate locations;
- diverse clinical, drug safety, drug quality, drug supply, healthcare compliance and other pharmaceutical regulatory regimes, and any future changes to such requirements, in the countries and regions where we are located or do business;
- multiple, differing and changing laws and regulations such as tax laws, privacy regulations, tariffs, trade restrictions, export and import restrictions, employment, immigration and labor laws, corporate laws, and other governmental approvals, permits and licenses;

- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- adverse tax consequences, including changes in applicable tax laws and regulations;
- political tensions, economic weakness, including inflation, or political or economic instability in particular economies and markets;
- currency fluctuations, which could result in increased operating expenses or reduced revenues;
- challenges inherent in efficiently managing employees in diverse geographies and different languages;
- challenges in adapting systems, policies, benefits and compliance programs for different countries;
- reliance on vendors who are located far from our headquarters and with whom we have not worked previously; and
- workforce uncertainty in countries where labor unrest is more common.

For example, the U.S. government and other nations have imposed sanctions, including significant restrictions on most companies' ability to do business in Russia, as a result of the ongoing military conflict between Russia and Ukraine. It is not possible to predict the broader or longer-term consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates, the price and availability of energy, and financial markets. Such geopolitical instability and uncertainty could have a negative impact on our ability to continue expanding our operations internationally and to otherwise generate revenues and develop our product candidates internationally. In addition, a significant escalation or expansion of economic disruption or the conflict's current scope could have a material adverse effect on our business, results of operations, financial condition and growth prospects. Recent strengthening of the U.S. dollar as compared to other currencies, including currencies in jurisdictions where we and our licensees sell products, has adversely affected royalty revenues and TUKYSA net product sales in Europe and could further adversely affect these sources of revenues.

Additionally, the U.S. Foreign Corrupt Practices Act, or FCPA, and the anti-bribery laws and regulations of other countries are extensive and far-reaching. We must ensure that accurate records and controls required by the FCPA are maintained with respect to the activities of our employees, distributors and service providers in all of the countries where we operate. In the course of conducting operations internationally, we interact with regulatory authorities, as well as with healthcare professionals who are often employed by governments and may be deemed to be foreign officials under the FCPA. Any interactions with any such third parties that are found to be in violation of relevant laws could result in substantial fines and penalties and could materially harm our business. Emerging-market countries may be especially vulnerable to periods of political, legal, and financial instability and may have a higher risk of corrupt business practices. As we expand our international operations, we continue to supplement and expand our global compliance program, controls, policies and procedures. However, there can be no assurance that such measures will work effectively at all times or protect us against liability. There is a risk that acts committed by our employees, agents, distributors, collaborators or third-party providers might violate the FCPA and other anti-corruption laws and that we might be held responsible. Furthermore, any finding of a violation under one country's laws may increase the likelihood that we will be prosecuted and be found to have violated another country's laws. Our failure, or the failure of others who we engage to act on our behalf, to comply with the laws and regulations of the countries in which we operate, or will operate in the future, could result in criminal and civil penalties, other remedial measures and reputational damage, all of which could materially harm our business, financial condition, results of operations, and prospects. As we continue to expand our footprint and activities internationally, our exposure to compliance risks under the FCPA and other similar laws will likewise increase.

As a business, we do not have significant experience conducting operations outside of the U.S. and Canada. We might not be successful in establishing and conducting commercial and other operations in these regions and may not realize a positive return on our investment. Our failure to successfully do so could have a material adverse effect on our business, results of operations, financial condition and growth prospects. These and other risks associated with expanding our international operations, as described elsewhere in these risk factors, could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

We have engaged in, and may in the future engage in, strategic transactions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, product candidates, technologies or businesses. We may spend significant amounts, issue dilutive securities and/or assume or incur significant debt obligations in connection with these transactions. In addition, these transactions, including our in-license of development and commercialization rights to disitamab vedotin and LAVA-1223, also known as SGN-EGFRd2, and any potential future acquisitions or licensing transactions entail numerous risks, including:

- risks associated with satisfying the closing conditions relating to such transactions and realizing their anticipated benefits;
- increased operating expenses and cash requirements;
- difficulty integrating acquired technologies, products, operations, compliance programs and personnel with our existing business;
- acquired or licensed products, product candidates or technologies, such as disitamab vedotin and SGN-EGFRd2, may not perform as expected and may not result in regulatory approvals;
- failure to successfully develop and commercialize acquired or licensed products, product candidates or technologies or to achieve other strategic objectives;
- the potential disruption of our historical core business;
- diversion of management's attention in connection with both negotiating the acquisition or license and integrating the business, technology or product;
- retention of key employees;
- uncertainties in our ability to maintain key business relationships of any acquired companies;
- difficulty implementing and maintaining effective internal control over financial reporting of businesses that we acquire;
- exposure to unanticipated liabilities of acquired companies or companies in which we invest;
- the potential need to write down assets or recognize impairment charges or significant amortization expenses; and
- potential costly and time-consuming litigation, including stockholder lawsuits.

As a result of these or other problems and risks, businesses, technologies or products we acquire or invest in or obtain licenses to may not produce the revenues, earnings, business synergies or other benefits that we anticipated, within the expected timeframe or at all. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We cannot assure you that any acquisitions or investments we have made or may make in the future will be completed or that, if completed, the acquired business, licenses, investments, products, or technologies will generate sufficient revenue to offset the costs or other negative effects on our business. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that we fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks, liabilities and uncertainties effectively, including in connection with our in-license of development and commercialization rights to disitamab vedotin and SGN-EGFRd2, could have a material adverse effect on our business, results of operations, financial condition and growth prospects. Moreover, we may not be able to identify, negotiate and close strategic acquisition or in-licensing opportunities in the future, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Other pharmaceutical companies, many of which may have substantially greater resources, compete with us for these opportunities. Failure to effectively advance our business strategy and manage our operations through acquisitions or in-licensing transactions could have a material adverse effect on our business, results of operations, financial condition, and growth prospects.

If we lose our key personnel or are unable to attract and retain additional qualified personnel, our future growth and ability to compete would suffer.

We are highly dependent on the efforts and abilities of the principal members of our senior management and other key personnel. For example, we have scientific personnel with significant and unique expertise in monoclonal antibodies, ADCs and related technologies, and our products and product candidates. The loss of the services of any one of the principal members of our managerial, scientific or other key staff may prevent us from achieving our business objectives. For example, in May 2022, Clay B. Siegall resigned as our President and Chief Executive Officer and as a member of our Board of Directors, and Roger Dansey, M.D., our Chief Medical Officer, was appointed as our Interim Chief Executive Officer. In November 2022, David R. Epstein was appointed as Chief Executive Officer and as a member of our Board of Directors, and Dr. Dansey was appointed President, Research and Development and Chief Medical Officer. Changes to company strategy, which can often times occur with the appointment of new executive leadership, can create uncertainty. Failure to ensure a smooth transition and successfully implement our strategy could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled biotechnology employees. In order to continue to commercialize our products, and advance the development and commercialization of our product candidates, we will be required to expand our workforce and management team, particularly in the areas of manufacturing, clinical trials, regulatory affairs, business development, sales and marketing, both in the U.S. and in Europe. We continue to face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, as well as academic and other research institutions, and with increasing reliance on remote work arrangements, the geographic market in which we compete for talent is expanding. Our ability to attract and retain talent in this competitive environment may be further complicated by evolving employment trends arising from the COVID-19 pandemic, including an increased preference for remote, alternative or flexible work arrangements. Our failure to effectively compete for and retain talent could negatively affect our ability to achieve our business objectives and have a material adverse effect on our business, results of operations, financial condition and growth prospects.

If our information technology systems or data are or were compromised, we could experience interruptions to our operations, legal claims, liability, harm to our reputation, a loss of sales and other adverse impacts.

We and our collaborators, suppliers and service providers rely on information technology systems to keep financial and other records, capture laboratory and clinical trial data, support internal and external communications and operate other critical functions. Despite our security measures, these systems are potentially vulnerable to malware, cyber-attacks, security breaches, natural disasters, terrorism, software and hardware failures, telecommunication and electrical failures, and similar issues. If such an event were to occur, it could result in material interruptions to our operations, loss of data or applications, loss of sales, significant extra expenses to restore data or systems, reputational harm and diversion of funds. For example, the loss of preclinical study or clinical trial data could result in delays in our product development or regulatory approval efforts and significantly increase our costs in order to recover or reproduce the data. The effects of the COVID-19 pandemic and the transition to more remote and hybrid work schedules have intensified our dependence on information technology systems as many of our critical business activities are being conducted remotely, and our increased reliance on personnel working from home could increase our cybersecurity risk. In addition, our cybersecurity risk could be increased as a result of the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia.

In addition to traditional computer "hackers" and threat actors, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). Ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity. We cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our systems and networks or the systems and networks of third parties that support us.

Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Although, to our knowledge, we have not experienced any material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. While we have taken steps to protect the security of the personal data and other sensitive information that we handle, there can be no assurance that any security measures will be effective against current or future security threats. Any unauthorized or accidental access to, or disclosure, modification, misuse, or loss of, personal or other data could result in legal claims or proceedings, liability, significant regulatory penalties, and loss of trade secrets or other intellectual property. In addition, such an event could disrupt our operations, damage our reputation and delay development of our product candidates.

Risks Related to Our Operating Results, Financial Condition and Capital Requirements

Our operating results are difficult to predict and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results are difficult to predict and may fluctuate significantly from quarter to quarter and year to year. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- customer ordering patterns for our products, which may vary significantly from period to period;
- the overall level of demand for our products, including the impact of any competitive or biosimilar products;
- the extent to which coverage and adequate reimbursement for our products is available from government and other third-party payors;
- changes in the amount of deductions from gross sales, including government-mandated rebates, chargebacks and discounts that can vary because of changes to the government discount percentage, including increases in the discount percentage resulting from price increases, or due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;
- increases in the scope of eligibility for customers to purchase our products at the discounted government price or to obtain government-mandated rebates on purchases of our products;
- the timing, receipt and amount of development funding and milestone, royalty and other payments under collaboration and license arrangements, which may vary significantly from quarter to quarter;
- entry into new strategic transactions, such as collaborations, license agreements or acquisitions of products, technologies or businesses;
- changes in our cost of sales due to potential new product launches, royalties owed under technology license agreements or write-offs of inventory;
- the incidence rate of new patients in the approved indications for our products;
- the evolving effects of the COVID-19 pandemic, including those leading to past and potential future reductions in rates of cancer diagnoses;
- the timing, cost and level of investment in our sales and marketing efforts to support our products sales;
- the timing, cost and level of investment in clinical trials, research and development, pre-commercialization, manufacturing and other activities by us or our collaborators; and
- expenditures to develop and/or commercialize any additional products, product candidates, or technologies that we may develop, in-license, or acquire.

Sales of a newly-approved product, or sales of an existing product in a newly-approved indication or territory, are particularly difficult to predict. Sales results or trends for such products, indications or territories in any period may not necessarily be indicative of future performance. Changes in our operations, such as new or expanding pipeline programs, the continued expansion or our international operations, additional business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses, may cause significant fluctuations in our expenses. In addition, stock-based compensation expense may vary significantly from period to period. The variables we use for valuing these awards, including our underlying stock price, change over time. Additionally, from time to time, we have granted performance-based equity awards to eligible employees with vesting of the awards contingent upon the achievement of certain regulatory milestones. Costs of performance-based compensation for these awards are not recorded as an expense until the achievement of the applicable milestones is deemed probable, which may result in large fluctuations to the expense we must recognize in any particular period.

For these and other reasons, it is difficult for us to accurately forecast future sales of our current or any future approved products, collaboration and license agreement revenues, royalty revenues, operating expenses or future profits or losses. In addition, although we provide financial guidance from time to time, such guidance is based on assumptions that may be incorrect or that may change from quarter to quarter. You also should not rely on operating results in any period as being indicative of future performance. Our operating results have on occasion been, and in in future periods may also be, below prior period results, our own guidance and/or the expectations of securities analysts or investors. Such results could cause the trading price of our common stock to decline, perhaps substantially.

We have a history of net losses. We expect to continue to incur net losses and may not achieve future sustained profitability for some time, if at all.

We have incurred substantial net losses in each of our years of operation, other than the year ended December 31, 2020. We have incurred these losses principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect to continue to spend substantial amounts on research and development, including amounts for conducting clinical trials of our products and product candidates. In addition, we expect to make substantial expenditures to commercialize our products and potentially commercialize our product candidates. For example, in connection with our in-license of development and commercialization rights to disitamab vedotin, we have incurred and expect to continue to incur substantial expenses, including to further develop and potentially commercialize disitamab vedotin. We may also pursue new operations or continue the expansion of our existing operations, including with respect to the continued development of our commercial infrastructure in Europe and our plans to otherwise continue to expand our operations internationally. Accordingly, we expect to continue to incur net losses in the future and may not achieve sustained profitability for some time, if at all. Although we recognize revenue from product sales and we continue to earn amounts under our collaboration agreements, our revenue and profit potential is unproven and our future operating results are difficult to predict. Even if we do achieve profitability in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We may need to raise additional capital that may not be available to us.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees, support our development and commercialization activities, invest in our facilities, and expand globally, which may require us to raise additional capital. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to the continued development of our commercial infrastructure in Europe and our plans to otherwise continue to expand our operations internationally. Our commitment of resources to the continuing development, regulatory and commercialization activities for our products, the continued research, development and manufacturing of our product candidates, our pursuit of regulatory approvals for and preparing to potentially launch and commercialize our product candidates, and the anticipated expansion of our pipeline and operations may require us to raise additional capital. Further, we actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses, and we may require significant additional capital in order to complete or otherwise provide funding for such transactions. We may seek additional capital through some or all of the following methods: corporate collaborations, licensing arrangements and public or private debt or equity financings. We do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be required to scale back our operations, delay, reduce the scope of, or eliminate development programs, enter into collaboration or license agreements on terms that are not favorable to us, sell or relinquish rights to certain assets, proprietary technologies or product candidates or forego strategic opportunities. Our future capital requirements will depend upon a number of factors, including:

- the level of sales of our products and any future approved products;
- the time and costs involved in pursuing regulatory approvals and the timing of any approvals;
- the costs, timing, progress and results of our research and development, including preclinical testing and clinical trials;
- the timing, receipt and amount of royalty revenue generated from commercial sales by our collaborators and licensees, as well as development funding, milestone payments and other payments under collaboration and license arrangements;
- the cost of establishing and maintaining clinical supplies of our products and product candidates and commercial supplies of our current and any future approved products;
- the extent of our investment in development, manufacturing and commercialization outside the U.S.;
- the costs associated with past and potential future strategic transactions, including acquisitions or licenses of additional technologies, products or businesses as well as licenses we may need to commercialize our current or any future approved products;
- the terms and timing of any future collaboration, licensing and other arrangements;
- expenses associated with current or future litigation;
- the potential costs associated with international, state and federal taxes; and
- competing technological and market developments.

In addition, changes in our spending rate may occur that would consume available capital resources sooner, such as increased development, manufacturing and clinical trial expenses in connection with our expanding pipeline programs or our undertaking of additional programs, business activities or entry into additional strategic transactions, including potential future acquisitions of products, technologies or businesses. Moreover, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. Debt financing arrangements may require us to pledge certain assets or enter into covenants that could restrict our operations or our ability to pay dividends or other distributions on our common stock or incur further indebtedness. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

During the past several years, domestic and international financial markets have experienced, and they may continue to experience, extreme disruption from time to time, including, among other things, high volatility, significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. Such adverse capital and credit market conditions could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects. For example, our ability to raise additional capital may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the evolving effects of the COVID-19 pandemic, inflationary pressures, rising interest rates, the ongoing military conflict between Russian and Ukraine and related sanctions imposed against Russia and otherwise.

The potential future impairment of intangible assets and goodwill may negatively affect our results of operations and financial position.

As of December 31, 2022, we carried $512.2 million of intangible assets, net and goodwill on our consolidated balance sheet. Our intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Our results of operations and financial position in future periods could be negatively impacted should future impairments of intangible assets or goodwill occur.

Risks Related to Our Common Stock

Our stock price is volatile and our shares may suffer a decline in value.

The market price of our stock has been, and is likely to continue to be, volatile. As a result of fluctuations in the price of our common stock, you may be unable to sell your shares at or above the price you paid for them. The market price of our common stock may be subject to substantial volatility in response to many risk factors listed in this section, and others beyond our control, including:

- the levels of product sales;
- regulatory approval or non-approval of our products or product candidates, specific label indications for or restrictions, warnings or limitations in their use, or delays in the regulatory review process;
- clinical trial results;
- announcements regarding the results of discovery efforts, product development and commercial activities by us, our collaborators or our competitors;
- announcements regarding, or negative publicity concerning, adverse events or safety concerns associated with the use of our products or product candidates;
- issuance of new or changed analysts' reports and recommendations regarding us or our competitors;
- termination of or changes in our existing collaborations or licensing arrangements, or establishment of new collaborations or licensing arrangements;
- our failure to achieve the perceived benefits of our strategic transactions, including our in-license of development and commercialization rights to disitamab vedotin, as rapidly or to the extent anticipated by financial analysts or investors;
- our entry into additional material strategic transactions including licensing or acquisition of products, businesses or technologies;
- regulatory actions with respect to our products, product candidates, clinical trials or regulatory filings;
- our raising of additional capital and the terms upon which we may raise any additional capital;
- developments or disputes concerning our proprietary rights, including with respect to our disputes with Daiichi Sankyo;
- developments regarding any litigation or potential litigation;

- the evolving effects of the COVID-19 pandemic;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- changes in laws, regulations or government policies, including with respect to pricing and reimbursement;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular; and
- other economic, social or political conditions.

The stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. In the past, companies whose securities have experienced periods of volatility in market price have been subjected to securities class action or derivative litigation. In this regard, we have been, and may in the future again become, subject to claims and litigation alleging violations of the securities laws or other related claims. Lawsuits brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources.

Substantial future sales or issuances of shares of our common stock or equity-related securities could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock, and sales by members of our management or board of directors or entities affiliated with such members, could occur at any time. In addition, in December 2020, pursuant to a ten-year registration rights agreement we entered into with certain entities affiliated with Baker Bros. Advisors LP, or the Baker Entities, we registered up to 47,366,602 shares of our common stock for resale by the Baker Entities, and we may be required to register the resale of additional shares held by the Baker Entities from time to time in the future. Sales by our management, our directors, their affiliates, or significant shareholders like the Baker Entities, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock, perhaps substantially, and could impair our ability to raise capital through the sale of additional equity or equity-related securities. In addition, we may issue a substantial number of shares of our common stock or equity-related securities, including convertible debt, to meet our capital needs, including in connection with funding potential future acquisition or licensing opportunities, capital expenditures or product development costs. These issuances could be substantially dilutive and could adversely affect the market price of our common stock. Likewise, future issuances of our common stock upon the exercise, conversion or settlement of equity-based awards or other equity-related securities would dilute existing stockholders' ownership interest in our company.

Our existing stockholders have significant control of our management and affairs.

Based on information available to us as of December 31, 2022, the Baker Entities collectively beneficially owned approximately 25% of our common stock. In addition, based solely on the most recent Schedules 13G and 13D filed with the SEC, reports filed with the SEC under Section 16 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and our outstanding shares of common stock as of December 31, 2022, our executive officers and directors and holders of greater than five percent of our outstanding common stock beneficially owned approximately 52% of our voting power as of December 31, 2022. As a result, these stockholders are able to exert substantial influence over our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership may result in our taking corporate actions that other stockholders may not consider to be in their best interest. For example, it may have the effect of delaying, deferring or preventing a change in control, including a merger, consolidation, takeover or other business combination involving us or discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control, which might affect the market price of our common stock.

Anti-takeover provisions could make it more difficult for a third party to acquire us.

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the terms of those shares, including voting rights, without any further action by the stockholders. The rights of the holders of common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of Seagen. Further, certain provisions of our charter documents, including provisions eliminating the ability of stockholders to take action by written consent and limiting the ability of stockholders to raise matters at a meeting of stockholders without giving advance notice, may have the effect of delaying or preventing changes in control or management of Seagen, which could have an adverse effect on the market price of our stock. In addition, our charter documents provide for a classified board, which may make it more difficult for a third party to gain control of our Board of Directors. Similarly, state laws in Delaware and Washington related to corporate takeovers may prevent or delay a change of control of Seagen.

Our disclosures related to environmental, social and governance, or ESG, matters expose us to various risks, including risks to our reputation and stock price.

Investors are increasingly likely to factor ESG disclosures into their investment decisions. We have elevated the degree to which we manage, track and report on our ESG efforts and goals. Where provided, goal statements are aspirational, are subject to a number of risks, many of which are beyond our control, and are not guarantees. Our processes and operations may not always conform to various frameworks for identifying, measuring and reporting ESG metrics, and ESG reporting standards may change over time, either of which could result in significant revisions to reported metrics. In addition, our interpretation of reporting standards may differ from those of others. Any failure or perceived failure to pursue or fulfill our goals or to satisfy various reporting standards could have negative impacts on our reputation and stock price and expose us to litigation or government actions. Moreover, the SEC has recently proposed certain mandated ESG reporting requirements, such as the SEC's proposed rules designed to enhance and standardize climate-related disclosures, which, if finally approved, would significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders may deem to negatively impact our reputation and/or that harm our stock price.

General Risk Factors

Changes in tax laws or regulations may have a material adverse effect on our business, results of operations, financial condition or growth prospects.

Due to economic and political conditions, various countries have made or are actively considering changes to existing tax laws, which could adversely affect our business operations and financial performance, and we cannot predict the form or timing of such changes. For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to deduct research and development expenditures in the year incurred, requiring amortization in accordance with IRC Section 174. If this requirement is not repealed or otherwise modified, it will reduce our operating cash flows. In addition, the current U.S. presidential administration continues to pursue numerous corporate tax reform proposals to increase taxation of international business operations. Further, organizations such as the Organization for Economic Cooperation and Development have published actions plans that, if adopted by countries where we do business, could increase our tax obligations in those countries. Changes in corporate tax rates or in rules applicable to the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings or the deductibility of expenses could have a material impact on the value of our deferred tax assets, result in significant one-time charges, increase our future tax expense or otherwise have a material adverse effect on our business, results of operations, financial condition or growth prospects.

If our facilities are damaged or our research and development, manufacturing or other business processes are interrupted, our business could be seriously harmed.

We conduct most of our business in a limited number of facilities. Damage or extended periods of interruption to these facilities due to fire, natural disaster, severe weather, power loss, communications failure, unauthorized entry or other events could cause significant disruption and/or delays in our research and development, manufacturing and commercial activities and could cause us to incur large expenses to repair or replace the facilities. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such disruption, delays and costs.

Legislative actions and new accounting pronouncements are likely to impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result we may be required to make changes in our accounting policies that could adversely affect our reported revenues and expenses, future profitability or financial position. The application of existing or future financial accounting standards, particularly those relating to the way we account for revenues and costs, could have a significant impact on our reported results.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our headquarters are in Bothell, Washington. Our Bothell campus comprises 11 leased buildings of office and warehouse space that we use for laboratory, discovery, research and development and general and administrative purposes, and a biologics manufacturing facility which we own. We have signed a lease to a facility currently being constructed in Everett, Washington, which will be used for future manufacturing capability. We also have leased space in South San Francisco, California, Mississauga, Canada, Zug, Switzerland, and in several other European locations used for general and administrative purposes. All of our significant leases include renewal options. We believe that our real estate is currently adequate to meet our needs. As we continue to expand our operations, we may need to lease or purchase additional real estate.

