



ANNUAL
REPORT 2022

immun·gen

Nasdaq: IMGN

MESSAGE TO OUR SHAREHOLDERS

2022 was a landmark year for ImmunoGen as we transitioned to a commercial oncology company following the approval and launch of ELAHERE™ (mirvetuximab soravtansine-gynx). As the first and only antibody-drug conjugate (ADC) approved in ovarian cancer, and the first new drug indicated specifically for platinum-resistant disease since 2014, the addition of ELAHERE as a biomarker-defined treatment option was a major advance for women living with this devastating condition.

Beyond our first product launch, we successfully executed towards our strategic priorities across the business. As we look to establish ELAHERE as the standard of care for folate receptor alpha (FR α)-positive ovarian cancer, we completed enrollment in our confirmatory MIRASOL trial to support full approval of ELAHERE and advanced our broader development program, which targets a large portion of the recurrent disease market. In addition, we progressed the rest of our pipeline with encouraging data for our second pivotal program, pivekimab sunirine (PVEK) in blastic plasmacytoid dendritic cell neoplasm (BPDCN) and acute myeloid leukemia (AML), and clinical milestones for both of our earlier stage assets, IMG936 and IMG151.

Positioning us for the year ahead, we strengthened our leadership team with the recent appointments of Dr. Michael Vasconcelles as Head of Research, Development, and Medical Affairs, Daniel Char as Chief Legal Officer, and Isabel Kalofonos as Chief Commercial Officer. With the momentum generated over the last 12 months, we look forward to a productive year ahead as we grow our business, drive value for shareholders, and deliver more good days for patients.

APPROVAL AND LAUNCH OF ELAHERE

On November 14, 2022, we received accelerated approval of ELAHERE from the US Food and Drug Administration (FDA) for the treatment of FR α -positive platinum-resistant ovarian cancer (PROC).

STRONG MARKET ENTRY

In 2022, we built best-in-class commercial and medical affairs organizations to deliver ELAHERE to eligible patients upon approval and, on December 1, the first patient was treated in the community setting. Since then, we have seen strong performance across each of the key imperatives we set for the business.

- Uptake has been broad and deep. We generated \$2.6 million in net ELAHERE sales in the fourth quarter of 2022, nearly all of which came in December. Through the end of 2022, ~70% of our orders came from nonacademic settings, and ~75% of our orders were from accounts with no prior ELAHERE experience – an important indicator of the level of adoption. In the new year, revenue growth has accelerated as we are seeing a significant percentage of accounts with repeat orders complementing new patient starts.
- Strong demand continues for the VENTANA FOLR1 RxDx Assay, the companion diagnostic to identify patients eligible for treatment with ELAHERE. We estimate that ~1,500 tests were performed through the end of 2022 and volume has since substantially increased. We believe a significant percentage of these tests are being ordered for newly diagnosed patients, and while these patients are not eligible for treatment with ELAHERE today, this will enable oncologists to rapidly incorporate ELAHERE into their future treatment decisions.

- A growing number of payers are including ELAHERE in coverage policies aligned to its label. At the start of the year, 18% of Medicare and 25% of commercial lives were covered; driven by the efforts of our access team, coverage has rapidly increased during the first and second quarters of 2023. In addition, ELAHERE is included in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines as monotherapy and in combination with bevacizumab.
- Finally, our highly active customer-facing teams connected with 70% of their priority targets through the end of December, and these numbers are continuing to rise. Our teams continue to leverage field insights to ensure positive physician and patient experiences with ELAHERE.

We've made a strong start in the early months of launch and are excited to carry this momentum through the rest of the year.

EXPANDING ELAHERE'S LABEL

ELAHERE's broad label, for PROC patients regardless of prior treatment with bevacizumab, reflects the strength of the SORAYA data and reinforces our belief in ELAHERE's potential to become the new standard of care for patients with FR α -positive disease. Building upon this foundation, our development program is designed to move ELAHERE into platinum-sensitive ovarian cancer (PSOC) and position this innovative therapy as the combination agent of choice.

MIRASOL is our Phase 3 confirmatory trial evaluating ELAHERE compared to single-agent chemotherapy in patients with FR α -high PROC. MIRASOL is designed to support full approval in this population in the US and EU. Patient enrollment was completed in mid-2022 and we expect to report top-line data in early May 2023.

PICCOLO is our single-arm Phase 2 trial that expands the evaluation of ELAHERE monotherapy into FR α -high PSOC. Patient enrollment was completed in January 2023 and we expect to report data on the primary endpoint of objective response rate (ORR) before the end of this year.

GLORIOSA is our randomized Phase 3 trial of ELAHERE with bevacizumab maintenance in FR α -high PSOC. This trial is open in the US, and we are actively working to open sites around the globe.

TRIAL 0420 is our single-arm Phase 2 trial of ELAHERE plus carboplatin followed by ELAHERE continuation in PSOC patients with FR α -low, medium, and high expression, designed to inform a registrational path in recurrent PSOC. This trial is open in the US, and we are actively working to open sites in Europe.

PROGRESSING PVEK, OUR SECOND PIVOTAL PROGRAM

We advanced PVEK, our CD123-targeting ADC, in BPDCN and AML. PVEK has demonstrated encouraging safety and efficacy as a monotherapy in BPDCN and in combination regimens for AML.

CADENZA is our registrational trial in frontline BPDCN. We shared initial data demonstrating encouraging activity and favorable tolerability in both *de novo* patients and those with a prior or concomitant hematologic malignancy (PCHM). Following alignment with FDA in 2022 on an efficacy evaluable population of *de novo* patients, we expect to complete enrollment in this pivotal cohort in 2023 and report top-line data next year. Additionally, we continue to enroll PCHM patients to further evaluate PVEK's benefit in this population.

STUDY 802 is our Phase 1b/2 trial of PVEK in combination with venetoclax and azacitidine in AML, which we refer to as the "triplet." We shared encouraging data evaluating the triplet in relapsed/refractory (R/R) and frontline AML at the 2022 ASH Annual Meeting and are moving forward with two expansion cohorts in frontline AML to evaluate the optimal duration of venetoclax dosing in the triplet. Tolerability and efficacy outcomes from these cohorts will guide development of the triplet in pivotal trials in frontline AML. We also expect to initiate an additional cohort, as part of our collaboration with Gilead, of PVEK in combination with magrolimab in R/R AML during the second half of this year.

ADVANCING OUR EARLIER-STAGE PORTFOLIO

We completed dose escalation in our Phase 1 trial of IMG936 in multiple solid tumor types, identified the recommended Phase 2 dose, and initiated expansion cohorts in non-small cell lung cancer (NSCLC) and triple-negative breast cancer (TNBC). We expect to share data from the Phase 1 dose escalation and our initial experience from the expansion cohorts in the second quarter of this year.

With the enrollment of the first patient in our Phase 1 trial of IMG151, our next-generation anti-FR α ADC, we now have four assets in the clinic as we look to provide an option for patients with tumors across the range of FR α expression and build upon the success of ELAHERE.

PARTNERING TO MAXIMIZE OUR PIPELINE AND TECHNOLOGY

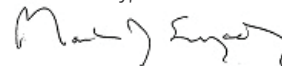
Partnering is a core element of our strategy, allowing us to lever complementary technologies and expertise to expand our pipeline, while providing an additional source of revenue for the Company. In addition to our existing partnership with Huadong Medicine to bring ELAHERE to patients in Greater China and our co-development agreement with MacroGenics for IMG936, over the past 12 months, we established a research collaboration with Oxford BioTherapeutics, multi-target license agreements with Lilly and Vertex, and a clinical collaboration with Gilead.

OUR NEXT CHAPTER AS A FULLY-INTEGRATED ONCOLOGY COMPANY

With strong momentum across all areas of the business, a clear strategy for commercial execution, key regulatory and data milestones on the horizon, and ongoing investment in our pipeline, we look forward to another exciting and productive year in 2023.

We would not be in this position without the remarkable efforts of our team, whose steadfast commitment and drive to deliver more good days to patients inspire me each and every day. I would also like to recognize our board and shareholders for their continued support. Finally, I thank the patients, caregivers, physicians, nurses, and scientific and clinical partners, who enable us to unlock the potential of our science to deliver improved outcomes for people living with cancer.

Sincerely,



Mark J. Enyedy

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-K

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

For the year ended December 31, 2022

OR

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

For the period from to
Commission file number 0-17999

ImmunoGen, Inc.

Massachusetts
(State or other jurisdiction
of incorporation or organization)

04-2726691
(I.R.S. Employer
Identification No.)

830 Winter Street, Waltham, MA 02451
(Address of principal executive offices, including zip code)

(781) 895-0600
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, \$0.01 par value	IMGN	Nasdaq Global Select Market

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 (§229.405 of this chapter) 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 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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Aggregate market value, based upon the closing sale price of the shares as reported by the Nasdaq Global Select Market, of common stock held by non-affiliates at June 30, 2022: \$989,665,866 (excludes shares held by executive officers and directors). Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant, or that such person is controlled by or under common control with the registrant. Common stock outstanding at February 21, 2023: 226,046,108 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement on Schedule 14A to be delivered to shareholders in connection with the Annual Meeting of Shareholders to be held on June 14, 2023 are incorporated by reference into Part III of this report.

ImmunoGen, Inc.

Form 10-K

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Forward-looking statements

The Annual Report on Form 10-K includes forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, these forward-looking statements relate to analyses and other information that are based on beliefs, expectations, assumptions, and forecasts of future results and estimates of amounts that are not yet determinable. These statements also relate to our prospects, future developments, product candidates, and business strategies.

These forward-looking statements are identified by their use of terms and phrases, such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” and other similar terms and phrases, including references to assumptions.

The forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the initiation, cost, timing, progress and results of our current and future research and development activities, preclinical studies, and clinical trials;
- the timing of, and our ability to obtain, regulatory approvals for our current and future product candidates, including full marketing approval of ELAHERE™ in the U.S., as well as for additional indications and additional geographies;
- our ability to advance any product candidates into, and successfully complete, clinical trials;
- the timing of our release of future data;
- the potential benefits of our product candidates;
- the potential benefits of our licensing arrangements;
- our expected sources of future revenues, including from product revenue and licensing arrangements;
- our estimates regarding expenses, capital requirements, the sufficiency of our current and expected cash resources, and our need for additional financing;
- the effect of the novel coronavirus (COVID-19) pandemic on the economy generally and on our business and operations specifically, including our research and development efforts, our clinical trials, and our employees, and the potential disruptions in supply chains and to our third-party manufacturers, including the availability of materials and equipment; and
- our commercialization, marketing, and manufacturing capabilities and strategy.

We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and investors should not place undue reliance on our forward-looking statements. Additionally, these forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to be materially different from those contemplated by our forward-looking statements. These known and unknown risks, uncertainties, and other factors are described in detail in the “Risk Factors” section and in other sections of this report.

The forward-looking statements contained herein represent our views as of the date of this Annual Report on Form 10-K. Except as required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

Risk Factors Summary

Our business is subject to varying degrees of risk and uncertainty. Investors should consider the risks and uncertainties summarized below, as well as the risks and uncertainties discussed further in Part I, Item 1A, “Risk Factors” of this Annual Report on Form 10-K.

Our business is subject to the following principal risks and uncertainties:

- We have a history of operating losses, expect to incur significant additional operating losses, and may never be profitable.
- There is substantial doubt about our ability to continue as a going concern.

- If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market ELAHERE or our product candidates.
- Our prospects are highly dependent on the success of our only approved product, ELAHERE, which received FDA approval under an accelerated approval pathway. If we are unable to maintain approval for, or successfully commercialize, ELAHERE, our business, financial condition, results of operations, as well as our prospects, could be adversely affected.
- If our Antibody-Drug Conjugate technology does not produce safe, effective, and commercially viable products or if such products fail to obtain or maintain FDA approval, our business will be severely harmed.
- Clinical trials for ELAHERE, our product candidates, and those of our collaborators will be lengthy and expensive, and their outcome is uncertain.
- Interim, top-line, or preliminary data from our clinical trials that we announce may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We may be unable to compete successfully.
- If we are unable to protect our intellectual property rights adequately, the value of our technology and our product candidates could be diminished.
- We rely on a third-party to develop, manufacture, and commercialize the companion diagnostic for ELAHERE, and any delay or interruption in supply could negatively impact our commercial activities.
- Side effects, serious adverse events, or other undesirable properties associated with ELAHERE or our product candidates could delay or halt clinical trials, affect our ability to obtain or maintain regulatory approval, limit the commercial profile reflected in product labeling, or negatively affect market acceptance and commercial sales.
- We have received orphan drug designation for ELAHERE and other product candidates for specified indications; we may seek additional orphan drug designation for additional indications and for our other drug candidates. However, we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.
- As our business grows, we will become subject to additional healthcare regulation and enforcement by various government entities, and our failure to strictly adhere to these regulatory regimes could have a detrimental impact on our business.
- We depend on our key personnel, and we must continue to attract and retain key employees and consultants.
- Our stock price may be volatile and fluctuate significantly and results announced by us and our collaborators or competitors could cause our stock price to decline.

Note Regarding Third-Party Trademarks

KADCYLA[®] is a registered trademark of Genentech, Inc. PROBODY[™] is a trademark of CytomX. ELZONRIS[®] is a registered trademark of Menarini Group. Any other trademarks referred to in this Annual Report on Form 10-K are the property of their respective owners.

PART I

Item 1. *Business*

We are a commercial-stage biotechnology company focused on developing and commercializing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer patients more good days. We call this our commitment to “target a better now.”

An ADC with our proprietary technology comprises an antibody that binds to a target found on tumor cells and is conjugated to one of our potent anti-cancer agents as a “payload” to kill the tumor cell once the ADC has bound to its target. ADCs are an expanding class of anticancer therapeutics, with twelve approved products and the number of agents in development growing significantly in recent years.

We have established a leadership position in ADCs with a portfolio of differentiated product candidates to address both solid tumors and hematologic malignancies. We have set four strategic priorities for the business:

- execute the commercial launch for ELAHERE™ (mirvetuximab soravtansine-gynx) (ELAHERE);
- expand the ELAHERE label by moving into platinum-sensitive ovarian cancer;
- advance our clinical pipeline of novel ADCs for hematologic and solid tumors; and
- strengthen and expand our pipeline through both internal discovery and external partnerships.

We believe that sound execution of these prioritized activities will create substantial short-and long-term value for shareholders, employees, patients, and other stakeholders in the Company.

ELAHERE (Mirvetuximab Soravtansine)

Approval and Launch

ELAHERE is a first-in-class ADC targeting folate receptor alpha (FR α), a cell-surface protein over-expressed in a number of epithelial tumors, including ovarian, endometrial, and non-small-cell lung cancers. On November 14, 2022, the U.S. Food and Drug Administration (FDA) granted accelerated approval for ELAHERE for the treatment of adult patients with FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. The accelerated approval of ELAHERE was based on efficacy and safety outcomes from SORAYA, a single-arm trial of ELAHERE in patients with platinum-resistant ovarian cancer whose tumors express high levels of FR α . Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. Patients eligible for treatment with ELAHERE are selected by the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay developed by Roche Tissue Diagnostics (RTD), which was also approved by the FDA on November 14, 2022. We completed the build out of our U.S. commercial infrastructure in 2022 and initiated sales in the U.S. in November 2022.

Ongoing Development

In addition to SORAYA, we are conducting MIRASOL, a randomized Phase 3 clinical trial designed to support full approval of ELAHERE. In July of 2022, we completed enrollment in MIRASOL and expect to report top-line data from this trial in the second quarter of 2023. If MIRASOL is successful, we plan to submit a marketing authorisation application, or MAA, for approval of ELAHERE for the treatment of adult patients with FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens with the European Medicines Agency, or EMA, in the second half of 2023. Additionally, our partner, Huadong Medicine, expects to submit a biologics license application to the National Medical Products Administration (NMPA) of China for ELAHERE in the same indication in the second half of 2023 to support potential approval and launch of ELAHERE in Greater China in 2024.

Beyond platinum-resistant ovarian cancer, our strategy is to move ELAHERE into platinum-sensitive disease, and to position the product as the combination agent of choice in ovarian cancer. To this end, in January 2023, we completed patient enrollment in PICCOLO, a single-arm trial of ELAHERE monotherapy in later-line FR α positive platinum-sensitive patients, and plan to report on the primary endpoint before the end of 2023. We have also generated encouraging data in recurrent platinum-sensitive disease with the combination of ELAHERE plus carboplatin and are supporting investigator sponsored trials (ISTs) with this combination in a single arm trial in the neoadjuvant setting and in a randomized trial comparing ELAHERE combined with carboplatin to standard of care in patients with recurrent platinum-sensitive disease. We also initiated a single-arm Phase 2 trial (0420) of this combination followed by ELAHERE continuation in FR α -low, medium, and high patients with platinum-sensitive disease. Results from this trial and our ongoing ISTs will inform a path to the potential registration for ELAHERE plus carboplatin and, in parallel, could support compendia listing for this combination. Finally, we have initiated GLORIOSA, a randomized Phase 3 trial of ELAHERE plus bevacizumab maintenance in FR α -high recurrent platinum-sensitive disease that we believe could support label expansion.

Pivekimab Sunirine

Pivekimab sunirine (PVEK), formerly known as IMG632, is an ADC comprised of a high-affinity antibody designed to target CD123 with site-specific conjugation to a DNA-alkylating payload of the novel IGN (indolinobenzodiazepine pseudodimer) class. Our IGNs are designed to alkylate DNA without cross-linking, which has provided a broad therapeutic index in preclinical models. We are advancing PVEK in clinical trials for patients with

blastic plasmacytoid dendritic cell neoplasm (BPDCN) and acute myeloid leukemia (AML).

BPDCN is a rare form of blood cancer, with an annual incidence of between 500 and 1,000 patients in the US. In October 2020, the FDA granted Breakthrough Therapy designation for PVEK for the treatment of patients with relapsed or refractory BPDCN. Based on feedback from the FDA, we amended our ongoing 801 Phase 2 trial, known as CADENZA, to include a new cohort of up to 20 frontline BPDCN patients.

Initial enrollment in CADENZA did not distinguish between de novo BPDCN patients and those who presented with a prior or concomitant hematologic malignancy (PCHM). Although complete responses have been observed in BPDCN patients who present with PCHM, most will not achieve full hematologic recovery due to the impact of their prior or concomitant malignancy. For these patients, we believe that achieving a complete response with partial hematological recovery (CRh) is a potentially important measure of clinical benefit.

In data from the first ten patients in the pivotal CADENZA frontline cohort, we observed: 2 of 4 de novo patients achieved CR (complete response)/CRc (clinical complete response); and 4 of 6 PCHM patients achieved CR/CRc/CRh. In addition, in three frontline patients (2 de novo, 1 PCHM) enrolled prior to the opening of the pivotal cohort, all three patients achieved CR/CRc.

A Type B meeting was held in August 2022 regarding these initial data from the CADENZA trial. Based on FDA feedback on trial design provided in this meeting, the efficacy analysis will be conducted in de novo BPDCN patients with CR/CRc as the primary endpoint and the key secondary endpoint of duration of CR/CRc. We will enroll up to 20 de novo patients for purposes of the efficacy analysis. We will also continue to enroll PCHM patients in CADENZA to further evaluate PVEK in this population. The Company expects to report top-line data on the primary and key secondary endpoints in 2024.

We are also conducting our 802 trial for PVEK, which is a Phase 1b/2 trial designed to determine the safety, tolerability, and preliminary antileukemia activity of PVEK when administered in combination with azacytidine and venetoclax to patients with relapsed and frontline CD123-positive AML. Having identified the recommended Phase 2 dose for the triplet, patients are accruing in both expansion cohorts. In December 2022, safety and efficacy findings in relapsed refractory AML and initial data in frontline AML was presented at the American Society of Hematology Annual Meeting. In the first 10 frontline patients enrolled, 5/10 (50%) patients achieved a CR and 3/4 (75%) patients tested had a minimal residual disease (MRD)-negative CR. Based upon these results, the Company will continue enrollment in two frontline AML expansion cohorts to optimize the duration of venetoclax therapy. In addition, in December 2022, the Company announced a clinical collaboration with Gilead Sciences, Inc. to study PVEK in combination with magrolimab in relapsed refractory AML and expects to initiate this cohort under the 802 trial in the second half of 2023.

Other Pipeline Programs

We continue to advance our earlier-stage pipeline programs. IMGC936 is an ADC in development with MacroGenics, Inc. that is designed to target ADAM9, an enzyme over-expressed in a range of solid tumors and implicated in tumor progression and metastasis. IMGC936 incorporates a number of innovations, including antibody engineering to extend half-life, site-specific conjugation with a fixed drug-antibody ratio to enable higher dosing, and a next-generation linker and payload designed for improved stability and bystander activity. Phase 1 dose escalation was completed and expansion cohorts in non-small cell lung cancer and triple-negative breast cancer initiated in the second half of 2022. We expect to provide initial data from these cohorts in the second quarter of 2023.

IMGN151 is our next generation anti-FR α product candidate in development. This ADC integrates innovation in each of its components, which we believe may enable IMGN151 to address patient populations with lower levels of FR α expression, including tumor types outside of ovarian cancer. We began enrollment in a Phase I clinical trial evaluating IMGN151 in patients with recurrent endometrial cancer and recurrent, high-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancers in January 2023.

Collaborations and Out-Licenses

Over the last 40 years, we believe ImmunoGen has assembled the most comprehensive “toolbox” in the ADC field. Our platform technology combines advanced chemistry and biochemistry with innovative approaches to antibody optimization, with a focus on increasing the diversity and potency of our payload agents, advancing antibody-payload linkage and release technologies, and integration of novel approaches to antibody engineering. These capabilities have enabled us to generate a pipeline of novel candidates with potent anti-tumor activity and favorable safety profiles that we can develop as monotherapies and in combination with existing and novel therapies.

Collaborating on ADC development with other companies allows us to enhance our capabilities, extend the reach of our proprietary platform, mitigate expenses, and generate revenue. We have selectively licensed restricted

access to our ADC platform technology to other companies to expand the use of our technology and to provide us with cash to fund our own product programs. These agreements typically provide the licensee with rights to use our ADC platform technology with its antibodies or related targeting vehicles to a defined target to develop products. The licensee is generally responsible for the development, clinical testing, manufacturing, registration, and commercialization of any resulting product candidate. As part of these agreements, we are generally entitled to receive upfront fees, potential milestone payments, royalties on the sales of any resulting products, and research and development funding based on activities performed at our collaborative partner's request.

Below is a table setting forth our current licensed ADC partnerships and status of the most advanced program in each partnership:

Partner	Licensed targets/compounds	Status of Most Advanced Program
Roche	HER2, 4 other ¹	Marketed
Huadong	ELAHERE – Greater China	Phase 3
Viridian	IGF-1R non-cancer radiopharmaceuticals	Phase 3
CytomX	CD166, EpCAM	Phase 2
Debiopharm	CD37 ²	Phase 2
Bayer	Mesothelin	Phase 1
Novartis	CCR7	Phase 1
Oxford BioTherapeutics/Menarini	CD205 ³	Phase 1
Fusion	Undisclosed	Phase 1
Lilly	Undisclosed	Preclinical
Magenta	Undisclosed	Preclinical

¹ Undisclosed.

² Debiopharm has an exclusive license for Debio 1562 (formerly known as IMG529).

³ Oxford BioTherapeutics and Menarini are developing MEN 1309, an ADC targeting CD205 and utilizing our DM4 payload, pursuant to a sublicense from Amgen, which in turn licensed our maytansinoid ADC technology to develop and commercialize ADCs targeting CD205.

Below is a brief description of material business relationships underlying certain of the foregoing programs. For more information concerning these relationships with partners, including their ongoing financial and accounting impact on our business, please read Note C, Collaboration and License Agreements, to our audited consolidated financial statements included in this Annual Report on Form 10-K.

Huadong

In October 2020, we entered into a collaboration and license agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (Huadong) a subsidiary of Huadong Medicine Co., Ltd., under which Huadong will exclusively develop and commercialize ELAHERE in the People's Republic of China, Hong Kong, Macau, and Taiwan, which we refer to as Greater China. Under the terms of the collaboration and license agreement, we received a non-refundable upfront payment of \$40 million and are eligible to receive additional payments of up to \$265.0 million as certain development, regulatory, and net sales milestones are achieved. We are also eligible to receive tiered low double digit to high teen royalties as a percentage of ELAHERE commercial sales by Huadong in Greater China. Through December 31, 2022, the Company had received an aggregate of \$15.0 million in milestone payments under this agreement. Although we hold the MAA, Huadong is responsible for the development and commercialization of ELAHERE in Greater China except in limited circumstances. In addition, we granted Huadong a right of first negotiation if we determine to enter into an agreement to grant a third party rights in Greater China to develop or commercialize a product, other than ELAHERE, that specifically binds to FR α . We retain all rights to ELAHERE in the rest of the world. The standard termination provisions discussed below apply to this license.

Lilly

In February 2022, we entered into a license agreement with Eli Lilly and Company (Lilly), pursuant to which we granted Lilly worldwide exclusive rights to research, develop, and commercialize antibody-drug conjugates based on the Company's novel camptothecin technology. Under the terms of the license agreement, we received a non-refundable upfront payment of \$13.0 million, reflecting initial targets selected by Lilly. During 2022, pursuant to the terms of the agreement, Lilly selected additional targets for which we received an additional \$13.0 million in non-refundable payments. Lilly may select a pre-specified number of additional targets, with the Company eligible to receive an additional \$19.5 million in exercise fees if Lilly licenses the full number of remaining additional targets over a specified period following the effective date of the license agreement, with the potential for up to \$1.7 billion in development and sales-based milestone payments if all targets are selected and all milestones are realized. In addition, we are entitled to receive tiered royalties, on a product-by-product basis, as a percentage of worldwide annual net sales by Lilly, based on certain net sales thresholds. Lilly is responsible for all costs associated with the research, development, and commercialization of any ensuing products. The standard termination provisions discussed below apply to this license.