Item 3. Legal Proceedings

The information set forth in Note 13 of the Notes to Consolidated Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K is incorporated by reference into this Item 3. In addition, from time to time, we may become involved in other lawsuits, claims and proceedings relating to the conduct of our business, including those pertaining to the defense and enforcement of our patent or other intellectual property rights and our contractual rights. These proceedings are costly and time consuming, and they may subject us to claims which may result in liabilities or require us to take or refrain from certain actions. Additionally, successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary technologies without a license from us or our collaborators.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol "SGEN." As of February 10, 2023, there were 186,789,367 shares of our common stock outstanding, which were held by approximately 51 holders of record.

Dividend Policy

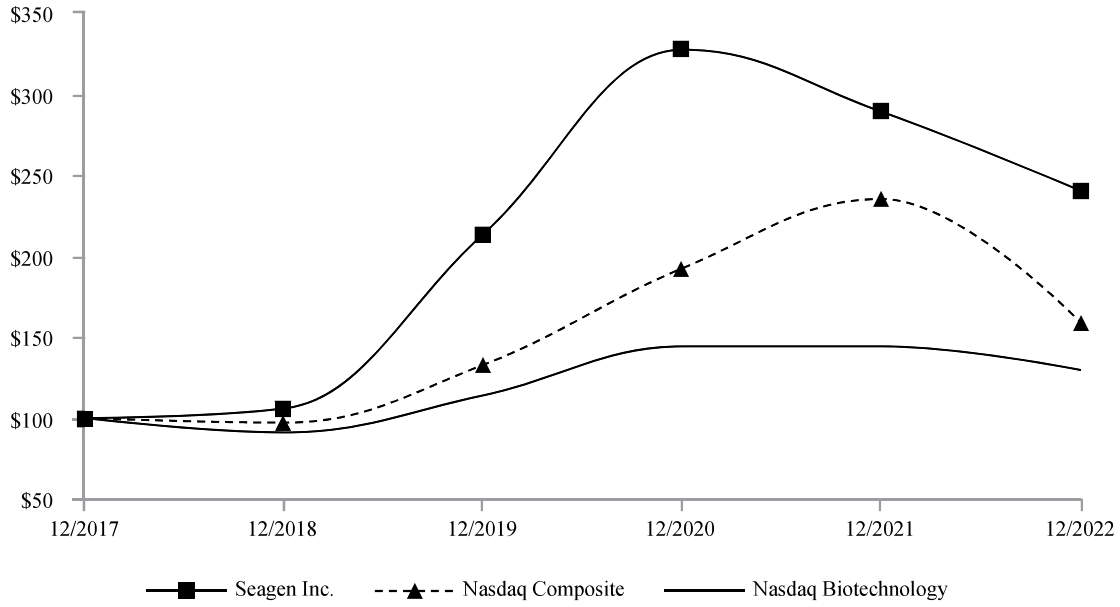
We have not paid any cash dividends on our common stock since our inception. We do not intend to pay any cash dividends in the foreseeable future, but intend to retain all earnings, if any, for use in our business operations.

Sales of Unregistered Securities and Issuer Repurchases of Securities

There were no unregistered sales of equity securities by us during 2022. In addition, we did not repurchase any of our equity securities during 2022.

Stock Performance Graph

The table below shows the cumulative total return to our stockholders during the period from December 31, 2017 through December 31, 2022 in comparison to the indicated indexes. The results assume that $100 was invested on December 31, 2017 in our common stock and each of the indicated indexes, including reinvestment of any dividends.



	December 31,					
	2017	2018	2019	2020	2021	2022
Seagen Inc.	$ 100.00	$ 105.91	$ 213.57	$ 327.36	$ 288.97	$ 240.21
Nasdaq Composite	100.00	97.16	132.81	192.47	235.15	158.65
Nasdaq Biotechnology	100.00	91.14	114.02	144.15	144.18	129.59

This information under "Stock Performance Graph" is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of Seagen Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K and irrespective of any general incorporation language in those filings.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail in "Part I Item 1A—Risk Factors." We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

You should read the following discussion and analysis in conjunction with our consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

Overview

Seagen is a biotechnology company that develops and commercializes targeted therapies to treat cancer. We are commercializing ADCETRIS for the treatment of certain CD30-expressing lymphomas, PADCEV for the treatment of certain metastatic urothelial cancers, TUKYSA for the treatment of certain metastatic HER2-positive breast and colorectal cancers, and TIVDAK for the treatment of certain metastatic cervical cancers. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients. Many of our programs, including ADCETRIS, PADCEV and TIVDAK, are based on our antibody-drug conjugate, or ADC, technology that utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells.

2022 highlights and recent developments

Business Highlights

- Achieved record net product sales with 23% growth for 2022 compared to 2021.
- Appointed David Epstein as CEO and member of the Board of Directors. Mr. Epstein has more than 30 years of experience in the biopharmaceutical industry, including more than 25 years at Novartis, where he built its oncology business unit from initiation to second largest in the world and then served as CEO of Novartis Pharmaceuticals, a division of Novartis AG. More recently, he was executive partner at Flagship Pioneering.
- Announced that Roger Dansey, M.D., who has served as Seagen's Chief Medical Officer, or CMO, since 2018 and who served as Interim CEO from May 2022 until Mr. Epstein's appointment, was appointed President, Research and Development.
- Received FDA accelerated approval of TUKYSA in combination with trastuzumab for previously treated patients with *RAS* wild-type, HER2-positive unresectable or metastatic colorectal cancer.
- Received FDA approval of ADCETRIS for treatment of children with previously untreated high risk Hodgkin lymphoma.

- Presented positive results for PADCEV as first-line treatment for patients with cisplatin-ineligible metastatic urothelial cancer that supported a supplemental Biologics License Application, or sBLA, to the FDA which was granted Priority Review with a PDUFA target action date of April 21, 2023. Additionally, we submitted an sBLA for ADCETRIS based on data demonstrating an overall survival benefit in previously untreated advanced Hodgkin lymphoma for inclusion in the label.
- Completed enrollment in two phase 3 clinical trials: the HER2CLIMB-02 trial evaluating TUKYSA with T-DM1 in locally advanced or metastatic HER2-positive breast cancer; and the EV-302 trial evaluating PADCEV as first-line treatment for both cis-eligible and ineligible patients with advanced urothelial cancer.
- Reported initial data from the innovaTV 207 phase 2 clinical trial of TIVDAK in solid tumors demonstrating promising preliminary antitumor activity in patients with squamous cell carcinoma of the head and neck.
- Initiated pivotal phase 2 clinical trial of disitamab vedotin in previously treated HER2-expressing metastatic urothelial cancer.
- Reported interim phase 1 data for SGN-B6A in relapsed or refractory metastatic solid tumors.
- Received a milestone payment under our ADC technology licensing agreement with an affiliate of AbbVie following the initiation of a phase 3 clinical trial of AbbVie's telisotuzumab vedotin for the treatment of non-small cell lung cancer.
- Entered into a collaboration with Sanofi to develop and potentially commercialize multiple novel ADCs.
- Entered into a corporate transaction for an innovative bispecific technology candidate that is directed toward a target not readily addressable by an ADC, adding to our portfolio of targeted drug therapies.
- Extended the geographic reach of TIVDAK with a new partnership for development and commercialization in mainland China, Hong Kong, Macau, and Taiwan.
- Continued construction of a new manufacturing facility in Everett, Washington designed to significantly expand our biomanufacturing capacity and to enable greater control and flexibility over the production of our products.

Details on these and other accomplishments are as follows:

Product and Pipeline Highlights

PADCEV

- In December 2022, the sBLA seeking accelerated approval for PADCEV with pembrolizumab as first-line treatment of certain patients with locally advanced or metastatic urothelial cancer was granted Priority Review by the FDA and the agency set a PDUFA target action date of April 21, 2023. The application was based on the results of the phase 1b/2 EV-103 clinical trial (also known as KEYNOTE-869) dose escalation/Cohort A and Cohort K.
- In April 2022, the European Commission approved PADCEV as monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a PD-1/L1 inhibitor. Additionally, in April 2022, the UK Medicines and Healthcare products Regulatory Agency granted marketing authorization in Great Britain for previously treated metastatic urothelial cancer.
- In February 2022, we reported initial results in patients with muscle-invasive bladder cancer, or MIBC, at the American Society of Clinical Oncology Genitourinary Cancers Symposium, or ASCO GU, demonstrating encouraging activity and tolerability.

TUKYSA

- In January 2023, we received accelerated approval of TUKYSA in combination with trastuzumab for adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy. The approval was based on data from the MOUNTAINEER clinical trial. This is the first FDA-approved treatment in HER2-positive metastatic colorectal cancer. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The National Comprehensive Cancer Network, or NCCN, Clinical Practice Guidelines in Oncology, or NCCN Guidelines, were updated classifying TUKYSA as a primary treatment for first and second-line plus treatment for HER2-amplified, *RAS* wild-type metastatic colorectal cancer.
- In July 2022, we presented positive results from the pivotal phase 2 MOUNTAINEER clinical trial evaluating TUKYSA in combination with trastuzumab in patients with previously treated HER2-positive metastatic colorectal cancer at the American Society of Clinical Oncology Gastrointestinal Cancer Symposium.
- In January 2023, the TUKYSA combination regimen was updated in the NCCN Guidelines for HER2-positive breast cancer to classify it as the preferred option in the third-line treatment setting and remains a Category 1 level of evidence.

ADCETRIS

- In November 2022, we received FDA approval of ADCETRIS for treatment of children with previously untreated high risk Hodgkin lymphoma. The approval was based on the results from The Children's Oncology Group Trial of ADCETRIS plus standard of care that demonstrated superior event-free survival versus standard of care alone in children and young adults with previously untreated high-risk Hodgkin lymphoma.
- In September 2022, we submitted an sBLA to the FDA based on longer-term follow-up data from the phase 3 ECHELON-1 clinical trial demonstrating that ADCETRIS in combination with chemotherapy resulted in a 41% reduction in risk of death versus standard of care in patients with previously untreated advanced Hodgkin lymphoma, for inclusion in the label.
- In September 2022, based on the overall survival benefit of ADCETRIS in combination with chemotherapy that was demonstrated in the ECHELON-1 trial, the NCCN Guidelines for Hodgkin lymphoma were updated elevating the ADCETRIS combination to Category 1, Preferred treatment option for adults with previously untreated Stage III or IV Hodgkin lymphoma with no known neuropathy. Category 1, Preferred is the highest recommendation by NCCN, indicating that based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

TIVDAK

- In December 2022, the NCCN Guidelines for Cervical Cancer were updated elevating TIVDAK to a Category 2A Preferred Regimen for second-line or subsequent recurrent or metastatic cervical cancer.
- In June 2022, reported interim data from the innovaTV 205 trial, which included data evaluating TIVDAK in combination with KEYTRUDA (Cohort E) in patients with recurrent or metastatic cervical cancer who have not received prior systemic therapy showing encouraging and durable anti-tumor activity for the combination.
- In February 2022, reported initial data from the innovaTV 207 phase 2 clinical trial of TIVDAK in solid tumors at the Multidisciplinary Head and Neck Cancers Symposium. The results demonstrated a manageable safety profile and promising preliminary antitumor activity in patients with squamous cell carcinoma of the head and neck.

Earlier-Stage Programs

- In January 2023, initiated phase 1 study of SGN-BB228, a novel bispecific antibody in advanced melanoma and other solid tumors.
- In November 2022, we reported interim phase 1 monotherapy results for SGN-B6A in patients with relapsed or refractory metastatic solid tumor at the SITC Annual Meeting. Participants had received a median of 3 lines of therapy for metastatic disease prior to enrollment in the study. SGN-B6A demonstrated a manageable and tolerable safety profile at the explored dose levels and schedules. Intermittent dosing schedules (2Q3W, 2Q4W) are being evaluated further. The initial anti-tumor activity observed in heavily pre-treated patients is encouraging and has triggered expansion cohorts in non-small cell lung cancer, head and neck cancer and esophageal cancer, which are currently ongoing.
- In April 2022, the pivotal phase 2 clinical trial of disitamab vedotin began enrolling patients with previously treated HER2-expressing metastatic urothelial cancer.

Corporate Development

- In September 2022, we entered into an agreement with LAVA to develop and commercialize LAVA-1223, also known as SGN-EGFRd2, a preclinical gamma delta bispecific T-cell engager for EGFR-expressing solid tumors. We received an exclusive global license for SGN-EGFRd2 and the opportunity to exclusively negotiate rights to apply LAVA's proprietary Gammabody™ platform on up to two additional tumor targets, for an upfront payment of $50.0 million and potential milestones and royalties.
- In September 2022, we announced an exclusive collaboration and license agreement with Zai Lab for the development and commercialization of TIVDAK in mainland China, Hong Kong, Macau, and Taiwan.
- In March 2022, we entered into a collaboration with Sanofi to develop and potentially commercialize multiple novel ADCs. The agreement is an exclusive collaboration that will utilize Sanofi's proprietary monoclonal antibody technology and our proprietary ADC technology for up to three cancer targets. Under the terms of the collaboration, Seagen and Sanofi will co-fund global development activities and share equally in any future profits.

Corporate Responsibility Report

- In October 2022, we published our second annual Corporate Responsibility Report providing an update on our environmental, social, and governance, or ESG, efforts, achievements and future commitments. Our program was recognized by Newsweek in their report on America's Most Responsible Companies ranking Seagen 52 out of 500 public companies. Notable accomplishments reviewed in the report include:
    - Increasing our focus on diversity, equity and inclusion by launching allyship training and implementing self-reporting for LGBTQIA+ populations in our engagement surveys. Our global workforce was comprised of 58% women as of December 31, 2022, and we aim to increase women in leadership roles as well as improve the percentage of underrepresented people in U.S. roles.
    - Implementing initiatives in our clinical trials aimed at improving diversity to better reflect real-world patient populations and advance inclusion.
    - Enhancing our environmental practices at our U.S. facilities through recycling and waste management. In 2022, the King County Industrial Waste Rewards and Recognition Program awarded us a "Gold Award" for our North Creek facility industrial wastewater program.
    - Enhancing our governance and compliance programs across areas such as ethics and compliance, data privacy, and information security, with the aim of supporting our growth and the expansion of our operations into international markets.

Also refer to Part I Item 1 "Business" for more information about our products, pipeline, technologies, research programs, and future plans for our clinical programs, including recent key business achievements.

Outlook

We recognize product sales revenue from ADCETRIS in the U.S. and Canada, from PADCEV in the U.S., Canada, and Latin America, from TUKYSA in the U.S., Europe and Canada, and TIVDAK in the U.S. We expect 2023 growth in net product sales of our portfolio to be primarily supported by sales volume growth and to a lesser degree net price growth. Recently, we have experienced a favorable effect on gross-to-net deductions in the U.S. market associated with high inflation, but it is not possible to predict how inflation will develop going forward and affect gross-to-net deductions in future periods. In addition, we experienced a reduction in diagnosis rates for the ADCETRIS frontline indications earlier in the COVID-19 pandemic; however, recently, we believe these diagnosis rates have returned to pre-pandemic levels. We cannot predict how these diagnosis rates will trend in the future. We expect that ADCETRIS and PADCEV will remain the largest contributors to our sales growth in 2023. We expect ADCETRIS growth to be driven by continued use across its seven indications, most notably in frontline Hodgkin lymphoma. We anticipate that the rate of growth of PADCEV for its currently approved labels in the U.S. will decelerate in 2023 compared to 2022 after three full years in the market since launch. Additionally, while growth in PADCEV sales has been primarily driven by use of checkpoint inhibitors as frontline maintenance therapy, uptake of checkpoint inhibitors in that setting has flattened, which has been limiting PADCEV's near-term growth in its current indications. We also expect that growth in TUKYSA will continue to be impacted by competitive headwinds related to Enhertu's recent approvals and its increased use in the second line plus setting, which is expected to continue into 2023.

Our ability to maintain or continue to grow net product sales and to realize the anticipated benefits of our investments in our products depends on a number of factors including:

- our and our collaborators' ability to demonstrate to the medical community the efficacy, safety and value of our products and their potential advantages compared to existing and future therapeutics in their approved indications;
- the extent to which we and our collaborators are able to obtain regulatory and other approvals of our products in additional territories and/or in additional indications, including any accelerated approval from the FDA based on the results of the EV-103 trial or any other approvals for PADCEV in the frontline metastatic urothelial cancer setting and any approvals for TUKYSA in earlier lines of breast cancer and/or other HER2-positive cancers;
- our and our collaborators' ability to successfully launch, market and commercialize our products in any new markets or new indications, if regulatory approval is obtained, including Astellas' ability to successfully launch, market and commercialize PADCEV in the European Union and its other markets;
- competition from other therapies and changing market dynamics, as further described in "Business—Competition" in Part I Item 1 of this Annual Report on Form 10-K; for example, the approval of Enhertu for second-line HER2-positive metastatic breast cancer has resulted and is expected to continue to result in increased competition for TUKYSA;
- the extent to which we are able to successfully work with Astellas to jointly market and commercialize PADCEV in the U.S., and with Genmab to jointly market and commercialize TIVDAK in the U.S.;
- our and Merck's abilities to successfully market and commercialize TUKYSA in our respective territories outside the U.S.;
- the extent to which coverage and adequate levels of reimbursement for our products are available from governments and other third-party payors;
- the extent to which we and our collaborators are able to obtain required pricing and reimbursement approvals of our products in additional territories, most notably with respect to TUKYSA and PADCEV;
- future inflation levels and their impact on mandatory discounts under U.S. government programs;
- the impact of current and future healthcare reform measures, including measures that could result in more rigorous coverage criteria or reduce the price that we receive for our products;
- the incidence flow of patients eligible for treatment in our products' approved indications;
- our and our collaborators' ability to accurately predict and supply product demand;

- duration of therapy for patients receiving our products;
- our and our collaborators' ability to successfully comply with rigorous post-marketing requirements, including requirements related to a confirmatory trial as a result of TIVDAK's accelerated approval by the FDA, and to convert TIVDAK's accelerated approval to regular approval in the U.S.;
- with respect to TIVDAK, the acceptance of TIVDAK and its required eye care by the medical community and patients; and
- impacts related to the COVID-19 pandemic, including potential future adverse effects on diagnosis rates for the ADCETRIS frontline indications and potential adverse impacts on diagnosis rates for other cancers.

As a result of these and other factors, our future net product sales for each of our products can be difficult to accurately predict from period to period. We cannot assure you that sales of any of our products will continue to grow or that we can maintain sales of any of our products at or near current levels.

The biopharmaceutical industry and the markets in which we operate are intensely competitive. Many of our competitors are working to develop or have commercialized products similar to those we market or are developing. Drug prices are under significant scrutiny and we expect drug pricing and other healthcare costs to continue to be subject to intense political and societal pressures on a global basis. For example, in July 2021, the Biden administration announced an Executive Order that includes initiatives aimed at lowering prescription drug costs and implementing Canadian drug importation, and in response to President Biden's Executive Order, in September 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 into law, which, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law; (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and (iii) redesigns the Medicare Part D program, increasing manufacturer rebates within the catastrophic coverage phase. In addition to pricing actions and other measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, our sales and operations could also be affected by other risks of doing business internationally.

We expect that amounts received from our collaboration agreements, including royalties, will continue to be an important source of our revenues and cash flows. These revenues and cash flows will be impacted by future development funding and the achievement of development, clinical and commercial success by our collaborators under our existing collaboration and license agreements, as well as by entering into potential new collaboration and license agreements.

Our ongoing research, development, manufacturing and commercial activities will require substantial amounts of capital and may not ultimately be successful. We expect that we will incur substantial expenses, and we will require significant financial resources and additional personnel in order to advance the development of, to pursue, obtain and maintain regulatory approvals for, and to commercialize our products and product candidates, and expand our pipeline. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to the continued development of our commercial infrastructure in Europe and our plans to otherwise continue to expand our operations internationally. As a result, we may need to raise additional capital, and our operating expenses may fluctuate as a result of such activities. We may also incur substantial milestone payment obligations to certain of our licensors, including RemeGen, as our product candidates progress through clinical trials towards potential commercialization.

We are continuing to monitor the impact of the evolving effects of the COVID-19 pandemic on our ability and the ability of our collaborators to effectively market, sell and distribute our products and to develop our products and product candidates. The evolving effects of the COVID-19 pandemic appear to have negatively affected our product sales in the past and could affect product sales in the future. In this regard, impacts associated with the COVID-19 pandemic appear to have led to a reduction in [diagnosis rates for the ADCETRIS frontline indications] earlier in the pandemic and, while we have recently seen those diagnosis rates increase to pre-pandemic levels, these impacts may have adversely affected diagnosis rates of other cancers, and may adversely affect rates of cancer diagnoses or patient access to healthcare settings in the future. As we resume more travel and in-person interactions after pauses earlier in the pandemic, we may subsequently decide or be forced to resume a more restrictive remote work model, whether as a result of further spikes or surges in COVID-19 infection or hospitalization rates, COVID-19 variants, government actions, restrictions at healthcare institutions, or otherwise. Future COVID-19 related restrictions could negatively impact research and development activities or sales and marketing efforts, or could present product distribution challenges.

Some of the sites participating in our clinical trials are affected by site closings, reduced capacity, staffing shortages, or other effects of the COVID-19 pandemic. At some sites, we are experiencing impacts to our ability to monitor patients, activate sites, screen and enroll patients, complete site monitoring and manage samples. The extent of the impact on a particular clinical trial depends on the current stage of activities at a given site, for example study start up versus post-enrollment, and the number of impacted sites participating in that trial. Impacts on diagnosis rates associated with the COVID-19 pandemic may also negatively impact enrollment. While we do not at this time anticipate the need to revise our publicly reported projected clinical milestone dates as a result of the effects of the COVID-19 pandemic, there may continue to be adverse impacts to our clinical study timelines, which, depending upon the duration and severity of the evolving effects of the COVID-19 pandemic, could ultimately delay data availability. Due to the suspension of data monitoring activities at sites that do not currently allow remote monitoring, as well as impacts on the ability to monitor patients, maintain patient treatment according to the trial protocols and manage samples, there is also the potential for negative impacts on data quality. While we are actively utilizing digital monitoring measures and other mitigations designed to prevent negative data quality impacts, if there were in fact a negative impact on data quality, we or our collaborators could be required to repeat, extend the duration of, or increase the size of clinical trials, which could significantly delay potential commercialization and require greater expenditures. We expect that similar factors will impact clinical studies operationalized by our collaborators.

The extent to which the evolving effects of the COVID-19 pandemic (or any future pandemic) impact our business will depend on future developments that are highly uncertain, such as virus variants that may prove to be especially contagious or virulent, the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of vaccine programs and other actions taken to contain and treat the disease. For more information on the risks and uncertainties associated with the evolving effects of the COVID-19 pandemic on our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts, see "Part II Item 1A—Risk Factors."

Because of the above and other factors, our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance.

Financial summary

For 2022, our total revenues increased to $2.0 billion, compared to $1.6 billion for 2021. The increase was primarily driven by $321.0 million or 23% higher net product sales, due to growth from each of our approved medicines in our commercial portfolio, and to a lesser extent, higher collaboration and license agreement revenues, and higher royalty revenues.

For 2022, total costs and expenses increased to $2.6 billion, compared to $2.3 billion in 2021. Expenses in 2022 included higher research and development expenses, higher selling, general and administrative expenses, and higher cost of sales.

As of December 31, 2022, we had $1.7 billion in cash, cash equivalents and investments and $2.8 billion in total stockholders' equity.

In addition, the section of this Management's Discussion and Analysis of Financial Condition and Results of Operations generally discusses 2022 and 2021 items and year-to-year comparisons between 2022 and 2021. Discussions of 2020 items and year-to-year comparisons between 2021 and 2020 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 9, 2022.

Critical Accounting Policies and Estimates

A summary of the significant accounting policies is provided in Note 1 to our Consolidated Financial Statements.

The preparation of financial statements in accordance with generally accepted accounting principles, or GAAP, requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities.

We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions and conditions.

Management considers an accounting estimate to be critical if:

- it requires a significant level of estimation uncertainty; and
- changes in the estimate are reasonably likely to have a material effect on our financial condition or results of operations.

We believe the following critical accounting policies and estimates describe the more significant judgments and estimates used in the preparation of our consolidated financial statements.

Net Product Sales. We sell our products primarily through a limited number of specialty distributors and specialty pharmacies in the U.S., and to a lesser extent, internationally. The delivery of our products represents a single performance obligation for these transactions, and we record net product sales when control is transferred to the customer, which generally occurs upon receipt by the customer. The transaction price for net product sales represents the amount we expect to receive, which is net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns, and other deductions. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. We reflect these accruals as either a reduction in the related account receivable from the distributor or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payor mix in target markets and experience to-date. These estimates involve a substantial degree of judgment, in particular, for government-mandated rebates and chargebacks, such as for the Medicaid and 340B programs.

U.S. government-mandated rebates and chargebacks: We have entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate based on covered purchases of our products. Medicaid rebates are invoiced to us by the various state Medicaid programs. These estimates involve a substantial degree of judgment in which we estimate Medicaid rebates using the expected value approach, based on a variety of factors, including payor mix and our experience to-date.

We have a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of our products. In addition, we have entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of our products. Under these agreements, distributors process a chargeback to us for the difference between wholesale acquisition cost and the applicable discounted price. We estimate expected chargebacks for FSS and PHS purchases based on the expected value of each entity's eligibility for the FSS and PHS programs. We also review historical rebate and chargeback information to further refine these estimates.

Performance-based equity Awards. We have granted performance-based equity awards that include vesting upon achievement of pre-determined performance milestones, which may include regulatory milestones, revenue-based milestones, or market-based performance metrics, which may include total shareholder return compared to our industry peer group or stock price targets. We record compensation expense over the estimated requisite service period for each performance milestone when we believe the performance milestone is considered probable, which we assess at each reporting date. Once a performance milestone is considered probable, we record compensation expense based on the portion of the service period elapsed to date with respect to that performance milestone, with a cumulative catch-up, net of estimated forfeitures, and recognize any remaining compensation expense over the remaining requisite service period. Assessing whether performance milestones are probable to be achieved and estimating the timing upon which the performance milestone may be achieved, each may involve a significant amount of uncertainty. The fair value of certain stock options or RSUs, subject to market-based performance metrics, is estimated using a Monte Carlo simulation model which utilizes multiple assumptions to estimate the amount and timing of compensation expense.

The assumptions used in computing the fair value of equity awards reflect our best estimates but involve uncertainties related to market and other conditions. Changes in any of these assumptions may materially affect the fair value of awards granted and the amount of stock-based compensation recognized.

Results of Operations - Years Ended December 31, 2022, 2021, and 2020

Net product sales

				Percentage change	
(dollars in thousands)	2022	2021	2020	2022/2021	2021/2020
ADCETRIS	$ 839,272	$ 705,561	$ 658,577	19 %	7 %
PADCEV	451,427	339,918	222,436	33 %	53 %
TUKYSA	353,083	333,952	119,585	6 %	179 %
TIVDAK	62,734	6,135	—	923 %	NM
Net product sales	$ 1,706,516	$ 1,385,566	$ 1,000,598	23 %	38 %

NM: No amount in comparable period or not a meaningful comparison.

Our net product sales grew 23% during 2022 as compared to 2021, driven by growth from each of our marketed products.

ADCETRIS net product sales grew due to higher net selling prices driven by favorable pricing dynamics in 2022 and higher volumes of vials sold associated with diagnosis rates, which we believe have returned to pre-pandemic levels for frontline indications, as well as greater use in frontline advanced Hodgkin lymphoma. PADCEV net product sales grew primarily due to higher sales volume as a result of additional eligible patients in second line post checkpoint maintenance during the 2022 period, higher net selling prices, and sales for use in clinical trials being conducted by another company. TUKYSA net product sales grew due to increased sales in our European markets following its commercial launches commencing in 2021, offset in part by lower net selling prices in our European markets and competitive dynamics in its current indication. We began commercializing TIVDAK in the U.S. following FDA approval in September 2021.

We expect growth in net product sales in 2023 from 2022 to be primarily driven by sales volume growth and to a lesser degree net price growth. Refer to "Overview—Outlook" above for additional information.

Gross-to-net deductions, net of related payments and credits, were as follows:

(in thousands)	December 31, 2022			December 31, 2021			December 31, 2020		
	Rebates and chargebacks	Distribution fees, product returns and other	Total	Rebates and chargebacks	Distribution fees, product returns and other	Total	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance, beginning of year	$ 74,889	$ 16,818	$ 91,707	$ 44,193	$ 15,689	$ 59,882	$ 38,084	$ 7,519	$ 45,603
Provision related to current year sales	612,241	48,377	660,618	492,527	40,491	533,018	358,238	28,724	386,962
Adjustments for prior period sales	(11,454)	(1,439)	(12,893)	(4,212)	(1,220)	(5,432)	(1,341)	—	(1,341)
Payments/credits for current year sales	(513,197)	(37,744)	(550,941)	(428,045)	(32,087)	(460,132)	(319,444)	(18,886)	(338,330)
Payments/credits for prior year sales	(51,228)	(4,034)	(55,262)	(29,574)	(6,055)	(35,629)	(31,344)	(1,668)	(33,012)
Balance, end of year	$ 111,251	$ 21,978	$ 133,229	$ 74,889	$ 16,818	$ 91,707	$ 44,193	$ 15,689	$ 59,882

Government-mandated rebates and chargebacks are the most significant component of our total gross-to-net deductions and the discount changes over time. The most significant portion of our gross-to-net accrual balances as of December 31, 2022 and 2021 was for ADCETRIS Medicaid rebates. For 2022, the provision related to current year sales and payments/credits for current year sales increased as compared to 2021, due to higher gross product sales. For 2022, payments/credits for prior year sales were consistent with 2021. We expect future gross-to-net deductions to fluctuate based on the volume of purchases eligible for government mandated discounts and rebates, as well as changes in the discount percentage which is impacted by potential future price increases, the rate of inflation, and other factors. We expect gross-to-net deductions to increase in 2023 as compared to 2022, driven by anticipated growth in our gross product sales.

Royalty revenues

Royalty revenues primarily reflect royalties earned under the ADCETRIS collaboration with Takeda. These royalties include commercial sales-based milestones and sales royalties. Sales royalties are based on a percentage of Takeda's net sales of ADCETRIS, with rates that range from the mid-teens to the mid-twenties based on annual net sales tiers. Takeda bears third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Royalty revenues also reflect, to a lesser extent, amounts from Genentech earned on net sales of Polivy beginning in 2019, and amounts from GlaxoSmithKline earned on net sales of Blenrep beginning in 2020, both of which utilizes technology that we have licensed to them, as well as royalties on TUKYSA sales by Merck in its territory, and royalties on disitamab vedotin sales by RemeGen in its territory.

(dollars in thousands)	2022	2021	2020	Percentage change 2022/2021	Percentage change 2021/2020
Royalty revenues	$ 164,554	$ 150,523	$ 126,756	9 %	19 %

Royalty revenues increased by 9% in 2022 as compared to 2021, primarily due to higher net product sales of ADCETRIS outside the U.S. and Canada by Takeda and royalties from sales of Polivy® by Roche, which is an ADC that use Seagen technology.

We expect that royalty revenues will increase in 2023 as compared to 2022 primarily due to higher royalties from anticipated growth of licensees' net product sales, including sales of ADCETRIS by Takeda in its territory along with contributions from sales of POLIVY by Roche.

Collaboration and license agreement revenues

Collaboration and license agreement revenues reflect amounts earned under certain of our license and collaboration agreements. These revenues reflect license fees, payments received by us for technology access and maintenance fees, sales of drug supply to our collaborators, milestone payments, and reimbursement payments for research and development support that we provide to our collaborators.

Collaboration and license agreement revenues were as follows:

				Percentage change	
(dollars in thousands)	2022	2021	2020	2022/2021	2021/2020
Collaboration and license agreement revenues	$ 91,342	$ 38,282	$ 1,048,182	139 %	(96)%

NM: No amount in comparable period or not a meaningful comparison.

Collaboration and license agreement revenues increased by 139% in 2022 compared to 2021, due primarily to the Zai Lab upfront license payment of $30.0 million in September 2022, contribution from Astellas' sales of PADCEV in its territory, and a milestone payment received from AbbVie, offset in part by a milestone payment received from GSK in 2021.

Collaboration and license agreement revenues from Merck in 2020 included license revenues of $975.2 million related to the LV Agreement and the TUKYSA Agreement. Refer to Note 10 of the Notes to Consolidated Financial Statements included in Part II Item 8 for additional information.

Collaboration and license agreement revenue is highly dependent on progress by our collaboration partners and new collaborations that are difficult to predict. We expect that collaboration and license agreements revenues will decrease in 2023 as compared to 2022. Our collaboration and license agreement revenues are impacted by the term and duration of those agreements and by progress-dependent milestones, annual maintenance fees, and reimbursement of materials and support services. Collaboration and license agreement revenues may vary substantially from year to year and quarter to quarter depending on the progress made by our collaborators with their product candidates, amount of drug supplied to our collaborators, the level of support we provide to our collaborators, specifically to Takeda under our ADCETRIS collaboration, the timing of milestones achieved and our ability to enter into potential additional collaboration and license agreements.

Collaboration and license agreements

We discuss the below arrangements in greater detail under the heading "Corporate Collaborations" in Part I Item 1 of this Annual Report on Form 10-K.

Takeda ADCETRIS collaboration

We have a collaboration agreement with Takeda for the global co-development of ADCETRIS and the commercialization of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We recognize payments from Takeda, including progress-dependent development and regulatory milestone payments, reimbursement for drug supplied, and net development cost reimbursement payments, as collaboration and license agreement revenues upon transfer of control of the goods or services over the development period. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, that payment reduces collaboration and license agreement revenues. We also recognize royalty revenues based on a percentage of Takeda's net sales of ADCETRIS in its licensed territories, ranging from the mid-teens to the mid-twenties based on annual net sales tiers, as well as sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS, which is included in royalty revenues.

Astellas PADCEV collaboration

We have a collaboration agreement with Agensys, Inc., which subsequently became an affiliate of Astellas, to jointly research, develop and commercialize ADCs for the treatment of several types of cancer. Under this collaboration, we and Astellas are equally co-funding all development and certain commercialization costs for PADCEV. In the U.S., we and Astellas jointly promote PADCEV. We record sales of PADCEV in the U.S. and are responsible for all U.S. distribution activities. The companies each bear the costs of their own sales organizations in the U.S., equally share certain other costs associated with commercializing PADCEV in the U.S., and equally share in any profits realized in the U.S. Gross profit share payments owed to Astellas in the U.S. under the joint commercialization agreement are recorded in cost of sales. Outside the U.S., we have commercialization rights in all countries in North and South America, and Astellas has commercialization rights in the rest of the world, including Europe, Asia, Australia and Africa.

Astellas or its affiliates are responsible for overseeing the initial manufacturing supply chain for PADCEV for development and commercial use. However, we are responsible for packaging and labeling in countries in which we sell PADCEV. In addition, we are in the process of establishing a second source manufacturing supply chain, through a combination of internal manufacturing capacity and third parties. In this regard, our manufacturing facility in Bothell, Washington is used to support commercial production of PADCEV antibody.

Merck TUKYSA collaboration

In September 2020, we entered into the TUKYSA Agreement with Merck. We granted exclusive rights to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Under the terms of the TUKYSA Agreement, Merck is responsible for marketing applications for approval in its territory, supported by the positive results from the HER2CLIMB clinical trial. We retained commercial rights in, and will record sales in, the U.S., Canada and Europe. Merck is also co-funding a portion of the TUKYSA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers. We will continue to lead ongoing TUKYSA global development operational execution. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. We received an upfront cash payment from Merck of $125.0 million and also received $85.0 million in prepaid research and development funding to be applied to Merck's global development cost sharing obligations. We are eligible to receive progress-dependent milestone payments of up to $65.0 million, and are entitled to receive tiered royalties on sales of TUKYSA by Merck that begin in the low twenty percent range and escalate based on sales volume by Merck in its territory.

We recognized license revenue of $125.0 million during the year ended December 31, 2020 associated with the TUKYSA Agreement, and we recognize such cost sharing proportionately with the performance of the underlying activities, while recording Merck's reimbursement of our expenses as a reduction of research and development expenses. Sales of TUKYSA drug product supplied is included in collaboration and license agreement revenues. The $85.0 million prepayment received for global development cost-sharing was recorded as a co-development liability in accrued liabilities and other or other long-term liabilities on our consolidated balance sheet as of December 31, 2020. As joint development expenses are incurred, we recognize the portion of Merck's prepayment as a reduction of our research and development expenses on our consolidated statements of comprehensive income (loss). As of December 31, 2022 and 2021, $15.5 million and $55.3 million was recorded as the remaining co-development liability, respectively.

Genmab TIVDAK collaborations

We have an agreement with Genmab to develop and commercialize ADCs targeting tissue factor, under which we previously exercised a co-development option for TIVDAK. Under this collaboration, we and Genmab are sharing all development costs for TIVDAK. TIVDAK was approved by FDA in September 2021. In the U.S., following FDA approval in September 2021, we and Genmab co-promote TIVDAK. We record sales of TIVDAK in the U.S. and are responsible for leading U.S. distribution activities. The companies are each responsible for maintaining 50% of the sales representatives and medical science liaisons, equally share those and certain other costs associated with commercializing TIVDAK in the U.S., individually bear the costs of certain other personnel in the U.S., and equally share in any profits realized in the U.S. Gross profit share payments owed to Genmab in the U.S. under the joint commercialization agreement are recorded in cost of sales. Outside the U.S., we have commercialization rights in the rest of the world except for Japan, where Genmab has commercialization rights, and certain territories where Zai Lab has commercialization rights, as further described below. In Europe, China, and Japan, we and Genmab equally share the costs associated with commercializing TIVDAK as well as any profits realized in these markets. In markets outside the U.S. other than Europe, China, and Japan, aside from certain costs specified in the agreement, we are solely responsible for all costs associated with commercializing TIVDAK and will pay Genmab a royalty based on a percentage of aggregate net sales ranging from the mid-teens to mid-twenties.

In September 2022, we announced an exclusive collaboration and license agreement with Zai Lab for the development and commercialization of TIVDAK in mainland China, Hong Kong, Macau, and Taiwan. Under the terms of the agreement, we received an upfront payment of $30.0 million in October 2022 which was recorded in collaboration revenue for the year ended December 31, 2022, and are entitled to receive potential future development, regulatory, and commercial milestone payments, and tiered royalties on net sales of TIVDAK in the Zai Lab territory. Based on our existing collaboration with Genmab, the upfront payment, milestone payments, and royalties will be equally shared with Genmab.

RemeGen disitamab vedotin license agreement

Effective in September 2021, we and RemeGen entered into an exclusive worldwide licensing agreement to develop and commercialize disitamab vedotin, a novel HER2-targeted ADC. Disitamab vedotin combines the drug-linker technology originally developed by us with RemeGen's novel HER2 antibody. Disitamab vedotin received FDA Breakthrough Therapy designation in 2020 for use in second-line treatment of patients with HER2-expressing, locally advanced or metastatic urothelial cancer who have previously received platinum-containing chemotherapy. Also in 2020, RemeGen announced FDA’s clearance of an IND application for a phase 2 clinical trial in locally advanced or metastatic urothelial cancer. Disitamab vedotin is conditionally approved for treating locally advanced metastatic gastric cancer in China, and in July 2021 the National Medical Products Administration of China also accepted an NDA for disitamab vedotin in locally advanced or metastatic urothelial cancer.

Under the terms of the agreement, we made a $200.0 million upfront payment to obtain exclusive license rights to disitamab vedotin for global development and commercialization, outside of RemeGen's territory. RemeGen retains development and commercialization rights for Asia, excluding Japan and Singapore. We will lead global development and RemeGen will fund and operationalize the portion of global clinical trials attributable to its territory. RemeGen will also be responsible for all clinical development and regulatory submissions specific to its territory. We may pay RemeGen up to $195.0 million in potential milestone payments across multiple indications and products based upon the achievement of specified development goals, and up to $2.2 billion in potential milestone payments based on the achievement of specified regulatory and commercialization goals. RemeGen will be entitled to a tiered, high single digit to mid-teen percentage royalty based on net sales of disitamab vedotin in our territory.

Merck LV collaboration

In September 2020, we entered into the LV Agreement with a subsidiary of Merck. We are pursuing a broad joint development program evaluating LV as monotherapy and in combination setting, including with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. Under the terms of the LV Agreement, we granted Merck a co-exclusive worldwide development and commercialization license for LV, and agreed to jointly develop and commercialize LV on a worldwide basis. We received an upfront cash payment of $600.0 million, and we are eligible to receive up to $850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional $1.75 billion in milestone payments upon the achievement of specified annual global net sales thresholds of LV. Each company is responsible for 50% of global costs to develop and commercialize LV and will receive 50% of potential future profits. In connection with the LV Agreement, we entered into a stock purchase agreement with Merck in September 2020, pursuant to which we agreed to issue and sell, and Merck agreed to purchase 5,000,000 newly-issued shares of our common stock, at a purchase price of $200 per share, for an aggregate purchase price of $1.0 billion, referred to as the Purchase Agreement. We closed the Purchase Agreement in October 2020.

We recognized license revenue of $850.1 million during the year ended December 31, 2020 associated with the LV Agreement and Purchase Agreement, and we recognize such cost sharing proportionately with the performance of the underlying activities, while recording Merck's reimbursement of our expenses as a reduction of research and development expenses.

Other technology collaboration and license agreements

We have other collaboration and license agreements for our technology with a number of biotechnology and pharmaceutical companies. We typically receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. These amounts are recognized as revenue over the performance obligation period if the license is determined not to be distinct from other goods and services provided, or, if there is no performance obligation, upon transfer of control of the goods or services to the customer.

Since we do not control the research, development or commercialization of any of the products that would generate these milestones, we are not able to reasonably estimate when, if at all, any potential future milestone payments or royalties may be payable by our collaborators. We do not expect, and investors should not assume, that we will receive all of the potential milestone payments described above, and it is possible that we may never receive any additional significant milestone payments under these ADC license and collaboration agreements.

Cost of sales

Cost of sales includes manufacturing and distribution costs of product sold, gross profit share with Astellas and Genmab pursuant to those respective collaborations, amortization of acquired technology license costs, royalties owed on our PADCEV net product sales, and royalties owed on global ADCETRIS, TUKYSA and TIVDAK net product sales.

				Percentage change	
(dollars in thousands)	2022	2021	2020	2022/2021	2021/2020
Cost of sales	$ 410,058	$ 311,565	$ 217,720	32 %	43 %

Cost of sales increased in 2022 as compared to 2021, driven by higher sales of our medicines resulting in higher gross profit sharing owed to our collaboration partners, and to a lesser extent, higher product sales costs from sales volume increases.

The gross profit share owed to collaborators totaled $253.4 million, $162.0 million, and $104.6 million for the years ended December 31, 2022, 2021, and 2020, respectively. We recorded amortization expense of $23.1 million, $23.1 million and $16.3 million for acquired TUKYSA technology costs during the years ended December 31, 2022, 2021 and 2020, respectively.

We expect cost of sales to increase in 2023 as compared to 2022 as a result of the net product sales growth of our marketed products, contributing to higher manufacturing costs for products sold and higher anticipated gross profit sharing with our collaborators.

Research and development

(dollars in thousands)	2022	2021	2020	Percentage change 2022/2021	Percentage change 2021/2020
Research and clinical development	$ 1,039,217	$ 950,309	$ 581,496	9 %	63 %
Process sciences and manufacturing	305,144	278,363	245,633	10 %	13 %
Total research and development	$ 1,344,361	$ 1,228,672	$ 827,129	9 %	49 %

Research and clinical development expenses include personnel, occupancy and laboratory expenses, technology access fees, preclinical translational biology and in vitro and in vivo studies, IND-enabling pharmacology and toxicology studies, and external clinical trial costs including costs for clinical sites, clinical research organizations, contractors and regulatory activities associated with conducting human clinical trials. Research and clinical development expenses in 2021 were impacted by the $200.0 million RemeGen upfront license payment made in 2021. Other research and clinical development costs grew during 2022 compared to 2021, driven by higher employee-related costs and clinical trial costs to support our early- and late-stage pipeline of product candidates, as well as the $50.0 million upfront payment to LAVA.

Process sciences and manufacturing expenses include personnel and occupancy expenses, manufacturing costs for the scale-up and pre-approval manufacturing of product candidates used in research and our clinical trials, and costs for drug product supplied to our collaborators. Process sciences and manufacturing expenses also include quality control and assurance activities, and storage and shipment of our product candidates. The increase in 2022 compared to 2021 primarily reflected higher employee-related costs and the manufacturing costs of our product candidates for use in clinical trials.

We utilize our employee and infrastructure resources across multiple research and development projects. We track human resource efforts expended on many of our programs for purposes of billing our collaborators for time incurred at agreed upon rates and for resource planning. We do not account for actual costs on a project basis as it relates to our infrastructure, facility, employee and other indirect costs; however, we do separately track significant third-party costs including clinical trial costs, manufacturing costs and other contracted service costs on a project basis. To that end, the following table shows third-party costs incurred for research, manufacturing of our product candidates and clinical and regulatory services, as well as development milestone payments for in-licensed technology for our products and certain of our clinical-stage product candidates. The table also presents other costs and overhead consisting of third-party costs for our preclinical stage programs, personnel, facilities, manufacturing, and other indirect costs not directly charged to development programs, as well as cost reimbursements received from or payments made to collaborators related to our product candidates.

(dollars in thousands)	2022	2021	2020	Percentage change 2022/2021	Percentage change 2021/2020
TUKYSA (tucatinib)	$ 198,906	$ 153,546	$ 81,292	30 %	89 %
PADCEV (enfortumab vedotin-ejfv)	81,449	79,564	38,031	2 %	109 %
ADCETRIS (brentuximab vedotin)	83,521	77,539	75,589	8 %	3 %
TIVDAK (tisotumab vedotin)	42,093	45,712	15,573	(8)%	194 %
Ladiratuzumab vedotin	15,072	21,975	19,715	(31)%	11 %
Disitamab vedotin	36,951	5,151	—	617 %	NM
Other clinical stage programs	86,110	71,106	50,355	21 %	41 %
Total third-party costs for clinical stage programs	544,102	454,593	280,555	20 %	62 %
Upfront technology costs	60,000	200,000	5,000	(70)%	NM
Other costs, overhead, and net cost-sharing with collaborators	740,259	574,079	541,574	29 %	6 %
Total research and development	$ 1,344,361	$ 1,228,672	$ 827,129	9 %	49 %

NM: No amount in comparable period or not a meaningful comparison.

Third-party costs for TUKYSA and ADCETRIS increased in 2022 as compared to 2021, due primarily to higher clinical trials expenses.