Standard Termination Provisions

Standard termination provisions in our license agreements state that the partner may terminate the agreement for convenience at any time upon prior written notice to us. The agreement may also be terminated by either party for a material breach by the other, subject to notice and cure provisions. We may also terminate certain of these agreements upon the occurrence of specified events. Upon termination, the partner's rights to our intellectual property with respect to the applicable target are canceled and could then be used by us or re-licensed for that target. Unless earlier terminated, each agreement will continue in effect until the expiration of partner's royalty obligations, which are determined on a product-by-product and country-by-country basis. For each product and country, royalty obligations commence upon first commercial sale of that product in that country and extend until the later of either the expiration of the last-to-expire ImmunoGen patent covering that product in that country or the expiration for that country of the minimum royalty period specified in the agreement.

Patents, Trademarks and Trade Secrets

ImmunoGen has a substantial and robust intellectual property portfolio comprising over 1,800 issued patents and over 700 pending patent applications on a worldwide basis. Our intellectual property strategy centers on obtaining high quality patent protection directed to various embodiments of our proprietary technologies and product candidates. Using this strategy, our ADC technology and our product candidates are protected through a multi-layered approach. In this regard, we have patents and patent applications covering antibodies and other cell binding agents, linkers, cytotoxic payload agents (e.g., tubulin-acting maytansinoids, DNA-alkylating IGNs, and DNA-acting camptothecins), conjugation methodologies and complete ADCs, comprising one or more of these components, as well as methods of making and using each of the above. Typically, multiple issued patents and pending patent applications cover various embodiments of each of ImmunoGen's and our licensees' product candidates.

We consider our tubulin-acting maytansinoid, DNA-alkylating IGN, and DNA-acting camptothecin cytotoxic payload agent technologies to be key components of our overall patent strategy. With regard to our tubulin-acting maytansinoid cytotoxic payload agents, we currently own 22 issued U.S. patents covering various embodiments of our maytansinoid technology including those with claims directed to certain maytansinoids, including DM4 and DM21, and methods of manufacturing DM1, DM4, and DM21, as well as methods of using the same. These issued patents are expected to remain in force until various times between 2023 and 2038. With regard to our IGN payload agents, we have 39 issued U.S. patents covering various aspects of our DNA-acting cytotoxic payload agents, which will expire at various times between 2030 and 2038. With regard to our camptothecin agents, we have an issued U.S. patent covering various aspects of our camptothecin cytotoxic payload agents, which expires in 2040. In addition, we have received or are applying for comparable patent protection in other major commercial and manufacturing jurisdictions, including Europe, Japan, and China. In nearly all cases for our maytansinoid, IGN, and camptothecin patent portfolios, we have additional pending patent applications disclosing and claiming many other related and strategically important embodiments of these technologies which, upon issuance or grant, will extend our patent protection term over these technologies by several additional years.

Our intellectual property strategy also includes pursuing patents directed to linkers, antibodies, conjugation methods, ADC formulations and the use of specific antibodies and ADCs to treat certain diseases. In this regard, we have 22 issued patents related to many of our linker technologies, as well as additional pending patent applications disclosing and claiming many other related and strategically important embodiments of these linker technologies, including methods of making the linkers and antibody maytansinoid conjugates comprising these linkers. These issued patents are expected to remain in force until various times between 2023 and 2034. We also have 23 issued U.S. patents

covering methods of assembling ADCs from their constituent antibody, linker, and cytotoxic payload agent moieties. These issued patents will expire between 2026 and 2039. In nearly all instances for both our linker and conjugation patent portfolios, we have additional pending patent applications disclosing and claiming many other related and strategically important embodiments of these technologies which, upon issuance or grant, would extend our patent protection term over these technologies by several additional years. In addition, we have received or are applying for comparable patents in other major commercial and manufacturing jurisdictions including Europe, Japan, and China.

We also file, prosecute, and maintain a substantial portfolio of patents and patent applications specifically directed to ImmunoGen's and our licensees' ADC candidates. In this regard, we craft a detailed patent protection strategy for each ADC as it approaches clinical evaluation. Such strategies make use of the patents and patent applications described in the preceding paragraphs, as well as ADC-specific filings, to create a multi-layered and multi-jurisdictional patent protection approach for each ADC as it enters the clinic. These ADC-specific patent strategies are intended to provide the exclusivity basis for revenue and royalties arising from commercial development of each of ImmunoGen's and our licensees' ADCs. In addition to the platform patent strategy described above and specific to ELAHERE, we have 21 issued U.S. patents and 15 pending U.S. applications covering various embodiments of the composition of matter and methods of treatment using ELAHERE, expiring at various times between 2031 and 2043. We have filed 5 applications for patent term extension of patents covering various aspects of ELAHERE with the U.S. Patent and Trademark Office. We expect the U.S. Patent and Trademark Office to deem one or more of these patent term extension applications allowable. We will elect to have the term of one of the patents underlying the patent term extension applications extended for the period of time set forth in the application for patent term extension. With respect to PVEK, we have 6 issued U.S. patents and 5 pending U.S. applications covering various embodiments of the composition of matter and methods of treatment using PVEK, expiring at various times between 2036 and 2043.

We expect our continued independent and collaborative work in each of these areas will lead to other patent applications. We will be the owner of all patents covering our independently generated inventions. In all other instances, we expect to either be the sole owner or co-owner of any patents covering collaboratively generated inventions insofar as they relate to co-developed products or our ADC platform technology, or otherwise have an exclusive or non-exclusive license to the technology covered by such patents.

We cannot provide assurance that pending patent applications will issue as patents or that any patents, if issued, will provide us with adequate protection against competitors with respect to the covered products, technologies, or processes. Defining the scope and term of patent protection involves complex legal and factual analyses and, at any given time, the result of such analyses may be uncertain. In addition, other parties may challenge our patents in litigation or administrative proceedings resulting in a partial or complete loss of certain patent rights owned or controlled by ImmunoGen. Furthermore, as a patent does not confer any specific freedom to operate, other parties may have patents that may block or otherwise hinder the development and commercialization of our technology.

In addition, many of the processes and much of the know-how that are important to us depend upon the skills, knowledge, and experience of our key scientific and technical personnel, which skills, knowledge, and experience are not patentable. To protect our rights in these areas, we require that all employees, consultants, advisors, and collaborators enter into confidentiality agreements with us. Further, we require that all employees enter into assignment of invention agreements as a condition of employment. We cannot provide assurance, however, that these agreements will provide adequate or any meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use or disclosure of such trade secrets, know-how, or proprietary information. Further, in the absence of patent protection, we may be exposed to competitors who independently develop substantially equivalent technology or otherwise gain access to our trade secrets, know-how, or other proprietary information.

Competition

We focus on highly competitive areas of product development. Our competitors include major pharmaceutical companies and other biotechnology firms. For example, Mersana Therapeutics, Eisai, and Sutro BioPharma have clinical-stage ADCs targeting platinum resistant ovarian cancer, and Pfizer, Seattle Genetics, Roche, Astellas, AstraZeneca, Daiichi Sankyo, GlaxoSmithKline, AbbVie, and the Menarini Group have programs to attach a cell-killing small molecule to an antibody for targeted delivery to cancer cells. Pharmaceutical and biotechnology companies, as well as other institutions, also compete with us for promising targets for antibody-based therapeutics, for obtaining licenses and collaboration agreements with other companies to develop targets for antibody-based therapeutics, and in recruiting highly qualified scientific personnel. Additionally, there are non-ADC therapies available and/or in development for the cancer types we and our partners are targeting. Many competitors and potential competitors have substantially greater scientific, research, and product development capabilities, as well as greater financial, sales, marketing, and human resources than we do. In addition, many specialized biotechnology firms have formed

collaborations with large, established companies to support the research, development, and commercialization of products that may be competitive with ours.

In particular, competitive factors within the antibody and cancer therapeutic market include:

- the safety, efficacy, and convenience of products;
- the timing of regulatory approvals and commercial introductions;
- special regulatory designation of products, such as orphan drug and breakthrough therapy designations; and
- the effectiveness of marketing, sales, and reimbursement efforts.

Our competitive position depends on a combination of factors. These include effectively pursuing the development of proprietary products, the implementation of clinical development programs, the ability to appropriately manufacture, sell, and market our products, and the procurement of patent protection for our products. In addition, we must secure sufficient capital resources to accomplish all of the previously mentioned activities.

Continued development of conventional and targeted chemotherapeutics by large pharmaceutical companies and biotechnology companies may result in new compounds that may compete with our product candidates. Antibodies developed by certain of these companies have been approved for use as cancer therapeutics. In the future, new antibodies or other targeted therapies may compete with our product candidates. Other companies have created or have programs to create potent cell-killing agents for attachment to antibodies. These companies may compete with us for technology out-license arrangements.

Managing the Impact of the COVID-19 Pandemic

Since the first quarter of 2020, although we have experienced some delays or disruptions due to the COVID-19 pandemic, we have successfully continued to move our clinical trials forward while adapting to meet the evolving challenges of the pandemic. We implemented business continuity plans in March 2020 that enabled our workforce to remain productive while working from home until mid-September 2021, at which time our workforce returned to the office. From a regulatory perspective, since the beginning of the pandemic, we have received timely reviews of our submissions to the FDA and other health authorities covering our clinical trial applications. From a manufacturing and supply chain perspective, we believe we have sufficient inventory on hand for all of our ongoing and near-term clinical trials and to support the launch and continued commercialization of ELAHERE. COVID-19 may impact our commercial activities for ELAHERE, including patient access to testing and identification, but we will conduct commercial and medical affairs field activities in virtual formats where in-person interactions are not feasible.

Regulatory Matters

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, and export and import of drug products. A new drug must be approved by the FDA through the new drug application, or NDA, process and a new biologic must be approved by the FDA through the biologics license application, or BLA, process before it may be legally marketed in the U.S.

U.S. Drug Development Process

In the U.S., the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act (FDCA) and in the case of biologics, also under the Public Health Service Act (PHSA) and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, and local statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to adverse administrative or judicial actions. These actions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any such administrative or judicial action could have a material adverse effect on our business.

The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical and other nonclinical laboratory tests, animal studies, and formulation studies according to current Good Laboratory Practices (cGLP) or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to current Good Clinical Practices (cGCP) to establish the safety and efficacy of the proposed drug for its intended use;
- development and approval of a companion diagnostic if the FDA or the sponsor believes that its use is essential for the safe and effective use of a corresponding product;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice (cGMP) to assure that the facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality, and purity; and
- the FDA's review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a clinical protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some nonclinical testing may continue even after the IND is submitted and clinical trials have begun. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about ongoing or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the sponsor submits additional information that alleviates the FDA's concerns, and the FDA notifies the sponsor that the hold has been lifted.

Each clinical trial must be conducted under the supervision of one or more qualified investigators in accordance with cGCP requirements in accordance with a protocol for each phase of the clinical trial included as part of the IND, and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. A local or central institutional review board (IRB) acting on behalf of each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the trial until completed, and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- **Phase 1:** The product candidate is initially introduced into healthy human subjects and tested for safety and dosage tolerance, absorption, metabolism, distribution, and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- **Phase 2:** This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- **Phase 3:** These trials are undertaken to further evaluate dosage, clinical efficacy, and safety in an expanded patient population at geographically dispersed clinical trial sites and to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4, may be conducted after initial marketing approval. These trials are used to gain additional information about the use of the approved drug in the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of post-approval trials as a condition of approval of an NDA or BLA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected or serious patient reactions. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. Phase 1, Phase 2, and Phase 3 testing may not be completed successfully within any specified period, if at all.

During the development of a new drug, sponsors may request meetings with the FDA to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Most sponsors of clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of all trial-related information, and it is possible that data and other information from trials involving drugs that never garner approval could require disclosure in the future.

Companion Diagnostics

For ELAHERE, (and potentially other of our product candidates), we work with collaborators to develop or obtain access to *in vitro* companion diagnostic tests to identify appropriate patients for these targeted therapies. For example, we partnered with RTD to develop a companion diagnostic device for ELAHERE. In conjunction with the FDA's approval of ELAHERE, the agency also approved the VENTANA FOLR1 RxDx Assay as a companion diagnostic device to select patients eligible for treatment with ELAHERE.

If the FDA believes that a diagnostic test is essential for the safe and effective use of a corresponding therapeutic product, the FDA may require the sponsor to develop, and obtain contemporaneous clearance or approval for a companion diagnostic. Companion diagnostics can be used to identify patients likely to be more responsive to a particular therapy or at increased risk for serious side effects as a result of treatment with a particular therapeutic product. They may also be useful for monitoring the response to treatment for the purpose of adjusting treatment or doses to achieve improved safety or effectiveness.

Companion diagnostics are regulated by the FDA as medical devices. The FDA applies a risk-based approach to determine the regulatory pathway for companion diagnostics. This means that the regulatory pathway will depend on the level of risk to patients, based on the intended use of the companion diagnostic device and the controls necessary to provide a reasonable assurance of safety and effectiveness. The two primary types of marketing pathways for medical

devices are clearance of a premarket notification under Section 510(k) of the FDCA, or 510(k), and approval of a premarket approval application (PMA). We expect that any companion diagnostic developed for use with our drug candidates will utilize the PMA pathway. If the diagnostic test and the therapeutic drug are studied together to support their respective approvals, the clinical trial must meet both the IND requirements and the FDA's companion diagnostic requirements that apply to clinical trials of significant risk devices.

The FDA expects that the therapeutic sponsor will address the need for a companion diagnostic device in its therapeutic product development plan and that, in most cases, the therapeutic product and its corresponding companion diagnostic device will be developed contemporaneously.

PMAs must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical, and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation (QSR) which requires manufacturers to follow design, testing, control, documentation, and other quality assurance procedures. The FDA's review of an initial PMA may require several years to complete.

After approval, the use of a companion diagnostic device with a therapeutic product will be stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product. In addition, a diagnostic test that was approved through the PMA process or one that was cleared through the 510(k) process and placed on the market will be subject to ongoing regulatory requirements, including requirements related to device labeling and promotion, registration and listing, QSR, and medical device reporting.

U.S. Review and Approval Processes

The results of product development, preclinical and other non-clinical studies, and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may analyze and interpret data differently than we analyze and interpret the same data. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure, and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured to assure compliance with cGMPs and may also inspect clinical trial sites to assure compliance with GCPs.

NDAs or BLAs receive either standard or priority review. Priority review, which is requested at the time of BLA or NDA submission, is designed to expedite the review for drugs that provide meaningful therapeutic benefit to patients over existing treatments. Priority review for an NDA for a new molecular entity and original BLAs will be 6 months from the date that the NDA or BLA is filed, compared to 10 months under standard review. Although the FDA's goal is to take action on priority review applications within 6 months, the agency does not always meet this goal and the review process may be significantly extended by requests for additional information or clarification from the FDA. Priority review does not change the standards for approval, but may expedite the approval process.

After the FDA evaluates an NDA or BLA, it will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete, and the application will not be

approved in its present form. A complete response letter usually describes the specific deficiencies in the NDA or BLA identified by the FDA and may require additional clinical data, such as an additional Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a complete response letter is issued, the sponsor has one year to resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy (REMS) to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if one is required. A REMS could include medication guides, physician communication plans, or other elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

The Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs, BLAs, and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or the FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data need to be collected before the pediatric clinical trials begin. Orphan disease indications are exempt from PREA. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, submit a request for approval of a pediatric formulation.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA's approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the filing of the relevant NDA.

The FDCA provides a five-year period of marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or 505(b)(2) NDA for another drug that contains the same active moiety where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the first applicant.

The FDCA also provides three years of data exclusivity for an NDA or 505(b)(2) NDA (or supplement thereto) that contains reports of new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant and are deemed by the FDA to be essential to the approval of the application, such as clinical

investigations for new indications, strength, or routes of administration. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving 505(b)(2) NDAs or ANDAs for drugs containing the original active agent.

Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the U.S. Under the Best Pharmaceuticals for Children Act (BPCA) an additional six months of marketing exclusivity may be available if a sponsor conducts clinical trials in children in response to a written request from the FDA (Written Request). If the Written Request does not include clinical trials in neonates, the FDA is required to include its rationale for not requesting those clinical trials. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described clinical trials. To date, we have not received any Written Requests.

Biologics Price Competition and Innovation Act of 2009

The Patient Protection and Affordable Care Act, which included the Biologics Price Competition and Innovation Act of 2009 (BPCIA), amended the PHSA to create an abbreviated approval pathway for two types of “generic” biologics—biosimilars and interchangeable biologic products, and provides for a twelve-year data exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric clinical trials are performed and accepted by the FDA, the twelve-year data exclusivity period will be extended for an additional six months. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. An interchangeable product is a biosimilar product that meets additional requirements that show, among other things, that the product will produce the same clinical result as the reference product in any given patient. In addition, for products administered to a patient more than once, the effects of switching back and forth between the interchangeable product and a reference product on safety and efficacy will have to be evaluated. An interchangeable product may be substituted for the reference product by the pharmacy without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical trials to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage, and strength, and the production facility must meet standards designed to assure product safety, purity, and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

The FDA has issued a number of final and draft guidance documents in order to implement the law and will likely continue to publish new guidance as new issues relating to biosimilars and interchangeability are identified. The guidance documents provide the FDA’s current thinking on approaches to demonstrating that a proposed biological product is biosimilar to or interchangeable with, a reference product. Although the FDA intends to issue additional guidance documents in the future, the absence of final guidance documents covering all issues does not prevent a sponsor from seeking licensure of a biosimilar or interchangeable product under the BPCIA, as evidenced by the products already approved by the FDA.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA;

the posting will also indicate whether a drug is no longer designated as an orphan drug. More than one product candidate may receive an orphan drug designation for the same indication. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan drug exclusivity. Orphan drug exclusivity means that the FDA cannot approve another sponsor's marketing application for the same product for the same indication, except in very limited circumstances. For example, the FDA may approve a subsequent application for the same product in the same indication if the product is clinically superior to the previously approved drug. Additionally, orphan drug exclusivity may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

Expedited Review and Approval; Breakthrough Therapy Designation

The FDA has various programs, including Fast Track and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for the FDA's review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious diseases and fill an unmet medical need. The request may be made at the time of IND submission and generally no later than the pre-BLA or pre-NDA meeting. The FDA will respond within 60 days of receipt of the request. Although Fast Track does not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug.

Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). A sponsor may request Breakthrough Therapy designation at the time that the IND is submitted, or no later than at the end-of-Phase 2 meeting. The FDA will respond to a Breakthrough Therapy designation request within sixty days of receipt of the request. A drug that receives Breakthrough Therapy designation is eligible for all Fast-Track designation features, intensive guidance on an efficient drug development program, beginning as early as Phase I, and commitment from the FDA involving senior managers. In October 2020, we announced that the FDA granted Breakthrough Therapy designation for pivekimab for the treatment of patients with relapsed or refractory BPDCN.

Accelerated approval provides an earlier approval of drugs to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that demonstrates an effect on a surrogate endpoint, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit or on an intermediate clinical endpoint that is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit. Discussions with the FDA about the feasibility of an accelerated approval typically begin early in the development of the drug in order to identify, among other things, an appropriate endpoint. Accelerated approval does not change the standards for approval, but may expedite the approval process. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-approval clinical trials to confirm the appropriateness of the surrogate marker trial. Failure to conduct required post-approval trials, confirm a clinical benefit during post-approval trials, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for therapeutic candidates approved under accelerated regulations are subject to prior review by the FDA. ELAHERE was granted accelerated approval based on the results of the SORAYA trial and we plan to seek full approval on the basis of the confirmatory Phase 3 MIRASOL trial.

Post-Approval Requirements

Once an approval is granted, the sponsor will be required to comply with all post-approval regulatory requirements as well as any specific post-approval commitments that the sponsor has undertaken as part of the approval process. After approval, some types of changes to the approved product, such as adding new indications, certain

manufacturing changes, additional labeling claims, and required additional testing are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs 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 cGMP and other laws and regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in regulatory or enforcement actions.

Approved drug products, such as ELAHERE, are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with the FDA's promotion and advertising requirements. Compliance with these requirements will require us to expend significant time, money, and effort.

The FDA strictly regulates labeling, advertising, promotion, and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. If a company, including any agent of the company or anyone speaking on behalf of the company, is found to have promoted the drug for an indication that is not in the approved label, the company may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA may withdraw an approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, may result in revisions to the approved labeling to add new safety information, requirements to conduct post-approval studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and issuance of corrective information.

From time to time, legislation is drafted, introduced, and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance, or interpretations changed, or what the impact of such changes, if any, may be.

Other Healthcare Laws

In the U.S., activities of pharmaceutical manufacturers are subject to numerous other federal, state, and local laws designed to, for example, prevent fraud and abuse; promote transparency in interactions with others in the healthcare industry; protect the privacy of individual information; and ensure integrity of research or protect human subjects involved in research. These laws are enforced by various federal and the state enforcement authorities and non-

compliance, or alleged non-compliance, with such laws could adversely affect our reputation, our business and our financial results. See “*Risk Factors – Risks Related to Government Regulation.*”

We may be subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws (which typically prohibit soliciting, offering, receiving, or paying anything of value to generate healthcare business reimbursable by third party payors, including Medicare and Medicaid), and false claims laws (which generally prohibit anyone from knowingly and willingly presenting, or causing to be presented, any false or fraudulent claims for payment for reimbursed drugs or services to third-party payors, including Medicare and Medicaid). Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance, or court decisions that apply the laws to particular industry practices.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers, including laws that require manufacturers to adopt certain compliance standards; disclose financial interactions with health care providers to the government and public; or report pricing information or marketing expenditures. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to challenge.

We may need to obtain and maintain licenses for our manufacturing and distribution activities in the states in which we operate or distribute our products.

We are subject to federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs. Reporting requirements are complex and, in some instances, require reporting manufacturers to make reasonable assumptions in interpreting their obligations.

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain, or store personally identifiable information. Numerous U.S. federal and state laws govern the collection, use, disclosure, and storage of personal information. See “*Risk Factors - Risks Related to Our Business and Industry.*”

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Foreign Regulation

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain the FDA’s approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from place to place, and the time to obtain these approvals may be longer or shorter than that required for the FDA’s approval.

Under the European Union regulatory regime, a company may submit marketing authorization applications under a centralized, decentralized, or mutual recognition procedure. Where the product is intended to be marketed in one EU member state, a national application for a marketing authorization is filed. The centralized procedure is compulsory for medicinal products produced by biotechnology, designated orphan medicines, advanced-therapy medicines such as gene-therapies, and those medicinal products containing new active substances for specific indications such as the treatment of HIV, AIDS and immune dysfunctions, cancer, neurodegenerative diseases, diabetes, and viral diseases, and is optional for other medicines, which are highly innovative. Under the centralized procedure, a single marketing authorization application is submitted to the European Medicines Agency (EMA) where it will be evaluated by the CHMP. A favorable CHMP opinion typically results in a single marketing authorization granted by the European Commission in an implementing decision, known as a centralized marketing authorization. A centralized marketing authorization is valid for all European Union member states and, by extension (after taking the corresponding national implementing measures), in Norway, Iceland, and Liechtenstein. In general, the initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days, excluding clock-stops. Clock-stops allow the applicant the necessary time to provide additional information in response to questions raised by

the CHMP. The clock-stops considerably extend the time taken by the CHMP to complete the evaluation of a marketing authorization application. Ordinarily, within 67 days of receipt of the positive scientific opinion provided by the EMA, the European Commission will issue a binding decision on the marketing authorization application.

The decentralized procedure allows marketing authorization applications to be submitted simultaneously in two or more EU member states, whereas the mutual recognition procedure must be used if the product has been authorized in at least one EU member state on a national basis, and the applicant seeks approval progressively of the same medicinal product in one or more EU member state(s). Both the decentralized and mutual recognition procedures provide for approval by one or more “concerned” member state(s) based on an assessment of an application performed by one “reference” member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member state(s). The reference member state prepares a draft assessment and drafts of the related materials within 120 days of the receipt of a valid application. Within 90 days of receiving the reference member state’s positive assessment report, each concerned member state must approve the assessment report and related materials, unless they identify a potential serious risk to public health. Under the mutual recognition procedure, the concerned member state(s) have the same 90-day period to recognize the marketing authorization in the reference member state. The decentralized procedure contemplates a single clock-stop at day 105, which may extend the process for completing the assessment procedure. In either case, if there is a disagreement between member states during the assessment of the submitted data based on concerns about serious risks to public health, the Coordination Group for Mutual Recognition and Decentralised Procedures will consider the matter and seek to reach a conclusion within 60 days. If this is not possible, the reference member state can escalate the issue to the EMA for arbitration. The purely national procedure results in a marketing authorization in a single EU member state.

In relation to the United Kingdom, high quality marketing authorization applications can be submitted for an expedited 150-day assessment to be initiated. At least 90 days prior to the intended marketing authorization application submission date, applicants should request a pre-submission meeting from the Medicines and Healthcare products Regulatory Agency (MHRA). At this meeting, the applicant will provide a short summary of the dossier and, if necessary, request input on specific issues, such as consideration for an orphan marketing authorization, conditional marketing authorization or marketing authorization under exceptional circumstances. When the marketing authorization applications is submitted to the MHRA, the clock will start when the application is validated for completeness of dossier for the regulatory review to commence. The assessment process involves two phases which are separated by a ‘clock-off’. At Day 80 constituting the Phase 1 of the assessment procedure, matters requiring clarification will be raised with the applicant as a letter requesting further information (RFI). Applicants must address these matters within 60 days. Phase 2 of the marketing authorization assessment process begins as soon as the MHRA receives the applicant’s responses to the RFIs. By day 150, the MHRA will provide a decision on approvability of the product. If the MHRA proposes to refuse the grant of the marketing authorization, the applicant can request a review of the decision.

In the European Union, orphan designations are assessed by the EMA’s Committee for Orphan Medicinal Products for binding decisions to be issued by the European Commission to promote the development of medicinal products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions which either affect not more than five in 10,000 persons in the EU, or where it is unlikely that the marketing of the medicinal product in the EU would generate sufficient return to justify the necessary investment in its development. In each case, there can be no satisfactory method of diagnosis, prevention or treatment of the condition already authorized (or, if such a method exists, the product would be a significant benefit to those affected by the condition).

If the European Commission grants an orphan designation, the developer will be entitled to financial incentives such as reduction of fees or fee waivers. If orphan status is maintained when the marketing authorization is granted, the medicinal product will benefit from certain economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another “similar medicinal product” applicant can show that its product is safer, more effective, or otherwise clinically superior to the orphan-designated product. The 10-year market exclusivity can also be broken by another company developing a similar medicinal product if the marketing authorization holder is unable to supply sufficient quantities of the marketed orphan medicinal product. A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The period of market exclusivity can be reduced if the medicinal product no longer meets the orphan drug designation criteria at the end of the fifth year, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. As in the U.S., we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe

enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective, or otherwise clinically superior to the orphan-designated product.

An equivalent regime is in place in the United Kingdom. Under the United Kingdom's regime, there is no pre-authorization orphan designation and instead a decision is made at the point of the marketing authorization grant.

Reimbursement

Significant uncertainty exists regarding the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of ELAHERE and any other products for which we may obtain approval depend, in part, on the availability of coverage and the adequacy of reimbursement from third-party payors.

Within the U.S., third-party payors include government authorities or government healthcare programs, such as Medicare and Medicaid (which provides prescription drug benefits to low-income individuals), and private entities, such as managed care organizations, private health insurers and other organizations. Third-party payors may limit coverage of certain drug products or may manage utilization of a particular product (e.g., by requiring pre-approval (known as "prior authorization") for coverage of particular prescriptions (to allow the payor to assess medical necessity)). A third-party payor's decision to provide coverage for a drug product does not mean that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain net price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate.

Third-party payors are increasingly challenging the price and examining the cost-effectiveness of new products and services in addition to their safety and efficacy. To obtain or maintain coverage and reimbursement for any approved drug product, we may need to collect real-world evidence and conduct pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain or maintain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product or, if they do, the level of payment may not be sufficient to allow sales of a product at a profit. Thus, obtaining and maintaining reimbursement status is complex and costly.

Within the U.S., we may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicare and Medicaid or to sell products to government purchasers.

In the U.S., there have been ongoing efforts by federal and state governments to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare generally and drugs specifically. *See "Risk Factors – Risks Related to Government Regulation."* Healthcare reform efforts or any future legislation or regulatory actions aimed at controlling and reducing healthcare costs, including through measures designed to limit reimbursement, restrict access, or impose unfavorable pricing modifications on pharmaceutical products, could impact our ability to obtain or maintain coverage and adequate reimbursement for any approved products which could materially harm our business and financial results.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and prices generally tend to be significantly lower.

Companion Diagnostics

Under the EU regulatory regime, namely Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices (IVD), companion diagnostics (CDx) are classified as Class C devices, the second highest risk level of IVD. In order to place a CDx on the EU market, the general safety and performance of the CDx must be subject to a conformity assessment, which involves a notified body, an independent body designated by a regulatory authority in an EU Member State to assess the conformity with the regulatory requirements under the IVDR.

As part of the conformity assessment procedure, the notified body will seek a scientific opinion on the suitability of the CDx with the corresponding medicinal product from either a competent authority of an EU member state or the EMA. Where the CDx is to be used exclusively with a medicinal product that falls within the mandatory scope of the centralized procedure, then the EMA must be consulted. If the corresponding medicinal product has already been authorized, the notified body will consult the competent authority responsible for the authorization.

To initiate this process the notified body will provide an “intention-to-submit-letter” to the EMA at least 3 months prior to the planned submission date of request for a scientific opinion on suitability. This letter also triggers the timely appointment of the rapporteur by the CHMP or, in the case of advanced therapy medicinal products, a Committee for Advanced Therapies (CAT) rapporteur will be appointed and the CHMP coordinator will work closely with them.

After the EMA’s acceptance of the “intention-to-submit-letter”, the notified body can submit questions concerning timing, regulatory or procedural aspects to the EMA within 2 months of the planned submission and request a pre-submission meeting with the EMA and relevant stakeholders.

The IVDR requires the EMA’s consultation to be based on the draft summary of safety and performance and draft instructions for use of the device as submitted by the notified body. Aspects including the scientific validity of a biomarker, analytical performance and clinical performance are assessed whereas the technical documentation dossier for the device, including the adequacy of the analytical measures used to assess these aspects is assessed by the notified body as part of the conformity assessment.

The EMA will provide its opinion within 60 days of the start of its scientific assessment, with a maximum extension of a further 60 days on justified grounds. If further clarification is required by the CHMP/CAT, a list of questions may be issued to the notified body within this 60-day extension. The CHMP will then issue a scientific opinion to the notified body on the suitability of the device in relation to the corresponding medicinal product by, at the latest, the end of this extension period. The notified body will then give due consideration to this opinion when issuing its decision and will convey a final decision to the EMA in the form of a formal notification to the EMA.

Manufacturing

We contract with third-party contract manufacturers (CMOs) for the manufacture of our product candidates for both our clinical and potential commercial needs. Our CMO network manufactures antibody, linker, and payload, and conjugates the foregoing to create bulk drug substance of our product candidates and processes the bulk drug substance into vialled and labeled drug product for use in humans. Although we are reliant on third parties to manufacture our product candidates, we have personnel with extensive manufacturing experience to oversee the relationships with our CMOs.

CMOs are subject to extensive governmental regulations, and we depend on them to manufacture our product candidates in accordance with cGMP. We have an established quality assurance program designed to ensure that the CMOs involved in the manufacture of product candidates do so in accordance with cGMP and other applicable U.S. and foreign regulations. We believe that our current CMO network complies with such regulations.

Human Capital Resources

As of December 31, 2022, we had 277 full-time employees, of whom 155 were engaged in research and development activities. Of the 155 research and development employees, 116 employees hold post-graduate degrees, of which 44 hold Ph.D. degrees and 12 hold M.D. degrees. We consider our relations with our employees to be good. None of our employees are covered by a collective bargaining agreement. We believe our employee relations are good.

We have entered into confidentiality agreements with all of our employees, members of our board of directors, and consultants. Further, we have entered into assignment of invention agreements with all of our employees.

Our key human capital management objectives are to attract, retain, and develop the highest quality talent. These objectives are critical to our success and our ability to increase the value we provide for patients, shareholders, and stakeholders. We have several initiatives in place that support these objectives:

- Enhancement of our culture through efforts aimed at making the workplace more engaging and inclusive, such as team events, service days, and wellbeing programs.
- Commitment to diversity, equity, and inclusion across all aspects of our organization, including in our hiring, promotion, and development practices. At ImmunoGen, we are an equal opportunity employer where prejudice, racism, and intolerance are unacceptable.

- Development of employees through trainings and mentorship opportunities to prepare them for critical roles and leadership positions for the future.
- Reward and support our employees through robust compensation packages, including competitive base pay, incentive compensation and equity programs, and provide a range of benefits, including 401(k) plan, healthcare and insurance benefits, paid time off, flexible work schedules, paid family and medical leave, and health and wellbeing programs.

Through the company mission and these initiatives, we want to inspire our employees to build their careers with us and reward those who exemplify our values.

Corporate Responsibility

At ImmunoGen, how we do our jobs is just as important as what we do. Our culture is about putting people first, innovation, accountability, and teamwork. Living these values means managing our environmental, social, and governance (ESG) impacts effectively.

We are currently laying the foundation for our ESG strategy. Over the last two years, we formalized board oversight over our ESG strategy and recently begun to assess our material ESG issues. This materiality assessment considers ESG topics from a wide range of stakeholders and global reporting frameworks. In the coming months, we will narrow our focus to a few priority areas that are most material for our business. We are committed to operationalizing these ESG topics through a top-down approach and maintaining consistent stakeholder engagement to continue to evolve our strategy.

Corporate Information

We were organized as a Massachusetts corporation in March 1981. Our principal offices are located at 830 Winter Street, Waltham, Massachusetts 02451, and our telephone number is (781) 895-0600. Our internet address is www.immunogen.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the “Investors & Media – Financials & Filings - SEC Filings” section of our website as soon as reasonably practicable after those materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. Please note that the information contained on the web site is not a part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. BEFORE DECIDING WHETHER TO INVEST IN OUR COMMON STOCK, YOU SHOULD CAREFULLY CONSIDER THE RISKS DESCRIBED BELOW, TOGETHER WITH THE OTHER INFORMATION CONTAINED IN THIS ANNUAL REPORT ON FORM 10-K, INCLUDING OUR CONSOLIDATED FINANCIAL STATEMENTS AND RELATED NOTES. THE RISKS AND UNCERTAINTIES DESCRIBED BELOW ARE THOSE THAT WE CURRENTLY BELIEVE MAY MATERIALLY AFFECT OUR COMPANY AND IF ANY OF THESE RISKS ACTUALLY OCCURS, OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, OR CASH FLOW COULD BE SERIOUSLY HARMED. ADDITIONAL RISKS AND UNCERTAINTIES THAT WE ARE UNAWARE OF OR THAT WE CURRENTLY DEEM IMMATERIAL ALSO MAY BECOME IMPORTANT FACTORS THAT AFFECT OUR COMPANY AND MAY MATERIALLY IMPAIR OUR BUSINESS.

Risks Related to our Financial Condition

We have a history of operating losses, expect to incur significant additional operating losses, and may never be profitable.

We have generated operating losses since our inception. As of December 31, 2022, we had an accumulated deficit of \$1.7 billion. We may never be profitable. We expect to incur substantial additional operating losses for at least the near term as our development, preclinical testing, clinical trials, and commercialization of ELAHERE continue. We intend to continue to invest significantly in ELAHERE and our product candidates. We may encounter technological, regulatory, or marketing difficulties as part of this development and commercialization process that we cannot overcome or remedy. Our revenues to date have been primarily from upfront and milestone payments, research and development support, clinical materials reimbursement from our collaborators, and from royalties received from the commercial sales

of KADCYLA (to which we have sold our cash rights). We received approval of our first product, ELAHERE, in the fourth quarter of 2022, and have started generating revenue from product sales. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. In addition, our expenses could increase beyond expectations as we expand our commercial activities for ELAHERE and continue our ongoing trials with ELAHERE and our product candidates. Even with the approval and commercialization of ELAHERE, we will need to generate significant revenues from ELAHERE to achieve and maintain profitability. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our development efforts, expand our business, or continue our operations and may require us to raise additional capital that would dilute your ownership interest. A decline in the value of our company could also cause you to lose all or part of your investment.

There is substantial doubt about our ability to continue as a going concern.

At December 31, 2022, we had \$275.1 million of cash and cash equivalents on hand. Our current level of cash and cash equivalents is not sufficient to meet our current operating plans for the next twelve months following the issuance of the financial statements appearing in this Annual Report on Form 10-K. As a result, substantial doubt is deemed to exist regarding our ability to continue as a going concern for a period of one year from the issuance of these financial statements. We plan to meet our operating cash flow requirements with our current cash and cash equivalents, cash generated from commercial sales of ELAHERE, milestone payments from new or existing collaborations, and additional funds accessed through equity, debt, or other financings such as royalty financing transactions, as well as cash preservation activities. Such activities may not succeed. The failure of the Company to obtain sufficient funds on acceptable terms could have a material adverse effect on the Company's business, results of operations, and financial condition and require the Company to defer or limit some or all of its research, development, clinical, and/or commercial projects, including trials to support potential label expansion of ELAHERE, and may materially and adversely affect our share price.

If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market ELAHERE or our product candidates.

We will continue to expend substantial resources developing and commercializing ELAHERE and our product candidates, including costs associated with research and development, acquiring new technologies, conducting preclinical studies and clinical trials, obtaining regulatory approvals, manufacturing products, establishing marketing and sales capabilities to commercialize ELAHERE, as well as providing certain support to our collaborators in the development of their products. Conducting preclinical studies and clinical trials is a time-consuming, expensive, and uncertain process that can take years to complete, and we may never generate the necessary data or results required to obtain marketing approval for ELAHERE in additional indications or for our product candidates. In addition, ELAHERE or any of our product candidates that may receive marketing approval may not achieve commercial success. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives.

In addition, we cannot provide assurance that anticipated collaborator payments will, in fact, be received. Should such future collaborator payments not be received, we expect we could seek additional funding from other sources. We may elect or need to seek additional financing sooner due to a number of other factors as well, including:

- if either we incur higher than expected costs or we or any of our collaborators experience slower than expected progress in developing product candidates and obtaining regulatory approvals; and
- the acquisition of technologies and other business opportunities that require financial commitments.

Additional funding may not be available to us in sufficient amounts, on favorable terms, or at all. We may raise additional funds through public or private financings, collaborative arrangements, or other arrangements such as royalty financing transactions. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize ELAHERE or our product candidates. Volatility in the financial markets has generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. Debt and debt-like financing, if available, may involve covenants that could restrict our business activities. If we are unable to raise additional funds through equity, royalty, or debt financing when needed, we may be required to delay, scale back, or eliminate

expenditures for some of our commercialization activities and development programs, including restructuring our operations, or grant rights to develop and market ELAHERE or our product candidates that we would otherwise prefer to internally develop and market. If we are required to grant such rights, the ultimate value of ELAHERE or our product candidates to us may be reduced.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an “ownership change,” is subject to limitations on its ability to use its pre-change net operating loss carryforwards (NOLs), and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. For these purposes, an ownership change generally occurs where the equity ownership of one or more shareholders or groups of shareholders who own at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year period. We may have experienced such ownership changes in the past, and we may experience shifts in our stock ownership, some of which are outside our control. These ownership changes may subject our existing NOLs or credits to substantial limitations under Sections 382 and 383. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. As of December 31, 2022, we had federal NOLs of \$443.3 million available to reduce federal taxable income, if any, that can be carried forward indefinitely. As of December 31, 2022, we also had \$85.6 million of federal credit carryforwards that will begin to expire in 2027. Limitations on our ability to utilize those NOLs to offset U.S. federal taxable income could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to Our Business and Industry

Our prospects are highly dependent on the success of our only approved product, ELAHERE, which received FDA approval under an accelerated approval pathway. If we are unable to maintain approval for, or successfully commercialize, ELAHERE, our business, financial condition, results of operations, as well as our prospects, could be adversely affected.

We obtained FDA approval for ELAHERE for the treatment of adult patients with FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. We have not obtained any other marketing approvals for ELAHERE or our product candidates. We first commercialized ELAHERE in the U.S. in the fourth quarter of 2022 and therefore do not have a long history operating as a commercial company.

The FDA approved ELAHERE under the accelerated approval pathway and continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. Our intent is for our ongoing Phase 3 MIRASOL trial to serve as our confirmatory trial and, if successful, to support full approval of ELAHERE. If the MIRASOL trial is unsuccessful, the FDA could require us to conduct additional trials to remain on the market, could require updates to our label, or could ultimately seek to withdraw marketing approval for ELAHERE. Separate from the confirmatory trial, ELAHERE is subject to additional post-approval requirements and commitments, including post-approval requirements to conduct a randomized clinical trial to evaluate the safety of the recommended dose of ELAHERE and alternative dosing schedules, conduct a dose escalation trial to determine the appropriate starting dose in patients with moderate hepatic impairment, and conduct a clinical trial or revise existing trials to incorporate prospectively scheduled ophthalmologic assessments to characterize the incidence and severity of ocular events and evaluate risk mitigation strategies. We are also subject to other post-approval requirements, including submission to the FDA of all promotional materials 30-120 days prior to their dissemination.

Failure to meet any of our post-approval requirements or commitments may result in adverse regulatory actions. Products that receive accelerated approval may be subject to expedited withdrawal procedures if post-approval trials fail to verify the predicted clinical benefit. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post-approval trial, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false or misleading.

Our long-term viability, growth, and ability to generate revenue depend heavily on successfully commercializing and obtaining full regulatory approval for ELAHERE. ELAHERE will be our first commercial launch,

and its successful commercialization and our receipt of full regulatory approval in the United States are subject to many risks.

If ELAHERE or our product candidates or those of our collaborators do not gain market acceptance, our business will suffer.

ELAHERE may not gain market acceptance among physicians, patients, healthcare payors, and other members of the medical community. The degree of market acceptance of ELAHERE, or other products we may develop, will depend on a number of factors, including:

- their level of clinical efficacy and safety;
- the clinical indications for which they are approved;
- the prevalence and severity of any adverse events and their overall safety profile;
- the willingness of physicians to include FR α testing as part of routine patient care;
- their advantage over alternative treatment methods;
- our/the marketer's and our collaborators' ability to gain acceptable reimbursement and the reimbursement policies of government and other third-party payors; and
- the quality of the distribution capabilities of the party(ies) responsible to market and distribute the product(s).

Physicians may elect not to recommend the therapies for any number of other reasons, including whether the physicians are already using competing products that satisfy their treatment objectives. If our products do not achieve significant market acceptance and use, we will not be able to recover the significant investment we have made in developing such products and our business will be severely harmed.

ELAHERE has received FDA approval as a monotherapy in a limited patient population, and additional successful clinical trials and regulatory approvals may be needed to expand its indications. Such trials may fail, or we may fail to obtain such regulatory approvals, either of which could adversely affect our business and prospects.

The FDA granted accelerated approval of ELAHERE as a monotherapy for the treatment of patients with FR α -positive platinum-resistant epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer who have been previously treated with one to three prior systemic treatments. We do not anticipate obtaining regulatory approval for ELAHERE in additional patient populations or as a combination therapy without additional clinical data. Such additional clinical trials are ongoing and will require time and expense, and these trials may fail to generate results that support additional indications. If we are unable to expand the indications for use of ELAHERE, our business and prospects could be adversely affected.

We currently do not have the direct sales, marketing, or distribution capabilities necessary to successfully commercialize our products on a global scale and may rely on third parties to support development and commercialization activities.

We are commercializing ELAHERE in the United States and currently intend to commercialize ELAHERE in the European Union and UK if we receive marketing approval in these territories. We may choose to rely on third parties to market and sell ELAHERE outside of the United States, the European Union, and the UK, either through distributor or out-licensing arrangements. For example, in October 2020, we entered into a collaboration and license agreement with Huadong under which Huadong will exclusively develop and commercialize ELAHERE in Greater China. We retain all rights to ELAHERE in the rest of the world. In addition, arrangements with third parties to develop and commercialize ELAHERE or other future products could significantly limit the revenues we derive from these compounds, and these third parties, including Huadong, may fail to commercialize our compounds successfully.

If our ADC technology does not produce safe, effective, and commercially viable products or if such products fail to obtain or maintain FDA approval, our business will be severely harmed.

Our ADC technology yields novel product candidates for the treatment of cancer. To date, only two ADCs using our technology, KADCYLA and ELAHERE, have obtained marketing approval. Our ADC product candidates and/or those of our collaborators' may not prove to be safe, effective, or commercially viable treatments for cancer and as a result, our ADC technology may not result in any future meaningful benefits to us or for our current or potential

collaborators. Furthermore, we are aware of only a limited number of other compounds that are based on technology similar to our ADC technology that have obtained marketing approval by the FDA. If our ADC technology fails to generate additional product candidates that are safe, effective, and commercially viable treatments for cancer or such product candidates fail to obtain or maintain FDA and foreign regulatory authorities approval, our business will be severely harmed.

Clinical trials for ELAHERE, our product candidates, and those of our collaborators will be lengthy and expensive, and their outcome is uncertain.

Before we can convert our accelerated approval for ELAHERE to full approval, obtain regulatory approval for ELAHERE in additional indications, or obtain regulatory approval for our product candidates, we must demonstrate through clinical testing that our products are safe and effective for use in humans. Conducting clinical trials is a time-consuming, expensive, and uncertain process and typically requires years to complete. In our industry, the results from preclinical studies and early clinical trials often are not predictive of results obtained in later-stage clinical trials. Some compounds that have shown promising results in preclinical studies or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. For example, despite encouraging results from earlier clinical trials of ELAHERE, our FORWARD I Phase 3 clinical trial evaluating ELAHERE compared to chemotherapy in women with FR α -positive, platinum-resistant ovarian cancer, did not meet the primary endpoint in either the entire treatment population or the pre-specified high FR α expression population. Based on post hoc exploratory analyses of the FORWARD I results and consultations with the FDA, we implemented two new trials of ELAHERE, SORAYA and MIRASOL. We reported positive results from our SORAYA trial, which served as the basis for ELAHERE's accelerated approval, but results from our ongoing MIRASOL trial may not show positive results consistent with our SORAYA trial, which would cause significant harm to our business and future prospects.

Before we can commence clinical trials for a therapeutic candidate, we must conduct extensive preclinical testing and studies and submit an IND to the FDA and foreign regulatory authorities. We cannot be sure that submission of an IND will result in the FDA and/or foreign regulatory authorities allowing our clinical trials to begin on the timelines we expect, if at all, as the FDA and/or foreign regulatory authorities may require additional preclinical, toxicology, or other *in vivo* or *in vitro* data to support the IND. Additionally, at any time during the clinical trials, we, our collaborators, or the FDA or other regulatory authority might delay or halt any clinical trials of our products for various reasons, including:

- occurrence of unacceptable toxicities or side effects;
- ineffectiveness of the product;
- insufficient drug supply, including delays in obtaining supplies/materials necessary for manufacturing such drugs;
- negative or inconclusive results from the clinical trials, or results that necessitate additional nonclinical studies or clinical trials;
- delays in obtaining or maintaining required approvals from institutions, review boards, or other reviewing entities at clinical sites;
- delays in patient enrollment;
- insufficient funding or a reprioritization of financial or other resources;
- our or our collaborators' inability to develop and obtain approval for any companion *in vitro* diagnostic devices that the FDA or other regulatory authority may conclude must be used with such drug to ensure its safe use; or
- other reasons that are internal to the businesses of our collaborators and third-party suppliers, which they may not share with us.

If we are required by the FDA, or foreign regulatory agencies, to perform studies and clinical trials in addition to those that we currently anticipate, or if there are any delays in our or our partners completing clinical trials or the development of any of ELAHERE or our product candidates, our expenses could increase beyond expectations. Any failure or substantial delay in successfully completing clinical trials and obtaining additional regulatory approvals for ELAHERE or our product candidates could severely harm our business.

Interim, top-line, or preliminary data from our clinical trials that we announce may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we have publicly disclosed, and in the future will disclose, preliminary or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Therefore, final results from the trials may differ from the top-line results initially reported, and the final results may indicate different conclusions once additional data have been evaluated. As such, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the outcomes may materially change as patient enrollment continues and more data become available. Adverse differences between top-line, preliminary, or interim data, on the one hand, and final data, on the other, could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses, or may interpret or weigh the importance of data differently, which could negatively affect the approvability or commercialization of the particular product.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the final results differ from the interim, top-line, or preliminary data, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain or maintain approval for, and to commercialize, ELAHERE or our product candidates may be harmed, which may negatively affect our business, financial condition, results of operations, and prospects.

We face product liability risks and may not be able to obtain adequate insurance.

The use of ELAHERE or our product candidates during testing or after approval entails an inherent risk of adverse effects, which could expose us to product liability claims. Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We may not have sufficient resources to satisfy any liability resulting from these claims. While we currently have product liability insurance for the use of ELAHERE and products that are in clinical testing, our coverage may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to maintain our current insurance, increase our insurance coverage as may be needed, or obtain general product liability insurance on reasonable terms and at an acceptable cost as we expand commercial activities for ELAHERE. This insurance, even if we can obtain and maintain it, may not be sufficient to provide us with adequate coverage against potential liabilities. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of ELAHERE or our product candidates, which could severely harm our business.

We may be unable to compete successfully.

The markets in which we compete are well-established and intensely competitive. We may be unable to compete successfully against our current and future competitors. Our failure to compete successfully may result in lower volume sold, pricing reductions, reduced gross margins, and failure to achieve market acceptance for ELAHERE or any of our product candidates that may receive marketing approval. Our competitors include research institutions, pharmaceutical companies, and biotechnology companies, such as Pfizer, Seattle Genetics, Roche, Astellas, AstraZeneca, Daiichi Sankyo, GlaxoSmithKline, AbbVie, Mersana Therapeutics, Eisai, Sutro BioPharma, and the Menarini Group. For example, pivekimab is in development for the treatment of BPDCN and, if approved, would compete with the Menarini Group's ELZONRIS® (tagraxofusp), which is approved by the FDA for sale in the United States and by the EMA for sale in the European Union for the treatment of BPDCN. Many of our competitors have substantially more experience and more capital, research and development, regulatory, manufacturing, human, and other resources than we do. As a result, they may:

- develop products that are safer or more effective than ELAHERE or our product candidates;
- obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the sales or potential sales of ELAHERE or any of our product candidates that may receive marketing approval;
- devote greater resources to market or sell their products;
- adapt more quickly to new technologies and scientific advances;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licensing and collaboration arrangements; and
- take advantage of acquisitions or other opportunities more readily than we can.

A number of pharmaceutical and biotechnology companies are currently developing products targeting the same types of cancer that we target, and some of our competitors' products have entered clinical trials or already are commercially available.

ELAHERE and any of our product candidates that may receive marketing approval will also compete against well-established, existing therapeutic products that are currently reimbursed by government healthcare programs, private health insurers, and health maintenance organizations. In addition, ELAHERE and our product candidates, if approved and commercialized, may face competition from biosimilars. The ACA, which included the BPCIA, amended the Public Health Service Act to create an abbreviated approval pathway for two types of "generic" biologics-biosimilars and interchangeable biologic products. The BPCIA establishes a pathway for the FDA approval of follow-on biologics and provides twelve years data exclusivity for reference products and an additional six-month exclusivity period if pediatric trials are conducted. In Europe, the EMA has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of ELAHERE or one of our product candidates was approved in the United States or Europe, it could have a negative effect on sales and gross profits of the product and our financial condition.

We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for relationships with academic and research institutions, and for licenses to proprietary technology. In addition, we anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments surrounding antibody-based therapeutics for cancer continue to accelerate. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or ELAHERE or our product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us.

Unfavorable global economic conditions, as well as regional conflicts, could adversely affect our business, financial condition, and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global economy has experienced extreme volatility and disruptions, including significant volatility in commodity and market prices, declines in consumer confidence, declines in economic growth, supply chain interruptions, uncertainty about economic stability, and inflation. Unfavorable economic conditions could result in a variety of risks to our business, including demand and pricing for our products, difficulty in forecasting our

financial results, and our ability to raise additional capital when needed and on acceptable terms. A weak or declining economy could also strain our suppliers, possibly resulting in supply chain disruptions. These and other economic factors or regional conflicts could adversely affect our business and results of operations.

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business and our financial results.