Third-party costs for PADCEV increased in 2022 as compared to 2021, due to the timing of clinical trials expenses.

Third-party costs for TIVDAK decreased in 2022 as compared to 2021, due to the timing of clinical trials expenses.

Third-party costs for ladiratuzumab vedotin decreased in 2022 as compared to 2021, due primarily to lower clinical trials expenses.

Third-party expenses for disitamab vedotin increased in 2022 as compared to 2021 as we only obtained exclusive license rights to disitamab vedotin for global development and commercialization outside of RemeGen's territory in September 2021.

Third-party costs for other clinical stage programs increased in 2022 as compared to 2021 due to higher clinical trial expenses.

Upfront technology costs decreased in 2022 as compared to 2021 due to the $200.0 million RemeGen upfront license payment made in 2021, partially offset by the $50.0 million upfront license payment made to LAVA in 2022.

Other costs, overhead, and net cost-sharing reimbursements from or payments made to collaborators increased in 2022 as compared to 2021 due to higher employee-related costs. During the years ended December 31, 2022, 2021, and 2020 net research and development cost-sharing reimbursements from and payments made to collaborators were $91.3 million, $83.8 million, and $(2.2) million, respectively.

In order to advance our product candidates toward commercialization, the product candidates are tested in numerous preclinical safety, toxicology and efficacy studies. We then conduct clinical trials for those product candidates that take several years or more to complete. The length of time varies substantially based upon the type, complexity, novelty and intended use of a product candidate. We will also need to conduct additional clinical trials in order to expand labeled indications of use for our commercial products. The outcome of our clinical trials is uncertain. The cost of clinical trials may vary significantly as a result of a variety of factors, including the number of patients enrolled, patient site costs, quantity and source of drug supply required, safety and efficacy of the product candidate, and extent of regulatory efforts, among others.

We anticipate that our total research and development expenses in 2023 will increase compared to 2022 primarily due to higher costs for the continued development of our approved products and product candidates.

The risks and uncertainties associated with our research and development projects are discussed more fully in "Part I Item 1A—Risk Factors." As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates, or when and to what extent we will receive cash inflows from the commercialization and sale of our products in any additional approved indications or of any of our product candidates.

Selling, general and administrative

				Percentage change	
(dollars in thousands)	2022	2021	2020	2022/2021	2021/2020
Selling, general and administrative	$ 820,963	$ 716,190	$ 533,835	15 %	34 %

Selling, general and administrative expenses increased in 2022 compared to 2021, reflecting higher investments to support our ongoing European TUKYSA launches and the U.S. commercial launch of TIVDAK, and higher legal expenses primarily associated with the Daiichi Sankyo legal proceedings.

We anticipate that selling, general and administrative expenses will increase in 2023 as compared to 2022 due to higher commercial activities to drive growth of our approved products and to support our overall growth strategy.

Investment and other income, net

(dollars in thousands)	2022	2021	2020	Percentage change 2022/2021	Percentage change 2021/2020
(Loss) gain on equity securities	$ (10,154)	$ 4,744	$ 11,604	(314)	(59)%
Investment and other income, net	20,809	1,607	7,245	NM	(78)%
Total investment and other income, net	$ 10,655	$ 6,351	$ 18,849	68	(66)%

NM: No amount in comparable period or not a meaningful comparison.

Investment and other income, net includes other non-operating income and loss, such as unrealized holding gains and losses on equity securities, realized gains and losses on equity and debt securities, and amounts earned on our investments in U.S. Treasury securities.

The loss on equity securities for the year ended December 31, 2022 as compared to 2021, was due to unrealized holding losses resulting from a decline in the share price of securities held during the respective periods. At times, we hold equity investments in certain companies acquired in relation to a strategic partnership. Investment and other income, net increased for the year ended December 31, 2022 due to higher yields on our debt securities investments in 2022.

Income taxes

For the year ended December 31, 2022, we had taxable profits in the U.S. as a result of amendments to Internal Revenue Code (IRC) Section 174 pursuant to the 2017 Tax Cuts and Jobs Act, which took effect January 1, 2022. We recorded a provision for income taxes of $8.0 million for the year ended December 31, 2022 compared to a benefit from income taxes of $1.2 million for the year ended December 31, 2021. The provision for income taxes in 2022 primarily related to estimated state tax liabilities for which there were limitations on the use of existing state tax carryforwards. We had existing federal tax carryforwards sufficient to offset most of the federal liability. Our income tax provision also reflected taxable profits in foreign jurisdictions. The benefit from income taxes in 2021 reflected the generation of additional available state research and development tax credits.

Liquidity and capital resources

(dollars in thousands)	December 31, 2022	December 31, 2021	December 31, 2020
Cash, cash equivalents and investments	$ 1,735,070	$ 2,160,036	$ 2,660,250
Working capital	1,984,129	2,300,340	2,674,246
Stockholders' equity	2,803,819	3,065,139	3,488,100

(dollars in thousands)	Years ended December 31, 2022	Years ended December 31, 2021	Years ended December 31, 2020
Cash provided by (used in):			
Operating activities	$ (453,751)	$ (499,007)	$ 856,568
Investing activities	228,237	288,884	(1,419,012)
Financing activities	125,360	77,779	846,108

The change in net cash from operating activities from 2022 as compared to 2021 was primarily related to a decrease in net loss and an increase in net working capital.

The change in net cash from investing activities from 2022 as compared to 2021 reflected differences between the amounts used for purchases of securities and the proceeds from maturities of securities, the difference for purchases of property, plant, and equipment, and the payment for lessor-owned assets.

The change in net cash from financing activities in 2022 as compared to 2021 was driven by higher proceeds from the exercise of stock options and the employee stock purchase plan.

We primarily have financed our operations through the issuance of our common stock, collections from commercial sales of our products, amounts received pursuant to license and collaboration agreements, and royalty revenues. To a lesser degree, we also have financed our operations through investment income. These financing and revenue sources have allowed us to maintain adequate levels of cash and investments.

Our cash, cash equivalents, and investments are held in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs. However, if our liquidity needs should be accelerated for any reason in the near term, or investments do not pay at maturity, we may be required to sell investment securities in our portfolio prior to their scheduled maturities, which may result in a loss. As of December 31, 2022, we had $1.7 billion held in cash, cash equivalents, and investments.

At our currently planned spending rates, we believe that our existing financial resources, together with product and royalty revenues, and reimbursements and profit sharing we expect to receive under our existing collaboration and license agreements, will be sufficient to fund our operations for at least the next twelve months from the date of this filing.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees, and support our development, commercialization, invest in our facilities, and expand globally, which may require us to raise additional capital. In addition, we may pursue new operations or continue the expansion of our existing operations, including with respect to the continued development of our commercial infrastructure in Europe and our plans to otherwise continue to expand our operations internationally. Our commitment of resources to the continuing development, regulatory and commercialization activities for our products, the continued research, development and manufacturing of our product candidates, our pursuit of regulatory approvals for and preparing to potentially launch and commercialize our product candidates, and the anticipated expansion of our pipeline and operations may require us to raise additional capital. Further, we actively evaluate various strategic transactions on an ongoing basis, including licensing or otherwise acquiring complementary products, technologies or businesses, and we may require significant additional capital in order to complete or otherwise provide funding for such transactions. We may seek additional capital through some or all of the following methods: corporate collaborations, licensing arrangements, and public or private debt or equity financings. We have no committed sources of funding and do not know whether additional capital will be available when needed, or that, if available, we will obtain financing on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be required to scale back our operations, delay, reduce the scope of, or eliminate development programs enter into collaboration or license agreements on terms that are not favorable to us, sell or relinquish rights to certain assets, proprietary technologies or product candidates or forego strategic opportunities.

Material Cash Requirements

Our material cash requirements in the short- and long-term consist of the following operational, capital, and manufacturing expenditures, a portion of which contain contractual or other obligations. We plan to fund our material cash requirements with our current financial resources together with our anticipated receipts of accounts receivable, product sales and royalty revenues, and reimbursements we expect to receive under our existing collaboration and license agreements.

Operating expenditures. Our primary uses of cash and operating expenses relate to paying employees and consultants, administering clinical trials, marketing our products, and providing technology and facility infrastructure to support our operations. Our research and development expenses in 2022 were $1.3 billion, and we expect to increase our investment in research and development expenses in 2023. Our sales, general and administrative expenses were $821.0 million in 2022, and we expect to increase our sales, general, and administrative expenses to support our business growth in 2023. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

Operating costs also relate to our building leases for our office and laboratory facilities expiring in 2023 through 2029 that contain rate escalations and options for us to extend the leases. Our future minimum lease payments as of December 31, 2022 totaled $17.0 million related to short-term lease liabilities, and $49.2 million related to long-term lease liabilities. We signed a 20-year lease in June 2021 for a building complex in Everett, Washington that has not commenced as of December 31, 2022, and therefore rent payments are not included in lease liability balances as of December 31, 2022. Refer to Note 3 in the Notes to Financial Statements in Item 8 for further detail of our lease obligations.

Capital expenditures. We make investments in our office, laboratory, and manufacturing facilities to enable continued expansion of our business. These include leasehold and building improvements at our approximately 1 million square feet of leased and owned properties, installation of laboratory and manufacturing equipment, computers, software, and office equipment. Our purchases for property and equipment for 2022 were $77.3 million, and we anticipate these investments to grow in 2023 to support our anticipated business growth and long-term facility needs, including a significant multi-year investment in a building complex being constructed in Everett, Washington, which is expected to provide us additional manufacturing, laboratory, and office space in the future. We expect our capital expenditures for this Everett facility to be approximately $300 million to $350 million through 2024.

Manufacturing costs, and supply agreements. Some of our inventory components and products require long lead times to manufacture. Therefore, we make substantial and often long-term investments in our supply chain in order to ensure we have enough drug product to meet current and future revenue forecasts, as well as clinical trial needs. Supply agreements primarily include non-cancelable obligations under our manufacturing, license and collaboration, and technology agreements. Further, a substantial portion of those non-cancelable obligations include minimum payments related to manufacturing our product candidates for use in our clinical trials and for commercial operations in the case of ADCETRIS. Future minimum contractual commitments under these arrangements December 31, 2022 totaled $202.5 million related to short-term obligations, and $150.4 million related to long-term obligations. Refer to Note 12 in the Notes to Financial Statements in Item 8 for further detail of our manufacturing supply agreements.

Royalties, milestones and profit-sharing associated with our licensed technology and collaboration agreements. Some of our license and collaboration agreements provide for periodic maintenance fees over specified time periods, profit share payments, and/or payments by us upon the achievement of development and regulatory milestones. Some of our licensing agreements also obligate us to pay royalties based on net sales of products utilizing licensed technology. Such royalties and profit share payments are dependent on future product sales and are contingent on events that have not yet occurred. Royalties and profit share payments totaled $308.9 million in 2022 and are expected to increase in future periods. Milestone payments generally become due and payable upon the achievement of certain events. Future milestone payments potentially owed related to in-licensed technology totaled $4.5 billion as of December 31, 2022, consisting of up to approximately $0.4 billion in development and clinical milestones, up to approximately $1.6 billion in regulatory milestones, and up to approximately $2.4 billion in commercial milestones.

Recent accounting pronouncements

See the section "Recent accounting pronouncements" in Note 1 to the Notes to Consolidated Financial Statements in Part II Item 8 of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We currently have holdings in U.S. Treasury securities. A summary of our investment securities follows:

	December 31,	
(dollars in thousands)	**2022**	**2021**
Short-term investments	$ 1,415,130	$ 1,735,202

We have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent to be a reduction of $2.4 million in the fair value of our investments as of December 31, 2022. In addition, a hypothetical decrease of 10% in the effective yield of our investments would reduce our expected investment income by $4.3 million over the next twelve months based on our investment balance at December 31, 2022.

Foreign Currency Risk

Most of our revenues and expenses are denominated in U.S. dollars and as a result, we have not experienced significant foreign currency transaction gains and losses to date. Our commercial sales in Europe are primarily denominated in Euros and in Canada are denominated in Canadian Dollars. We also had other transactions denominated in foreign currencies during the year ended December 31, 2022, primarily related to operations in Europe, contract manufacturing and ex-U.S. clinical trial activities, and we expect to continue to do so. Our royalties from Takeda are derived from their sales of ADCETRIS in multiple countries and in multiple currencies that are converted into U.S. dollars for purposes of determining the royalty owed to us. Our limited foreign currency exposure is to fluctuations in the Euro, British Pound, Canadian Dollar, Swiss Franc, Danish Krone, and Swedish Krona. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, transaction gains or losses may become significant in the future as we continue to expand our operations internationally. We have not engaged in foreign currency hedging to date; however, we may do so in the future.

Item 8. Financial Statements and Supplementary Data

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Seagen Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Seagen Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of comprehensive (loss) income, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Government-mandated rebates - Medicaid

As described in Note 1 to the consolidated financial statements, the Company records product sales net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. As disclosed by management, amounts accrued for rebates and chargebacks as of December 31, 2022 are $111.3 million, with the most significant portion of the accrual balance related to ADCETRIS Medicaid rebates. Management estimates Medicaid rebates using the expected value approach, based on a variety of factors, including payor mix and experience to-date. Management also reviews historical rebate information to further refine these estimates.

The principal considerations for our determination that performing procedures relating to government-mandated rebates – Medicaid is a critical audit matter are (i) the significant judgment by management when determining the rebate estimate and (ii) the high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence related to management's estimate and significant assumptions related to payor mix and estimated purchases covered by the various state Medicaid programs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the various state Medicaid programs, including controls over the assumptions used to estimate the rebate. These procedures also included, among others, (i) testing management's process for determining the rebate estimate; (ii) evaluating the appropriateness of management's model; (iii) testing the completeness and accuracy of the underlying data used by management; and (iv) evaluating the significant assumptions used by management including payor mix and estimated purchases covered by the various state Medicaid programs. Evaluating management's assumptions involved evaluating whether the assumptions were reasonable considering (i) the consistency of the historical covered purchases and rebate processing times; (ii) expansion of state Medicaid programs; (iii) comparing assumptions to other industry data; (iv) testing of actual rebate claims processed by the Company; and (v) whether these assumptions were consistent with evidence obtained in other areas of the audit.

/s/ PricewaterhouseCoopers LLP

Seattle, Washington
February 15, 2023

We have served as the Company's auditor since 1998.

Seagen Inc.
Consolidated Balance Sheets
(In thousands, except par value)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 319,940	$ 424,834
Short-term investments	1,415,130	1,735,202
Accounts receivable, net	501,912	389,256
Inventories	427,211	200,663
Prepaid expenses and other current assets	138,340	119,239
Total current assets	2,802,533	2,869,194
Property and equipment, net	248,179	210,073
Operating lease right-of-use assets	46,738	57,889
Intangible assets, net	237,516	260,593
Goodwill	274,671	274,671
Other non-current assets	64,895	47,184
Total assets	$ 3,674,532	$ 3,719,604
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 207,851	$ 114,824
Accrued liabilities and other	610,553	454,030
Total current liabilities	818,404	568,854
Long-term liabilities:		
Operating lease liabilities, long-term	43,474	56,665
Other long-term liabilities	8,835	28,946
Total long-term liabilities	52,309	85,611
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized; none issued	—	—
Common stock, $0.001 par value, 250,000 shares authorized; 186,559 shares issued and outstanding at December 31, 2022 and 183,381 shares issued and outstanding at December 31, 2021	187	183
Additional paid-in capital	4,954,469	4,607,816
Accumulated other comprehensive income	3,510	1,179
Accumulated deficit	(2,154,347)	(1,544,039)
Total stockholders' equity	2,803,819	3,065,139
Total liabilities and stockholders' equity	$ 3,674,532	$ 3,719,604

The accompanying notes are an integral part of these consolidated financial statements.

Seagen Inc.
Consolidated Statements of Comprehensive (Loss) Income
(In thousands, except per share amounts)

	Years ended December 31,		
	2022	2021	2020
Revenues:			
Net product sales	$ 1,706,516	$ 1,385,566	$ 1,000,598
Royalty revenues	164,554	150,523	126,756
Collaboration and license agreement revenues	91,342	38,282	1,048,182
Total revenues	1,962,412	1,574,371	2,175,536
Costs and expenses:			
Cost of sales	410,058	311,565	217,720
Research and development	1,344,361	1,228,672	827,129
Selling, general and administrative	820,963	716,190	533,835
Total costs and expenses	2,575,382	2,256,427	1,578,684
(Loss) income from operations	(612,970)	(682,056)	596,852
Investment and other income, net	10,655	6,351	18,849
(Loss) income before income taxes	(602,315)	(675,705)	615,701
Provision (benefit) for income taxes	7,993	(1,234)	2,031
Net (loss) income	$ (610,308)	$ (674,471)	$ 613,670
Net (loss) income per share - basic	$ (3.30)	$ (3.70)	$ 3.51
Net (loss) income per share - diluted	$ (3.30)	$ (3.70)	$ 3.37
Shares used in computation of per share amounts - basic	184,676	182,048	174,834
Shares used in computation of per share amounts - diluted	184,676	182,048	182,287
Comprehensive (loss) income:			
Net (loss) income	$ (610,308)	$ (674,471)	$ 613,670
Other comprehensive income:			
Unrealized loss on securities available-for-sale, net of income tax provision of $0, $0, and $0, respectively	(1,401)	(211)	(186)
Foreign currency translation gain, net of income tax provision of $0, $0, and $0, respectively	3,732	825	522
Total other comprehensive income	2,331	614	336
Comprehensive (loss) income	$ (607,977)	$ (673,857)	$ 614,006

The accompanying notes are an integral part of these consolidated financial statements.

Seagen Inc.
Consolidated Statements of Stockholders' Equity
(In thousands)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balances at December 31, 2019	171,994	$ 172	$ 3,359,124	$ 229	$ (1,483,238)	$ 1,876,287
Net income	—	—	—	—	613,670	613,670
Other comprehensive income	—	—	—	336	—	336
Issuance of common stock for stock option exercises and employee stock purchase plan	2,466	2	96,255	—	—	96,257
Restricted stock vested during the period, net	1,442	2	(2)	—	—	—
Issuance of common stock	5,000	5	749,845	—	—	749,850
Share-based compensation	—	—	151,700	—	—	151,700
Balances at December 31, 2020	180,902	181	4,356,922	565	(869,568)	3,488,100
Net loss	—	—	—	—	(674,471)	(674,471)
Other comprehensive income	—	—	—	614	—	614
Issuance of common stock for stock option exercises and employee stock purchase plan	1,545	1	77,778	—	—	77,779
Restricted stock vested during the period, net	934	1	(1)	—	—	—
Share-based compensation	—	—	173,117	—	—	173,117
Balances at December 31, 2021	183,381	183	4,607,816	1,179	(1,544,039)	3,065,139
Net loss	—	—	—	—	(610,308)	(610,308)
Other comprehensive income	—	—	—	2,331	—	2,331
Issuance of common stock for stock option exercises and employee stock purchase plan	2,281	3	125,357	—	—	125,360
Restricted stock vested during the period, net	897	1	(1)	—	—	—
Share-based compensation	—	—	221,297	—	—	221,297
Balances at December 31, 2022	186,559	$ 187	$ 4,954,469	$ 3,510	$ (2,154,347)	$ 2,803,819

The accompanying notes are an integral part of these consolidated financial statements.

Seagen Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Years ended December 31,		
	2022	2021	2020
Operating activities:			
Net (loss) income	$ (610,308)	$ (674,471)	$ 613,670
Adjustments to reconcile net (loss) income to net cash (used) provided by operating activities			
Share-based compensation	221,297	173,117	147,233
Depreciation and amortization	46,727	42,854	36,045
Amortization of intangible assets	23,077	23,087	16,345
Amortization of right-of-use-assets	12,354	12,685	10,994
Amortization of premiums, accretion of discounts, and (gains) losses on debt securities	(7,065)	15,933	3,104
Loss (gain) on equity securities	10,154	(4,744)	(11,604)
Gain on disposals of property and equipment	—	—	(26)
Deferred income taxes	553	548	(2,053)
Changes in operating assets and liabilities:			
Accounts receivable, net	(112,656)	(64,268)	(88,727)
Inventories	(226,548)	(84,527)	(30,204)
Prepaid expenses and other assets	(16,306)	(66,422)	(22,231)
Lease liabilities	(15,509)	(14,388)	(11,271)
Other liabilities	220,479	141,589	195,293
Net cash (used) provided by operating activities	(453,751)	(499,007)	856,568
Investing activities:			
Purchases of securities	(2,462,264)	(3,424,286)	(2,483,336)
Proceeds from maturities of securities	2,788,000	3,765,500	952,000
Proceeds from sales of securities	—	—	194,733
Payments for lessor-owned assets	(20,159)	—	—
Purchases of property and equipment	(77,340)	(52,330)	(82,409)
Net cash provided (used) by investing activities	228,237	288,884	(1,419,012)
Financing activities:			
Net proceeds from issuance of common stock	—	—	749,850
Proceeds from exercise of stock options and employee stock purchase plan	125,360	77,779	96,258
Net cash provided by financing activities	125,360	77,779	846,108
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(1,194)	(1,246)	198
Net (decrease) increase in cash, cash equivalents, and restricted cash	(101,348)	(133,590)	283,862
Cash, cash equivalents, and restricted cash at beginning of year	424,834	558,424	274,562
Cash, cash equivalents, and restricted cash at end of year	$ 323,486	$ 424,834	$ 558,424

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Summary of Significant Accounting Policies

Organization

We are a biotechnology company that develops and commercializes targeted therapies to treat cancer. We are commercializing ADCETRIS®, or brentuximab vedotin, for the treatment of certain CD30-expressing lymphomas, PADCEV®, or enfortumab vedotin-ejfv, for the treatment of certain metastatic urothelial cancers, TIVDAK™, or tisotumab vedotin-tftv, for the treatment of certain metastatic cervical cancers, and TUKYSA®, or tucatinib, for treatment of certain metastatic HER2-positive breast cancers. We are also advancing a pipeline of novel therapies for solid tumors and blood-related cancers designed to address unmet medical needs and improve treatment outcomes for patients. Many of our programs, including ADCETRIS, PADCEV and TIVDAK, are based on our antibody-drug conjugate, or ADC, technology that utilizes the targeting ability of monoclonal antibodies to deliver cell-killing agents directly to cancer cells.

Basis of presentation

The accompanying consolidated financial statements reflect the accounts of Seagen Inc. and its wholly-owned subsidiaries (collectively "Seagen," "we," "our," or "us"). The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. All intercompany transactions and balances have been eliminated. Management has determined that we operate in one segment: the development and sale of pharmaceutical products on our own behalf or in collaboration with others.

Use of estimates

The preparation of financial statements in accordance with GAAP requires us to make estimates, assumptions, and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. Estimates include those used for revenue recognition, valuation of investments, inventory valuation, accrued liabilities, including those related to the long-term incentive plans and performance-based equity, clinical trials and contingencies, and stock option valuation.

Cash and cash equivalents

We consider all highly liquid investments with maturities of three months or less at the date of acquisition to be cash equivalents.

Non-cash activities

We had $20.1 million and $9.9 million of accrued capital expenditures as of December 31, 2022 and 2021, respectively. Accrued capital expenditures have been treated as a non-cash investing activity and, accordingly, have not been included in the consolidated statement of cash flows until such amounts have been paid in cash. During the years ended December 31, 2022, 2021 and 2020, we recorded $1.2 million, $9.1 million, and $7.2 million, respectively, of right-of-use assets in exchange for lease liabilities, which has been treated as a non-cash operating activity. See Note 3 for additional information.