The spread of COVID-19 has affected the global economy, our operations, clinical trial activities, and supply chain and may continue to do so. Even with the approval of vaccines for COVID-19, the COVID-19 pandemic is still evolving. In the recent past, the pandemic resulted in the implementation of various responses, including government-imposed quarantines, travel restrictions, and other public health safety measures, as well as reported adverse impacts on healthcare resources, facilities, and providers across the United States, and in other countries worldwide. The continued impact of COVID-19 may result in a period of business disruption, including delays in our clinical trials or delays or disruptions in our supply chain. For example, COVID-19 slowed site activation and patient enrollment for both SORAYA and MIRASOL, which resulted in a limited delay in patient accrual for each of these trials. The pandemic may further delay enrollment in trials due to prioritization of hospital resources toward the pandemic, the resumption of restrictions on travel, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results. COVID-19 may also affect employees of third-party contract research organizations that we rely upon to carry out our clinical trials or the operations at our third-party manufacturers, which could result in delays or disruptions in our trials or in product supply.

We cannot presently predict the scope and severity of any additional potential business shutdowns or disruptions as a result of the COVID-19 pandemic, including due to new variants of COVID-19. If we or any of the third parties with whom we engage, however, were to experience further shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

Risks Related to Our Dependence on Third Parties

If our collaborators fail to perform their obligations under our agreements with them or determine not to continue with clinical trials, our business could be severely affected.

The development and commercialization of ELAHERE and our product candidates depends, in part, upon the formation and maintenance of collaborative arrangements. Collaborations provide an opportunity for us to:

- generate cash flow and revenue;
- fund some of the costs associated with our internal research and development, preclinical testing, clinical trials, and manufacturing;
- seek and obtain regulatory approvals faster than we could on our own;
- successfully commercialize ELAHERE and our product candidates; and
- secure access to targets which, due to intellectual property restrictions, would otherwise be unavailable to our technology.

If we fail to secure or maintain successful collaborative arrangements, the development and marketing of compounds that use our technology may be delayed, scaled back, or otherwise may not occur. In addition, we may be unable to negotiate other collaborative arrangements or, if necessary, modify our existing arrangements on acceptable terms. We cannot control the amount and timing of resources our collaborators may devote to ELAHERE or our product candidates. Our collaborators may separately pursue competing product candidates, therapeutic approaches, or technologies to develop treatments for the diseases targeted by us or our collaborative efforts, or may decide, for reasons that may not be known to us or with which we may disagree, to discontinue development of our products under our agreements with them. Any of our collaborators may slow or discontinue the development of a product covered by a collaborative arrangement for reasons that include, but are not limited to:

- a change in the collaborative partner's strategic focus as a result of merger, management changes, adverse business events, or other causes;
- a change in the priority of the product relative to other programs in the collaborator's pipeline;
- a reassessment of the patent situation related to the compound or its target;
- a change in the anticipated competition for the product candidate;
- preclinical studies and clinical trial results; and
- a reduction in the financial resources the collaborator can or is willing to apply to the development of new compounds.

Even if our collaborators continue their collaborative arrangements with us, they may nevertheless determine not to actively pursue the development or commercialization of any resulting product candidates. Also, our collaborators may fail to perform their obligations under the collaborative agreements or may be slow in performing their obligations. Our collaborators can terminate our collaborative agreements under certain conditions. The decision to advance a product candidate that is covered by a collaborative agreement through clinical trials and ultimately to commercialization is, in some cases, at the discretion of our collaborators. If any collaborative partner were to terminate or breach our agreements, fail to complete its obligations to us in a timely manner, or decide to discontinue its development of a product candidate, our anticipated revenue from the agreement and the development and commercialization of the product candidates could be severely limited or eliminated. If we are not able to establish additional collaborations or any or all of our existing collaborations are terminated and we are not able to enter into alternative collaborations on acceptable terms, or at all, our continued development, manufacture, and commercialization of our product candidates could be delayed or scaled back as we may not have the funds or capability to continue these activities. If our collaborators fail to successfully develop and commercialize ADC compounds, our business prospects could be harmed.

If our product requirements for clinical trials or commercialization are significantly higher than we estimated, the inability to procure additional antibody production, conjugation, or fill/finish services in a timely manner could impair our ability to initiate or advance our clinical trials or commercialization of ELAHERE or our product candidates.

We rely on third-party suppliers to manufacture antibodies used in our own proprietary compounds. Due to the specific nature of the antibody and availability of production capacity, there is significant lead time required by these suppliers to provide us with the needed materials. If our antibody requirements for clinical or commercial materials to be manufactured are significantly higher than we estimated, we may not be able to readily procure additional antibody which would impair our ability to advance our clinical trials currently in process or initiate additional trials or commercialize ELAHERE or our product candidates. We also rely on third parties to manufacture bulk drug substance and convert it into filled and finished vials of drug product for clinical use and commercial sales. If our product requirements are significantly higher than we estimated, we may not be able to readily procure slots to manufacture bulk drug substance or to convert drug substance into filled and finished vials of drug product for clinical or commercial use. There can be no assurance that we will not have supply problems that could delay or stop our clinical trials, hinder our commercialization efforts, or otherwise could have a material adverse effect on our business.

We are currently contractually required to obtain DM4 used in ELAHERE from a single third-party manufacturer, and any delay or interruption in such manufacturer's operations could impair our ability to advance preclinical and clinical trials and commercialization of ELAHERE.

We rely on a sole third-party supplier, Società Italiana Corticosteroidi S.r.l, to manufacture the DM4 used in ELAHERE. Any delay or interruption in the operations of our sole third-party supplier and/or our supply of DM4 could lead to a delay or interruption in our manufacturing operations, preclinical studies, clinical trials, and commercialization of ELAHERE, which could negatively affect our business.

We currently rely on, and expect to continue to rely on, third-party manufacturers to produce our antibodies, linkers, payloads, drug substance, and drug product for ELAHERE and our product candidates and any delay or interruption in such manufacturers' operations could impair our ability to advance clinical trials and commercialization.

We rely on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of ELAHERE and our product candidates. We have

established relationships with third-party manufacturers to provide clinical and commercial supply, but these third-party manufacturers may not be able to meet our needs with respect to timing, quantity, or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our ability to commercialize ELAHERE may be adversely affected. Additionally, our clinical trials may be delayed, thereby delaying the submission of applications for regulatory approval and the market introduction and subsequent commercialization of our product candidates. Any such delays may lower our revenues and potential profitability.

The facilities used to manufacture ELAHERE and our product candidates (drug substance and drug product) are subject to periodic inspection by the FDA and similar regulatory authorities. These facilities generally must be inspected by the FDA (and other similar regulatory agencies outside the United States depending on where marketing authorizations are filed) before marketing authorizations are approved. In the United States, if we want to change manufacturers or add additional manufacturers following product approval, the FDA must approve the use of these manufacturers through a supplemental BLA. We are completely dependent on our contract manufacturers for compliance with cGMPs in connection with the manufacture of ELAHERE and our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA or others, we will not be able to use the products produced at their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or a comparable foreign regulatory authority finds that these facilities do not comply with cGMP, we may need to find alternative manufacturing facilities, which would significantly impact our ability to successfully develop and commercialize ELAHERE and our product candidates and could result in inventory write-offs that adversely affect our results of operations. Further, our failure, or the failure of our third-party manufacturers, to comply with these or other applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of ELAHERE or our product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and product supplies.

We rely on a third-party to develop, manufacture, and commercialize the companion diagnostic for ELAHERE, and any delay or interruption in supply could negatively impact our commercial activities.

We rely on RTD for the design, development, manufacture, and commercialization of a companion diagnostic for ELAHERE. Roche has received FDA approval for the VENTANA FOLR1 RxDx Assay, a companion diagnostic that measures FR α tumor expression to select patients eligible for treatment with ELAHERE. Risks related to the development, manufacture, and commercialization of companion diagnostics are similar to the risks we face with respect to our drug products, including risks related to manufacturing sufficient supply, compliance with manufacturing standards and other regulatory requirements, and gaining market acceptance. Any delays or difficulties in the manufacture or commercialization of the companion diagnostic, could impact our commercialization of ELAHERE. For example, a manufacturing delay might result in a shortage of the companion diagnostic being supplied to the testing laboratories, which might impede their ability to deliver test results promptly and impact our commercialization of ELAHERE. In addition, if Roche decides to discontinue selling or manufacturing the companion diagnostic or our relationship otherwise terminates, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use with ELAHERE or do so on commercially reasonable terms, which could adversely affect commercialization.

The FDA, the EMA, or comparable foreign regulatory authorities could require the clearance or approval of additional companion diagnostics as a condition of approval for our product candidates, which would require substantial financial resources and could delay regulatory approval. We would be dependent on the sustained cooperation and effort of third-party collaborators to develop these companion diagnostics, and our collaborators may encounter difficulties in developing such tests, including issues relating to the selectivity and/or specificity of the diagnostic, analytical validation, reproducibility, or clinical validation, or in obtaining regulatory clearance or approval for such companion diagnostic. Any delay or failure by our collaborators to develop or obtain regulatory clearance or approval of such companion diagnostics, if necessary, could delay or prevent approval of our product candidates.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights adequately, the value of our technology, ELAHERE, and our product candidates could be diminished.

Our success depends in part on obtaining, maintaining, and enforcing our patents and other proprietary rights and our ability to avoid infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and in foreign countries that cover ELAHERE, our other novel product candidates and their uses, pharmaceutical formulations and dosages, and processes for the manufacture of them. Our patent portfolio currently includes both patents and patent applications. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving, is surrounded by a great deal of uncertainty, and involves complex legal, scientific, and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. Accordingly, our pending patent applications may not result in issued patents or in patent claims as broad as in the original applications. Although we own numerous patents, the issuance of a patent is not conclusive as to its validity or enforceability. Through litigation, a third party may challenge the validity or enforceability of a patent after its issuance. In addition, the patent prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. Under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

Following approval of ELAHERE in the U.S., we timely filed five applications for patent term extension. If one or more of the applications for patent term extension are deemed to be allowable by the U.S. Patent and Trademark Office, we will be able to designate one to proceed to grant, and thereby extend the term of one U.S. patent covering ELAHERE. Even if an extension is granted, any such extension may be shorter than what we seek or may otherwise fail to provide meaningful protection for ELAHERE.

Patents and patent applications owned or licensed by us may become the subject of inter partes review, post-grant review, ex parte reexamination, interference, opposition, nullity, or other proceedings in a court or patent office in the United States or in a foreign jurisdiction to determine validity, enforceability, patentability, or priority of invention, which could result in substantial cost to us. An adverse decision in such a proceeding may result in our inability to gain issuance of a patent from a pending patent application or our loss of rights under a patent or patent application. It is unclear how much protection, if any, will result from our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. A competitor may successfully invalidate our patents, or a challenge could result in limitations of the patents' coverage. The courts continue to interpret various aspects of patent-related laws and related agency rules in ways that we cannot predict, potentially making it easier for competitors and other interested parties to challenge our patents, which, if successful, could have a material adverse effect on our business and prospects. In addition, the cost of litigation or patent office proceedings to uphold the validity of patents can be substantial. If we are unsuccessful in these proceedings, third parties may be able to use our patented technology and may be able to do so without paying us licensing fees or royalties. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In an infringement proceeding, a court may decide that a patent of ours is not valid. Even if the validity of our patents were upheld, a court may refuse to stop the other party from using the technology at issue on the ground that its activities are not covered by our patents or that the facts surrounding the other party's use of our technology do not satisfy the legal requirements to grant such an injunction.

Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

In addition to our patent rights, we also rely on unpatented technology, trade secrets, know-how, and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We may not be able to effectively protect our rights in unpatented technology, trade secrets, know-how, and confidential information. We require each of our employees, consultants, and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting, or collaborative relationship with us. Further, we require that all employees enter into assignment of invention agreements

as a condition of employment. However, these agreements may not provide effective protection of our information, or, in the event of unauthorized use or disclosure, they may not provide adequate remedies. If we are unable to prevent material disclosure of the trade secrets and other intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, adversely affecting our market position and business and operational results.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights held by third parties and we may be unable to protect our rights to, or to commercialize, ELAHERE or our product candidates.

Patent litigation is very common in the biotechnology and pharmaceutical industries. Third parties may assert patent or other intellectual property infringement claims against us with respect to our technologies, products, or other matters. From time to time, we have received correspondence from third parties alleging that, or inquiring whether, we infringe their intellectual property rights. Any claims that might be brought against us alleging infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and limit our ability to use the intellectual property subject to these claims. Even if we were to prevail, any litigation would be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit, we may be forced to stop or delay developing, manufacturing, or selling products that incorporate the challenged intellectual property unless we enter into royalty or license agreements. There may be third-party patents, patent applications, and other intellectual property relevant to our products that may block or compete with our products or processes of which we are currently unaware with claims that cover the use or manufacture of our drug candidates or the practice of our related methods. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our drug candidates may infringe. In addition, we sometimes undertake research and development with respect to products even when we are aware of third-party patents that may be relevant to our products, on the basis that such patents may be challenged or licensed by us or that the Safe Harbor under 35 U.S.C. 271(e) applies. If our subsequent challenge to such patents were not to prevail, we may not be able to commercialize our products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain such license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Ultimately, we may be unable to commercialize some of our products or may have to cease some of our business operations, which could severely harm our business.

Any inability to license proprietary technologies or processes from third parties that we use in connection with the development and manufacture of ELAHERE or our product candidates may impair our business.

Other companies, universities, and research institutions have or may obtain patents that could limit our ability to use, manufacture, market, or sell ELAHERE or our product candidates or impair our competitive position. As a result, we would have to obtain licenses from other parties before we could continue using, manufacturing, marketing, or selling ELAHERE or our potential candidates. Any necessary licenses may not be available on commercially acceptable terms, if at all. If we do not obtain the required licenses, we may not be able to market our products at all or we may encounter significant delays in product development while we redesign products or methods that are found to infringe the patents held by others.

Risks Related to Government Regulation

Side effects, serious adverse events, or other undesirable properties associated with ELAHERE or our product candidates could delay or halt clinical trials, affect our ability to obtain or maintain regulatory approval, limit the commercial profile reflected in product labeling, or negatively affect market acceptance and commercial sales.

The prescribing information for ELAHERE includes a boxed warning related to the risk of severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis, as well as other warnings and precautions for various toxicities and reactions, including pneumonitis, peripheral neuropathy, and embryo-fetal toxicity. Side effects and toxicities associated with ELAHERE, as well as the warnings, precautions, and requirements listed in the prescribing information, could affect the willingness of physicians to prescribe, and patients to use, ELAHERE and negatively affect market acceptance and commercial sales. Patients receiving ELAHERE may experience serious adverse events in the future, whether the serious adverse events are disclosed in the prescribing

information or are newly reported. Further, patients receiving our products with co-morbid diseases not previously studied may experience new or different serious adverse events. Reports of adverse events or new safety concerns involving ELAHERE, including from our ongoing and recently completed trials, could result in the limitation or withdrawal of regulatory approval, implementation of a risk evaluation mitigation strategy or the inclusion of unfavorable information in our product labeling, such as additional boxed warnings, limitations of use, contraindications, and warnings and precautions.

Additionally, undesirable side effects or serious adverse events caused by ELAHERE or our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a restrictive label or the delay, denial, or withdrawal of regulatory approval by the FDA or other comparable foreign regulatory authorities.

Any related drug-side effects or serious adverse events in our clinical trials could affect clinical trial patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims.

If we or others identify undesirable side effects or serious adverse events caused by ELAHERE or any of our product candidates that may receive marketing approval, a number of potentially significant negative consequences could result, including:

- we may suspend or be forced to suspend marketing;
- we may be obliged to conduct a product recall or withdrawal;
- regulatory authorities may suspend, vary, or withdraw their approvals;
- regulatory authorities may order the seizure of product;
- regulatory authorities may require additional warnings on the label or a risk evaluation and mitigation strategy (REMS) that could diminish the usage or otherwise limit commercial success;
- we may be required to conduct post-approval trials;
- we could be sued and held liable for harm caused to patients;
- we could be required to pay fines and face other administrative, civil, and criminal penalties; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ELAHERE or any of our product candidates that may receive marketing approval.

We have received orphan drug designation for ELAHERE and our product candidates for specified indications; we may seek additional orphan drug designation for additional indications and for our other product candidates. However, we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

ELAHERE has been granted orphan drug designation by the FDA in the United States, and orphan medicinal product status by the EMA in the European Union for the treatment of ovarian cancer. Pivekimab has been granted orphan drug designation by the FDA for the treatment of AML and for the treatment of BPDCN, and by the EMA for the treatment of BPDCN. As part of our business strategy, we may seek orphan drug designation for our other product candidates; however, we may be unsuccessful.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for the indication for that time period. Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve another product that meets the definition of a “same drug” under 21 C.F.R. 316.3 for the same condition if the FDA concludes that the later product is clinically superior by evidence that it is safer, more effective, or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage

in the regulatory review or approval process. While we intend to seek additional orphan drug designation for our other product candidates, we may never receive such designations. Even if we receive orphan drug designation, there is no guarantee that we will enjoy the benefits of those designations or obtain orphan drug exclusivity.

We and our collaborators are subject to extensive government regulations and we and our collaborators may not be able to obtain or maintain necessary regulatory approvals.

We and our collaborators may not obtain or maintain the regulatory approvals necessary to commercialize our product candidates, which would cause our business to be severely harmed. Pharmaceutical products, including ELAHERE and our product candidates, are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, record-keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of pharmaceutical products. If ELAHERE or our product candidates are marketed outside of the United States, they will also be subject to extensive regulation by foreign governments. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product, is lengthy, complex, expensive, and uncertain. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the authorities for each indication to establish the product's safety and efficacy. Data obtained from preclinical and other nonclinical studies and clinical trials are susceptible to varying interpretation, which may delay, limit, or prevent regulatory approval. The approval process may take many years to complete and may involve ongoing requirements for post-approval trials. The FDA may approve our product candidate for indications that are significantly more limited than what we apply for or require labeling statements that limit the use of our products, such as a boxed warning or warnings, contra-indications, or precaution statements. The FDA may also require a REMS, which could include physician communication plans or restricted distribution methods, such as training, certification, or other requirements for prescribers, pharmacies, or patients. Any FDA or other regulatory approvals, once obtained, may be withdrawn or limited. Any of these actions could diminish the usage of the product or otherwise limit the commercial success of our product candidates. The effect of government regulation may be to:

- delay marketing of product candidates for a considerable period of time;
- limit the indicated uses for which product candidates may be marketed;
- impose costly requirements on our activities; and
- place us at a competitive disadvantage to other pharmaceutical and biotechnology companies.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in regulatory policy during the period of product development, clinical trials, and regulatory review. Failure to comply with applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our products or us. In addition, we are, or may become, subject to various federal, state, and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions, and civil and criminal penalties.

We remain subject to ongoing regulatory requirements and review. If we or our collaborators fail to comply with regulations applicable to approved products, these approvals could be lost and the sale of our or our collaborators' products could be suspended.

ELAHERE and any of our product candidates that may receive marketing approval will continue to be subject to extensive regulatory requirements related to product manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, registration and listing, and reporting of adverse events and other post-market information. The approval of a product could be conditioned on us or our collaborators conducting costly post-approval trials or could limit the indicated uses included in product labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us or our collaborators to withdraw it from the market, or impede or delay our or our collaborators' ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to regulatory review and periodic inspections to ensure adherence to applicable regulations. We may be unable or slow to comply with existing regulations, including changes in existing regulatory requirements, or new regulations. Furthermore, our collaborators may be slow to adapt, or may never adapt,

to changes in existing regulatory requirements or adoption of new regulatory requirements pertaining to products that have already received approval.

The FDA closely regulates the post-approval marketing and promotion of drugs and biologics to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. If we market our products outside of their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the FDA's restrictions relating to the promotion of prescription drugs may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

If we or our collaborators fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or if previously unknown problems with our or our partners' products, manufacturers, or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers, or manufacturing processes;
- warning or untitled letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

Any one of these could have a material adverse effect on our business or financial condition.

Adequate coverage and reimbursement from third-party payors may not be available for our products and we may be unable to successfully contract for coverage from third-party payors; conversely, to secure coverage from third-party payors, we may be required to pay rebates or other discounts; and we may confront other restrictions to reimbursement, any of which could diminish our sales or adversely affect our ability to sell our products profitably.

Our ability to successfully commercialize and achieve market acceptance of our products depends in significant part on adequate financial coverage and reimbursement from third-party payors, including government healthcare programs, such as the Medicare and Medicaid programs within the U.S., and private entities, such as managed care organizations and private health insurers. Moreover, a third-party payor's decision to provide coverage for a product does not mean that an adequate reimbursement rate will be approved. We may be required to provide discounts or rebates to certain purchasers to obtain coverage under federal healthcare programs, or to sell products to government purchasers. Adequate third-party reimbursement may not be available to enable us to maintain net price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. The demand for, and the profitability of, our products could be materially harmed if state Medicaid programs, the Medicare program, other government healthcare programs, or third-party commercial payors deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms.

Third-party payors are increasingly challenging the price and examining the cost-effectiveness of new products and services in addition to their safety and efficacy. To obtain or maintain coverage and reimbursement for any approved drug product, we may need to collect real-world evidence and conduct pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain or maintain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product or, if they do, the level of payment may not be sufficient to allow sale of a product at a profit. Thus, obtaining and maintaining reimbursement status is complex and costly.

As part of the overall trend toward cost containment, third-party payors, directly or through pharmacy benefit managers, or PBMs, may seek to restrict coverage or control utilization of certain drug products. Third-party PBMs and third-party payors can limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication and can exclude drugs from their formularies in favor of competitor drugs or alternative treatments. We cannot guarantee that we will be able to agree to coverage terms with all PBMs and third-party payors. Payors could decide to exclude our products from formulary coverage lists, impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for our products, limit the types of diagnoses for which coverage will be provided, require pre-approval (known as “prior authorization”) for coverage of a prescription for each patient (to allow the payor to assess medical necessity) or impose a moratorium on coverage for products while the payor makes a coverage decision. An inability to maintain adequate access, including through formulary positions, could increase patient cost-sharing for our products and cause some patients to determine not to use our products.

Healthcare reform efforts, future legislation, and regulatory actions aimed at reducing healthcare costs could impact our ability to obtain or maintain coverage and adequate reimbursement. This could materially harm our business and financial result. *See “Regulatory Matters - Reimbursement”*. *See also, “Risks Related to Government Regulation - Healthcare reform initiatives and other legislative action applicable to our product candidates could limit our potential product revenue.”*

We may never receive approval to commercialize ELAHERE or our product candidates outside of the U.S.

We are not permitted to market or sell ELAHERE in the EU or in any other foreign countries on a commercial basis until we receive the requisite approval from such country’s regulatory authorities. Obtaining and maintaining marketing approval, or pricing and reimbursement approval, of ELAHERE or our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain equivalent approvals in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. The process for obtaining marketing approval in a foreign country is an extensive, lengthy, expensive, and uncertain process and the regulatory authority may reject a filing or delay, limit, or deny marketing approval for many reasons. In many jurisdictions outside the United States, a product must be approved for reimbursement before it can be approved for sale. Failure to obtain marketing approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for ELAHERE and could adversely affect our business and financial condition. Any such complications may reduce our target market and delay or limit the full commercial potential of ELAHERE.

Government pricing requirements, such as those under the Medicaid Drug Rebate Program, other federal government programs, and state price transparency laws, and their related reporting and payment obligations require strict adherence; our failure to adhere to such requirements could subject us to penalties, sanctions, and fines that could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

We participate in the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule, or FSS, pricing program, and the Tricare Retail Pharmacy program, and have obligations to report the average sales price for certain drug products to the Medicare program. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Requirements are subject to change. For example, as of January 1, 2022, all manufacturers must report the average sales price for drugs under the Medicare program regardless of whether they are enrolled in the Medicaid Drug Rebate Program.

If we become aware that our reporting for a prior quarter or other time period was incorrect or has changed as a result of recalculation of pricing data, we generally are obligated to resubmit the corrected data and provide refunds or other reconciliations. Price recalculations may affect the ceiling price at which we are required to offer our products to certain customers under the 340B program and increase our general costs.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales

price, if we fail to submit the required price data on a timely basis, or if we are found to have charged certain customers more than the statutorily mandated ceiling price. The Centers for Medicare & Medicaid Services, or CMS, also could decide to terminate our Medicaid Drug Rebate agreement. Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs could negatively impact our financial results.

Several states have passed or are considering legislation that requires or purports to require companies to report pricing information, including proprietary pricing information. Such reporting requirements are not always clearly defined and failure to appropriately disclose in accordance with these requirements may lead to the imposition of penalties.

Healthcare reform initiatives and other legislative action applicable to our product candidates could limit our potential product revenue.

In the U.S., federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare generally and drugs specifically. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (the “ACA”), which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. Since its enactment, there have been and likely will be judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. For example, tax reform legislation was enacted at the end of 2017 that eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called “individual mandate”). In 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Changes resulting from any successful challenges or other future modifications may have a material impact on our business.

Beyond the ACA, there are ongoing and widespread health care reform efforts, a number of which have focused on regulation of prices or payment for drug products. Drug pricing and payment reform was a focus of the Trump Administration and has been a focus of the Biden Administration. For example, federal legislation enacted in 2021 eliminates a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the Inflation Reduction Act (IRA) of 2022 contains various drug price negotiation, inflationary rebate, and pricing provisions. Among other provisions, the IRA imposes penalties if drug prices are increased at a rate faster than inflation, redesigns Medicare Part D benefits to shift a greater portion of the costs to manufacturers, and allows for the U.S. government to set prices for certain drugs in Medicare. More specifically, the IRA creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be limited by a cap that is defined by reference to, among other things, a specified non-federal average manufacturer price, starting in 2026 for certain products. It is not yet clear which products the government will select and subject to the cap, but if one of our products is subject to the government-established price, there could be a significant impact to our business. Further, failure to comply with requirements under the drug price negotiation program can result in an excise tax and/or a civil monetary penalty. The impact of the IRA on our business and the broader pharmaceutical industry remains uncertain, as the federal government has yet to make various IRA implementation decisions. This or any other legislative change could affect the market conditions for our products. We expect continued scrutiny on drug pricing and government price reporting from Congress, agencies, and other bodies.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price constraints, restrictions on copayment assistance by pharmaceutical manufacturers, value-based pricing, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed, and the IRA further delayed implementation of the rule until January 1, 2032.

Health care reform at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot, however, predict the ultimate content, timing, or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

In addition, other broader legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' commercial success. For example, the Budget Control Act of 2011, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and remains in effect through 2031 (except May 1, 2020 to March 31, 2022) unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

As our business grows, we will become increasingly subject to additional healthcare regulation and enforcement by various government entities, and our failure to strictly adhere to these regulatory regimes could have a detrimental impact on our business.

In the United States, pharmaceutical manufacturers and their products are subject to extensive federal and state regulation, including laws intended to prevent fraud and abuse in the healthcare industry. These laws subject us to regulations by regional, national, state and local agencies, including, but not limited to the DOJ, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, and other regulatory bodies. These laws include:

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing products prior to approval or for off-label use, and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including state anti-kickback and false claims laws and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers, report drug product pricing information, financial interactions with health care providers, or marketing expenditures and/or require the registration of pharmaceutical sales representatives.

Ensuring compliance is time-consuming and costly. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations, and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices are non-compliant. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may

be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

If we fail to comply with environmental, health, and safety laws and regulations that apply to us, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous federal, state, and local environmental, health, and safety laws and regulations, including those governing the manufacture and transportation of hazardous materials and pharmaceutical compounds. Although we believe that our contracted research, development, and manufacturing safety procedures for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could exceed our resources. We may be required to incur significant costs to comply with these laws in the future, including civil or criminal fines and penalties, which we may not be able to afford.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations applicable to us. These current or future laws and regulations may impair our research, development, or production efforts or impact the research activities we pursue, particularly with respect to research involving human subjects or animal testing. Our failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions, which could cause our financial condition to suffer.

Failure to comply with the Foreign Corrupt Practices Act and other similar anti-corruption laws and anti-money laundering laws, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations could subject us to significant penalties and damage our reputation.

We are subject to the Foreign Corrupt Practices Act (FCPA), which generally prohibits U.S. companies and intermediaries acting on their behalf from offering or making payments to “foreign officials” for the purpose of obtaining or retaining business or securing an improper business advantage. The FCPA also requires companies whose securities are publicly listed in the United States to maintain accurate books and records and to maintain adequate internal accounting controls. We are also subject to other similar anti-corruption laws and anti-money laundering laws, as well as export control laws, customs laws, sanctions laws, and other laws that apply to our activities in the countries where we operate. Certain of the jurisdictions in which we conduct or expect to conduct business have heightened risks for public corruption, extortion, bribery, pay-offs, theft, and other fraudulent practices. In many countries, health care professionals who serve as investigators in our clinical trials or may prescribe or purchase ELAHERE or any of our product candidates if they are approved, are employed by a government or an entity owned or controlled by a government. Dealings with these investigators, prescribers, and purchasers are subject to regulation under the FCPA. Under these laws and regulations, as well as other anti-corruption laws, anti-money-laundering laws, export control laws, customs laws, sanctions laws, and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties, and other sanctions.

Inadequate funding for the FDA, the Securities and Exchange Commission, and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively affect our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the U.S. Securities and Exchange Commission (SEC) and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time required for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, the U.S. government has shut down several times, including December 22, 2018 to January 25, 2019, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough employees and stop critical activities. If a prolonged government shutdown or a series of shutdowns occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to gain access to the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be subject to, or may in the future become subject to, U.S. federal and state and foreign laws and regulations imposing obligations on how we collect, use, disclose, store, and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and adversely affect our business. Ensuring compliance with such laws and regulations could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In many activities, including the conduct of clinical trials, we are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, destruction, and disposal of personal data. They also impose requirements with respect to notification and remediation of security breaches involving personal data. We must comply with laws and regulations associated with the international transfer of personal data based on the location in which the personal data originates and the location in which such data are processed. There is also heightened sensitivity around certain types of health data, which may be subject to additional protections. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause reputational harm, which could have a material adverse effect on our business.

The legislative and regulatory landscape for privacy and data security continues to evolve. For example, the EU General Data Protection Regulation (GDPR), which was effective as of May 25, 2018, introduced new data protection requirements in the European Union relating to the consent of the individuals to whom the personal data relate, the information provided to the individuals, the documentation we must retain, the security and confidentiality of the personal data, data breach notification, and the use of third-party processors in connection with the processing of personal data. The GDPR has increased our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR. However, our ongoing efforts related to compliance with the GDPR may not be successful and could increase our cost of doing business. In addition, data protection authorities of the different EU member states may interpret the GDPR differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union.

In the United States, numerous federal and state data protection laws govern our collection, use and disclosure of personal information. For example, the California Consumer Privacy Act of 2018 as amended and expanded by the California Privacy Rights Act of 2020 (together, the CCPA), mirrors a number of the key provisions of the EU GDPR and applies to a broad range of information deemed to be personal information. The CCPA establishes data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, requires additional disclosures and transparency, and requires us to allow consumers to opt-out of certain online disclosures. The CCPA also creates potentially significant statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Other similar laws will go into operation in 2023 or are under consideration in additional states and abroad in jurisdictions worldwide. Additionally, laws in all 50 states require businesses to provide notice to individuals whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly.

Any such additional legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, and may require additional investment of resources in compliance programs, impact strategies, reduce the availability of previously useful data and result in increased compliance costs and/or changes in business practices and policies.

Risks Related to Our Key Personnel and Other Service Providers

We depend on our key personnel, and we must continue to attract and retain key employees and consultants.

We depend on our key scientific and management personnel. Our ability to pursue the development and commercialization of ELAHERE and our product candidates depends largely on retaining the services of our existing personnel and hiring additional qualified personnel to perform research, development, and commercialization activities. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited. Attracting and retaining qualified personnel will be critical to our success. We may not be able to attract and retain personnel, or, in the event key personnel leave, suitable replacements for such personnel, on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical, and healthcare companies, universities, and non-profit research institutions. Failure to retain our existing key management and scientific personnel or to attract additional highly qualified personnel could harm our business.

Our employees, independent contractors, principal investigators, CROs, consultants, and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, third-party contract research organizations (CROs), consultants, and collaborators may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) laws or regulations in jurisdictions where we are performing activities in relation to ELAHERE or our product candidates, including those laws requiring the reporting of true, complete, and accurate information to such authorities; (2) manufacturing regulations and standards; (3) applicable laws prohibiting the promotion of a medical product for a use that has not been cleared or approved; (4) fraud and abuse, anti-corruption, and anti-money laundering laws, as well as similar laws and regulations and other laws; or (5) laws that require the reporting of true and accurate financial information and data. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to laws intended to prevent fraud, bias, misconduct, kickbacks, self-dealing, and other abusive practices, and these laws may differ substantially from country to country. Misconduct by these parties could also include the improper use of information obtained in the course of clinical trials or performing other services, which could result in investigations, sanctions, and serious harm to their or our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions and procedures we currently take or may establish in the future as our operations and employee, CRO, consultant, and collaborator base expands to detect and prevent this type of activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure by these parties to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to Our Technology Systems

Our business and operations could suffer in the event of system failures.

We utilize information technology systems and networks to process, transmit, and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability, and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other contractors and consultants, are vulnerable to damage from cyber-attack, computer viruses, unauthorized access,

natural disasters, terrorism, war, and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third-party CROs and other contractors and consultants. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

Risks Related to the Ownership of Our Common Stock

Our stock price may be volatile and fluctuate significantly and results announced by us and our collaborators or competitors could cause our stock price to decline.

Our stock price could fluctuate significantly due to the risks listed in this section, business developments announced by us and by our collaborators and competitors, or as a result of market trends and daily trading volume. The business developments that could affect our stock price include disclosures related to clinical findings with compounds that make use of our ADC technology, new collaborations, clinical advancement, or discontinuation of product candidates that make use of our ADC technology or product candidates that compete with our compounds or those of our collaborators, and regulatory approvals for our product candidates or product candidates that compete with our compounds or those of our collaborators. Our stock price could also fluctuate significantly with the level of overall investment interest in small-cap biotechnology stocks or for other reasons unrelated to our business.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenue is unpredictable and may fluctuate due to the timing of non-recurring licensing fees, decisions of our collaborators with respect to our agreements with them, and the achievement of milestones and our receipt of the related milestone payments under new and existing licensing and collaboration agreements. Revenue historically recognized under our prior collaboration agreements may not be an indicator of revenue from any future collaboration. In addition, our expenses are unpredictable and may fluctuate from quarter to quarter due to the timing of expenses, which may include obligations to manufacture or supply product or payments owed by us under licensing or collaboration agreements. It is possible that our quarterly and/or annual operating results will not meet the expectations of securities analysts or investors, causing the market price of our common stock to decline. We believe that quarter-to-quarter and year-to-year comparisons of our operating results are not good indicators of our future performance and should not be relied upon to predict the future performance of our stock price.

The potential sale of additional shares of our common stock may cause our stock price to decline.

We may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest of existing shareholders will be diluted, and the price of our stock may decline. The price of our common stock may also decline if the market expects us to raise additional capital through the sale of equity or convertible debt securities whether or not we actually plan to do so.

We do not intend to declare or pay cash dividends on our common stock in the foreseeable future.

We have not declared or paid cash dividends on our common stock since our inception and do not intend to declare or pay cash dividends in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Therefore, shareholders will have to rely solely on appreciation in our stock price, if any, in order to achieve a gain on an investment.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

We lease approximately 120,000 square feet of laboratory and office space in a building located at 830 Winter Street, Waltham, MA. The term of the 830 Winter Street lease expires on March 31, 2026, with an option for us to extend the lease for two additional five-year terms. We currently sublet approximately 37,000 square feet of this space through the remaining term of the initial lease, and we continue to use the remaining space.

Item 3. *Legal Proceedings*

From time to time, we may be a party to various legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

Item 4. *Mine Safety Disclosures*

None.

PART II**Item 5. *Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities*****Market Price of Our Common Stock and Related Stockholder Matters**

Our common stock is quoted on the Nasdaq Global Select Market under the symbol “IMGN.” As of February 21, 2023, we had 398 holders of record of our common stock.

We have not paid any cash dividends on our common stock since our inception and do not intend to pay any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities; Uses of Proceeds from Registered Securities; Issuer Repurchases of Equity Securities

None.

Item 6. *Reserved*

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

Overview

We are a commercial-stage biotechnology company focused on developing and commercializing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer patients more good days. We call this our commitment to “target a better now.”

An ADC with our proprietary technology comprises an antibody that binds to a target found on tumor cells and is conjugated to one of our potent anti-cancer agents as a “payload” to kill the tumor cell once the ADC has bound to its target. ADCs are an expanding class of anticancer therapeutics, with twelve approved products and the number of agents in development growing significantly in recent years.

We have established a leadership position in ADCs with a portfolio of differentiated product candidates to address both solid tumors and hematologic malignancies. We have set four strategic priorities for the business:

- execute the commercial launch for ELAHERE;
- expand the ELAHERE label by moving into platinum-sensitive ovarian cancer;
- advance our clinical pipeline of novel ADCs for hematologic and solid tumors; and
- strengthen and expand our pipeline through both internal discovery and external partnerships.

We believe that sound execution of these prioritized activities will create substantial short-and long-term value for shareholders, employees, patients, and other stakeholders in the Company.

ELAHERE (Mirvetuximab Soravtansine)

Approval and Launch

ELAHERE is a first-in-class ADC targeting folate receptor alpha (FR α), a cell-surface protein over-expressed in a number of epithelial tumors, including ovarian, endometrial, and non-small-cell lung cancers. On November 14, 2022, the FDA granted accelerated approval for ELAHERE for the treatment of adult patients with FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. The accelerated approval of ELAHERE was based on efficacy and safety outcomes from SORAYA, a single-arm trial of ELAHERE in patients with platinum-resistant ovarian cancer whose tumors express high levels of FR α . Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. Patients eligible for treatment with ELAHERE are selected by the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay developed by RTD, which was also approved by the FDA on November 14, 2022. We completed the build out of our U.S. commercial infrastructure in 2022 and initiated sales in the U.S. in November 2022.

Ongoing Development

In addition to SORAYA, we are conducting MIRASOL, a randomized Phase 3 clinical trial designed to support full approval of ELAHERE. In July of 2022, we completed enrollment in MIRASOL and expect to report top-line data from this trial in the second quarter of 2023. If the MIRASOL trial is successful, we plan to submit a marketing authorisation application for approval of ELAHERE for the treatment of adult patients with FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens with the EMA in the second half of 2023. Additionally, our partner, Huadong Medicine, expects to submit a biologics license application to the National Medical Products Administration (NMPA) of China for ELAHERE in the same indication in the second half of 2023 to support potential approval and launch of ELAHERE in Greater China in 2024.

Beyond platinum-resistant ovarian cancer, our strategy is to move ELAHERE into platinum-sensitive disease, and to position the product as the combination agent of choice in ovarian cancer. To this end, in January 2023, we completed patient enrollment in PICCOLO, a single-arm trial of ELAHERE monotherapy in later-line FR α positive platinum-sensitive patients, and plan to report on the primary endpoint before the end of 2023. We have also generated encouraging data in recurrent platinum-sensitive disease with the combination of ELAHERE plus carboplatin and are supporting investigator sponsored trials (ISTs) with this combination in a single arm trial in the neoadjuvant setting and in a randomized trial comparing ELAHERE combined with carboplatin to standard of care in patients with recurrent

platinum-sensitive disease. We also initiated a single-arm Phase 2 trial (0420) of this combination followed by ELAHERE continuation in FR α -low, medium, and high patients with platinum-sensitive disease. Results from this trial and our ongoing ISTs will inform a path to the potential registration for ELAHERE plus carboplatin and, in parallel, could support compendia listing for this combination. Finally, we have initiated GLORIOSA, a randomized Phase 3 trial of ELAHERE plus bevacizumab maintenance in FR α -high recurrent platinum-sensitive disease that we believe could support label expansion.

Pivekimab Sunirine

Pivekimab sunirine (PVEK), formerly known as IMG632, is an ADC comprised of a high-affinity antibody designed to target CD123 with site-specific conjugation to a DNA-alkylating payload of the novel IGN (indolinobenzodiazepine pseudodimer) class. Our IGNs are designed to alkylate DNA without cross-linking, which has provided a broad therapeutic index in preclinical models. We are advancing PVEK in clinical trials for patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) and acute myeloid leukemia (AML).

BPDCN is a rare form of blood cancer, with an annual incidence of between 500 and 1,000 patients in the US. In October 2020, the FDA granted Breakthrough Therapy designation for PVEK for the treatment of patients with relapsed or refractory BPDCN. Based on feedback from the FDA, we amended our ongoing 801 Phase 2 trial, known as CADENZA, to include a new cohort of up to 20 frontline BPDCN patients.

Initial enrollment in CADENZA did not distinguish between de novo BPDCN patients and those who presented with a prior or concomitant hematologic malignancy (PCHM). Although complete responses have been observed in BPDCN patients who present with PCHM, most will not achieve full hematologic recovery due to the impact of their prior or concomitant malignancy. For these patients, we believe that achieving a complete response with partial hematological recovery (CRh) is a potentially important measure of clinical benefit.

A Type B meeting was held in August 2022 regarding the initial data from the CADENZA trial. Based on FDA feedback on trial design provided in this meeting, the efficacy analysis will be conducted in de novo BPDCN patients with CR/CRc as the primary endpoint and the key secondary endpoint of duration of CR/CRc. We will enroll up to 20 de novo patients for purposes of the efficacy analysis. We will also continue to enroll PCHM patients in CADENZA to further evaluate PVEK in this population. The Company expects to report top-line data on the primary and key secondary endpoints in 2024.

We are also conducting our 802 trial for PVEK, which is a Phase 1b/2 trial designed to determine the safety, tolerability, and preliminary antileukemia activity of PVEK when administered in combination with azacytidine and venetoclax to patients with relapsed and frontline CD123-positive AML. Having identified the recommended Phase 2 dose for the triplet, patients are accruing in both expansion cohorts. In December 2022, safety and efficacy findings in relapsed refractory AML and initial data in frontline AML was presented at the American Society of Hematology Annual Meeting. In the first 10 frontline patients enrolled, 5/10 (50%) patients achieved a CR and 3/4 (75%) patients tested had a minimal residual disease (MRD)-negative CR. Based upon these results, the Company will continue enrollment in two frontline AML expansion cohorts to optimize the duration of venetoclax therapy. In addition, in December 2022, the Company announced a clinical collaboration with Gilead Sciences, Inc. to study PVEK in combination with magrolimab in relapsed refractory AML and expects to initiate this cohort under the 802 trial in the second half of 2023.

Other Pipeline Programs

We continue to advance our earlier-stage pipeline programs. IMG936 is an ADC in co-development with MacroGenics, Inc. that is designed to target ADAM9, an enzyme over-expressed in a range of solid tumors and implicated in tumor progression and metastasis. IMG936 incorporates a number of innovations, including antibody engineering to extend half-life, site-specific conjugation with a fixed drug-antibody ratio to enable higher dosing, and a next-generation linker and payload designed for improved stability and bystander activity. Phase 1 dose escalation was completed and expansion cohorts in non-small cell lung cancer and triple-negative breast cancer initiated in the second half of 2022. We expect to provide initial data from these cohorts in the second quarter of 2023.

IMG151 is our next generation anti-FR α product candidate in development. This ADC integrates innovation in each of its components, which we believe may enable IMG151 to address patient populations with lower levels of FR α expression, including tumor types outside of ovarian cancer. We began enrollment in a Phase I clinical trial evaluating IMG151 in patients with recurrent endometrial cancer and recurrent, high-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancers in January 2023.

We have selectively licensed restricted access to our ADC platform technology to other companies to expand the use of our technology and to provide us with cash to fund our own product programs. These agreements typically provide the licensee with rights to use our ADC platform technology with its antibodies or related targeting vehicles to a defined target to develop products. The licensee is generally responsible for the development, clinical testing, manufacturing, registration, and commercialization of any resulting product candidate. As part of these agreements, we are generally entitled to receive upfront fees, potential milestone payments, and royalties on the sales of any resulting products. For more information concerning these relationships, including their ongoing financial and accounting impact on our business, please read Note C, “Significant Collaborative Agreements,” to our consolidated financial statements included in this report.

We expect to continue to incur substantial operating losses for at least the near term as we incur significant operating expenses related to research and development and selling and marketing of ELAHERE. As of December 31, 2022, we had \$275.1 million in cash and cash equivalents compared to \$478.8 million as of December 31, 2021.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make certain estimates and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reported periods. These items are monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are reflected in reported results for the period in which the change occurs. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We believe that our application of the following accounting policies, each of which requires significant judgments and estimates on the part of management, are the most critical to aid in fully understanding and evaluating our reported financial results:

- inventory capitalization;
- revenue recognition;
- clinical trial accruals; and
- stock-based compensation.

Our accounting policies are more fully described in the Notes to our consolidated financial statements, including Note B, “Summary of Significant Accounting Policies,” included in this Annual Report on Form 10-K.

Managing the Impact of the COVID-19 Pandemic

Since the first quarter of 2020, although we have experienced some delays or disruptions due to the COVID-19 pandemic, we have successfully continued to move our clinical trials forward while adapting to meet the evolving challenges of the pandemic. We implemented business continuity plans in March 2020 that enabled our workforce to remain productive while working from home until mid-September 2021, at which time our workforce returned to the office. From a regulatory perspective, since the beginning of the pandemic, we have received timely reviews of our submissions to the FDA and other health authorities covering our clinical trial applications. From a manufacturing and supply chain perspective, we believe we have sufficient inventory on hand for all of our ongoing and near-term clinical trials and to support the launch of ELAHERE. COVID-19 may impact our commercial activities for ELAHERE, including patient access to testing and identification, but we will conduct commercial and medical affairs field activities in virtual formats where in-person interactions are not feasible.

Results of Operations

For a discussion related to the results of operations for 2021 compared to 2020, refer to Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 28, 2022.

Revenues

For 2022, our total revenues increased to \$108.8 million compared to \$69.9 million for 2021, driven by increases in license and milestone fees and ELAHERE net product revenue, partially offset by a decrease in non-cash royalty revenue, all of which are discussed further below.

Product revenue, net

On November 14, 2022, the FDA granted accelerated approval for ELAHERE for the treatment of adult patients with FRa positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. We recorded \$2.6 million of net product revenue related to U.S. sales of ELAHERE in the fourth quarter of 2022.

License and milestone fees

The amount of license and milestone fees we earn is directly related to the number of our collaborators, the collaborators' advancement of the product candidates, and the overall success in clinical trials of the product candidates. As such, the amount of license and milestone fees may vary widely from quarter to quarter and year to year. Total revenue recognized from license and milestone fees for the years ended December 31, 2022 and 2021 was \$76.0 million and \$22.7 million, respectively. Driving the increase, pursuant to our license agreement with Huadong executed in October 2020, upon delivery of clinical supply in 2022 and 2021, we recognized \$25.4 million and \$14.6 million, respectively, of the one-time upfront payment previously received pursuant to our license agreement. Additionally, pursuant to license agreements executed with Lilly and Magenta in 2022, we recognized \$18.4 million and \$6.0 million, respectively, of upfront payments received. We also recorded \$23.2 million of revenue related to development and regulatory milestones achieved under various license and collaboration agreements in 2022 compared to \$7.4 million in 2021, and \$2.8 million of deferred revenue related to upfront payments previously received pursuant to certain license agreements with Novartis that were terminated in 2022.

Deferred revenue of \$50.2 million as of December 31, 2022 includes \$7.6 million related to the multi-target license agreement with Lilly and \$41.2 million related to the sale of our residual rights to receive royalty payments on commercial sales of KADCYLA in 2019, with the remainder of the balance primarily representing consideration received from our other collaborators pursuant to our license agreements that we have yet to earn pursuant to our revenue recognition policy.

Non-cash royalty revenue related to the sale of future royalties

KADCYLA is a marketed ADC resulting from one of our development and commercialization licenses with Roche, through its Genentech unit. We receive royalty reports and payments related to sales of KADCYLA from Roche one quarter in arrears. We sold our rights to receive royalty payments on the net sales of KADCYLA through two separate transactions in 2015 and 2019. In accordance with our revenue recognition policy, \$29.3 million and \$46.8 million of non-cash royalties on net sales of KADCYLA were recorded and included in royalty revenue for 2022 and 2021, respectively. The decrease in non-cash royalty revenue in 2022 compared to 2021 is a result of the aggregate royalty threshold, as outlined in the 2015 royalty purchase agreement, being met in the second quarter of 2021, effectively reducing the royalty payments under the 2015 transaction from 100% to 15% of KADCYLA royalty payments received over the remaining royalty term. See further details regarding these agreements in Note H, "Liability Related to Sale of Future Royalties," of the Consolidated Financial Statements.

Cost of Sales

Our cost of sales includes the cost of producing and distributing inventories that are related to product revenue, including freight. In addition, shipping and handling costs for product shipments are recorded as incurred. Finally, cost of sales may also include costs related to excess or obsolete inventory adjustment charges.

Prior to receiving FDA approval for ELAHERE in November 2022, we manufactured inventory to be sold upon commercialization and recorded the costs as research and development expense. As a result, the manufacturing costs related to the inventory build-up incurred before FDA approval were expensed in a prior period and are therefore excluded from the cost of goods sold for the year ended December 31, 2022. We estimate our cost of sales related to product revenue as a percentage of net product revenue will continue to be positively affected as we sell through certain inventory that was previously expensed prior to FDA approval. We expect to utilize zero and low-cost inventory for an extended period of time.

Research and Development Expenses

Our research and development expenses relate to (i) research to evaluate new targets and to develop and evaluate new antibodies, linkers, and cytotoxic agents, (ii) preclinical testing of our own and, in certain instances, our collaborators' product candidates, and the cost of our own clinical trials, (iii) development related to clinical and commercial manufacturing processes, (iv) regulatory activities, (v) medical affairs activities, and (vi) external manufacturing operations.

Clinical trial and regulatory approval processes for our product candidates that have advanced or that we intend to advance to clinical testing are lengthy, expensive, and uncertain in both timing and outcome. As a result, the pace and timing of the clinical development of our product candidates is highly uncertain and may never result in approved products. Completion dates and development costs will vary significantly for each product candidate and are difficult to predict. A variety of factors, many of which are outside our control, could cause or contribute to the prevention or delay of the successful completion of our clinical trials, or delay or prevent our obtaining necessary regulatory approvals. The costs to take a product through clinical trials are dependent upon, among other factors, the clinical indications, the timing, size, and design of each clinical trial, the number of patients enrolled in each trial, and the speed at which patients are enrolled and treated. Product candidates may be found to be ineffective or to cause unacceptable side effects during clinical trials, may take longer to progress through clinical trials than anticipated, may fail to receive necessary regulatory approvals, or may prove impractical to manufacture in commercial quantities at reasonable cost or with acceptable quality.

The lengthy process of securing FDA approvals for new drugs requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals, could materially adversely affect our product development efforts and our business overall. Accordingly, we cannot currently estimate, with any degree of certainty, the amount of time or money that we will be required to expend in the future on our product candidates prior to their regulatory approval, if such approval is ever granted.

Research and development expense was \$213.4 million and \$151.1 million for 2022 and 2021, respectively, with increased expenses related to personnel, third-party staffing costs, external manufacturing costs, clinical trial costs, and contract services, including medical affairs activities in support of advancing ELAHERE, which are discussed further below.

We do not track our research and development costs by project. Since we use our research and development resources across multiple research and development projects, we manage our research and development expenses within each of the categories listed in the following table and described in more detail below (in thousands):

Research and Development Expenses	Year Ended December 31,		Increase/ (Decrease)
	2022	2021	
Research	\$ 8,913	\$ —	\$ 8,913
Preclinical and clinical testing	140,873	99,971	40,902
Process and product development	7,499	7,010	489
Manufacturing operations	56,085	44,136	11,949
Total research and development expenses	<u>\$ 213,370</u>	<u>\$ 151,117</u>	<u>\$ 62,253</u>

Research

Research includes expenses to evaluate new targets and to develop and evaluate new antibodies, linkers, and cytotoxic agents. Such expenses include third-party license fees, research funding payments, and contract services. Pursuant to a research collaboration agreement executed with Oxford BioTherapeutics in June 2022, we recognized \$1.4 million of committed research costs in 2022, as well as a \$7.5 million upfront license fee paid upon execution of the agreement. No similar expenses were recorded in 2021.