Investments

We hold certain equity securities which are reported at estimated fair value based on quoted market prices. Changes in the fair value of equity securities are recorded in income or loss. The cost of equity securities for purposes of computing gains and losses is based on the specific identification method.

We invest our available cash primarily in debt securities. These debt securities are classified as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains, realized losses and declines in the value of debt securities judged to be other-than-temporary are included in investment and other income, net. The cost of debt securities for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts on debt securities are included in investment and other income, net. Interest and dividends earned are included in investment and other income, net. Accrued interest receivable as of December 31, 2022 and 2021, were $5.2 million and $0.4 million, respectively, and were included in prepaid expenses and other current assets. We classify investments in debt securities maturing within one year of the reporting date, or where management's intent is to use the investments to fund current operations or to make them available for current operations, as short-term investments.

If the estimated fair value of a debt security is below its carrying value, we evaluate whether it is more likely than not that we will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. We also evaluate whether or not we intend to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. In addition, we consider whether credit losses exist for any securities. A credit loss exists if the present value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are included in investment and other income, net.

Fair value of financial instruments

The recorded amounts of certain financial instruments, including cash and cash equivalents, interest receivable, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. Investments that are classified as available-for-sale are recorded at estimated fair value. The estimated fair value for securities held is determined using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency.

Restricted Cash

As of December 31, 2022, we had $3.5 million cash held in escrow restricted by a contractual agreement related to our Everett, Washington building construction project. The restricted cash was recorded in prepaid expenses and other current assets in the consolidated balance sheet. We determine classification based on the expected duration of the restriction.

Our total cash, cash equivalents, and restricted cash, as presented in the consolidated statements of cash flows, was as follows:

	December 31,	
(dollars in thousands)	**2022**	**2021**
Cash and cash equivalents	$ 319,940	$ 424,834
Restricted cash included in prepaid expenses and other current assets	3,546	—
Total cash, cash equivalents, and restricted cash as presented in the consolidated statements of cash flows	$ 323,486	$ 424,834

Leases

We determine if an arrangement is a lease at inception date. All of our currently effective leases are classified as operating leases. Operating lease liabilities and the corresponding right-of-use assets are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The operating lease right-of-use asset also excludes lease incentives and initial direct costs incurred. As our existing leases do not contain an implicit interest rate, we estimate our incremental borrowing rate based on information available at commencement date in determining the present value of future payments. We include options to extend the lease in our lease liability and right-of-use asset when it is reasonably certain that we will exercise that option. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants. Variable lease cost primarily includes building operating expenses as charged to us by our landlords.

Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For our short-term leases, we recognize lease payments as an expense on a straight-line base over the lease term.

Inventories

We consider regulatory approval of product candidates to be uncertain. Accordingly, we charge manufacturing costs to research and development expense until such time as a product has received regulatory approval for commercial sale. Production costs for our marketed products are capitalized into inventory. Inventory that is deployed for clinical, research or development use is charged to research and development expense when it is no longer available for commercial sales. Production costs for our other product candidates are charged to research and development expense.

We value our inventories at the lower of cost or market value. Cost is determined on a specific identification basis. Inventory includes the cost of materials, third-party contract manufacturing and overhead associated with the production of our commercialized products. In the event that we identify excess, obsolete or unsalable inventory, its value is written down to net realizable value.

Property and equipment

Property and equipment are stated at cost. Land is not depreciated, while all other property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which are generally as follows:

	Years
Building and improvements	20-30
Laboratory and manufacturing equipment	5-15
Furniture and fixtures	5
Computers, software and office equipment	3

Leasehold improvements are amortized over the shorter of the remaining term of the applicable lease or the useful life of the asset. Gains and losses from the disposal of property and equipment are reflected in income or loss at the time of disposition and have not been significant. Expenditures for additions and improvements to our facilities are capitalized and expenditures for maintenance and repairs are charged to expense as incurred.

Intangible assets, net

Our intangible assets are primarily comprised of acquired TUKYSA technology. Upon FDA approval and commercial launch of TUKYSA in April 2020, we classified in-process research and development costs related to the acquired TUKYSA technology as finite-lived intangible assets. The following table presents the balances of our finite-lived intangible assets for the periods presented:

	December 31,	
(dollars in thousands)	2022	2021
Gross carrying value	$ 305,650	$ 305,650
Less: accumulated amortization	(68,134)	(45,057)
Total	$ 237,516	$ 260,593

The following table presents our amortization expense related to acquired TUKYSA technology costs, included in cost of sales in our consolidated statements of comprehensive income (loss), for the periods presented:

	Years ended December 31,		
(dollars in thousands)	2022	2021	2020
Amortization expense	$ 23,077	$ 23,087	$ 16,345

The weighted average useful life of our finite-lived intangible assets was 10 years as of December 31, 2022, and estimated future amortization expense related to acquired TUKYSA technology costs is $23.1 million for each of the years ending December 31, 2023 through December 31, 2027.

Goodwill

We evaluate goodwill for impairment annually, as of October 1, or more frequently when events or circumstances indicate that impairment may have occurred. As part of the impairment evaluation, we may elect to perform an assessment of qualitative factors. If this qualitative assessment indicates that it is more likely than not that the fair value of the reporting unit (for goodwill) is less than its carrying value, we then would proceed with the quantitative impairment test to compare the fair value to the carrying value and record an impairment charge if the carrying value exceeds the fair value. We have not recognized any impairment losses through December 31, 2022 as there have been no events warranting an impairment analysis.

Impairment of long-lived assets

We assess the impairment of long-lived assets, including intangible assets and property and equipment, whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, we determine whether there has been an impairment in value by comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. If an impairment in value exists, the asset is written down to its estimated fair value. We have not recognized any impairment losses through December 31, 2022 as there have been no events warranting an impairment analysis. Our long-lived assets are primarily located in the U.S.; however, we have multiple subsidiaries in foreign jurisdictions, including several subsidiaries in Europe.

Revenue recognition - Net product sales

We sell our products primarily through a limited number of specialty distributors and specialty pharmacies in the U.S, and to a lesser extent, internationally. The delivery of our products represents a single performance obligation for these transactions and we record net product sales at the point in time when control is transferred to the customer, which generally occurs upon receipt by the customer. The transaction price for net product sales represents the amount we expect to receive, which is net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns, and other deductions. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. We reflect these accruals as either a reduction in the related account receivable from the distributor or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payor mix in target markets and experience to-date. These estimates involve a substantial degree of judgment.

Outside of the U.S., the transaction price for net product sales represents the amount we expect to receive, which is net of estimated discounts, estimated government mandated rebates, distribution fees, estimated product returns, and other deductions. Accruals are established for these deductions, and actual amounts incurred are offset against applicable accruals. These estimates involve judgment in estimating net product sales.

U.S. government-mandated rebates and chargebacks: We have entered into a Medicaid Drug Rebate Agreement, or MDRA, with the Centers for Medicare & Medicaid Services. This agreement provides for a rebate based on covered purchases of our products. Medicaid rebates are invoiced to us by the various state Medicaid programs. We estimate Medicaid rebates using the expected value approach, based on a variety of factors, including payor mix and our experience to-date.

We have a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of our products. In addition, we have entered into a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services, which enables certain entities that qualify for government pricing under the Public Health Services Act, or PHS, to receive discounts on their qualified purchases of our products. Under these agreements, eligible customers receive an applicable discount which is processed through the distributor as a chargeback to us for the difference between wholesale acquisition cost and the applicable discounted price. We estimate expected chargebacks for FSS and PHS purchases based on the expected value of each entity’s eligibility for the FSS and PHS programs. We also review historical rebate and chargeback information to further refine these estimates.

Distribution fees, product returns and other deductions: Our distributors charge a volume-based fee for distribution services that they perform for us. We allow for the return of product that is within a specified number of days of its expiration date or that is damaged. We estimate product returns based on our experience to-date using the expected value approach. We provide financial assistance to qualifying patients that are underinsured or cannot cover the cost of commercial coinsurance amounts through our patient support programs. Estimated contributions for commercial coinsurance under our patient assistance program, Seagen Secure, are deducted from gross sales and are based on an analysis of expected plan utilization. These estimates are adjusted as necessary to reflect our actual experience.

Revenue recognition - Royalty revenues

Royalty revenues primarily reflect amounts earned under the ADCETRIS collaboration with Takeda Pharmaceutical Company Limited, or Takeda. These royalties include commercial sales-based milestones and sales royalties that relate predominantly to the license of intellectual property. Sales royalties are based on a percentage of Takeda's net sales of ADCETRIS, with rates that range from the mid-teens to the mid-twenties based on annual net sales tiers. Takeda bears a portion of low single digit third-party royalty costs owed on its sales of ADCETRIS. This amount is included in royalty revenues. Amounts owed to our third-party licensors related to Takeda's sales of ADCETRIS are recorded in cost of sales. These amounts are recognized in the period in which the related sales by Takeda occur. Royalty revenues also reflect amounts from Genentech, Inc., a member of the Roche Group, or Genentech, earned on net sales of Polivy, and amounts from GlaxoSmithKline earned on net sales of Blenrep.

Revenue recognition - Collaboration and license agreement revenues

We have collaboration and license agreements for our technology with a number of biotechnology and pharmaceutical companies. Under these agreements, we typically receive or are entitled to receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. We also are entitled to receive royalties on net sales of any resulting products incorporating our technology. Generally, our licensees are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these collaborations, which includes the achievement of the potential milestones. Since we may not take a substantive role or control the research, development or commercialization of any products generated by some of our licensees, we may not be able to reasonably estimate when, if at all, any potential future milestone payments or royalties may be payable to us by our licensees. As such, the potential future milestone payments associated with certain of our collaboration and license agreements involve a substantial degree of uncertainty and risk that they may never be received.

Collaboration and license agreements are initially evaluated as to whether the intellectual property licenses granted by us represent distinct performance obligations. If they are determined to be distinct, the value of the intellectual property licenses would be recognized up-front while the research and development service fees would be recognized as the performance obligations are satisfied. Variable consideration is assessed at each reporting period as to whether it is not subject to future reversal of cumulative revenue and, therefore, should be included in the transaction price. Assessing the recognition of variable consideration requires judgment. If a contract includes a fixed or minimum amount of research and development support, this also would be included in the transaction price. Changes to collaboration and license agreements, such as the extensions of the research term or increasing the number of targets or technology covered under an existing agreement, are assessed for whether they represent a modification or should be accounted for as a new contract.

We have concluded that the license of intellectual property in certain collaboration and license agreements is not distinct from the perspective of our customers at the time of initial transfer, since we often do not license intellectual property without related technology transfer and research and development support services. Such evaluation requires significant judgment since it is made from the customer's perspective. Our performance obligations under our collaborations may include such things as providing intellectual property licenses, performing technology transfer, performing research and development consulting services, providing reagents, ADCs, and other materials, and notifying the customer of any enhancements to licensed technology or new technology that we discover, among others. We determined our performance obligations under certain collaboration and license agreements as evaluated at contract inception were not distinct and represented a single performance obligation. Upfront payments are amortized to revenue over the performance period. Upfront payment contract liabilities resulting from our collaborations do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by us. For agreements beyond the initial performance period, we have no remaining performance obligations. We may receive license maintenance fees and potential milestones and royalties based on collaborator development and regulatory progress, which are recorded in the period achieved in the case of milestones, and during the period of the related sales for royalties.

When no performance obligations are required of us, or following the completion of the performance obligation period, such amounts are recognized upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as collaboration and license agreement revenues. Sales-based milestones and royalties are recognized as royalty revenue in the period the related sale occurred.

We generally invoice our collaborators and licensees on a monthly or quarterly basis, or upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Research and development expenses

Research and development, or R&D, expenses consist of salaries, benefits and other headcount-related costs of our R&D staff, preclinical activities, clinical trials and related manufacturing costs, lab supplies, contract and outside service fees and facilities and overhead expenses for research, development and preclinical studies focused on drug discovery, development and testing. R&D activities are expensed as incurred.

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third-party clinical trial expenses include investigator fees, site costs, clinical research organization costs, and costs for central laboratory testing and data management. Costs associated with activities performed under co-development collaborations are reflected in R&D expense. In-licensing fees, milestones, maintenance fees and other costs to acquire technologies utilized in R&D for product candidates that have not yet received regulatory approval and that are not expected to have alternative future use are expensed when incurred. Non-refundable advance payments for goods or services that will be used or rendered for future R&D activities are capitalized and recognized as expense as the related goods are delivered or the related services are performed. This results in the temporary deferral of recording expense for amounts incurred for research and development activities from the time payments are made until the time goods or services are provided.

Advertising

Advertising costs are expensed as incurred. We incurred $114.1 million, $88.8 million, and $59.3 million in advertising expenses during 2022, 2021, and 2020, respectively.

Concentration of credit risk

Cash, cash equivalents and investments are invested in accordance with our investment policy. The policy includes guidelines for the investment of cash reserves and is reviewed periodically to minimize credit risk. Most of our investments are in U.S. Treasury securities and are not federally insured. We have accounts receivable from the sale of our products from a small number of distributors, and from our collaborators. We do not require collateral on amounts due from our distributors or our collaborators and are therefore subject to credit risk. We maintain our cash, cash equivalents, and investments at accredited financial institutions that we believe are creditworthy. From time to time, these deposits may exceed federally insured limits.

Allowance for doubtful accounts

We estimate an allowance for doubtful accounts based on our assessment of the collectability of customer accounts. We regularly review the allowance by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. As of December 31, 2022 and 2021, there was no allowance for doubtful accounts, and we recognized no credit losses during the years ended December 31, 2022, 2021, and 2020.

Geographic and customer information

Net product revenues are attributed to countries based on the location of the customer. Royalty revenues and collaboration and licenses agreements revenues are attributed to countries based on the location of the Company's subsidiary associated with the royalty or collaborative arrangement related to such revenues. Over 90% of our revenues and assets are related to operations in the U.S. for all periods presented; however, we have multiple subsidiaries in foreign jurisdictions, including several subsidiaries in Europe.

We sell our products through a limited number of distributors and specialty pharmacies. The following table presents each major distributor or collaborator that comprised more than 10% of total revenue:

	Years ended December 31,		
	2022	2021	2020
Distributor A	34 %	36 %	18 %
Distributor B	27 %	27 %	15 %
Distributor C	16 %	17 %	10 %
Collaborator B	— %	— %	45 %

The following table presents each major distributor or collaborator that accounted for more than 10% of accounts receivable:

	December 31,	
	2022	2021
Distributor A	30 %	29 %
Distributor B	28 %	22 %
Distributor C	17 %	16 %
Collaborator A	9 %	11 %

Major suppliers

The use of a relatively small number of contract manufacturers to supply drugs necessary for our commercial and clinical operations create a concentration of risk for us. For certain components of our approved products and our clinical product candidates we primarily use one source of supply, though other sources are available should we need to change suppliers. For PADCEV, in particular, we rely on Astellas for both commercial and clinical supply as Astellas oversees the manufacturing supply chain. As a form of reducing near-term risk, we endeavor to maintain reasonable levels of drug supply inventory across the supply chain. A change in suppliers or disruption at one of our suppliers, however, could cause a delay or interruption in delivery of drug or clinical trials. Such an event would adversely affect our business.

Income taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement and tax bases of assets and liabilities using tax rates in effect for the year in which the differences are expected to reverse. We have provided a valuation allowance against substantially all our deferred tax assets for all periods presented. A valuation allowance is recorded when it is more likely than not that some portion or all of the net deferred tax asset will not be realized. Future realization of deferred tax assets is dependent upon a number of factors, including the existence of sufficient taxable income based on future earnings, the timing and amount of which is uncertain. The assessment regarding whether a valuation allowance is required considers the evaluation of both positive and negative evidence when concluding whether it is more likely than not that deferred tax assets are realizable. Based upon a review of all available evidence, we determined that it is not more likely than not that the U.S. deferred tax assets will be realized, and therefore the deferred tax assets have been fully offset by a valuation allowance.

We follow the guidance related to accounting for uncertainty in income taxes, which requires the recognition of an uncertain tax position when it is more likely than not to be sustainable upon audit by the applicable taxing authority. If this threshold is met, the tax benefit is then measured and recognized at the largest amount that is greater than 50% likely of being realized upon ultimate settlement.

Share-based compensation

The Company recognizes compensation expense based upon the grant date fair value for our equity awards. The fair value of certain stock options is estimated using the Black-Scholes option pricing model and restricted stock units, or RSUs, is estimated based upon the fair value of our common stock. The fair value of stock options or RSUs, subject to market-based performance metrics, is estimated using a Monte Carlo simulation model.

We use the graded-vesting attribution method for recognizing compensation expense for certain stock options and RSUs. Compensation expense is recognized over the requisite service periods on awards ultimately expected to vest and reduced for forfeitures that are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For performance-based stock options and RSUs, subject to the achievement of pre-determined performance milestones, which may include regulatory milestones or revenue-based milestones, we record compensation expense over the requisite service period once the achievement of the performance-based milestone is considered probable. The vesting of performance-based awards generally includes vesting upon achievement of pre-determined regulatory milestones, revenue-based milestones, or market-based performance metrics, in addition to the passage of time.

At each reporting date, we assess whether achievement of a milestone is considered probable, and if so, record compensation expense based on the portion of the service period elapsed to date with respect to that milestone, with a cumulative catch-up, net of estimated forfeitures. We recognize any remaining compensation expense with respect to a milestone, over the estimated remaining requisite service period.

For performance-based stock options and RSUs, subject to market-based performance metrics, which may include total shareholder return compared to our industry peer group or stock price targets, we record compensation expense over the requisite service periods irrespective of the probability of achieving the market-based condition and compensation expense is not reversed if the market condition is not satisfied.

Comprehensive (loss) income

Comprehensive (loss) income is the change in stockholders' equity from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. Our comprehensive (loss) income is comprised of net (loss) income, unrealized gains and losses on available-for-sale securities, net of income tax provision and foreign currency translation adjustments, net of income tax provision.

Loss contingencies

We are involved in various legal proceedings in the normal course of business. A loss contingency is recorded if it is probable that an asset has been impaired or a liability has been incurred and the amount of the loss can be reasonably estimated. We evaluate, among other factors, the probability of an unfavorable outcome and our ability to make a reasonable estimate and the amount of the ultimate loss. Loss contingencies that are determined to be reasonably possible, but not probable, are disclosed but not recorded. Legal fees incurred as a result of our involvement in legal procedures are expensed as incurred.

Certain risks and uncertainties

Our revenues are derived from net product sales, royalties, and from collaboration and license agreements. Our products are subject to regulation by the FDA in the U.S. and other regulatory agencies outside the U.S., as well as competition by other pharmaceutical companies. Our collaboration and license agreement revenues are derived from a relatively small number of agreements. Each of these agreements can be terminated by our collaborators at their discretion. We are also subject to risks common to companies in the pharmaceutical industry, including risks and uncertainties related to commercial success and acceptance of our products and our potential future products by patients, physicians and payers, competition from other products, regulatory approvals, regulatory requirements, business combinations and product or product candidate acquisition and in-licensing transactions, and protection of intellectual property. Also, drug development is a lengthy process characterized by a relatively low rate of success. We may commit substantial resources toward developing product candidates that never result in further development, achieve regulatory approvals or achieve commercial success. Likewise, we have committed and expect to continue to commit substantial resources towards additional clinical development of our products in an effort to continue to expand our products' labeled indications of use, and there can be no assurance that we and/or our partners will obtain and maintain the necessary regulatory approvals to market our products for any additional indications.

Guarantees

In the normal course of business, we indemnify our directors, certain employees and other parties, including distributors, collaboration partners, lessors and other parties that perform certain work on behalf of, or for us to take licenses to our technologies. We have agreed to hold these parties harmless against losses arising from our breach of representations or covenants, intellectual property infringement or other claims made against these parties in performance of their work with us. These agreements typically limit the time within which the party may seek indemnification by us and the amount of the claim. It is not possible to prospectively determine the maximum potential amount of liability under these indemnification agreements. Further, each potential claim would be based on the unique facts and circumstances of the claim and the particular provisions of each agreement.

Recent accounting pronouncements adopted

In December 2019, the FASB issued “ASU 2019-12, Simplifying the Accounting for Income Taxes.” The objective of the standard is to improve areas of GAAP by removing certain exceptions permitted by ASC Topic 740--Income Taxes and clarifying existing guidance to facilitate consistent application. We adopted the standard on January 1, 2021. The adoption of this ASU did not have a material impact on our financial condition, results of operations, cash flows, or financial statement disclosures.

2. Revenue from contracts with customers

The following table presents our disaggregated revenue for the years presented.

(dollars in thousands)	Years ended December 31, 2022	2021	2020
ADCETRIS	$ 839,272	$ 705,561	$ 658,577
PADCEV	451,427	339,918	222,436
TUKYSA	353,083	333,952	119,585
TIVDAK	62,734	6,135	—
Net product sales	$ 1,706,516	$ 1,385,566	$ 1,000,598
Royalty revenues	$ 164,554	$ 150,523	$ 126,756
Collaboration and license agreement revenues	$ 91,342	$ 38,282	$ 1,048,182
Total revenues	$ 1,962,412	$ 1,574,371	$ 2,175,536

In 2020, collaboration and license agreement revenues included $975.2 million related to our LV and TUKYSA license and collaboration agreements with Merck. See Note 10 for further information.

Contract balances and performance obligations

We had no contract assets or liabilities as of December 31, 2022 and 2021. We recognized no collaboration and license agreement revenues during the years ended December 31, 2022, 2021, and 2020 that were included in deferred revenue as of the beginning of the respective years.

3. Leases

We have operating leases for our office and laboratory facilities with terms that expire from 2023 through 2029. During the years ended December 31, 2022, 2021 and 2020, we recorded $1.2 million, $9.1 million and $7.2 million of right-of-use assets in exchange for lease liabilities, respectively. All of our significant leases include options for us to extend the lease term. None of our options to extend the rental term of any existing leases were considered reasonably certain as of December 31, 2022.

In June 2021, we entered into a lease agreement for an approximately 258,000 square foot building complex to be constructed by the landlord on approximately 20.5 acres of land in Everett, Washington. We intend to use the building for future manufacturing, laboratory, and office space. Under the terms of the lease, base rent is payable at an initial rate of $4.0 million per year, subject to annual escalations of 3% during the initial term of 20 years. The lease commenced in January 2023 and we will record a lease liability and right-of-use assets on our consolidated balance sheet following the lease commencement date. We have an option to renew the lease for two additional terms of ten years each. In addition, we have an option to purchase the premises in the future.