Preclinical and clinical testing

Preclinical and clinical testing includes expenses related to preclinical testing of our own, and, in certain instances, our collaborators' product candidates, regulatory activities, the cost of clinical trials, and expenses related to medical affairs. Such expenses include those related to personnel, third-party staffing, patient enrollment at our clinical testing sites, consultant fees, contract services, and facility expenses. Preclinical and clinical testing expenses increased to \$140.9 million for 2022 compared to \$100.0 million for 2021. This increase is primarily the result of increases in personnel, third-party staffing costs, contract services driven by medical affairs' activities in support of advancing ELAHERE, and clinical trial costs driven by our ELAHERE and PVEK trials.

Process and product development

Process and product development expenses include costs for development of clinical and commercial manufacturing processes for our own and collaborator compounds. Such expenses include the costs of personnel, third-party staffing, contract services, and facility expenses. Process and product development expenses increased to \$7.5 million for 2022 compared to \$7.0 million for 2021, due primarily to increased personnel-related costs.

Manufacturing operations

Manufacturing operations expense includes costs to have preclinical and clinical materials manufactured for our product candidates and quality control and quality assurance activities. Such expenses include personnel, third-party staffing, raw materials for our preclinical studies and clinical trials, non-pivotal and pivotal development costs with contract manufacturing organizations, and facility expenses. Manufacturing operations expense increased \$11.9 million to \$56.1 million for 2022 compared to 2021. The increase in 2022 is principally due to increases in personnel-related costs and external manufacturing activity across our programs.

Manufacturing operations expense also includes antibody development and supply expense in support of commercial validation and in anticipation of potential future clinical trials, as well as our ongoing trials, of \$18.9 million and \$20.6 million for 2022 and 2021, respectively. The process of antibody production is lengthy due in part to the lead time to establish a satisfactory production process at a vendor. Accordingly, costs incurred related to antibody production and development have fluctuated from period to period. Additionally, antibody used in the manufacture and sale of ELAHERE produced subsequent to FDA accelerated approval is capitalized and, therefore, we expect to record lower antibody expense in 2023 as compared to 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs, including stock-based compensation, for commercial operations and for personnel in executive, finance, accounting, business development, information technology, legal, and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, commercial development activities, legal fees related to intellectual property and corporate matters, and fees for accounting and consulting services.

Selling, general and administrative expenses increased \$72.3 million to \$116.1 million for 2022 due primarily to building our commercial capabilities, including personnel-related costs and infrastructure as well as expenses related to sales and marketing activities, in support of the U.S. launch of ELAHERE in the fourth quarter of 2022.

Investment Income, net

Investment income for 2022 and 2021 was \$4.3 million and \$0.1 million, respectively. The increase in 2022 was driven by a greater average cash balance and an increase in interest rates.

Non-Cash Interest Expense on Liability Related to Sale of Future Royalty

In 2015, IRH purchased our right to receive 100% of the royalty payments on commercial sales of KADCYLA arising under our development and commercialization license with Genentech, subject to a residual cap. In January 2019, OMERS purchased IRH's right to the royalties the Company previously sold in 2015. As described in Note H, "Liability Related to Sale of Future Royalties," to our Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over the estimated royalty payment period as KADCYLA royalties are remitted directly to the purchaser. During 2022 and 2021, we recorded \$4.2 million and \$13.1 million, respectively, of non-cash interest expense, which includes amortization of deferred financing costs. The decrease in 2022 was a result of a lower average royalty liability balance for the year and the KADCYLA royalty threshold being met in the second quarter of 2021, effectively reducing the royalty payments under the 2015 transaction from 100% to 15% of KADCYLA royalty payments received over the remaining royalty term.

We record interest expense at the imputed interest rate, which we currently estimate to be 10.5%. There are a number of factors that could materially affect the estimated interest rate in the future, in particular, the estimated amount and timing of royalty payments from future net sales of KADCYLA. We assess this estimate on a periodic basis and any resulting change in interest rate will be adjusted prospectively.

Other Expense, net

Other expense, net for 2022 and 2021 was \$1.0 million and \$1.1 million, respectively, substantially consisting of foreign currency exchange losses related to obligations with non-U.S. dollar-based suppliers and Euro cash balances maintained to fulfill them during the respective periods.

Income Tax Expense

For the year ended December 31, 2022, we incurred a tax expense of \$1.2 million, primarily related to a significant income inclusion for U.S. tax purposes resulting from the transfer of certain intellectual property rights to a newly formed Swiss subsidiary and the impact of R&E capitalization pursuant to Section 174 of the 2017 Tax Act in 2022, partially offset by net operating loss carryforwards and credits. No similar expense was recorded in 2021.

Liquidity and Capital Resources

For a discussion related to our cash flows for 2021 compared to 2020, refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 28, 2022.

The following tables show certain balance sheet and cash flow information as of and for the periods indicated (in thousands):

	As of December 31,	
	2022	2021
Cash and cash equivalents	\$ 275,138	\$ 478,750
Working capital	182,263	399,054
Shareholders' equity	155,826	325,586

	Year Ended December 31,	
	2022	2021
Cash used for operating activities	\$ (229,802)	\$ (169,416)
Cash used for investing activities	(1,364)	(1,434)
Cash provided by financing activities	27,554	355,744

Cash Flows

We require cash to fund our operating expenses, including the advancement of our clinical programs, and to make capital expenditures. Historically, we have funded our cash requirements primarily through equity and convertible debt financings in private and public markets and payments from our collaborators, including license fees, milestones, research funding, and royalties. We also monetized our rights to receive royalties on KADCYLA for upfront consideration. As of December 31, 2022, we had \$275.1 million in cash and cash equivalents. Net cash used for operating activities was \$229.8 million and \$169.4 million during 2022 and 2021, respectively. The principal use of cash in operating activities for these periods was to fund our net loss, adjusted for non-cash items, with 2022 benefiting from \$32.0 million of upfront payments pursuant to license agreements with Lilly and Magenta.

Net cash used for investing activities was \$1.4 million for each of 2022 and 2021, consisting of cash outflows for capital expenditures in both periods, including leasehold improvements, computer and office equipment, and dedicated equipment at third-party manufacturing vendors.

Net cash provided by financing activities was \$27.6 million and \$355.7 million for 2022 and 2021, respectively. During 2022 and 2021, we sold 5.2 million and 6.7 million shares, respectively, of our common stock under our Open Market Sale AgreementSM (Sale Agreement) with Jefferies, LLC as sales agent, dated December 18, 2020, generating net proceeds of \$25.6 million and \$45.8 million in 2022 and 2021, respectively. Pursuant to the Sale Agreement, we may offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$150.0 million. As of December 31, 2022, \$76.3 million remains available under the Sale Agreement. In connection with entering into the Sale Agreement, we filed a prospectus supplement to the prospectus included in our registration statement on Form S-3 (No. 333-251502), which became effective upon filing on December 18, 2020, with the SEC relating to the offer and sale of the up to \$150.0 million of our common stock under the Sale Agreement.

In December 2021, pursuant to a public offering, we issued and sold 17.5 million shares of common stock and issued pre-funded warrants to purchase 27.4 million shares of common stock, resulting in aggregate net proceeds of \$277.6 million. Additionally, in August 2021, pursuant to a Securities Purchase Agreement with RA Capital Healthcare Fund, L.P., we issued a pre-funded warrant to purchase up to approximately 5.4 million shares of common stock, resulting in net proceeds of \$29.8 million.

Net cash provided by financing activities for 2022 and 2021 also include proceeds from the exercise of stock options and sale of shares through our ESPP.

Future Capital Requirements

We have significant future capital requirements including:

- significant expected operating expenses to commercialize ELAHERE;
- significant expected operating expenses to conduct research and development activities and to

potentially commercialize additional product candidates from our portfolio;

- noncancelable in-process and future manufacturing obligations, including commercial supply of ELAHERE; and
- substantial facility lease obligations as described in Note K, “Leases,” included in this Annual Report on Form 10-K.

Our current level of cash and cash equivalents is not sufficient to meet our current operating plans for the next twelve months following the issuance of these financial statements. We plan to meet our operating cash flow requirements with current cash and cash equivalents, cash generated from commercial sales of ELAHERE, milestone payments from new or existing collaborations, and additional funds accessed through equity, debt, or other financings such as royalty financing transactions, as well as cash preservation activities. Such activities may not succeed. The failure to obtain sufficient funds on acceptable terms could have a material adverse effect on our business, results of operations, and financial condition and require us to defer or limit some or all of our research, development, clinical and/or commercial projects, including trials to support potential label expansion of ELAHERE.

Recent Accounting Pronouncements

The information set forth under Note B to the consolidated financial statements under the caption “Recently Adopted Accounting Pronouncements” is incorporated herein by reference.

Item 7A. *Quantitative and Qualitative Disclosure About Market Risk*

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs, and maximize yields. Our investments are comprised of money market funds consisting principally of U.S. Government-issued securities and high quality, short-term commercial paper. We do not currently own derivative financial instruments in our investment portfolio. Accordingly, we do not believe there is any material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

Our foreign currency hedging program uses either forward contracts or a Euro-denominated bank account to manage the foreign currency exposures that exist as part of our ongoing business operations. Our foreign currency risk management strategy is principally designed to mitigate the future potential financial impact of changes in the value of transactions, anticipated transactions, and balances denominated in foreign currency resulting from changes in foreign currency exchange rates. Our market risks associated with changes in foreign currency exchange rates are currently limited to a Euro-denominated bank account as we had no forward contracts at December 31, 2022. Accordingly, we do not believe there was any material market risk exposure with respect to foreign currency exposures that would require disclosure under this item.

Item 8. Financial Statements and Supplementary Data

IMMUNOGEN, INC.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of ImmunoGen, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ImmunoGen, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at 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 U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2023 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note A to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note A. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter 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 account or disclosure to which it relates.

Clinical Trial Accrual

Description of the Matter As discussed in Note B to the consolidated financial statements, the Company estimates certain clinical trial expenses due to a lag in receiving information from third parties. Moreover, payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred. The Company maintained a clinical trial accrual of \$15.7 million at December 31, 2022 included as a component of other accrued liabilities.

Auditing the Company's clinical trial accruals was especially subjective due to the management judgment used to estimate the patient-related costs incurred but not yet invoiced. While the Company's estimates of patient-related costs incurred but not yet invoiced are primarily based on information received from its vendors related to each clinical trial, the Company may need to use assumptions such as estimates of patient enrollment, patient cycles incurred, clinical sites activated, and other pass-through costs in determining its accrual. Additionally, due to the duration of the clinical trials as well as the timing of invoices received from vendors, actual amounts incurred are not typically known at the time the financial statements are issued.

*How We
Addressed the
Matter in Our
Audit*

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls related to clinical trial accruals. For example, we tested management's review controls over the accuracy and completeness of the underlying data and the assumptions used in the Company's process for recording accrued patient-related costs.

Our audit procedures to test clinical trial accruals included, among others, testing the accuracy and completeness of the underlying data used to estimate costs incurred but not yet invoiced as well as evaluating and testing the assumptions used by management. We inspected the contracts and any amendments to the contracts with third parties and assessed the pattern of historical invoicing activity and the associated billing lags. We also corroborated the progress of clinical trials and other research and development projects through discussion with the Company's research and development personnel that oversee the clinical trials. In addition, we inspected information obtained by the Company directly from third-party vendors, which included the third-party vendors' estimate of costs incurred to date. We also compared subsequent invoices received from third-party vendors to the amounts accrued.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2001.
Boston, Massachusetts
March 1, 2023

IMMUNOGEN, INC.
CONSOLIDATED BALANCE SHEETS

In thousands, except per share amounts

	December 31, 2022	December 31, 2021
ASSETS		
Cash and cash equivalents	\$ 275,138	\$ 478,750
Accounts receivable	12,596	4,467
Unbilled receivable	1,531	2,345
Contract assets	—	3,000
Non-cash royalty receivable	3,851	4,115
Prepaid and other current assets	11,005	7,322
Total current assets	304,121	499,999
Property and equipment, net of accumulated depreciation	4,377	4,663
Operating lease right-of-use assets	10,231	12,392
Inventory	16,196	—
Other assets	14,011	8,711
Total assets	\$ 348,936	\$ 525,765
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	\$ 45,353	\$ 18,434
Accrued compensation	11,111	5,469
Other accrued liabilities	38,783	23,077
Current portion of liability related to the sale of future royalties, net of deferred financing costs of \$162 and \$198, respectively	8,659	6,077
Current portion of operating lease liability	4,096	3,537
Current portion of deferred revenue	13,856	44,351
Total current liabilities	121,858	100,945
Deferred revenue, net of current portion	36,355	47,717
Operating lease liability, net of current portion	11,148	15,244
Liability related to the sale of future royalties, net of current portion and deferred financing costs of \$205 and \$381, respectively	23,449	34,967
Other long-term liabilities	300	1,306
Total liabilities	193,110	200,179
Commitments and contingencies (Note L)		
Shareholders' equity:		
Preferred stock, \$.01 par value; authorized 5,000 shares; no shares issued and outstanding as of each of December 31, 2022 and 2021	—	—
Common stock, \$.01 par value; authorized 600,000 shares; 226,046 and 220,361 shares issued and outstanding as of December 31, 2022 and 2021, respectively	2,260	2,204
Additional paid-in capital	1,847,638	1,794,525
Accumulated deficit	(1,694,072)	(1,471,143)
Total shareholders' equity	155,826	325,586
Total liabilities and shareholders' equity	\$ 348,936	\$ 525,765

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

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

In thousands, except per share amounts

	Year Ended December 31,		
	2022	2021	2020
Revenues:			
License and milestone fees	\$ 76,027	\$ 22,650	\$ 63,742
Non-cash royalty revenue related to the sale of future royalties	29,261	46,808	68,529
Product revenue, net.	2,554	—	—
Research and development support.	940	398	28
Total revenues	<u>108,782</u>	<u>69,856</u>	<u>132,299</u>
Cost and operating expenses:			
Cost of sales	176	—	—
Research and development	213,370	151,117	114,592
Selling, general and administrative	116,129	43,812	38,600
Restructuring charge	—	—	1,487
Total cost and operating expenses	<u>329,675</u>	<u>194,929</u>	<u>154,679</u>
Loss from operations.	(220,893)	(125,073)	(22,380)
Investment income, net.	4,341	51	729
Non-cash interest expense on liability related to the sale of future royalties and convertible senior notes	(4,165)	(13,103)	(23,107)
Interest expense on convertible senior notes	—	(47)	(95)
Other (expense) income, net.	(994)	(1,131)	481
Net loss before income taxes	<u>\$ (221,711)</u>	<u>\$ (139,303)</u>	<u>\$ (44,372)</u>
Income tax expense	1,218	—	—
Net loss.	<u>(222,929)</u>	<u>(139,303)</u>	<u>(44,372)</u>
Basic and diluted net loss per common share	<u>\$ (0.88)</u>	<u>\$ (0.68)</u>	<u>\$ (0.25)</u>
Basic and diluted weighted-average common shares outstanding.	<u>253,631</u>	<u>206,147</u>	<u>176,153</u>
Total comprehensive loss	<u>\$ (222,929)</u>	<u>\$ (139,303)</u>	<u>\$ (44,372)</u>

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

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

In thousands

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Shareholders' Equity
Balance at December 31, 2019	150,136	\$ 1,501	\$ 1,209,846	\$ (1,287,468)	\$ (76,121)
Net loss	—	—	—	(44,372)	(44,372)
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	458	5	1,466	—	1,471
Issuance of common stock, net of issuance costs	44,496	445	193,826	—	194,271
Restricted stock units vested	395	4	(4)	—	—
Restricted stock award forfeitures	(487)	(5)	5	—	—
Stock option and restricted stock compensation expense	—	—	13,978	—	13,978
Directors' deferred share unit compensation	—	—	343	—	343
Balance at December 31, 2020	194,998	\$ 1,950	\$ 1,419,460	\$ (1,331,840)	\$ 89,570
Net loss	—	—	—	(139,303)	(139,303)
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	998	10	3,759	—	3,769
Issuance of common stock, net of issuance costs	24,181	242	153,788	—	154,030
Issuance of pre-funded warrants, net of issuance costs	—	—	199,045	—	199,045
Conversion of convertible senior notes	239	3	997	—	1,000
Restricted stock units vested	2	—	—	—	—
Restricted stock award forfeitures	(57)	(1)	1	—	—
Stock option and restricted stock compensation expense	—	—	16,794	—	16,794
Directors' deferred share unit compensation	—	—	681	—	681
Balance at December 31, 2021	220,361	\$ 2,204	\$ 1,794,525	\$ (1,471,143)	\$ 325,586
Net loss	—	—	—	(222,929)	(222,929)
Issuance of common stock, net of issuance costs	5,167	51	25,598	—	25,649
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	491	5	1,900	—	1,905
Stock option and restricted stock compensation expense	—	—	24,899	—	24,899
Restricted stock units vested	27	—	—	—	—
Directors' deferred share unit compensation	—	—	716	—	716
Balance at December 31, 2022	226,046	\$ 2,260	\$ 1,847,638	\$ (1,694,072)	\$ 155,826

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

IMMUNOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands

	Year Ended December 31,		
	2022	2021	2020
Cash flows from operating activities:			
Net loss.....	\$ (222,929)	\$ (139,303)	\$ (44,372)
Adjustments to reconcile net loss to net cash used for operating activities:			
Non-cash royalty revenue related to sale of future royalties.....	(12,836)	(39,155)	(68,529)
Non-cash interest expense on liability related to sale of future royalties and convertible senior notes.....	4,165	13,103	23,107
Depreciation and amortization.....	1,783	2,017	2,101
Gain on sale/disposal of fixed assets and impairment charges.....	—	—	(691)
Stock and deferred share unit compensation.....	25,615	17,475	14,321
Change in operating assets and liabilities:			
Accounts receivable.....	(8,129)	(4,432)	7,465
Unbilled receivable.....	814	(2,334)	990
Inventory.....	(16,196)	—	—
Contract asset.....	3,000	(3,000)	3,631
Prepaid and other current assets.....	(3,683)	579	(2,476)
Operating lease right-of-use assets.....	2,161	1,680	1,515
Other assets.....	(5,300)	2,275	(7,202)
Accounts payable.....	26,735	9,148	(819)
Accrued compensation.....	5,642	849	(4,100)
Other accrued liabilities.....	14,750	(7,261)	16,734
Deferred revenue.....	(41,857)	(18,041)	(17,323)
Operating lease liability.....	(3,537)	(3,016)	(2,972)
Net cash used for operating activities.....	(229,802)	(169,416)	(78,620)
Cash flows from investing activities:			
Proceeds from sale of equipment.....	—	—	1,426
Purchases of property and equipment.....	(1,364)	(1,434)	(917)
Net cash used for investing activities.....	(1,364)	(1,434)	509
Cash flows from financing activities:			
Payments upon settlement of convertible senior notes.....	—	(1,100)	—
Proceeds from issuance of common stock under stock plans.....	1,905	3,769	1,471
Proceeds from warrant issuance, net of \$391 of transaction costs.....	—	199,045	—
Proceeds from common stock issuance, net of \$373 and \$701 of transaction costs, respectively.....	25,649	154,030	194,271
Net cash provided by financing activities.....	27,554	355,744	195,742
Net change in cash and cash equivalents.....	(203,612)	184,894	117,631
Cash and cash equivalents, beginning of period.....	478,750	293,856	176,225
Cash and cash equivalents, end of period.....	\$ 275,138	\$ 478,750	\$ 293,856
Supplemental cash flow information:			
Cash paid during the year for interest.....	\$ —	\$ 47	\$ 95

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

IMMUNOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. Nature of Business and Plan of Operations

ImmunoGen, Inc. (the Company) was incorporated in Massachusetts in 1981 and is focused on the development and commercialization of antibody-drug conjugates, or ADCs. On November 14, 2022, the U.S. Food and Drug Administration (FDA) granted accelerated approval for ELAHERE™ (mirvetuximab soravtansine-gynx) for the treatment of adult patients with folate receptor alpha (FR α)-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. ELAHERE was approved under FDA's accelerated approval program based on objective response rate (ORR), duration of response (DOR), and safety data from the pivotal SORAYA trial. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial.

The Company has generally incurred operating losses and negative cash flows from operations since inception, incurred a net loss of \$222.9 million during the year ended December 31, 2022, and had an accumulated deficit of approximately \$1.7 billion as of December 31, 2022. The Company has primarily funded these losses through payments received from its collaborations and equity, convertible debt, and other financings such as royalty financing transactions. Until the Company can generate significant cash flows from sales of ELAHERE, management expects to continue to generate substantial operating losses for at least the near term as the Company incurs significant operating expenses related to research and development and selling and marketing of ELAHERE.

At December 31, 2022, the Company had \$275.1 million of cash and cash equivalents on hand. The Company's current level of cash and cash equivalents is not sufficient to meet its current operating plans for the next twelve months following the issuance of these financial statements. As a result, substantial doubt is deemed to exist regarding the Company's ability to continue as a going concern for a period of one year from the issuance of these financial statements.

The Company plans to meet its operating cash flow requirements with its current cash and cash equivalents, cash generated from commercial sales of ELAHERE, milestone payments from new or existing collaborations, and additional funds accessed through equity, debt, or other financings such as royalty financing transactions, as well as cash preservation activities. Such activities may not succeed. The failure of the Company to obtain sufficient funds on acceptable terms could have a material adverse effect on the Company's business, results of operations, and financial condition and require the Company to defer or limit some or all of its research, development, clinical and/or commercial projects, including trials to support potential label expansion of ELAHERE.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, the development by its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, manufacturing and marketing limitations, challenges entering into new collaborations, complexities associated with managing collaboration arrangements, third-party reimbursements, and compliance with governmental regulations.

B. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, ImmunoGen Switzerland GmbH, ImmunoGen U.S. Holding, Inc., ImmunoGen Securities Corp., ImmunoGen Europe Limited, ImmunoGen BioPharma (Ireland) Limited, and Hurricane, LLC. All intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (U.S.) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Subsequent Events

The Company has evaluated all events or transactions that occurred after December 31, 2022 up through the date the Company issued these financial statements. On February 28, 2023, the Company and Vertex Pharmaceuticals Incorporated (“Vertex”) entered into a multi-target license and option agreement, pursuant to which the Company granted Vertex rights to the Company’s ADC technology to research and evaluate ADCs directed to specified targets, with an option to take exclusive development and commercialization licenses to a specified number of targets over a specified term. Under the terms of the agreement, the Company is entitled to receive an upfront payment of \$15.0 million. The Company did not have any other material subsequent events.

Revenue Recognition

Product Revenue

The Company generates product revenue from sales of ELAHERE in the U.S. to a limited number of specialty distributors and specialty pharmacy providers. These customers subsequently resell the products or dispense the products directly to patients. In addition, the Company has entered into arrangements with payors that provide for government mandated rebates, discounts, and allowances with respect to the utilization of its products.

Product revenue is recognized when the customer takes control of the product, typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price, which includes estimated reserves for variable consideration resulting from chargebacks, government rebates, trade discounts and allowances, product returns and other incentives that are offered within the contract with customers, healthcare providers, payors and other indirect customers relating to the sales of the Company’s product. Reserves are established based on the amounts earned or to be claimed on the related sales. Where appropriate, the Company utilizes the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as the Company’s current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns, the percentage of our products that are sold via these programs, and our product pricing. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company’s estimates. If actual results vary from the Company’s estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Chargebacks: Chargebacks for fees and discounts represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers and government agencies at prices lower than the list prices charged to the customers who directly purchase the product from the Company. The customers charge the Company for the difference between what they pay for the product and the ultimate contractually committed or government required lower selling price to the qualified healthcare providers. These reserves are estimated using the expected value method based upon a range of possible outcomes and are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue.

Government rebates: Government rebates consist of Medicare and Medicaid rebates, which were estimated using the expected value method, based upon a range of possible outcomes for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue.

Trade discounts and allowances: The Company provides the customers with discounts that are explicitly stated in the contracts and recorded as a reduction of revenue in the period the related product revenue is recognized.

Product returns: The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities based on available industry data and its visibility into the inventory remaining in the distribution channel.

Other deductions: Co-pay assistance relates to financial assistance provided to qualified patients, whereby the Company may assist them with prescription drug co-payments required by the patient’s insurance provider. Reserves for co-pay assistance are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue.

The Company entered into a third-party logistics distribution agreement (the 3PL Agreement) to engage a logistics distribution agent (the 3PL Agent) to distribute the Company’s products to its customers. The 3PL Agent provides services to the Company that include storage, distribution, processing product returns, customer service support, logistics

support, electronic data interface and system access support. Revenue is recognized upon transfer of control of the product to the customer.

As a practical expedient, sales commissions, which represent costs to obtain a contract, are expensed when incurred because the amortization period would have been one year or less. Sales commissions are recorded in selling, general and administrative expense and costs of sales, respectively, in the statements of operations and comprehensive loss. Additionally, as a practical expedient, the Company has elected to treat all shipping and handling fees related to delivery of product as fulfillment activities.

License and Milestone Fee Revenue

The Company enters into licensing and development agreements with collaborators for the development of ADCs. The terms of these agreements contain multiple promised goods and services which may include (i) licenses, or options to obtain licenses, to the Company's ADC technology, (ii) rights to future technological improvements, (iii) technology transfer services and other activities to be performed on behalf of the collaborative partner, and (iv) delivery of cytotoxic agents and/or the manufacture of preclinical and clinical materials for the collaborative partner. Payments to the Company under these agreements may include upfront fees, option fees, exercise fees, payments for services, payments for preclinical or clinical materials, payments based upon the achievement of certain milestones, and royalties on product sales. The Company follows the provisions of ASC 606, *Revenue from Contracts with Customers*, in accounting for these agreements.

Revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when or as the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations based on its assessment of whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

The Company exercises judgment in assessing those promised goods and services that are distinct and thus representative of performance obligations. To the extent the Company identifies multiple performance obligations in a contract, the Company must develop assumptions that require judgment to determine the estimated standalone selling price for each performance obligation in order to allocate the transaction price among the identified performance obligations. These judgments and assumptions are discussed in further detail below.

At December 31, 2022, the Company had the following types of agreements with the parties identified below:

- Development and commercialization licenses, which provide the counterparty with the right to use the Company's ADC technology and/or certain other intellectual property to develop and commercialize compounds to a specified antigen target:
 - Bayer (one exclusive single-target license)
 - CytomX (two exclusive single-target licenses)
 - Debiopharm (one exclusive single-compound license)
 - Eli Lilly and Company (multiple exclusive single-target licenses)
 - Fusion Pharmaceuticals (one exclusive single-target license)
 - Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (one territory-specific exclusive single-compound license)
 - Magenta Therapeutics (one exclusive single-target license)

Novartis (one exclusive single-target licenses)

Oxford BioTherapeutics/Menarini (one exclusive single-target license sublicensed from Amgen)

Roche, through its Genentech unit (five exclusive single-target licenses)

Viridian (one exclusive single-target license)

- Collaboration and license agreement to co-develop and co-commercialize a specified anticancer compound on established terms:

MacroGenics

During the year ended December 31, 2022, pursuant to notice received, certain exclusive development and commercialization licenses granted to Novartis were terminated.

There are no performance, cancellation, termination, or refund provisions in any of the arrangements that contain material financial consequences to the Company.

Development and Commercialization Licenses

The obligations under a development and commercialization license agreement generally include the license to the Company's ADC technology with respect to a specified antigen target or compound and may also include obligations related to rights to future technological improvements and other activities to be performed on behalf of the collaborative partner.

Generally, development and commercialization licenses contain non-refundable terms for payments and, depending on the terms of the agreement, provide that the Company will earn payments upon the achievement of certain milestones and royalty payments, generally until the later of the last applicable patent expiration or a fixed period of years after product launch. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights and/or the presence of comparable competing products. In certain instances, the Company may also provide cytotoxic agents and/or clinical materials or other services in addition to the development and commercialization licenses. For example, the Company may provide technology transfer services in connection with the out-licensing of product candidates initially developed by the Company and may also provide technical assistance and share any technology improvements with its collaborators during the term of the collaboration agreements. The Company does not directly control when or whether any collaborator will request certain services, achieve milestones, or become liable for royalty payments.

In determining the performance obligations for these arrangements, management evaluates whether the license is distinct and has significant standalone functionality either alone or with other readily available resources based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of ADC technology research expertise and ADC manufacturing capabilities in the general marketplace and whether technological improvements are required for the continued functionality of the license. If the license to the Company's intellectual property is determined to be distinct, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If the license is not distinct, the license is combined with other goods or services into a single performance obligation and revenue is recognized over time.

The Company estimates the standalone selling prices of the license and all other performance obligations based on market conditions, similar arrangements entered into by third parties, and entity-specific factors such as the terms of the Company's previous collaborative agreements, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, the Company's pricing practices and pricing objectives, the likelihood that technological improvements will be made, and, if made, will be used by the Company's collaborators, and the nature of the other services to be performed on behalf of its collaborators and market rates for similar services.

The Company recognizes revenue related to technology transfer activities and other services as the services are performed. The Company is generally compensated for these activities at negotiated rates that are consistent with what other third parties would charge. The Company records amounts recognized for services performed as a component of research and development support revenue.

The Company may also provide cytotoxic agents and/or preclinical and clinical materials (drug substance/drug product) to its collaborators at negotiated prices generally consistent with what other third parties would charge. The

Company recognizes revenue on cytotoxic agents and/or preclinical and clinical materials when control transfers to the collaborator as a component of research and development support revenue.

The Company recognizes revenue related to the rights to future technological improvements over the estimated term of the applicable license.

The Company's development and commercialization license agreements have milestone payments which for reporting purposes are aggregated into two categories: (i) development and regulatory milestones, and (ii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the FDA or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each arrangement, the Company evaluates any development and regulatory milestone payments to determine whether the milestone is considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated; otherwise, such amounts are considered constrained and excluded from the transaction price. As part of its evaluation of the constraint, the Company considers numerous factors, including whether the achievement of the milestone is outside the control of the Company and contingent upon the future success of clinical trials, the collaborator's efforts, or the receipt of regulatory approval. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development or regulatory milestones and any related constraint, and if necessary, adjusts the estimate of the transaction price. In addition, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service. If the milestone payment is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method. Amounts allocated to a satisfied performance obligation are recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

For development and commercialization license agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied) in accordance with the royalty recognition constraint. Under the Company's development and commercialization license agreements, the Company receives royalty payments based upon its licensees' net sales of covered products. Generally, under the development and commercialization agreements, the Company receives royalty reports and payments from its licensees approximately one quarter in arrears. The Company estimates the amount of royalty revenue to be recognized based on historical and forecasted sales and/or sales information from its licensees if available.

Collaboration and Option Agreements/Right-to-Test Agreements

The Company's right-to-test agreements provide collaborators the right to test the Company's ADC technology for a defined period of time through a research, or right-to-test, license. Under both right-to-test agreements and collaboration and option agreements, collaborators may (a) "take" options, for a defined period of time, to specified targets and (b) upon exercise of those options, secure or "take" licenses to develop and commercialize products for the specified targets on established terms. Under these agreements, fees may be due to the Company (i) at the inception of the arrangement (referred to as "upfront" fees or payments), (ii) upon the opt-in to acquire a development and commercialization license(s) (referred to as exercise fees or payments earned, if any, when the development and commercialization license is "taken"), (iii) after providing services at the collaborator's request at negotiated prices, which are generally consistent with what other third parties would charge, or (iv) upon some combination of all of these fees.

The accounting for collaboration and option agreements and right-to-test agreements is dependent on the nature of the options granted to the collaborative partner. Options are considered distinct performance obligations if they provide a collaborator with a material right. Factors that are considered in evaluating whether options convey a material right include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the fair value of the licenses, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options.

If the Company concludes that an option provides the customer a material right, and therefore is a separate performance obligation, the Company then determines the estimated standalone selling price of the option using the following inputs: (a) estimated fair value of the license underlying each option, (b) the amount the partner would pay to exercise the option to obtain the license, and (c) probability of exercise.

The Company does not control when or if any collaborator will exercise its options for development and commercialization licenses. As a result, the Company cannot predict when or if it will recognize revenues in connection with any of the foregoing.

Upfront payments on development and commercialization licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license is distinct from the other promised goods and services.

In determining whether a collaboration and option agreement is within the scope of ASC 808, *Collaborative Arrangements*, management evaluates the level of involvement of both companies in the development and commercialization of the products to determine if both parties are active participants and if both parties are exposed to risks and rewards dependent on the commercial success of the licensed products. If the agreement is determined to be within the scope of ASC 808 and not representative of a vendor-customer relationship, the Company segregates the research and development activities and the related cost sharing arrangement. Payments made by the Company for such activities are recorded as research and development expense and reimbursements received from the partner are recognized as an offset to research and development expense.

Transaction Price Allocated to Remaining Performance Obligations

Deferred revenue under ASC 606 represents the portion of the transaction price received under various contracts for which work has not been performed (or has been partially performed) and includes unexercised contract options that are considered material rights. As of December 31, 2022, the aggregate amount of the transaction price allocated to remaining performance obligations comprising deferred revenue was \$50.2 million. The Company expects to recognize revenue on approximately 28%, 70%, and 2% of the remaining performance obligations over the next 12 months, 13 to 60 months, and 61 to 120 months, respectively, however, it does not control when or if any collaborator will terminate existing development and commercialization licenses.

Contract Balances from Contracts with Customers

The following tables present changes in the Company's contract assets and contract liabilities during the years ended December 31, 2022 and 2021 (in thousands):

	<u>Balance at December 31, 2021</u>	<u>Additions</u>	<u>Deductions</u>	<u>Impact of Netting</u>	<u>Balance at December 31, 2022</u>
Contract asset.	\$ 3,000	\$ —	\$ (3,000)	\$ —	\$ —
Contract liabilities (deferred revenue) . .	\$ 92,068	\$ 7,605	\$ (49,462)	\$ —	\$ 50,211

	<u>Balance at December 31, 2020</u>	<u>Additions</u>	<u>Deductions</u>	<u>Impact of Netting</u>	<u>Balance at December 31, 2021</u>
Contract asset.	\$ —	\$ 5,500	\$ (2,500)	\$ —	\$ 3,000
Contract liabilities (deferred revenue) . .	\$ 110,109	\$ 4,753	\$ (22,794)	\$ —	\$ 92,068

During the years ended December 31, 2022, 2021, and 2020 the Company recognized the following revenues as a result of changes in contract asset and contract liability balances in the respective periods (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Revenue recognized in the period from:			
Amounts included in contract liabilities at the beginning of the period . .	\$ 49,462	\$ 22,765	\$ 61,872
Performance obligations satisfied in previous periods	\$ 13,661	\$ 5,500	\$ —

The timing of revenue recognition, billings, and cash collections results in billed receivables, unbilled receivables, contract assets, and contract liabilities on the consolidated balance sheets. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded (under the caption deferred revenue). Contract liabilities are recognized as revenue after control of the products or services is transferred to the customer and all revenue recognition criteria have been met.

The Company recorded the following during the year ended December 31, 2022: (i) pursuant to the Company's license agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (Huadong), upon delivery of clinical materials in 2022, the Company recognized as license and milestone fee revenue the remaining \$28.5 million of the deferred revenue balance as of December 31, 2021 related to the \$45.0 million of upfront and development milestone payments previously received; (ii) pursuant to a license agreement executed with Eli Lilly and Company (Lilly) during 2022, the Company received upfront payments of \$26.0 million, of which \$18.4 million was recognized as license and milestone fee revenue and the remainder deferred, further details of which can be found in Note C, "Agreements"; (iii) pursuant to a license agreement executed with Magenta Therapeutics in 2022, the Company recorded \$6.0 million as license and milestone fee revenue, of which \$1.6 million had been previously received and recorded as deferred revenue as of December 31, 2021; (iv) \$16.4 million of previously deferred non-cash royalty revenue related to the sale of rights to KADCYLA royalties, further details of which can be found in Note H, "Liability Related to Sale of Future Royalties"; and (v) \$2.9 million of license and milestone fee revenue related to numerous collaborators' rights to technological improvements that had been previously deferred, which includes \$2.8 million related to Novartis Institutes for BioMedical Research, Inc.'s (Novartis) termination of certain of the license agreements between the Company and Novartis in August 2022, further details of which can be found in Note C, "Agreements." Lastly, during 2021, the Company recorded a contract asset of \$3.0 million for a probable development milestone pursuant to its license agreement with Viridian Therapeutics, Inc. (Viridian), which was subsequently achieved in April 2022.

Pursuant to the Company's license agreement with Huadong, upon delivery of clinical materials in 2021, the Company recorded \$14.6 million of the \$40.0 million upfront payment received and deferred in 2020 as license and milestone fee revenue. Additionally, in December 2021, the Company received a \$5.0 million payment for a development milestone achieved pursuant to its agreement with Huadong, of which \$1.8 million was recorded as license and milestone fee revenue in 2021, with the remainder deferred and recorded as revenue upon delivery of clinical material in 2022 as noted above. Also, during 2021, pursuant to its license agreement with Viridian, the Company recorded \$2.5 million as license and milestone fee revenue related to a development milestone achieved in October 2021 and a contract asset of \$3.0 million for a second probable development milestone which was subsequently achieved and paid in 2022 as discussed above. The Company also recorded \$0.2 million as license and milestone fee revenue for delivery of certain materials to Viridian that had been previously deferred, \$0.3 million of license and milestone fee revenue related to numerous collaborators' rights to technological improvements that had been previously deferred, and recorded \$7.7 million of previously deferred non-cash royalty revenue related to the sale of rights to KADCYLA royalties, further details of which can be found in Note H, "Liability Related to Sale of Future Royalties." Lastly, pursuant to a research agreement with Magenta, the Company received a \$1.6 million upfront option fee that was included in deferred revenue at December 31, 2021.

During 2020, the Company recognized \$60.5 million of previously deferred license revenue upon Jazz's opt-out of its right to the last remaining license under the agreement and \$3.2 million of upfront fees previously received from other partners, of which \$1.4 million was included in contract liabilities at the beginning of 2020. As noted above, a \$40.0 million upfront payment received in 2020 pursuant to a license agreement executed with Huadong was recorded as deferred revenue and none of this amount was recognized as revenue during 2020. Additionally, a contract asset of \$3.6 million, net of \$4.4 million in related contract liabilities, was recorded for two probable milestones in 2019 pursuant to license agreements with CytomX and Novartis, which were subsequently achieved and paid during 2020.

Financial Instruments and Concentration of Credit Risk

Cash and cash equivalents are primarily maintained with three financial institutions in the U.S. Deposits with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. The Company's cash equivalents consist of money market funds with underlying investments primarily being U.S. Government-issued securities and high quality, short-term commercial paper. Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, and marketable securities. The Company held no marketable securities as of December 31, 2022 and 2021. The Company's investment policy, approved by the Board of Directors, limits the amount it may invest in any one type of investment, thereby reducing credit risk concentrations.

Cash and Cash Equivalents

All highly liquid financial instruments with maturities of three months or less when purchased are considered cash equivalents. As of December 31, 2022 and 2021, the Company held \$275.1 million and \$478.8 million, respectively, in cash and money market funds consisting principally of U.S. Government-issued securities and high quality, short-term commercial paper which were classified as cash and cash equivalents.

Non-cash Investing Activities

The Company had \$0.3 million and \$0.2 million of accrued capital expenditures as of December 31, 2022 and 2021, respectively, which have been treated as a non-cash investing activity and accordingly, are not reflected in the consolidated statement of cash flows.

Fair Value of Financial Instruments

ASC 820, *Fair Value Measurement*, defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the U.S., and provides for disclosures about fair value measurements. Fair value is defined under ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a hierarchy to measure fair value which is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2022 and 2021, the Company held certain assets that are required to be measured at fair value on a recurring basis. The fair value of the Company's cash equivalents is based on quoted prices from active markets (Level 1 inputs). The carrying amounts reflected in the consolidated balance sheets for accounts receivable, unbilled receivable, contract assets, non-cash royalty receivable, prepaid and other current assets, accounts payable, accrued compensation, and other accrued liabilities approximate fair value due to their short-term nature.

Accounts Receivable

Accounts receivable arise from product sales and amounts due from the Company's collaboration partners. The amount from product sales represents amounts due from specialty distributors and specialty pharmacy providers in the U.S. The Company monitors economic conditions and the financial performance and credit worthiness of its counterparties to identify facts or circumstances that may indicate that its receivables are at risk of collection. The Company provides reserves against accounts receivable for estimated losses that may result from a customer's inability to pay based on the composition of its accounts receivable, considering past events, current economic conditions, and reasonable and supportable forecasts about the future economic conditions. The contractual life of our accounts receivable is generally short-term. Amounts determined to be uncollectible are charged or written-off against the reserve. For the years ended December 31, 2022 and 2021, the Company did not record any expected credit losses related to outstanding accounts receivable.

Unbilled Receivable

Unbilled receivable primarily represents research funding earned based on actual resources utilized and external expenses incurred under certain of the Company's collaborator agreements.

Inventory

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in first-out method. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials. The Company classifies its inventory costs as long-term when it expects to utilize the inventory beyond its normal operating cycle based on forecasted levels of sales.

Prior to the regulatory approval of its drug candidates, the Company incurs expenses for the manufacture of drug product to support clinical development that could potentially be available to support the commercial launch of those drugs. Until the date at which regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expenses. Inventory used in clinical trials is also expensed as research and development expense, when selected for such use.

The Company performs an assessment of the recoverability of capitalized inventories during each reporting period and writes down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of sales in the consolidated statements of operations and comprehensive loss. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required.

Clinical Trial Accruals

Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these activities to third parties. Third-party clinical trial expenses include investigator fees, site costs (patient cost), clinical research organization costs, and costs for central laboratory testing and data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred. Clinical trial costs are reflected on the consolidated balance sheets as prepaid assets (to the extent payments exceed costs incurred) or accrued clinical trial costs (to the extent costs incurred exceed payments). These third-party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future R&D activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. The Company also records accruals for estimated ongoing clinical research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received, and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical clinical accrual estimates made by the Company have not been materially different from the actual costs.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases include right-of-use (ROU) assets and operating lease liabilities (current and non-current), which are recorded in the Company's consolidated balance sheets. Single payment capital leases for equipment that are considered finance leases are included in property and equipment in the Company's consolidated balance sheets. As the single payment obligations have all been made, there is no related liability recorded.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses the implicit rate when readily determinable. As a number of the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate applicable to the Company based on the information available at the commencement date in determining the present value of lease payments. As the Company has no existing or proposed collateralized borrowing arrangements, to determine a reasonable incremental borrowing rate, the Company considers collateral assumptions, the lease term, the Company's current credit risk profile, and rates for existing borrowing arrangements for comparable peer companies. The Company accounts for the lease and fixed non-lease components as a single lease component. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term.

Other Accrued Liabilities

Other accrued liabilities consisted of the following at December 31, 2022 and 2021 (in thousands):

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
Accrued contract payments	\$ 15,971	\$ 5,558
Accrued clinical trial costs	15,716	15,556
Accrued professional services	2,020	839
Accrued employee benefits	340	40
Accrued public reporting charges	265	309
Accrued tax provision	1,218	—
Other current accrued liabilities	3,253	775
Total	<u>\$ 38,783</u>	<u>\$ 23,077</u>

Accrued contract payments included in the table above primarily relate to external manufacturing, regulatory, and quality-related services. The increase in the balance as of December 31, 2022 compared to prior year was driven by timing of external manufacturing expenses.

Research and Development Expenses

The Company's research and development expenses are charged to expense as incurred and relate to (i) research to evaluate new targets and to develop and evaluate new antibodies, linkers, and cytotoxic agents, (ii) preclinical testing of its own and, in certain instances, its collaborators' product candidates, and the cost of its own clinical trials, (iii) development related to clinical and commercial manufacturing processes, (iv) regulatory activities, (v) medical affairs activities, and (vi) external manufacturing operations. Payments made by the Company in advance for research and development services not yet provided and/or materials not yet delivered and accepted are recorded as prepaid expenses and are included in the accompanying consolidated balance sheets as prepaid and other current assets.

Income Taxes

The Company uses the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and income tax basis of assets and liabilities, as well as net operating loss carry forwards and tax credits and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. A valuation allowance against net deferred tax assets is recorded if, based on the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Property and Equipment

Property and equipment are stated at cost. The Company provides for depreciation based upon expected useful lives using the straight-line method over the following estimated useful lives:

Machinery and equipment	5 years
Computer hardware and software	3 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of remaining lease term or 7 years

Equipment under capital leases is amortized over the lives of the respective leases or the estimated useful lives of the assets, whichever is shorter, and included in depreciation expense. Maintenance and repairs are charged to expense as incurred. Upon retirement or sale, the cost of disposed assets and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the statement of operations.

Impairment of Long-Lived Assets

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired if impairment indicators are present. The Company evaluates the realizability of its long-lived assets based on cash flow expectations for the related asset. Any write-downs to fair value are treated as permanent reductions in the carrying amount of the assets. Based on this evaluation, the Company believes that, as of each of the balance sheet dates presented, none of the Company's long-lived assets were impaired.

Common Stock Warrants

The Company accounts for common stock warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance included in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance and remeasured each balance sheet date thereafter. Changes in the estimated fair value of the liability-classified warrants are recognized as a non-cash gain or loss in the accompanying consolidated statements of operations and comprehensive loss.

Computation of Net Loss per Common Share

Basic and diluted net loss per share is calculated based upon the weighted average number of shares of common stock outstanding during the period. Shares of the Company's common stock underlying pre-funded warrants are included in the calculation of basic and diluted earnings per share. During periods of income, participating securities are allocated a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities (the "two-class method"). Shares of the Company's restricted stock participate in any dividends that may be declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to participating securities since they have no contractual obligation to share in the losses of the Company. Diluted loss per share is computed after giving consideration to the dilutive effect of stock options, convertible notes, and restricted stock that are outstanding during the period, except where such non-participating securities would be anti-dilutive.

The Company's common stock equivalents, as calculated in accordance with the treasury-stock method for options and unvested restricted stock and the if-converted method for the convertible notes, are shown in the following table (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Options outstanding to purchase common stock, shares issuable under the employee stock purchase plan, and unvested restricted stock/units at end of period	33,264	21,296	18,459
Common stock equivalents under treasury stock method for options, shares issuable under the employee stock purchase plan, and unvested restricted stock/units	1,596	2,546	1,301
Shares issuable upon conversion of convertible notes at end of period	—	—	501
Common stock equivalents under if-converted method for convertible notes . . .	—	—	501

The Company's common stock equivalents have not been included in the net loss per share calculation because their effect is anti-dilutive due to the Company's net loss position.

Stock-based Compensation

As of December 31, 2022, the Company is authorized to grant future awards under three employee share-based compensation plans, which are the ImmunoGen, Inc. 2018 Employee, Director and Consultant Equity Incentive Plan, or the 2018 Plan, the Employee Stock Purchase Plan, or ESPP, and the ImmunoGen Inducement Equity Incentive Plan, or the Inducement Plan. At the annual meeting of shareholders on June 15, 2022, the 2018 Plan was amended to provide for

the issuance of stock grants, the grant of options, and the grant of stock-based awards for up to an additional 13,000,000 shares of the Company's common stock, as well as up to 28,742,013 shares of common stock, which represent the number of shares of common stock remaining under the 2018 Plan as of April 1, 2022, and awards previously granted under the 2018 Plan and the Company's former stock-based plans, including the ImmunoGen, Inc. 2016 and 2006 Employee, Director and Consultant Equity Incentive Plans, that forfeit, expire, or cancel without delivery of shares of common stock or which resulted in the forfeiture of shares of common stock back to the Company subsequent to April 1, 2022. The Inducement Plan was approved by the Board of Directors in December 2019, and pursuant to subsequent amendments, provides for the issuance of non-qualified option grants for up to 10,500,000 shares of the Company's common stock. Options awarded under the two plans are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Options vest at various periods of up to four years and may be exercised within ten years of the date of grant under each of these plans.

The stock-based awards are accounted for under ASC 718, "Compensation—Stock Compensation." Pursuant to ASC 718, the estimated grant date fair value of awards is charged to the statement of operations over the requisite service period, which is the vesting period. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the weighted-average assumptions noted in the following table. As the Company has not paid dividends since inception, nor does it expect to pay any dividends for the foreseeable future, the expected dividend yield assumption is zero. Expected volatility is based exclusively on historical volatility of the Company's stock. The expected term of stock options granted is based exclusively on historical data and represents the period of time that stock options granted are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as the Company does not expect substantially different exercise or post-vesting termination behavior amongst its employee population. The risk-free rate of the stock options is based on the U.S. Treasury rate in effect at the time of grant for the expected term of the stock options.

	Year Ended December 31,		
	2022	2021	2020
Dividend	None	None	None
Volatility	83.09%	84.67%	85.07%
Risk-free interest rate	2.76%	0.80%	1.21%
Expected life (years)	5.9	6.0	6.0

Using the Black-Scholes option-pricing model, the weighted-average grant date fair values of options granted during the years ended December 31, 2022, 2021, and 2020, were \$3.62, \$5.07, and \$3.28 per share, respectively.

A summary of option activity under the option plans for 2022 is presented below (in thousands, except weighted-average data):

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Life in Yrs.	Aggregate Intrinsic Value
Outstanding at December 31, 2021	21,219	\$ 6.28		
Granted	13,892	5.11		
Exercised	(313)	3.89		
Forfeited/Canceled	(1,672)	7.40		
Outstanding at December 31, 2022	<u>33,126</u>	<u>\$ 5.76</u>	7.71	\$ 11,013
Exercisable at December 31, 2022	<u>15,018</u>	<u>\$ 6.27</u>	<u>6.14</u>	<u>\$ 7,685</u>
Vested and expected to vest at December 31, 2022	<u>33,126</u>	<u>\$ 5.76</u>	<u>7.71</u>	<u>\$ 11,013</u>

In 2020, the Company issued 2.6 million performance-based stock options to certain employees that will vest upon the achievement of specified performance goals. Upon assessment of the performance-based stock option awards as of December 31, 2021, the Company determined the first performance goal to be probable of vesting and, as such, recorded \$2.6 million of stock-based compensation expense for the year ended December 31, 2021. In May 2022, the first performance goal was achieved, resulting in the vesting of 25% of the 2.6 million performance-based stock options. In November 2022, the second performance goal was achieved, resulting in the vesting of 50% of the 2.6 million performance-based stock options and \$5.2 million of stock-based compensation expense recorded for the year ended December 31, 2022. On December 31, 2022, 12.5% of the 2.6 million performance-based stock options forfeited. The fair value of the remaining unvested performance-based stock options that could be expensed in future periods is \$1.3 million.

A summary of restricted stock and restricted stock unit activity under the option plans for 2022 is presented below (in thousands, except weighted-average data):

	<u>Number of Restricted Stock Shares</u>	<u>Weighted- Average Grant Date Fair Value</u>
Unvested at December 31, 2021.....	77	\$ 5.59
Granted.....	138	5.45
Vested.....	(27)	5.43
Forfeited.....	(50)	5.68
Unvested at December 31, 2022.....	<u>138</u>	<u>\$ 5.45</u>

In June 2018, the Company's Board of Directors, with shareholder approval, adopted the Employee Stock Purchase Plan. Following the share increase on January 1, 2021 under the ESPP's "evergreen" provision, an aggregate of 2,000,000 shares of common stock have been reserved for issuance under the ESPP. Under the ESPP, eligible participants purchase shares of the Company's common stock at a price equal to 85% of the lesser of the closing price of the Company's common stock on the first business day and the final business day of the applicable plan purchase period. Plan purchase periods are six months and begin on January 1 and July 1 of each year, with purchase dates occurring on the final business day of the given purchase period. The fair value of each ESPP award is estimated on the first day of the offering period using the Black-Scholes option-pricing model. The Company recognizes share-based compensation expense equal to the fair value of the ESPP awards on a straight-line basis over the offering period. During 2022, 2021, and 2020, approximately 178,000, 126,000, and 122,000 shares, respectively, were issued to participating employees at fair values ranging from \$1.72 to \$2.37 per share.