Supplemental operating lease information was as follows:

(dollars in thousands, except term and rate)	Years ended December 31, 2022	2021	2020
Operating lease cost	$ 15,812	$ 16,219	$ 15,013
Variable lease cost	4,454	4,227	3,937
Total lease cost	$ 20,266	$ 20,446	$ 18,950
Cash paid for amounts included in measurement of lease liabilities	$ 17,236	$ 16,814	$ 14,265

	As of December 31, 2022	2021
Weighted average remaining lease term (in years)	5.25	5.87
Weighted average discount rate	4.9 %	5.0 %

Rent expense attributable to non-cancelable operating leases totaled approximately $15.9 million, $16.5 million, and $16.6 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Operating lease liabilities were recorded in the following captions of our consolidated balance sheet as follows:

(dollars in thousands)	As of December 31, 2022	2021
Accrued liabilities and other	$ 14,517	$ 13,905
Operating lease liabilities, long-term	43,474	56,665
Total	$ 57,991	$ 70,570

As of December 31, 2022, future minimum lease payments under the lease agreements were as follows:

(dollars in thousands)	
Years ending December 31,	
2023	$ 17,046
2024	12,714
2025	8,718
2026	8,053
2027	8,053
Thereafter	11,665
Total future minimum lease payments	66,249
Less: imputed interest	(8,258)
Total	$ 57,991

4. Fair Value

We have certain assets that are measured at fair value on a recurring basis according to a fair value hierarchy that prioritizes the inputs, assumptions and valuation techniques used to measure fair value. The three levels of the fair value hierarchy are:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. We consider observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

The fair value hierarchy of assets carried at fair value and measured on a recurring basis was as follows:

	Fair value measurement using:			
(dollars in thousands)	Quoted prices in active markets for identical assets (Level 1)	Other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
December 31, 2022				
Short-term investments—U.S. Treasury securities	$ 1,415,130	$ —	$ —	$ 1,415,130
Other non-current assets—equity securities	3,854	—	—	3,854
Total	$ 1,418,984	$ —	$ —	$ 1,418,984
December 31, 2021				
Short-term investments—U.S. Treasury securities	$ 1,735,202	$ —	$ —	$ 1,735,202
Other non-current assets—equity securities	14,009	—	—	14,009
Total	$ 1,749,211	$ —	$ —	$ 1,749,211

Our short-term debt investments portfolio only contains investments in U.S. Treasury and other U.S. government-backed securities. We review our portfolio based on the underlying risk profile of the securities and have a zero loss expectation for these investments. We also regularly review the securities in an unrealized loss position and evaluate the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. During the years ended December 31, 2022, 2021 and 2020, we recognized no year-to-date credit loss related to our investments, and had no allowance for credit loss recorded as of December 31, 2022.

Our debt securities consisted of the following:

(dollars in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
December 31, 2022				
U.S. Treasury securities	$ 1,416,717	$ 96	$ (1,683)	$ 1,415,130
Contractual maturities (at date of purchase):				
Due in one year or less	$ 1,400,852			$ 1,399,382
Due in one to two years	15,865			15,748
Total	$ 1,416,717			$ 1,415,130
December 31, 2021				
U.S. Treasury securities	$ 1,735,388	$ 12	$ (198)	$ 1,735,202
Contractual maturities (at date of purchase):				
Due in one year or less	$ 1,635,307			$ 1,635,118
Due in one to two years	100,081			100,084
Total	$ 1,735,388			$ 1,735,202

5. Investment and Other Income, Net

Investment and other income, net consisted of the following:

(dollars in thousands)	Years ended December 31, 2022	2021	2020
(Loss) gain on equity securities	$ (10,154)	$ 4,744	$ 11,604
Investment and other income, net	20,809	1,607	7,245
Total investment and other income, net	$ 10,655	$ 6,351	$ 18,849

(Loss) gain on equity securities includes the realized and unrealized holding gains and losses on our equity securities. At times, we hold equity investments in certain companies acquired in relation to a strategic partnership. Shares held at the end of reporting periods are marked to market in our consolidated financial statements, which can result in unrealized gains and losses.

6. Inventories

Inventories consisted of the following:

(dollars in thousands)	December 31, 2022	2021
Raw materials	$ 14,916	$ 12,181
Work in process	357,275	152,635
Finished goods	55,020	35,847
Total	$ 427,211	$ 200,663

We capitalize our commercial inventory costs. Work in process represents inventory at various stages of the production process, which includes costs for materials, labor, and overhead applied during the production process. Inventory that is deployed into clinical, research or development use is charged to research and development expense when it is no longer available for use in commercial sales.

7. Property and equipment

Property and equipment consisted of the following:

(dollars in thousands)	December 31, 2022	2021
Leasehold improvements	$ 238,161	$ 193,635
Laboratory and manufacturing equipment	127,031	104,702
Building	49,942	49,806
Computers, software and office equipment	64,042	52,078
Furniture and fixtures	20,985	17,563
Land	4,771	4,771
	504,932	422,555
Less: accumulated depreciation and amortization	(256,753)	(212,482)
Total	$ 248,179	$ 210,073

Depreciation and amortization expenses on property and equipment totaled $46.7 million, $42.9 million, and $36.0 million for the years ended December 31, 2022, 2021, and 2020, respectively. Leasehold improvements included $58.9 million and $44.0 million of construction in process at December 31, 2022 and 2021, respectively.

8. Accrued liabilities

Accrued liabilities consisted of the following:

(dollars in thousands)	December 31, 2022	December 31, 2021
Clinical trial and related costs	$ 194,006	$ 122,468
Employee compensation and benefits	175,506	139,052
Gross-to-net deductions and third-party royalties	119,289	81,316
Contract manufacturing	21,638	21,867
Other	100,114	89,327
Total	$ 610,553	$ 454,030

9. Income taxes

Our (loss) income before income taxes by jurisdiction consisted of the following:

(dollars in thousands)	Years ended December 31, 2022	2021	2020
U.S.	$ (612,004)	$ (680,398)	$ 613,054
Foreign	9,689	4,693	2,647
Total	$ (602,315)	$ (675,705)	$ 615,701

The provision (benefit) for income taxes consists of the following:

(dollars in thousands)	Years ended December 31, 2022	2021	2020
Current:			
Federal	$ 527	$ —	$ —
State	3,965	(2,553)	3,744
Foreign	2,956	844	224
Total Current	7,448	(1,709)	3,968
Deferred:			
Foreign	545	475	(1,937)
Total Deferred	545	475	(1,937)
Provision (benefit) for income taxes	$ 7,993	$ (1,234)	$ 2,031

A reconciliation of the federal statutory income tax rate to the effective income tax rate is as follows:

	Years ended December 31, 2022	2021	2020
Statutory federal income tax rate	21.0 %	21.0 %	21.0 %
Tax credits	3.8	7.2	(5.4)
State income taxes and other	2.0	4.6	1.5
Valuation allowance	(30.8)	(35.7)	(8.4)
Stock compensation	2.7	3.1	(8.4)
Effective tax rate	(1.3)%	0.2 %	0.3 %

For the year ended December 31, 2022, we recorded a tax expense of $8.0 million primarily related to taxable profits in the U.S. as a result of amendments to Internal Revenue Code (IRC) Section 174 pursuant to the 2017 Tax Cuts and Jobs Act, which took effect January 1, 2022. We had existing federal tax carryforwards sufficient to offset most of the federal liability; however, there were limitations on the use of existing state tax carryforwards. Our income tax provision also reflected taxable profits in foreign jurisdictions.

For the year ended December 31, 2021, we recorded a tax benefit of $1.2 million, consisting of a current tax benefit of $1.7 million and a deferred tax expense of $0.5 million, primarily related to the generation of additional available state research and development tax credits.

For the year ended December 31, 2020, we recorded a provision for income taxes of $2.0 million consisting primarily of $3.7 million of current state taxes offset by a net $1.7 million deferred foreign tax benefit primarily related to the release of a valuation allowance on our foreign deferred tax asset for net operating losses. We had existing federal tax carryforwards sufficient to offset any federal tax liability, and we incurred state tax liabilities of $3.7 million due to limitations on the use of existing state carryforwards against taxable income.

As of December 31, 2022, unremitted earnings of our foreign subsidiaries will be retained indefinitely by the foreign subsidiaries for continuing investment. If foreign earnings were to be repatriated to the U.S., we could be subject to additional insignificant amount of foreign, federal and state income taxes.

Our net deferred tax assets consisted of the following:

	December 31,	
(dollars in thousands)	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 152,834	$ 331,284
Foreign net operating loss carryforwards	2,795	7,566
Tax credit carryforwards	305,151	278,925
Share-based compensation	46,695	41,087
Allowance and accruals	54,442	47,119
Operating lease liabilities	13,337	16,461
Inventory	34,214	14,629
Capitalized research and development	248,704	6,947
Intangibles and amortization	22,758	5,399
Outside basis difference in partnerships	28,828	—
Other	3,124	—
Total deferred tax assets	912,882	749,417
Less: valuation allowance	(897,490)	(730,130)
Total deferred tax assets, net of valuation allowance	15,392	19,287
Deferred tax liability:		
Right-of-use assets	(11,218)	(13,434)
Depreciation	(3,222)	(3,428)
Other	—	(920)
Net deferred tax assets	$ 952	$ 1,505

A valuation allowance of $897.5 million and $730.1 million at December 31, 2022 and 2021, respectively, has been recognized to offset net deferred tax assets where realization of such assets is uncertain. The valuation allowance increased by $167.4 million in 2022, increased by $240.6 million in 2021, and decreased by $46.8 million in 2020, which was mostly related to the changes in our deferred tax asset balances. The 2022 increase in the valuation allowance was primarily related to deferred assets for tax credit carryforwards, share-based compensation, and capitalized research and development expense partially offset by net operating loss utilization. The 2021 increase in the valuation allowance was primarily due to the net operating loss and tax credit generation. The 2020 decrease in the valuation allowance was primarily due to the net operating loss utilization, partially offset by tax credit generation.

At December 31, 2022, we had gross federal NOL carryforwards of $682 million of which $663 million may be carried forward indefinitely and $19 million expire from 2029 to 2036 if not utilized, gross state NOL carryforwards of $171.4 million, gross foreign NOL carryforwards of $33.7 million, and tax credit carryforwards of $328.2 million expiring from 2024 to 2042.

Utilization of the NOL and tax credit carryforwards may be subject to a substantial annual limitation in the event of a change in ownership as set forth in Section 382 of the Internal Revenue Code of 1986, as amended. We have evaluated ownership changes through the year ended December 31, 2021 and believe that it is likely that utilization of NOLs would not be materially limited under Section 382 as of December 31, 2021. It is possible that there has been or may be a change in ownership after this date which would limit our ability to utilize our NOLs. Any limitation may result in the expiration of the NOLs and tax credit carryforwards before utilization.

Unrecognized tax benefits arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of uncertainties. The total amount of unrecognized tax benefit was $35.2 million and $30.3 million as of December 31, 2022 and 2021, respectively. Interest and penalties related to uncertain tax positions, if any, will be recognized as a component of income tax expense. We do not anticipate any significant changes to our unrecognized tax positions or benefits during the next twelve months. Tax years 2001 to 2022 remain subject to future examination for federal, state and foreign income taxes.

A reconciliation of the beginning and ending amount of unrecognized tax benefits was as follows:

	Years ended December 31,		
(dollars in thousands)	2022	2021	2020
Balance at January 1	$ 30,306	$ 23,078	$ 24,018
(Decrease) increase related to prior year tax positions	(661)	1,894	(4,008)
Increase related to current year tax positions	5,600	5,334	3,068
Balance at December 31	$ 35,245	$ 30,306	$ 23,078

10. Collaboration and license agreements

We have collaboration and license agreements with a number of pharmaceutical and biotechnology companies. Revenues recognized under these agreements are disclosed in Note 2.

These agreements generally may be terminated due to material and uncured breaches, insolvency of either party, mutual written consent, unilateral decision of one or either party upon prior written notice, expiration of payment obligations, cessation of development or commercialization of the products, and/or challenges to patents which are subject to the related agreement. Each agreement is discussed in more detail in the following sections.

Takeda ADCETRIS collaboration

We have a collaboration agreement with Takeda ADCETRIS which provides for the global co-development of ADCETRIS and the commercialization of ADCETRIS by Takeda in its territory. We have commercial rights for ADCETRIS in the U.S. and its territories and in Canada. Takeda has commercial rights in the rest of the world. Under the collaboration, we and Takeda can each conduct development activities and equally co-fund the cost of certain mutually agreed development activities. Costs associated with co-development activities are included in research and development expense.

We recognize payments received from Takeda, including progress-dependent development and regulatory milestone payments, reimbursement for drug supplied, and net development cost reimbursement payments, as collaboration and license agreement revenues upon transfer of control of the goods or services over the development period. When the performance of development activities under the collaboration results in us making a reimbursement payment to Takeda, that payment reduces collaboration and license agreement revenues. In addition, we recognize royalty revenues, where royalties are based on a percentage of Takeda's net sales of ADCETRIS in its licensed territories, with percentages ranging from the mid-teens to the mid-twenties based on annual net sales tiers, and sales-based milestones. Takeda bears a portion of third-party royalty costs owed on its sales of ADCETRIS, which is included in royalty revenues.

Astellas PADCEV collaboration

We have a collaboration agreement with Agensys, Inc., which subsequently became an affiliate of Astellas, to jointly research, develop and commercialize ADCs for the treatment of several types of cancer. The collaboration encompasses combinations of our ADC technology with fully-human antibodies developed by Astellas to proprietary cancer targets. Under this collaboration, we and Astellas are co-funding all development costs for PADCEV. We rely on Astellas to supply PADCEV for commercial sales and for our clinical trials, and Astellas oversees the manufacturing supply chain for PADCEV. Costs associated with co-development activities are included in research and development expense and amounted to $132.8 million, $145.4 million, and $99.3 million for the years ended December 31, 2022, 2021, and 2020, respectively.

In 2018, we and Astellas entered into a joint commercialization agreement to govern the global commercialization of PADCEV:

- In the U.S., we and Astellas jointly promote PADCEV. We record sales of PADCEV in the U.S. and are responsible for all U.S. distribution activities. The companies each bear the costs of their own sales organizations in the U.S., equally share certain costs associated with commercializing PADCEV in the U.S., and equally share in any profits realized in the U.S. We and Astellas launched PADCEV in the U.S. in December 2019. Gross profit share payments owed to Astellas in the U.S. are recorded in cost of sales and totaled $207.7 million, $159.0 million, and $104.6 million during the years ended December 31, 2022, 2021, and 2020, respectively.
- Outside the U.S., we have commercialization rights in all countries in North and South America, and Astellas has commercialization rights in the rest of the world, including Europe, Asia, Australia and Africa. The agreement is intended to provide that we and Astellas will effectively equally share in costs incurred and any profits realized in all of these markets. Cost and profit sharing in Canada, the United Kingdom, Germany, France, Spain and Italy are based on product sales and costs of commercialization. In the remaining markets, the commercializing party is responsible for bearing costs and paying the other party a royalty rate applied to net sales of the product based on a rate intended to approximate an equal profit share for both parties.

Either party may opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. Astellas or its affiliates are responsible for overseeing the initial manufacturing supply chain for PADCEV for development and commercial use. However, we are responsible for packaging and labeling in countries in which we sell PADCEV. In addition, we are in the process of establishing a second source manufacturing supply chain, through a combination of internal manufacturing capacity and third parties. In this regard, our manufacturing facility in Bothell, Washington is used to support commercial production of PADCEV antibody.

Genmab TIVDAK collaboration

We have an agreement with Genmab to develop and commercialize ADCs targeting tissue factor, under which we previously exercised a co-development option for TIVDAK. In October 2020, we and Genmab entered into a joint commercialization agreement to govern the global commercialization of TIVDAK. The FDA granted accelerated approval of TIVDAK in September 2021 for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

- In the U.S., we and Genmab co-promote TIVDAK. We record sales of TIVDAK in the U.S. and are responsible for leading U.S. distribution activities. The companies will each hire and maintain 50% of the sales representatives and medical science liaisons, equally share those and certain other costs associated with commercializing TIVDAK in the U.S., and equally share in any profits realized in the U.S. Gross profit share payments owed to Genmab in the U.S. are recorded in cost of sales.
- Outside the U.S., we have commercialization rights in the rest of the world except for Japan, where Genmab has commercialization rights, and certain territories where Zai Lab has commercialization rights, as further described below. In Europe, China, and Japan, we and Genmab equally share 50% of the costs associated with commercializing TIVDAK as well as any profits realized in these markets. In markets outside the U.S. other than Europe, China, and Japan, aside from certain costs specified in the agreement, we are solely responsible for all costs associated with commercializing TIVDAK and will pay Genmab a royalty based on a percentage of aggregate net sales ranging from the mid-teens to mid-twenties.

In September 2022, we announced an exclusive collaboration and license agreement with Zai Lab for the development and commercialization of TIVDAK in mainland China, Hong Kong, Macau, and Taiwan. Under the terms of the agreement, we received an upfront payment of $30.0 million in October 2022 which was recorded in collaboration revenue for the year ended December 31, 2022, and are entitled to receive potential future development, regulatory, and commercial milestone payments, and tiered royalties on net sales of TIVDAK in the Zai Lab territory. Based on our existing collaboration with Genmab, the upfront payment, milestone payments, and royalties will be shared on a 50:50 basis with Genmab.

Gross profit share payments owed to Genmab in the U.S. are recorded in cost of sales and totaled $45.8 million, $3.0 million, and $0.0 during the years ended December 31, 2022, 2021, and 2020, respectively. Costs associated with co-development activities are included in research and development expense and amounted $62.7 million, $63.7 million, and $50.1 million for the years ended December 31, 2022, 2021, and 2020, respectively. Either party may opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. Either party may also opt out of co-development and profit-sharing under the collaboration agreement in return for receiving milestones and royalties from the continuing party. The opt out provisions of the collaboration agreement may also be applied to the joint commercialization agreement. In addition, Genmab may elect to opt out of co-promotion of TIVDAK in the U.S. by providing us with prior written notice.

Merck LV and TUKYSA license and collaboration agreements, and stock purchase agreement

In September 2020, we entered into two license and collaboration agreements, and a stock purchase agreement, with Merck.

Under one of the license and collaboration agreements, referred to as the LV Agreement, we are pursuing a broad joint development program evaluating ladiratuzumab vedotin, or LV, as monotherapy and in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. Pursuant to the LV Agreement, we granted to Merck a co-exclusive worldwide development and commercialization license for LV, and agreed to jointly develop and commercialize LV on a worldwide basis. We received an upfront cash payment of $600.0 million, and we are eligible to receive up to $850.0 million in milestone payments upon the initiation of certain clinical trials and regulatory approval in certain major markets, and up to an additional $1.75 billion in milestone payments upon the achievement of specified annual global net sales thresholds of LV. Each company is responsible for 50% of global costs to develop and commercialize LV and will receive 50% of potential future profits.

In connection with the LV Agreement, we entered into a stock purchase agreement with Merck, referred to as the Purchase Agreement, pursuant to which we agreed to issue and sell, and Merck agreed to purchase 5,000,000 newly issued shares of our common stock, at a purchase price of $200 per share, for an aggregate purchase price of $1.0 billion.

Under the other license and collaboration agreement, referred to as the TUKYSA Agreement, we granted Merck exclusive rights to commercialize TUKYSA in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Pursuant to the TUKYSA Agreement, Merck is responsible for marketing applications for approval in its territory, supported by the results from the HER2CLIMB clinical trial. We retained commercial rights in the U.S., Canada and Europe, where we will record sales. Merck is also co-funding a portion of the TUKYSA global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers. We will continue to lead ongoing TUKYSA global development operational execution. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. We received an upfront cash payment from Merck of $125.0 million and also received $85.0 million in prepaid research and development funding to be applied to Merck's global development cost sharing obligations. We are eligible to receive progress-dependent milestone payments of up to $65.0 million, and are entitled to receive tiered royalties on sales of TUKYSA by Merck that begin in the low twenty percent range and escalate based on sales volume by Merck in its territory. We owe a portion of any non-royalty payments received from sublicensing TUKYSA rights to a technology licensor, as well as a low double-digit royalty based on net sales of TUKYSA by us, and will owe a single-digit royalty based on net sales of TUKYSA by Merck in its territories.

We determined that these agreements are within the scope of ASC 808. Pursuant to ASC 808, we considered other authoritative guidance for distinct units of account related to these agreements, including ASC 606. Our performance obligations within the scope of ASC 606 consisted of the delivery of the LV license and transfer of regulatory information to enable the LV collaboration, the delivery of the TUKYSA license and transfer of regulatory materials for use by Merck in its territory, and supply of commercial TUKYSA inventory to Merck for use in its territory. The LV license and TUKYSA license are functional intellectual property and distinct from the other promises made under the contract. Since we also determined that Merck can benefit from the LV license and the TUKYSA licenses at the time of conveyance, the related performance obligations were satisfied at that point in time. Therefore, we recognized the license revenue under ASC 606 of $725.0 million in collaboration and license agreement revenues during the year ended December 31, 2020.

Potential development, regulatory, and sales-based milestones, and royalties, will be accounted for as variable transaction price related to the LV or TUKYSA licenses under ASC 606. Given the uncertain nature of these payments, we determined they were fully constrained upon entering the agreements and not included in the transaction price. We will re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

We and Merck will share equally in LV global development costs and profits, if any, and Merck is co-funding a portion of the TUKYSA global development plan. We consider the collaborative activities associated with the global development and commercialization of LV, and the global development of TUKYSA, to be units of account within the scope of ASC 808. We recognize development cost sharing proportionately with the performance of the underlying activities, and record Merck's reimbursement of our expenses as a reduction of research and development expenses. Merck's prepayment of $85.0 million towards the TUKYSA global development plan was recorded as a co-development liability in other long-term liabilities on our consolidated balance sheet as of December 31, 2020. As joint development expenses are incurred, we recognize the portion of Merck's prepayment as a reduction of our research and development expenses on our consolidated statements of comprehensive income (loss). As of December 31, 2021, $40.2 million and $15.1 million was the remaining co-development liability in accrued liabilities and other long-term liabilities, respectively. As of December 31, 2022, $15.5 million and $0.0 million was the remaining co-development liability in accrued liabilities and other long-term liabilities, respectively. Sales of TUKYSA drug product supplied to Merck were included in collaboration and license agreement revenues.

Costs associated with co-development activities for the LV and the TUKYSA agreements are included in research and development expense and amounted to $166.3 million, $123.1 million, and $21.8 million for the years ended December 31, 2022, 2021, and 2020, respectively. In addition, costs associated with co-development activities for the other cost sharing agreements related to PADCEV with Merck are included in research and development expense and amounted to $38.5 million, $32.0 million, and $14.0 million for the years ended December 31, 2022, 2021, and 2020, respectively.

The fair market value of 5,000,000 shares of our common stock was $749.9 million, based on the closing price of the last trading day prior to the Purchase Agreement being executed. We accounted for the associated premium of $250.1 million as a freestanding equity-linked instrument under ASC 815. The premium was determined to be variable consideration in the calculation of the total transaction price related to the LV license, and was initially recorded in deferred revenue due to the substantive contingency associated with closing of the sale of shares under the Purchase Agreement. The closing of the sale of the shares pursuant to the Purchase Agreement occurred in October 2020. Upon closing, we recorded the fair market value of the shares issued in stockholders' equity on our consolidated balance sheet. The variable consideration restraint was removed upon the closing of the sale of shares pursuant to the Purchase Agreement, and the premium was recognized in collaboration and license agreement revenues in the quarter and year ended December 31, 2020.

RemeGen license agreement

Effective in September 2021, we and RemeGen Co., Ltd., or RemeGen, entered into an exclusive worldwide licensing agreement to develop and commercialize disitamab vedotin, a novel HER2-targeted ADC. Disitamab vedotin combines the drug-linker technology originally developed by us with RemeGen's novel HER2 antibody. Disitamab vedotin received FDA Breakthrough Therapy designation in 2020 for use in second-line treatment of patients with HER2-expressing, locally advanced or metastatic urothelial cancer who have previously received platinum-containing chemotherapy. Also in 2020, RemeGen announced FDA's clearance of an Investigational New Drug application for a phase 2 clinical trial in locally advanced or metastatic urothelial cancer. Disitamab vedotin is conditionally approved for treating locally advanced metastatic gastric cancer in China, and in July 2021 the National Medical Products Administration of China also accepted a New Drug Application for disitamab vedotin in locally advanced or metastatic urothelial cancer.

Under the terms of the agreement, we obtained exclusive license rights to disitamab vedotin for global development and commercialization outside of RemeGen's territory for an upfront payment of $200.0 million. The license was accounted for as an asset acquisition and the upfront payment was included in research and development expenses for the year ended December 31, 2021. RemeGen retains development and commercialization rights for Asia, excluding Japan and Singapore. We will lead global development and RemeGen will fund and operationalize the portion of global clinical trials attributable to its territory. RemeGen will also be responsible for all clinical development and regulatory submissions specific to its territory. We may pay RemeGen up to $195.0 million in potential milestone payments across multiple indications and products based upon the achievement of specified development goals, and up to $2.2 billion in potential milestone payments based on the achievement of specified regulatory and commercialization goals. RemeGen will be entitled to a tiered, high single digit to mid-teen percentage royalty based on net sales of disitamab vedotin in our territory.

Other collaboration and license agreements

We have other collaboration and license agreements for our technology with a number of biotechnology and pharmaceutical companies. Under these agreements, we have granted research and commercial licenses to use our technology, most often in conjunction with the licensee's technology. In certain agreements, we also have agreed to conduct limited development activities and to provide other materials, supplies and services to our licensees during a specified term of the agreement. We typically receive upfront cash payments and progress- and sales-dependent milestones for the achievement by our licensees of certain events, and annual maintenance fees and support fees for research and development services and materials provided under the agreements. These amounts are recognized as revenue over the performance obligation period if the license is determined not to be distinct from other goods and services provided, or, if there is no performance obligation, upon transfer of control of the goods or services to the customer. We also are entitled to receive royalties on net sales of any resulting products incorporating our ADC technology. Our licensees are solely responsible for research, product development, manufacturing and commercialization of any product candidates under these agreements, which includes the achievement of the potential milestones. For agreements beyond the initial performance period, we have no remaining performance obligations. We may receive license maintenance fees and potential milestones and royalties based on collaborator development and regulatory progress, which are recorded in the period achieved in the case of milestones, and during the period of the related sales for royalties. In the first quarter of 2022, we entered into a collaboration with Sanofi to develop and potentially commercialize multiple novel ADCs. The agreement is an exclusive collaboration that will utilize Sanofi's proprietary monoclonal antibody technology and our proprietary ADC technology for up to three cancer targets. Under the terms of the collaboration, Sanofi will co-fund global development activities and share equally in any future profits. In the first quarter of 2022, the first, of up to three potential targets under the collaboration, was designated, for which Sanofi paid a license fee.

11. In-license agreements

We have in-licensed antibodies, targets and enabling technologies from pharmaceutical and biotechnology companies and academic institutions for use in our pipeline programs and ADC technology. We would potentially owe development, regulatory, and sales-based milestones, and royalties on net sales, as defined, of certain approved products. We were required to pay royalties in the low single digits on net sales of ADCETRIS under the terms of two exclusive license agreements, which expired in 2021.

We are a party to a license agreement in which we were granted an exclusive license to develop, manufacture and commercialize TUKYSA. We pay the licensor a portion of any non-royalty payments received from sublicensing TUKYSA rights, a low double-digit royalty based on net sales of TUKYSA by us, and a single-digit royalty based on net sales of TUKYSA by our sublicensees. The term of the license agreement expires on a country-by-country basis upon the later of the expiration of the last valid claim covering TUKYSA within that country or 10 years after the first commercial sale of TUKYSA within that country.

In September 2022, we entered into an agreement with LAVA Therapeutics to develop and commercialize LAVA-1223, also known as SGN-EGFRd2, a preclinical gamma delta bispecific T-cell engager for EGFR-expressing solid tumors. We received an exclusive global license for SGN-EGFRd2 and the opportunity to exclusively negotiate rights to apply LAVA's proprietary Gammabody™ platform on up to two additional tumor targets. We paid LAVA a $50 million upfront fee in October 2022 and have also agreed to pay LAVA up to approximately $650 million in potential development, regulatory and commercial milestones, as well as royalties ranging from the single digits to the mid-teens on future sales of any licensed products. The license was accounted for as an asset acquisition and the upfront payment was included in research and development expenses for the year ended December 31, 2022.

12. Commitments and contingencies

We have certain non-cancelable obligations under various agreements, including supply agreements relating to the manufacture of our commercial products, and our product candidates that contain annual minimum purchase commitments and other firm commitments when a binding forecast is provided. As of December 31, 2022, our future obligations related to supply and other agreements were as follows:

(dollars in thousands)	
Years ending December 31,	
2023	$ 259,731
2024	76,923
2025	45,198
2026	40,203
2027	3,778
Thereafter	—
Total	$ 425,833

Non-cancelable obligations under these agreements do not include payments that are contingent upon achievement of certain progress-dependent milestones or royalties based on net sales of commercial products. These amounts have been excluded from the table because the events triggering the obligations have not yet occurred.

See Note 3 for our future obligations related to operating leases as of December 31, 2022.

13. Legal matters

We are engaged in multiple legal disputes with Daiichi Sankyo Co. Ltd., or Daiichi Sankyo.

Dispute over ownership of intellectual property

We have been in a dispute with Daiichi Sankyo regarding the ownership of certain technology used by Daiichi Sankyo in its cancer drug Enhertu (fam-trastuzumab deruxtecan-nxki) and certain product candidates. We believe that the linker and other ADC technology used in Enhertu and these drug candidates are improvements to our ADC technology, the ownership of which, we contended, was assigned to us under the terms of a 2008 collaboration agreement between us and Daiichi Sankyo, or the Daiichi Sankyo Collaboration Agreement.

On November 4, 2019, Daiichi Sankyo filed a declaratory judgment action in the United States District Court for the District of Delaware, alleging that we are not entitled to the intellectual property rights under dispute, in an attempt to have the dispute adjudicated in federal court. The case has been stayed and administratively closed by court order.

On November 12, 2019, we submitted an arbitration demand to the American Arbitration Association seeking, among other remedies, a declaration that we are the owner of the intellectual property rights under dispute, monetary damages, and a running royalty. On April 27, 2020, the arbitrator confirmed the dispute should be resolved in arbitration. The arbitration hearing was conducted in June 2021 and April 2022. On August 12, 2022, the arbitrator ruled in favor of Daiichi Sankyo, citing statute of limitations and disagreement with us on the interpretation of the contract. On November 10, 2022, we filed a motion to vacate the arbitration award in the U.S. District Court for the Western District of Washington.

The Daiichi Sankyo Collaboration Agreement provides that judgment rendered by an arbitrator shall include costs of arbitration, reasonable attorneys' fees and reasonable costs for expert and other witnesses. On September 14, 2022, Daiichi Sankyo submitted a petition for approximately $58 million for reimbursement of its legal fees and costs associated with the arbitration. We filed an opposition to Daiichi Sankyo's request on October 12, 2022.

While we oppose any fees being awarded to Daiichi Sankyo, a liability between approximately $14-58 million is reasonably estimable. We have recorded an estimate of our liability for these fees towards the low end of the range in accrued liabilities and selling, general and administrative expenses in our consolidated financial statements as of and for the year ended December 31, 2022. It is reasonably possible the arbitrator will render an award pursuant to Daiichi Sankyo's request that is different from what we have accrued or estimated and that we will need to adjust our estimate in future periods pursuant to the arbitrator's award.

Patent infringement

On October 19, 2020, we filed a complaint in the United States District Court for the Eastern District of Texas to commence an action for infringement of our U.S. Patent No. 10,808,039, or the '039 Patent, by Daiichi Sankyo's importation into, offer for sale, sale, and use in the United States of the cancer drug Enhertu. The remedies sought in this action include, among other remedies, a judgment that Daiichi Sankyo infringed one or more valid and enforceable claims of the '039 Patent, monetary damages and a running royalty.

Daiichi Sankyo (as well as Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP, or AstraZeneca) subsequently filed an action on November 13, 2020 in the U.S. District Court for the District of Delaware seeking a declaratory judgment that Enhertu does not infringe the '039 Patent. The Delaware action has been stayed by court order.

Daiichi Sankyo, Inc. and AstraZeneca also filed two petitions for post-grant review on December 23, 2020 and January 22, 2021 with the U.S. Patent and Trademark Office, or USPTO, seeking to have claims of the '039 Patent cancelled as unpatentable. On June 24, 2021, the USPTO issued a decision denying both petitions for post-grant review. On April 7, 2022, the USPTO granted a request on rehearing and instituted two post-grant review proceedings, but on July 15, 2022, the USPTO issued a new decision denying post-grant review of the claims asserted in the patent infringement action. On February 7, 2023, in response to Daiichi Sankyo and AstraZeneca's second request for rehearing of the denial of the post-grant review to the USPTO and for Precedential Opinion Panel, or POP, review, the Precedential Opinion Panel issued an order denying the request for POP review but directing the USPTO panel evaluating the second rehearing request to make an explicit finding using its own discretion as to whether the post-grant review petition presents a "compelling" showing of invalidity as part of its ruling on the pending second rehearing request. The panel was also directed to rule on the second rehearing request within two weeks from the POP order. On February 14, 2023, the panel decided to institute the post-grant review of the claims of the '039 Patent asserted in the patent infringement action.

On April 8, 2022, a jury in the United States District Court for the Eastern District of Texas found that Daiichi Sankyo willfully infringed the asserted claims of the '039 Patent with its Enhertu product, and also found that the asserted claims were not invalid. The jury further awarded damages of $41.8 million for infringement from October 20, 2020 through March 31, 2022. The U.S. District Court for the Eastern District of Texas also denied Daiichi Sankyo's claim that the '039 Patent should be unenforceable under the equitable theory of prosecution laches, entered judgment in favor of us based on the jury's verdict that Daiichi Sankyo willfully infringed the '039 Patent consisting of pre-trial damages in the sum of $41.8 million, and awarded us pre- and post-trial interest and costs. We have requested a royalty in the range of 10-12% on Daiichi Sankyo's future sales of Enhertu in the United States through November 5, 2024, the current expiration date of the '039 Patent, as well as $12 million for reimbursement of our reasonable attorneys' fees. Pursuant to ASC 450, awards of this nature must be either realized or realizable to be reflected in the company's financial statements. No amounts related to these patent infringement matters have been reflected in our consolidated financial statements as of December 31, 2022.

As a result of these disputes, we have incurred and will continue to incur litigation expenses.

14. Stockholders' equity

In October 2020, we closed the sale of the shares pursuant to the Purchase Agreement, and issued 5,000,000 shares of our common stock to Merck at a purchase price of $200 per share, for proceeds of $1.0 billion. As a result, we recorded $749.9 million in stockholders' equity on our consolidated balance sheet as of December 31, 2020 and recognized the $250.1 million premium attributed to the Purchase Agreement in collaboration and license agreement revenues for the year ended December 31, 2020.

At December 31, 2022, shares of common stock reserved for future issuance are as follows:

(in thousands)	
Stock options and RSUs outstanding	9,888
Shares available for future grant under the 2007 Equity Incentive Plan	4,325
Employee stock purchase plan shares available for future issuance	657
Total	14,870

15. Net (loss) income per share

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted average number of common shares outstanding during the period. Diluted net (loss) income per share is computed by dividing net (loss) income by the weighted average number of common shares and potentially dilutive common shares outstanding during the period. Potentially dilutive common shares include incremental common shares issuable upon the vesting of unvested restricted stock units and the exercise of outstanding stock options, calculated using the treasury stock method.

	Years ended December 31,		
(dollars in thousands, except per share amounts)	2022	2021	2020
Net (loss) income	$ (610,308)	$ (674,471)	$ 613,670
Weighted average common shares outstanding - basic	184,676	182,048	174,834
Effect of potentially dilutive common shares	—	—	7,453
Weighted average common shares outstanding - diluted	184,676	182,048	182,287
Net (loss) income per share - basic	$ (3.30)	$ (3.70)	$ 3.51
Net (loss) income per share - diluted	$ (3.30)	$ (3.70)	$ 3.37

We excluded the potential shares of common stock from the computation of diluted net (loss) income per share because their effect would have been antidilutive. The following table presents the weighted average number of shares that have been excluded for all periods presented:

	Years ended December 31,		
(in thousands)	2022	2021	2020
Stock options and RSUs	9,284	10,001	356

16. Share-based compensation

2007 Equity Incentive Plan

Our 2007 Equity Incentive Plan, or the 2007 Plan, provides for the issuance of our common stock to employees, including our officers, directors and consultants and affiliates. The 2007 Plan was amended and restated in 2020 to reserve an additional 6,000,000 shares thereunder, such that an aggregate of 39,000,000 shares of our common stock were authorized for issuance as of December 31, 2022, and to extend the term of the 2007 Plan through May 2030 unless it is terminated earlier pursuant to its terms. Under the 2007 Plan, we may issue stock options (including incentive stock options and nonstatutory stock options), restricted stock, RSUs, stock appreciation rights and other similar types of awards. We have only issued options to purchase shares of common stock and RSUs under the 2007 Plan, including options and RSUs with time-based or performance-based vesting requirements.

Incentive stock options under the 2007 Plan may be granted only to our employees. The exercise price of an incentive stock option or a nonstatutory stock option may not be less than 100% of the fair market value of the common stock on the date the option is granted, and the options generally have a maximum term of ten years from the date of grant. Generally, options granted to employees under the 2007 Plan vest 25% one year after the grant date and thereafter ratably each month over the following thirty-six months. Generally, RSUs granted to employees vest 25% each year beginning one year after the grant date. Option and RSU grants to non-employee members of our board of directors vest over one year.

The 2007 Plan provides for (i) the full acceleration of vesting of equity awards upon a change in control if the successor company does not assume, substitute or otherwise replace the equity awards upon the change in control; and (ii) the full acceleration of vesting of any equity awards if at the time of, immediately prior to or within twelve months after a change in control of the Company, the holder of such equity awards is involuntarily terminated without cause or is constructively terminated by the successor company that assumed, substituted or otherwise replaced such stock awards in connection with the change in control.

Employee Stock Purchase Plan

Under the current terms of the Amended and Restated 2000 Employee Stock Purchase Plan, or the Employee Stock Purchase Plan, employees can purchase shares of our common stock based on a percentage of their compensation subject to certain limits. Shares are purchased at the lower of 85 percent of the fair market value of our common stock on either the first day or the last day of each six-month offering period. Share issuance activity under the Employee Stock Purchase Plan is disclosed in our consolidated statements of stockholders' equity. In May 2019, our stockholders approved an increase of 1,000,000 shares in the number of shares of common stock authorized for issuance under the Employee Stock Purchase Plan.

Share-based compensation expense

The following table presents our total share-based compensation expense for the periods presented:

	Years ended December 31,		
(dollars in thousands)	**2022**	**2021**	**2020**
Research and development	$ 111,091	$ 79,715	$ 72,749
Selling, general and administrative	110,206	93,402	74,484
Total share-based compensation expense	221,297	173,117	147,233

We recognized a tax benefit of $12.6 million and $55.7 million related to share-based compensation expense for the years ended December 31, 2022 and 2020. No tax benefit was recognized for the year ended December 31, 2021 since there is no taxable income for that year and a valuation allowance is available to offset all potential tax benefits associated with its deferred tax assets.

Valuation assumptions

We calculate the fair value of each time-based stock option award on the date of grant using the Black-Scholes option pricing model. The following weighted-average assumptions were used for the periods indicated:

	2007 Plan			Employee Stock Purchase Plan		
	Years ended December 31,			Years ended December 31,		
	2022	**2021**	**2020**	**2022**	**2021**	**2020**
Risk-free interest rate	3.6 %	0.8 %	0.3 %	1.2 %	0.1 %	1.3 %
Expected lives (in years)	5.6	5.7	5.7	0.5	0.5	0.5
Expected dividend	0 %	0 %	0 %	0 %	0 %	0 %
Expected volatility	42 %	44 %	44 %	40 %	44 %	47 %

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for the expected life of the award. Our computation of expected life was determined based on our historical experience with similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and expectations of future employee behavior. A forfeiture rate is estimated at the time of grant to reflect the amount of awards that are granted but are expected to be forfeited by the award holder prior to vesting. The estimated forfeiture rate applied to these amounts is derived from historical stock award forfeiture behavior. We have never paid cash dividends and do not currently intend to pay cash dividends. Our computation of expected volatility is based on the historical volatility of our stock price.

The fair value of RSUs is determined based on the closing price of our common stock on the date of grant.

Stock option activity

A summary of stock option activity for time-based awards using the Black-Scholes option pricing model is as follows:

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Balance at December 31, 2021	7,374,454	$ 79.53		
Granted	388,124	$ 138.32		
Exercised	(2,098,224)	$ 49.65		
Forfeited/expired	(247,267)	$ 138.17		
Balance at December 31, 2022	5,417,087	$ 92.62	5.93	$ 246,881
Expected to vest	5,297,800	$ 91.39	5.87	$ 246,625
Options exercisable	3,909,647	$ 73.69	4.98	$ 235,780

The weighted average grant-date fair values of options granted with exercise prices equal to market were $60.80, $64.22, and $64.66 for the years ended December 31, 2022, 2021, and 2020, respectively.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the quoted price of our common stock for all options that were in-the-money at December 31, 2022. The aggregate intrinsic value of options exercised was $185.5 million during 2022, $168.7 million during 2021, and $271.0 million during 2020, determined as of the date of option exercise. As of December 31, 2022, there was approximately $35.5 million of total unrecognized compensation cost related to unvested options, as adjusted for expected forfeitures. That cost is expected to be recognized over a weighted-average period of 1.15 years. We utilize newly issued shares to satisfy option exercises.

Stock options subject to market-based performance metrics

During 2022, we granted a total of 675,000 stock options subject to market-based performance metrics to our new Chief Executive Officer and President of Research and Development. These market-based stock options are subject to vesting in tranches tied to the Company's common stock achieving certain price targets. Each tranche will time-vest 1/3 on the date of achievement of the stock price target, 1/3 on the nine-month anniversary of achievement of the stock price target and 1/3 on the 18 month anniversary of achievement of the stock price target. In each case, the option awards are subject to continued employment with the Company. We estimated the fair value of the performance awards subject to market-based performance metrics on the date of grant using the Monte Carlo simulation model. For awards granted during 2022, the Monte-Carlo simulation model used the following assumptions to estimate the fair value: a risk-free interest rate of 4.1%, an expected life of 7.5 years, an expected volatility of 43% based upon historical volatility of our stock price, and a 0% expected dividend.

A summary of stock option activity for stock options subject to marked-based performance metrics using the Monte Carlo simulation model is as follows:

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Balance at December 31, 2021	—	$ —		
Granted	675,000	$ 137.96		
Exercised	—	$ —		
Forfeited/expired	—	$ —		
Balance at December 31, 2022	675,000	$ 137.96	9.86	$ —
Expected to vest	675,000	$ 137.96	9.86	$ —
Options exercisable	—	$ —	0.00	$ —

For the market-based performance awards, the grant-date fair values of options granted with exercise prices equal to market were $67.94 for the year ended December 31, 2022.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the quoted price of our common stock for all options that were in-the-money at December 31, 2022. The aggregate intrinsic value of options exercised was $0.0 million during 2022, determined as of the date of option exercise. As of December 31, 2022, there was approximately $43.2 million of total unrecognized compensation cost related to unvested performance options. That cost is expected to be recognized over a weighted-average period of 2.67 years.

RSU activity

A summary of RSU activity for time-based awards, excluding performance-based RSUs, is as follows:

	Share equivalent	Weighted-average grant date fair value
Non-vested at December 31, 2021	2,358,261	$ 135.07
Granted	1,763,357	$ 161.22
Vested	(784,527)	$ 120.21
Forfeited	(263,374)	$ 143.14
Non-vested at December 31, 2022	3,073,717	$ 152.29

The weighted average grant-date fair values of RSUs granted were $161.22, $157.45, and $159.51 for the years ended December 31, 2022, 2021, and 2020, respectively. The total fair value of RSUs that vested during 2022, 2021, and 2020 (measured on the date of vesting) was $123.0 million, $149.8 million, and $187.1 million, respectively. As of December 31, 2022, there was approximately $251.0 million of total unrecognized compensation cost related to non-vested RSU awards, excluding performance-based RSUs, as adjusted for expected forfeitures. That cost is expected to be recognized over a weighted-average period of 1.70 years. We utilize newly issued shares for RSUs that vest.

Performance-based RSUs

We have granted various performance-based RSU awards to certain senior leadership which includes vesting upon achievement of pre-determined regulatory milestones, revenue-based milestones, or market-based performance metrics.

A summary of activity related to these performance-based RSUs is as follows:

	Share equivalent	Weighted-average grant date fair value
Non-vested at December 31, 2021	802,721	$ 136.10
Granted	99,011	$ 170.01
Vested	(112,592)	$ 136.87
Forfeited	(67,420)	$ 147.05
Non-vested at December 31, 2022	721,720	$ 140.22

As of December 31, 2022, the estimated unrecognized compensation cost related to performance-based RSU awards was approximately $67 million.

Separation Agreement with Former CEO

On May 15, 2022, we entered into a separation agreement with our former CEO which modified certain terms of his previously granted equity awards. The agreement provided for the following equity considerations: acceleration of his outstanding and unvested restricted stock unit and stock option awards by an additional 18 months following his separation; the exercisability of his vested options would be extended to December 31, 2023 (or, if earlier, their 10-year expiration); and 5/6 of his outstanding and unvested restricted stock units subject to performance-based vesting conditions granted in 2019 remain eligible to vest on March 13, 2023, based on actual performance through December 31, 2022. Accounting for the equity awards impacted by the separation agreement resulted in $7.3 million of share-based compensation expense recorded in the second quarter of 2022, net of forfeitures for equity awards that will not vest, other than in the event that a change of control occurs on or prior to December 31, 2023.

17. Employee benefit plan

We have a 401(k) Plan for all of our U.S. employees. Eligible employees may contribute through payroll deductions, and we may match the employees' 401(k) contributions, at our discretion and not to exceed a prescribed annual limit. Under this matching program, we contributed $31.1 million in 2022, $24.8 million in 2021, and $18.0 million in 2020.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

a. *Evaluation of disclosure controls and procedures.* Our Chief Executive Officer and our Chief Financial Officer have evaluated our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this annual report. Based on that evaluation, they have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were, in design and operation, effective at the reasonable assurance level.

   A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

b. *Changes in internal control over financial reporting.* There have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

c. *Management's Annual Report on Internal Control over Financial Reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under the framework in *Internal Control—Integrated Framework,* our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

The effectiveness of our internal control over financial reporting as of December 31, 2022 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Item 8 in this Annual Report on Form 10-K.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

The information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our 2022 fiscal year pursuant to Regulation 14A for our 2023 Annual Meeting of Stockholders, or the 2023 Proxy Statement, and the information to be included in the 2023 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

1. The information required by this Item concerning our executive officers and our directors and nominees for director, including information with respect to our audit committee and audit committee financial expert, may be found under the section entitled "Proposal No. 1—Election of Directors" appearing in the 2023 Proxy Statement. Such information is incorporated herein by reference.
2. The information required by this Item concerning our code of ethics may be found under the section entitled "Proposal No. 1—Election of Directors—Corporate Governance—Code of Conduct and Business Ethics" appearing in the 2023 Proxy Statement. Such information is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item may be found under the sections entitled "Proposal No. 1—Election of Directors—Director Compensation" and "Proposal No. 2 – Advisory Vote on Executive Compensation—Compensation of Executive Officers" appearing in the 2023 Proxy Statement. Such information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

1. The information required by this Item with respect to security ownership of certain beneficial owners and management may be found under the section entitled "Security Ownership of Certain Beneficial Owners and Management" appearing in the 2023 Proxy Statement. Such information is incorporated herein by reference.
2. The information required by this Item with respect to securities authorized for issuance under our equity compensation plans may be found under the sections entitled "Equity Compensation Plan Information" appearing in the 2023 Proxy Statement. Such information is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

1. The information required by this Item concerning related party transactions may be found under the section entitled "Certain Relationships and Related Party Transactions" appearing in the 2023 Proxy Statement. Such information is incorporated herein by reference.
2. The information required by this Item concerning director independence may be found under the section entitled "Proposal No. 1—Election of Directors—Corporate Governance—Director Independence" appearing in the 2023 Proxy Statement. Such information is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item may be found under the section entitled "Proposal No. 5—Ratification of Appointment of Independent Registered Public Accounting Firm" appearing in the 2023 Proxy Statement. Such information is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

1. The following documents are filed as part of this report:

   a. Financial Statements and Report of Independent Registered Public Accounting Firm

   b. Financial Statement Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

   c. Exhibits are incorporated herein by reference or are filed with this report as indicated below (numbered in accordance with Item 601 of Regulation S-K).

2. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
2.1††	License Agreement dated as of August 8, 2021 between RemeGen Co. Ltd. and Seagen Inc.	8-K	000-32405	2.1	9/21/2021
3.1	Fourth Amended and Restated Certificate of Incorporation of Seagen Inc.	10-Q	000-32405	3.1	11/7/2008
3.2	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seagen Inc.	8-K	000-32405	3.3	5/26/2011
3.3	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of Seagen Inc.	8-K	000-32405	3.1	10/8/2020
3.4	Amended and Restated Bylaws of Seagen Inc.	8-K	000-32405	3.1	11/17/2022
4.1	Description of Securities of Seagen Inc.	10-K	000-32405	4.1	2/6/2020
4.2	Specimen Stock Certificate.	10-K	000-32405	4.2	2/12/2021
4.3	Investor Rights Agreement dated July 8, 2003 among Seagen Inc. and certain of its stockholders.	10-Q	000-32405	4.3	11/7/2008
4.4	Registration Rights Agreement, dated September 10, 2015, by and between Seagen Inc. and the persons listed on Schedule A attached thereto.	8-K	000-32405	10.1	9/11/2015
10.1††	Collaboration Agreement between Seagen Inc. and Takeda Manufacturing U.S.A., Inc. dated December 14, 2009.	10-K	000-32405	10.1	2/6/2020
10.2+††	Amendment to the Collaboration Agreement between Seagen Inc. and Takeda Manufacturing U.S.A., Inc. dated November 7, 2022.	—	—	—	—
10.3††	Collaboration and License Agreement dated January 7, 2007 between Seagen Inc. and Agensys, Inc.	10-K	000-32405	10.2	2/9/2022
10.4†	Amendment to the Collaboration and License Agreement between Seagen Inc. and Agensys, Inc. dated effective November 20, 2009.	10-K	000-32405	10.49	3/12/2010
10.5†	Joint Commercialization Agreement dated October 20, 2018 between Seagen Inc. and Agensys, Inc.	10-Q	000-32405	10.1	7/16/2019
10.6††	Amendment to Joint Commercialization Agreement between Seagen Inc. and Agensys, Inc. effective January 1, 2020.	10-Q	000-32405	10.1	7/29/2021

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.7††	Second Amendment to the Collaboration and License Agreement between Seagen Inc. and Agensys, Inc. dated effective January 1, 2022.	10-Q	000-32405	10.3	10/27/2022
10.8††	License and Collaboration Agreement, effective October 7, 2011, between Genmab A/S and Seagen Inc.	10-Q	000-32405	10.1	10/27/2022
10.9††	Joint Commercialization Agreement dated October 19, 2020 between Genmab A/S and Seagen Inc.	10-K	000-32405	10.6	2/12/2021
10.10††	License and Collaboration Agreement related to ladiratuzumab vedotin dated September 13, 2020 between Seagen Inc. and Merck Sharp & Dohme Corp.	10-Q	000-32405	10.1	10/30/2020
10.11††	Stock Purchase Agreement dated September 13, 2020 between Seagen Inc. and Merck Sharp & Dohme Corp.	10-Q	000-32405	10.2	10/30/2020
10.12	License Agreement between Cascadian Therapeutics, LLC (f.k.a. Cascadian Therapeutics, Inc.) and Array BioPharma Inc. dated December 11, 2014.	10-Q	000-32405	10.1	4/26/2018
10.13††	Amendment No. 1 to License Agreement dated April 23, 2020 between Cascadian Therapeutics, LLC (f.k.a Cascadian Therapeutics, Inc.) and Array Biopharma Inc.	10-Q	000-32405	10.5	7/31/2020
10.14	Development and Supply Agreement dated February 23, 2004 between Seagen Inc. and Abbott Laboratories.	10-K	000-32405	10.15	2/27/2015
10.15†	First Amendment to Development and Supply Agreement dated April 17, 2008 between Seagen Inc. and Abbott Laboratories.	10-Q	000-32405	10.1	8/8/2008
10.16†	Second Amendment to Development and Supply Agreement dated June 15, 2009 between Seagen Inc. and Abbott Laboratories.	10-Q	000-32405	10.4	11/4/2011
10.17†	Third Amendment to Development and Supply Agreement dated November 5, 2009 between Seagen Inc. and Abbott Laboratories.	10-Q	000-32405	10.5	11/4/2011
10.18†	Fourth Amendment to Development and Supply Agreement dated April 18, 2010 between Seagen Inc. and Abbott Laboratories.	10-Q	000-32405	10.6	11/4/2011
10.19†	Fifth Amendment to Development and Supply Agreement dated August 24, 2010 between Seagen Inc. and Abbott Laboratories.	10-Q	000-32405	10.7	11/4/2011
10.20††	Sixth Amendment to Development and Supply Agreement dated November 18, 2010 between Seagen Inc. and Abbott Laboratories.	10-K	000-32405	10.26	2/12/2021
10.21††	Seventh Amendment to Development and Supply Agreement dated January 2, 2013 between Seagen Inc. and Abbott Laboratories.	10-Q	000-32405	10.2	10/27/2022
10.22†	Eighth Amendment to Development and Supply Agreement dated July 7, 2015 between Seagen Inc. and AbbVie Inc. (formerly part of Abbott Laboratories).	10-Q	000-32405	10.2	7/30/2015
10.23††	Ninth Amendment to Development and Supply Agreement, effective as of August 28, 2016 between Seagen Inc. and AbbVie Inc. (formerly part of Abbott Laboratories).	10-Q	000-32405	10.1	10/28/2021

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.24††	Tenth Amendment to Development and Supply Agreement, effective as of December 26, 2016 between Seagen Inc. and AbbVie Inc. (formerly part of Abbott Laboratories).	10-K	000-32405	10.33	2/9/2022
10.25††	Eleventh Amendment to Development and Supply Agreement effective July 12, 2018 between Seagen Inc. and AbbVie Inc. (formerly part of Abbott Laboratories).	10-K	000-32405	10.29	2/6/2020
10.26†	Twelfth Amendment to Development and Supply Agreement, effective as of April 25, 2019 between Seagen Inc. and AbbVie Inc. (formerly part of Abbott Laboratories).	10-Q	000-32405	10.2	7/16/2019
10.27††	Thirteenth Amendment to Development and Supply Agreement, effective May 12, 2022 between Seagen Inc. and AbbVie Inc. (formerly part of Abbott Laboratories).	10-Q	000-32405	10.1	7/28/2022
10.28††	Commercial Supply Agreement dated June 13, 2019 between Seagen Inc. and Esteve Quimica, S.A.	10-Q	000-32405	10.1	7/31/2020
10.29††	Amendment No. 1 to Commercial Supply Agreement dated April 14, 2020 between Seagen Inc. and Esteve Quimica, S.A.	10-Q	000-32405	10.2	7/31/2020
10.30††	Commercial Supply Agreement dated April 2, 2020 between Seagen Inc. and Sterling Pharma Solutions Limited.	10-Q	000-32405	10.4	7/31/2020
10.31††	Commercial Supply Agreement between Hovione Farmaciencia, SA and Seagen Inc. dated July 1, 2021.	10-Q	000-32405	10.2	10/28/2021
10.32	Lease Agreement dated December 1, 2000 between Seagen Inc. and WCM 132-302, LLC.	S-1/A	333-50266	10.21	1/4/2001
10.33	First Amendment to Lease dated May 28, 2003 between Seagen Inc. and B&N 141-302, LLC.	10-Q	333-50266	10.1	8/12/2003
10.34†	Second Amendment to Lease dated July 1, 2008 between Seagen Inc. and B&N 141-302, LLC.	10-Q	000-32405	10.1	11/7/2008
10.35††	Third Amendment to Lease dated May 9, 2011 between Seagen Inc. and B&N 141-302, LLC.	10-Q	000-32405	10.2	4/29/2021
10.36†	Fourth Amendment to Lease dated October 24, 2017 between Seagen Inc. and SNH Medical Office Properties Trust, as successor in interest to B&N 141-302, LLC.	10-K	000-32405	10.12	02/15/2018
10.37††	Office Lease dated May 9, 2011 between Seagen Inc. and WCM Highlands II, LLC.	10-Q	000-32405	10.1	4/29/2021
10.38†	First Amendment to Office Lease dated October 24, 2017 between Seagen Inc. and SNH Medical Office Properties Trust, as successor in interest to WCM Highlands II, LLC.	10-K	000-32405	10.14	2/15/2018
10.39††	Lease agreement dated June 12, 2021 between Seagen Inc. and DPIF2 WA 7 Mountain View, LLC.	10-Q	000-32405	10.3	7/29/2021
10.40*	Form of Indemnification Agreement between Seagen Inc. and each of its officers and directors.	S-1/A	333-50266	10.29	1/4/2001

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.41+*††	Employment Agreement dated November 8, 2022, between Seagen Inc. and David Epstein.	—	—	—	—
10.42+*††	Amended and Restated Employment Agreement dated November 8, 2022, between Seagen Inc. and Roger Dansey.	—	—	—	—
10.43*	Amended and Restated Employment Agreement dated February 9, 2022, between Seagen Inc. and Vaughn Himes.	10-K	000-32405	10.54	2/9/2022
10.44*	Amended and Restated Employment Agreement dated February 9, 2022, between Seagen Inc. and Jean Liu.	10-K	000-32405	10.55	2/9/2022
10.45*	Amended and Restated Employment Agreement dated February 9, 2022, between Seagen Inc. and Charles Romp.	10-K	000-32405	10.56	2/9/2022
10.46*	Amended and Restated Employment Agreement dated February 9, 2022, between Seagen Inc. and Todd Simpson.	10-K	000-32405	10.57	2/9/2022
10.47*	Amended and Restated Employment Agreement dated February 9, 2022, between Seagen Inc. and Clay Siegall.	10-K	000-32405	10.52	2/9/2022
10.48*	Letter Agreement, dated as of May 15, 2022, by and between Seagen Inc. and Clay B. Siegall, Ph.D.	8-K	000-32405	99.1	5/15/2022
10.49*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 18, 2012.	10-Q	000-32405	10.1	8/8/2012
10.50*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 16, 2014.	10-Q	000-32405	10.1	8/8/2014
10.51*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 20, 2016.	10-Q	000-32405	10.4	7/26/2016
10.52*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 18, 2018.	10-Q	000-32405	10.2	7/26/2018
10.53*	Amended and Restated 2007 Equity Incentive Plan, effective as of May 15, 2020.	10-Q	000-32405	10.6	7/31/2020
10.54*	Long Term Incentive Plan for ECHELON-1, effective as of May 9, 2016.	10-Q	000-32405	10.2	7/26/2016
10.55*	Long Term Incentive Plan for EV and TV, effective as of September 29, 2017.	10-Q	000-32405	10.4	11/6/2017
10.56*	Senior Executive Annual Bonus Plan, as amended February 9, 2021.	10-K	000-32405	10.66	2/12/2021
10.57*	Amended and Restated 2000 Employee Stock Purchase Plan, effective March 12, 2021.	10-Q	000-32405	10.3	4/29/2021
10.59*	Form Stock Option Agreement for employees under 2007 Equity Incentive Plan.	10-K	000-32405	10.44	3/13/2009
10.60*	Form of Notice of Stock Option Grant and Stock Option Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan.	10-Q	000-32405	10.4	8/5/2011
10.61*	Form of Stock Option Agreement for Long Term Incentive Plan for ECHELON-1 under the Amended and Restated 2007 Equity Incentive Plan.	10-Q	000-32405	10.3	7/26/2016
10.62*	Form of Notice of Stock Option Grant and Stock Option Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.3	7/26/2018

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.63*	Form of Stock Unit Grant Notice and Stock Unit Agreement for non-employee directors under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.4	7/26/2018
10.64*	Form of Time-Based Stock Option Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan (approved May 18, 2018).	10-Q	000-32405	10.8	7/26/2018
10.65*	Form of Stock Option Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved August 30, 2018).	10-Q	000-32405	10.8	10/26/2018
10.66*	Form of Stock Unit Grant Notice and Stock Unit Agreement for US Participants under the Amended and Restated 2007 Equity Incentive Plan (approved October 24, 2018).	10-Q	000-32405	10.11	10/26/2018
10.67*	Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved August 26, 2019).	10-Q	000-32405	10.1	10/30/2019
10.68*	Form of Stock Option Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019).	10-K	000-32405	10.80	2/6/2020
10.69*	Form of Time-Based Stock Unit Grant Notice and Stock Unit Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan (approved December 19, 2019).	10-K	000-32405	10.82	2/6/2020
10.70*	Form of Performance-Based Stock Unit Notice and Stock Unit Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved December 24, 2019).	10-K	000-32405	10.87	2/6/2020
10.71*	Form of Stock Option Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved March 13, 2020).	10-Q	000-32405	10.1	4/30/2020
10.72*	Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved August 16, 2020).	10-Q	000-32405	10.3	10/30/2020
10.73*	Form of Stock Option Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved March 8, 2021).	10-Q	000-32405	10.4	4/29/2021
10.74*	Form of Stock Option Agreement for Non-Employee Directors under the Amended and Restated 2007 Equity Incentive Plan (approved March 8, 2021).	10-Q	000-32405	10.6	4/29/2021
10.75*	Form of Time-Based Stock Unit Grant Notice and Stock Unit Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved March 8, 2021).	10-Q	000-32405	10.7	4/29/2021
10.76*	Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement for employees under the Amended and Restated 2007 Equity Incentive Plan (approved August 16, 2021).	10-Q	000-32405	10.3	10/28/2021
10.77*	Form of Stock Option Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved August 16, 2021).	10-Q	000-32405	10.4	10/28/2021
10.78*	Form of Stock Unit Grant Notice and Stock Unit Agreement for U.S. Participants under the Amended and Restated 2007 Equity Incentive Plan (approved August 16, 2021).	10-Q	000-32405	10.6	10/28/2021

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.79*	Form of Performance-Based Stock Unit Grant Notice and Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved January 18, 2022).	10-K	000-32405	10.1	2/9/2022
10.80*	Form of Stock Unit Grant Notice and Stock Unit Agreement for Non-Employee Directors under the Amended and Restated 2007 Equity Incentive Plan (approved February 10, 2022).	10-Q	000-32405	10.8	4/28/2022
10.81*	Form of Stock Option Agreement for Non-Employee Directors under the Amended and Restated 2007 Equity Incentive Plan (approved February 10, 2022).	10-Q	000-32405	10.9	4/28/2022
10.82*	Form of Global Stock Unit Grant Notice and Global Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved August 15, 2022).	10-Q	000-32405	10.4	10/27/2022
10.83*	Form of Global Performance Stock Unit Grant Notice and Global Performance Stock Unit Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved August 15, 2022).	10-Q	000-32405	10.5	10/27/2022
10.84*	Form of Global Stock Option Grant Notice and Global Stock Option Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved August 15, 2022).	10-Q	000-32405	10.6	10/27/2022
10.85+*	Form of Global Performance Stock Option Grant Notice and Global Performance Stock Option Agreement under the Amended and Restated 2007 Equity Incentive Plan (approved November 8, 2022).	—	—	—	—
21.1+	Subsidiaries of Seagen Inc.	—	—	—	—
23.1+	Consent of Independent Registered Public Accounting Firm	—	—	—	—
31.1+	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).	—	—	—	—
31.2+	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).	—	—	—	—
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.	—	—	—	—
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.	—	—	—	—
101	The following financial statements from the Company's Annual Report on Form 10-K for the year ended December 31, 2022, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive (Loss) Income, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.	—	—	—	—
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	—	—	—	—

+	Filed herewith.
†	Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.
††	Certain confidential information contained in this Exhibit, marked by asterisks in the Exhibit, has been omitted pursuant to Item 601(b)(2) of Regulation S-K.
*	Indicates a management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SEAGEN INC.

Date: February 15, 2023

/S/ DAVID R. EPSTEIN

David R. Epstein
Chief Executive Officer
(Principal Executive Officer)

Date: February 15, 2023

/S/ TODD E. SIMPSON

Todd E. Simpson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ DAVID R. EPSTEIN David R. Epstein	Director and Chief Executive Officer (Principal Executive Officer)	February 15, 2023
/S/ TODD E. SIMPSON Todd E. Simpson	Chief Financial Officer (Principal Financial and Accounting Officer)	February 15, 2023
/S/ FELIX J. BAKER Felix J. Baker	Director	February 15, 2023
/S/ DAVID W. GRYSKA David W. Gryska	Director	February 15, 2023
/S/ TED W. LOVE Ted W. Love	Director	February 15, 2023
/S/ JOHN A. ORWIN John A. Orwin	Director	February 15, 2023
/S/ ALPNA H. SETH Alpna H. Seth	Director	February 15, 2023
/S/ NANCY A. SIMONIAN Nancy A. Simonian	Director	February 15, 2023
/S/ SANDRA M. SWAIN Sandra M. Swain	Director	February 15, 2023
/S/ DANIEL G. WELCH Daniel G. Welch	Director	February 15, 2023

Exhibit 31.1

CERTIFICATIONS

I, David R. Epstein, certify that:

1. I have reviewed this Annual Report on Form 10-K of Seagen Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ David R. Epstein

David R. Epstein

Chief Executive Officer

(Principal Executive Officer)

Date: February 15, 2023

Exhibit 31.2

CERTIFICATIONS

I, Todd E. Simpson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Seagen Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Todd E. Simpson

Todd E. Simpson

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: February 15, 2023

Exhibit 32.1

SEAGEN INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Seagen Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David R. Epstein, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ David R. Epstein

David R. Epstein

Chief Executive Officer

(Principal Executive Officer)

Date: February 15, 2023

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Seagen Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

SEAGEN INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Seagen Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Todd E. Simpson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Todd E. Simpson

Todd E. Simpson

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: February 15, 2023

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Seagen Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Corporate Information

Executive Management

David R. Epstein
Chief Executive Officer

Roger D. Dansey, M.D.
President, Research and Development
and Chief Medical Officer

Natasha A. Hernday
Chief Business Officer

Vaughn B. Himes, Ph.D.
Chief Technical Officer

Jean I. Liu, J.D.
Chief Legal Officer

Peggy M. Pinkston
Chief Human Resources Officer

Todd E. Simpson
Chief Financial Officer

Lee J. Heeson
Executive Vice President, Commercial International

Charles (Chip) R. Romp
Executive Vice President, Commercial U.S.

Board of Directors

Felix J. Baker, Ph.D.
Co-Managing Member, Baker Bros. Advisors LP

David R. Epstein
Chief Executive Officer, Seagen Inc.

David W. Gryska
Former Executive Vice President and Chief Financial Officer,
Incyte Corporation

Ted W. Love, M.D.
Former President and Chief Executive Officer,
Global Blood Therapeutics, Inc.

John A. Orwin
President and Chief Executive Officer, Atreca, Inc.

Alpna H. Seth, Ph.D.
Former President and Chief Executive Officer, Nura Bio Inc.

Nancy A. Simonian, M.D.
Chief Executive Officer, Syros Pharmaceuticals, Inc.

Sandra M. Swain, M.D.
Associate Dean for Research and Development and Professor
of Medicine at the Georgetown University Medical Center

Daniel G. Welch
Former Executive Partner of Sofinnova Ventures

Corporate Headquarters

Seagen Inc.
21823 30th Drive Southeast
Bothell, WA 98021
(425) 527-4000

Website

www.seagen.com

Corporate Responsibility Report

Available at www.seagen.com/who-we-are/corporate-responsibility

Transfer Agent & Registrar

Computershare
P.O. Box 505000
Louisville, KY 40233
(877) 419-8489
www.computershare.com/investor

Legal Counsel

Cooley LLP
Seattle, Washington

Independent Auditors

PricewaterhouseCoopers LLP
Seattle, Washington

Stock Listing

The Company's common stock is traded on the Nasdaq Global Select Market under the symbol SGEN.

Stockholder Inquiries

Communications regarding transfer requirements, lost stock certificates or changes of address should be directed to our Transfer Agent and Registrar. Inquiries regarding the Company and its activities, or requests for a copy of financial documents, such as this annual report and the Form 10-K, may be directed to the Corporate Secretary or the Investor Relations department at our corporate headquarters.

Seagen®

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Forward-Looking Statements This 2022 Annual Report, including Seagen's Annual Report on Form 10-K for the year ended December 31, 2022 included with the 2022 Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, such as those, among others, relating to the Company's 2023 outlook, including anticipated 2023 revenues, costs and expenses; the Company's potential to achieve the noted development and regulatory milestones in 2023 and in future periods, the Company's pipeline; 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 in the U.S. and in other countries; the opportunities for, and the therapeutic and commercial potential of, ADCETRIS, PADCEV, TUKYSA, TIVDAK, the Company's product candidates and those of its licensees and collaborators; the potential for regulatory submission to support regulatory approval; plans with respect to regulatory submissions; potential future milestone payments and royalties under the Company's collaborations; the potential for additional international launches of the Company's products; as well as other statements that are not historical fact. 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 without limitation: the risks that the Company's ADCETRIS, PADCEV, TUKYSA and TIVDAK net sales, revenues, expenses, costs, and other financial guidance may not be as expected; risks and uncertainties associated with maintaining or increasing sales of ADCETRIS, PADCEV, TUKYSA and TIVDAK due to competition, unexpected adverse events, regulatory action, reimbursement, market adoption by physicians, drug pricing reform; impacts associated with COVID-19 or other factors; the risk that the Company or its collaborators may be delayed or unsuccessful in planned clinical trial initiations, enrollment in and conduct of clinical trials, obtaining data from clinical trials, regulatory submissions, and regulatory approvals in the U.S. and in other countries 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 actions and the inherent uncertainty associated with the regulatory approval process; the possibility that the Company may encounter challenges in commercializing its therapeutic agents, including with respect to reimbursement, compliance, operational or other matters; the possibility of delays or setbacks in obtaining pricing and reimbursement approvals or otherwise commercializing PADCEV and TUKYSA in Europe and other jurisdictions; risks relating to the Company's collaboration agreements and its ability to achieve progress dependent milestones thereunder; risks related to the COVID-19 pandemic and resulting economic, financial and healthcare system disruptions; and risks associated with the ongoing military conflict between Russian and Ukraine, related sanctions, and related economic, financial and geopolitical disruptions. Seagen discusses many of these risks, uncertainties and other factors in greater detail under the heading "Item 1A-Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2022 included with this 2022 Annual Report. Seagen 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.

Neither our Corporate Responsibility Report nor any other information contained on our website is incorporated by reference into this annual report.