Stock compensation expense related to stock options and restricted stock awards granted under the option plans and the ESPP was \$24.9 million, \$16.8 million, and \$14.0 million during the years ended December 31, 2022, 2021, and 2020, respectively. The increase in stock compensation expense in 2022 was due primarily to the vesting of performance-based stock option awards as discussed above and an increase in the number of stock options granted in 2022 driven by significant hiring in the year. As of December 31, 2022, the estimated fair value of unvested employee awards was \$57.4 million. The weighted-average remaining vesting period for these awards is approximately three years. Also included in stock and deferred stock unit compensation expense in the consolidated statements of cash flows for the years ended December 31, 2022, 2021, and 2020 is \$0.7 million, \$0.7 million, and \$0.3 million, respectively, of expense recorded for directors' deferred share units, the details of which are discussed in Note J.

A summary of option activity for options vested during the years ended December 31, 2022, 2021, and 2020 is presented below (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2022</u>	<u>2021</u>	<u>2020</u>
Total fair value of options vested.....	\$ 25,442	\$ 15,839	\$ 11,465
Total intrinsic value of options exercised.....	451	3,322	746
Cash received from the exercise of stock options and ESPP purchases ..	1,905	3,769	1,471

Comprehensive Loss

The Company presents comprehensive loss in accordance with ASC 220, *Comprehensive Income*. Comprehensive loss is comprised of the Company's net loss for all periods presented.

Segment Information

During all periods presented, the Company continued to operate in one reportable business segment under the management approach of ASC 280, *Segment Reporting*, which is the business of the discovery and development of ADCs for the treatment of cancer.

The percentages of revenues recognized from significant customers of the Company in the years ended December 31, 2022, 2021, and 2020 are included in the following table:

Collaborative Partner:	Year Ended December 31,		
	2022	2021	2020
Huadong.....	37%	24%	-%
Roche.....	28%	67%	53%
Eli Lilly.....	17%	-%	-%
Viridian.....	10%	11%	1%
Jazz.....	-%	-%	46%

There were no other customers of the Company with significant revenues in the periods presented.

Pending Accounting Pronouncements

No recently issued or effective ASUs had, or are expected to have, a material effect on the Company's results of operations, financial condition, or liquidity.

C. Collaboration and License Agreements

The Company has numerous collaboration and license agreements with third parties. These agreements typically provide the licensee with rights to use the Company's ADC platform technology with its antibodies or related targeting vehicles to a defined target to develop products. The licensee is generally responsible for the development, clinical testing, manufacturing, registration, and commercialization of any resulting product candidate. As part of these agreements, the Company is generally entitled to receive upfront fees, potential milestone payments, royalties on the sales of any resulting products, and research and development funding based on activities performed at our collaborative partner's request. See below for details regarding the Company's collaboration and license agreements with activity in the financial statement periods presented.

Roche

In 2000, the Company granted Genentech, now a unit of Roche, an exclusive development and commercialization license to use the Company's maytansinoid ADC technology with antibodies, such as trastuzumab, or other proteins that target HER2. Under the terms of this agreement, Roche has exclusive worldwide rights to develop and commercialize maytansinoid ADC compounds targeting HER2. Pursuant to this agreement, Roche developed and received marketing approval for its HER2-targeting ADC, KADCYLA, in the U.S., Japan, the European Union, and numerous other countries. Roche is responsible for the manufacturing, product development, and marketing of any products resulting from the agreement. The Company received a \$2.0 million non-refundable upfront payment from Roche upon execution of the agreement. The Company is also entitled to receive up to a total of \$44.0 million in development and regulatory milestone payments, plus royalties on the commercial sales of KADCYLA or any other resulting products. Through December 31, 2022, the Company had received and recognized \$39.0 million in milestone payments related to KADCYLA.

The Company receives royalty reports and payments related to sales of KADCYLA from Roche one quarter in arrears. In accordance with the Company's revenue recognition policy, \$29.3 million, \$46.8 million, and \$68.5 million of non-cash royalties on net sales of KADCYLA were recorded and included in royalty revenue for the years ended December 31, 2022, 2021, and 2020, respectively. The Company sold its rights to receive royalty payments on the net sales of KADCYLA through two separate transactions in 2015 and 2019. Following the 2019 transaction, OMERS, the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, is entitled to receive all of these royalties.

Roche, through its Genentech unit, also has licenses for the exclusive right to use the Company's maytansinoid ADC technology with antibodies to four undisclosed targets, which were granted under the terms of a separate, now expired, 2000 right-to-test agreement with Genentech. For each of these licenses, the Company received a \$1.0 million license fee and is entitled to receive up to a total of \$38.0 million in development, regulatory, and sales-based milestone payments plus royalties on the sales of any resulting products. The Company has not received any milestone payments from these agreements through December 31, 2022. Roche is responsible for the development, manufacturing, and marketing of any products resulting from these licenses.

Novartis

The Company granted Novartis exclusive development and commercialization licenses to the Company's maytansinoid and IGN ADC technology for use with antibodies to six specified targets under a now-expired right-to-test agreement established in 2010. The Company received a \$45.0 million upfront payment in connection with the execution of the right-to-test agreement in 2010, \$8.5 million in extension and amendment fees, and an exercise fee of \$1.0 million for each of the six licenses taken. In May 2018, Novartis terminated one of its six licenses. In August 2022, Novartis terminated four of the remaining development and commercialization licenses. The Company had \$2.8 million of deferred revenue associated with the terminated licenses related to the portion of the transaction price previously allocated to rights to future technological improvements. In consideration that no technological improvements would be provided to Novartis and, therefore, no unsatisfied obligations were remaining related to such licenses, the \$2.8 million was recorded as revenue and is included in license and milestone fees for 2022. With respect to the remaining license, \$0.8 million of deferred revenue related to the portion of the transaction price previously allocated to rights to future technological improvements continues to be amortized over the remaining estimated term of the license agreement, and we are entitled to receive up to a total of \$199.5 million in potential milestone payments, of which \$5.0 million has been received to date, plus royalties on the commercial sales of any resulting products. Novartis is responsible for the manufacturing, development, and marketing of any products resulting from these licenses.

CytomX

In 2016, the Company granted CytomX an exclusive development and commercialization license to the Company's maytansinoid ADC technology for use with PROBODIES™ that target CD166 under a now expired reciprocal right-to-test agreement. The Company neither received nor made an upfront cash payment in connection with the execution of the right-to-test agreement or the license agreement. With respect to the development and commercialization license granted to CytomX, the Company is entitled to receive up to a total of \$160.0 million in development, regulatory, and sales-based milestone payments plus royalties on the commercial sales of any resulting product. Through December 31, 2022, the Company had received and recognized an aggregate of \$4.0 million in milestone payments under this agreement.

In December 2019, the Company granted CytomX an exclusive development and commercialization license to maytansinoid and IGN ADC technology for use with PROBODIES™ that target EpCAM. Pursuant to the license agreement, in January 2020, the Company received a \$7.5 million upfront payment. The Company is also entitled to receive up to a total of \$355.0 million in development, regulatory, and sales-based milestone payments plus royalties on the commercial sales of any resulting product. The Company had not received any milestone payments under this agreement through December 31, 2022. CytomX is responsible for the manufacturing, product development, and marketing of any products resulting from these licenses.

Viridian

In October 2020, the Company entered into a license agreement with Viridian Therapeutics, Inc. pursuant to which the Company granted Viridian the exclusive right to develop and commercialize an insulin-like growth factor-1 receptor (IGF-1R) antibody for all non-oncology indications that do not use radiopharmaceuticals in exchange for an upfront payment, with the potential to receive up to a total of \$143.0 million in development, regulatory, and sales-based milestone payments plus royalties on the commercial sales of any resulting product. Through December 31, 2022, the Company had achieved an aggregate \$15.5 million in development milestone payments under the agreement, of which \$10.0 million and \$5.5 million was included in license and milestone fee revenue for the years ended December 31, 2022 and 2021, respectively. The \$10.0 million milestone payment recorded in 2022 was included in accounts receivable as of December 31, 2022. Viridian is responsible for the manufacturing, development, and marketing of any products resulting from the license agreement.

Huadong

In October 2020, the Company entered into a collaboration and license agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (Huadong), a subsidiary of Huadong Medicine Co., Ltd. The collaboration and license agreement grants Huadong an exclusive, royalty-bearing, and sublicensable right to develop and commercialize ELAHERE (the Licensed Product) in the People's Republic of China, Hong Kong, Macau, and Taiwan (collectively, Greater China). The Company retains exclusive rights to the Licensed Product outside of Greater China. Under the terms of the collaboration and license agreement, the Company received a non-refundable upfront payment of \$40.0 million with the potential for approximately \$265.0 million in development, regulatory, and sales-based milestone payments. In addition, the Company is entitled to receive tiered percentage royalties ranging from low double digits to high teens as a percentage of commercial sales of the Licensed Product, if approved, by Huadong in Greater China, subject to

adjustment in specified circumstances. In December 2022 and December 2021, the Company received milestone payments of \$10.0 million and \$5.0 million, respectively, upon achievement of development and regulatory milestones.

The Company evaluated the agreement and determined it was within the scope of ASC 606. The Company determined the promised goods and services included the license to intellectual property and know-how and the clinical supply of the Licensed Product to Huadong for a specified period. The Company concluded that the license to intellectual property and know-how is not distinct from the clinical supply of the Licensed Product because the clinical supply is essential to the use of the license and an alternative source of clinical supply is not readily available in the marketplace. Accordingly, these two promised goods and services are considered a single combined performance obligation. The Company determined there were no options in the agreement that represented material rights.

The transaction price was determined to consist of the upfront payment of \$40.0 million and estimated payments to be received for clinical supply of the Licensed Product. At contract inception, future development and regulatory milestones were fully constrained. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Huadong. The Company re-evaluates the transaction price, including its estimated variable consideration included in the transaction price and all constrained amounts, at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company determined that revenue related to the agreement would be recognized as the clinical supply of the Licensed Product is delivered to Huadong, estimated to be completed over approximately two years. Accordingly, based on clinical supply delivered to Huadong during 2022 and 2021, the Company recorded \$28.5 million and \$16.5 million as license and milestone fee revenue in 2022 and 2021, respectively, related to \$45.0 million of upfront and milestone payments previously received and deferred. The Company also recorded \$10.0 million of license and milestone fee revenue related to a regulatory milestone achieved in 2022.

Lilly

In February 2022, the Company entered into a license agreement with Lilly, pursuant to which the Company granted Lilly worldwide exclusive rights to research, develop, and commercialize antibody-drug conjugates based on the Company's novel camptothecin technology. Under the terms of the license agreement, the Company received a non-refundable upfront payment of \$13.0 million, reflecting initial targets selected by Lilly. During 2022, pursuant to the terms of the agreement, Lilly selected additional targets for which the Company received an additional \$13.0 million in non-refundable payments. Lilly may select a pre-specified number of additional targets, with the Company eligible to receive an additional \$19.5 million in exercise fees if Lilly licenses the full number of remaining additional targets over a specified period following the effective date of the license agreement, with the potential for up to \$1.7 billion in development and sales-based milestone payments if all targets are selected and all milestones are realized. In addition, the Company is entitled to receive tiered royalties, on a product-by-product basis, as a percentage of worldwide annual net sales by Lilly, based on certain net sales thresholds. Lilly is responsible for all costs associated with the research, development, and commercialization of any ensuing products.

The Company evaluated the agreement and determined it was within the scope of ASC 606. The Company determined the promised goods and services included an exclusive license to use the Company's intellectual property and know-how to research, develop, and commercialize products related to each of the initial targets selected by Lilly. Each of these licenses is distinct, as Lilly can derive benefit from each license independent of any other initial target licenses. Accordingly, the license to each of the initial targets selected by Lilly represents a separate performance obligation. Lilly has the right to replace each of the initial licensed targets once during a specified term for no additional consideration. If Lilly fails to advance an initial or replacement target to a specified stage within a specified period from the date the target was selected, Lilly's rights to the respective target will cease and will revert back to the Company. The Company determined Lilly's right to a replacement target for each of the initial targets represented a material right. Each material right is therefore a separate performance obligation.

Lilly's right to select additional targets does not represent a material right as the target fee for each additional target is the same and is also consistent with the target fee for each of the initial targets selected by Lilly. Accordingly, each additional target selected by Lilly is accounted for as a separate arrangement.

The transaction price related to the initial targets was determined to consist of the upfront payment of \$13.0 million. Future development milestones have been fully constrained. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Lilly. The transaction price of \$13.0 million was allocated to the performance obligations based on their relative stand-alone selling prices. In consideration of each target being at the same stage of

development at the time of the initial license or at the time of replacement and each target having approximately the same earnings potential, the Company allocated the \$13.0 million transaction price equally across the initial target licenses and the corresponding material rights to obtain licenses to replacement targets, adjusted based on the probability that Lilly would exercise those rights. The Company considered pharmaceutical industry data of the probability of early-stage assets to advance to clinical stage in determining the probability that Lilly would exercise its option to a replacement target. Accordingly, \$9.2 million and \$3.8 million of the total transaction price was allocated to the initial targets and the material rights to obtain licenses to replacement targets, respectively.

The license terms and accounting outlined above are the same for the additional target licenses selected. Accordingly, \$9.2 million and \$3.8 million of the \$13.0 million transaction price was allocated to the targets selected and the material right to obtain a license to replacement targets, respectively.

The Company re-evaluates the transaction price for each arrangement, including its estimated variable consideration included in the transaction price and all constrained amounts, at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The transfer of intellectual property and know-how to Lilly to allow for Lilly to derive benefit from the initial and additional target licenses was completed during the three months ended March 31, 2022. As such, during 2022, the Company recognized \$18.4 million of license and milestone fee revenue related to the portion of the transaction price allocated to the initial and additional target licenses. The \$7.6 million allocated to the material rights to obtain licenses to replacement targets is included in long-term deferred revenue as of December 31, 2022 and will be recognized when the right is either exercised or expires.

Magenta

In November 2022, the Company granted Magenta an exclusive development and commercialization license to the Company's IGN ADC technology to a specified target and a non-exclusive license to use intellectual property and know-how resulting from the collaboration to research, develop, and commercialize products directed to the specified target. Under the terms of the license agreement, the Company received non-refundable upfront payments totaling \$6.0 million. The Company is also entitled to receive up to a total of \$125.0 million in development, regulatory, and sales-based milestone payments plus royalties on the commercial sales of any resulting product.

The Company evaluated the agreement and determined it was within the scope of ASC 606. The Company determined there was a single, combined performance obligation consisting of the license to use the Company's intellectual property and know-how and the non-exclusive license to use intellectual property and know-how resulting from the collaboration. The transaction price was determined to consist of the upfront payments totaling \$6.0 million. Future development and regulatory milestones have been fully constrained. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Magenta. The single, combined performance obligation was satisfied during 2022, and as such, the Company recognized \$6.0 million of license and milestone fee revenue in 2022.

In February 2023, Magenta announced its decision to halt further development of its programs and conduct a comprehensive review of strategic alternatives focusing on maximizing shareholder value. As part of this review process, Magenta will explore potential strategic alternatives that may include, but are not limited to, an acquisition, merger, business combination, or other transaction.

Terminated Agreements

Jazz Pharmaceuticals

In August 2017, the Company entered into a Collaboration and Option Agreement with Jazz Pharmaceuticals Ireland Limited (Jazz), a subsidiary of Jazz Pharmaceuticals plc, granting Jazz exclusive, worldwide rights to opt into development and commercialization of two early-stage, hematology-related ADC programs, as well as an additional program to be designated during the term of the agreement. Pursuant to the agreement, Jazz made an upfront payment of \$75.0 million to the Company. Additionally, Jazz had also agreed to pay the Company up to \$100.0 million in development funding over seven years to support the three ADC programs.

In October 2019 and December 2020, Jazz exercised certain opt-out rights under the agreement, thereby relinquishing its development and commercialization options and restoring all rights to the ADC programs to the Company. The non-refundable, upfront arrangement consideration of \$75.0 million was allocated to the three license options. In conjunction with the opt-outs, the Company recognized \$60.5 million of the remaining deferred upfront fee as license and milestone fee revenue in the year ended December 31, 2020.

Due to the involvement the Company and Jazz both had in the development and commercialization of the products, as well as both parties being part of the cost share agreement and exposed to significant risks and rewards dependent on the commercial success of the products, the arrangement was determined to be a collaborative arrangement within the scope of ASC 808. Accordingly, the Company separated the research and development activities and the related cost sharing arrangement with Jazz. Payments for such activities were recorded as research and development expense and reimbursements received from Jazz were recognized as an offset to research and development expense in the accompanying statement of operations during the development period. Included in research and development expense for each of the years ended December 31, 2021 and 2020 are \$6.7 million of credits related to reimbursements from Jazz.

D. Product Revenue Reserves and Allowances

In November 2022, the FDA granted accelerated approval for ELAHERE for the treatment of adult patients with FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. The Company recorded net product revenue of \$2.6 million from U.S. sales of ELAHERE through December 31, 2022.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the years ended December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Beginning balance at January 1	\$ —	\$ —
Provision related to sales in the current period	313	—
Credits and payments made	—	—
Ending balance at December 31	<u>\$ 313</u>	<u>\$ —</u>

E. Inventory

Capitalized inventory consists of the following at December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Raw materials	\$ 15,952	\$ —
Work in process	—	—
Finished goods	244	—
Total Inventory	<u>\$ 16,196</u>	<u>\$ —</u>

F. Property and Equipment

Property and equipment consisted of the following at December 31, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Leasehold improvements	\$ 22,867	\$ 22,051
Machinery and equipment	3,063	2,955
Computer hardware and software	6,248	5,846
Furniture and fixtures	3,383	3,265
Assets under construction	180	233
	<u>\$ 35,741</u>	<u>\$ 34,350</u>
Less accumulated depreciation	<u>(31,364)</u>	<u>(29,687)</u>
Property and equipment, net	<u>\$ 4,377</u>	<u>\$ 4,663</u>

Included in the table above are amounts capitalized for equipment under capital leases at December 31, 2022 and 2021 totaling \$2.2 million and \$2.1 million, net of accumulated amortization of \$1.8 million and \$1.6 million, respectively. Depreciation expense was \$1.8 million, \$2.0 million, and \$2.1 million for the years ended December 31, 2022, 2021 and 2020, respectively. As a result of the restructuring in 2019, during the year ended December 31, 2020, the Company liquidated laboratory equipment and certain other fixed assets with an aggregate cost basis of \$7.5 million and accumulated depreciation of \$6.8 million for \$1.4 million in payments to the Company.

G. Convertible 4.5% Senior Notes

In 2016, the Company issued convertible notes with an aggregate principal amount of \$100 million, of which \$2.1 million remained outstanding as of December 31, 2020. In June 2021, \$1.0 million of outstanding convertible notes were converted into 238,777 shares of the Company's common stock and the remaining \$1.1 million outstanding was repaid in full by a cash payment upon maturity on July 1, 2021. The convertible notes were senior unsecured obligations and bore interest at a rate of 4.5% per year, payable semi-annually in arrears on January 1 and July 1 of each year, commencing on January 1, 2017. The Company recorded \$0.1 million of interest expense in each of the years ended December 31, 2021 and 2020. The Company analyzed the terms of the convertible notes and determined the notes were entirely accounted for as debt and none of the terms of the notes required separate accounting.

H. Liability Related to Sale of Future Royalties

In 2015, Immunity Royalty Holdings, L.P. (IRH) purchased the right to receive 100% of the royalty payments on commercial sales of KADCYLA arising under the Company's development and commercialization license with Genentech, until IRH had received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reached a specified milestone. Once the applicable threshold was met, the Company would thereafter have received 85% and IRH would have received 15% of the KADCYLA royalties for the remaining royalty term. At consummation of the transaction, the Company received cash proceeds of \$200 million. As part of this sale, the Company incurred \$5.9 million of transaction costs, which are presented net of the liability in the accompanying consolidated balance sheet and are being amortized to interest expense over the estimated life of the royalty purchase agreement. Although the Company sold its rights to receive royalties from the sales of KADCYLA, as a result of its ongoing involvement in the cash flows related to these royalties, the Company continues to account for these royalties as revenue and recorded the \$200 million in proceeds from this transaction as a liability related to sale of future royalties (Royalty Obligation) that is being amortized using the interest method over the estimated life of the royalty purchase agreement.

In January 2019, the Company sold its residual rights to receive royalty payments on commercial sales of KADCYLA to OMERS, the defined benefit pension plan for municipal employees in the Province of Ontario, Canada, for a net payment of \$65.2 million (amount is net of \$1.5 million in broker fees). Simultaneously, OMERS purchased IRH's right to the royalties the Company previously sold as described above, therefore obtaining the rights to 100% of the royalties received from that date on. Because the Company will not be involved with the cash flows related to the residual royalties, the \$65.2 million of net proceeds received from the sale of its residual rights to receive royalty payments was recorded as deferred revenue and is being amortized as the royalty revenue related to the residual rights is earned using the units of revenue approach. During the second quarter of 2021, the aggregate royalty threshold was met and, in accordance with the Company's revenue recognition policy, \$16.4 million and \$7.7 million of revenue related to the residual rights was recorded and is included in non-cash royalty revenue for the years ended December 31, 2022 and 2021, respectively. Additionally, the purchase of IRH's interest by OMERS did not result in an extinguishment or modification of the original instrument and, accordingly, the Company will continue to account for the remaining obligation as a liability as outlined above.

The following table shows the activity within the liability account during the year ended December 31, 2022 and the period from inception (in thousands):

	<u>Year Ended</u> <u>December 31, 2022</u>	<u>Period from</u> <u>inception to</u> <u>December 31, 2022</u>
Liability related to sale of future royalties, net — beginning balance	\$ 41,044	\$ —
Proceeds from sale of future royalties, net	—	194,135
KADCYLA royalty payments received and paid	(13,101)	(276,958)
Non-cash interest expense recognized	4,165	114,931
Liability related to sale of future royalties, net — ending balance	<u>\$ 32,108</u>	<u>\$ 32,108</u>

The Company receives royalty reports and royalty payments related to sales of KADCYLA from Roche one quarter in arrears. As royalties are remitted to OMERS, the balance of the Royalty Obligation will be effectively repaid over the life of the agreement. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future royalty payments to be received and remitted as noted above over the life of the agreement. The sum of these amounts less the \$200 million proceeds the Company received from IRH will be recorded as interest expense over the life of the Royalty Obligation. The Company's estimate of this total interest expense has resulted in an imputed annual interest rate of 10.5% since inception and as of December 31, 2022. The Company periodically assesses the estimated royalty payments to IRH/OMERS and to the extent such payments are greater or less

than its initial estimates, or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the Royalty Obligation. There are a number of factors that could materially affect the amount and timing of royalty payments from Genentech, most of which are not within the Company's control. Such factors include, but are not limited to, changing standards of care, the introduction of competing products, manufacturing or other delays, biosimilar competition, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties are paid in U.S. dollars (USD) while significant portions of the underlying sales of KADCYLA are made in currencies other than USD, and other events or circumstances that could result in reduced royalty payments from KADCYLA, all of which would result in a reduction of non-cash royalty revenues and non-cash interest expense over the life of the Royalty Obligation. Conversely, if sales of KADCYLA are more than expected, the non-cash royalty revenues and the non-cash interest expense recorded by the Company would be greater over the term of the Royalty Obligation.

I. Income Taxes

For the years ended December 31, 2022, 2021 and 2020, the loss before provision for income taxes consist of the following (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Domestic	\$ 18,417	\$ (139,303)	\$ (44,372)
Foreign	(240,128)	—	—
Total	<u>\$ (221,711)</u>	<u>\$ (139,303)</u>	<u>\$ (44,372)</u>

For the year ended December 31, 2022, the Company's total tax expense was all federal current expense. The difference between the Company's expected tax benefit, as computed by applying the applicable U.S. federal corporate tax rate to loss before the benefit for income taxes, and actual tax is reconciled in the following table (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Loss before income tax expense	\$ (221,711)	\$ (139,303)	\$ (44,372)
Expected tax benefit at 21%	\$ (46,559)	\$ (29,254)	\$ (9,318)
Permanent differences	454	606	157
Intra-entity transfer of intangible assets	90,720	—	—
Incentive stock options	769	420	201
State tax provision (benefit) net of federal benefit	29,304	(7,376)	(2,250)
Change in valuation allowance, net	(75,683)	46,987	15,175
Federal research credit	(2,030)	(575)	(228)
Federal orphan drug credit	(9,286)	(7,429)	(6,218)
Expired loss and credit carryforwards	—	345	419
Withholding tax credit	(878)	(4,789)	—
Stock option expirations	—	1,065	2,062
Foreign rate differential	14,407	—	—
Income tax expense	<u>\$ 1,218</u>	<u>\$ —</u>	<u>\$ —</u>

In 2017, the Tax Cuts and Jobs Act of 2017 ("2017 Tax Act") was signed into law. Among other provisions, the 2017 Tax Act requires taxpayers to capitalize and amortize research and experimental (R&E) expenditures under Section 174 for tax years beginning after December 31, 2021. As such, the rule noted became effective for the Company during the year ended December 31, 2022 and resulted in the capitalization of certain R&E costs within its tax provision. The Company will amortize such costs for tax purposes over 5 years if the R&E was performed in the United States and over 15 years if the R&E was performed outside the United States.

During 2022, the Company transferred certain of its intellectual property rights to a newly formed Swiss subsidiary. This transfer resulted in a significant income inclusion for U.S. tax purposes which has been partially offset by utilization of a portion of the Company's net operating loss (NOL) carryforwards that existed before the transaction. The income inclusion for state tax purposes was completely offset by NOL carryforwards.

At December 31, 2022, the Company had NOL carryforwards of \$443.3 million available to reduce federal taxable income, if any, that can be carried forward indefinitely. The Company has \$251.1 million of NOL carryforwards

available to reduce state taxable income, if any, that expire in 2036 through 2042. The Company also has federal and state credit carryforwards of \$85.6 million and \$11.1 million, respectively, available to offset federal and state income taxes, which expire beginning in 2027 and foreign tax credits of \$6.5 million that begin to expire in 2030. Due to the degree of uncertainty related to the ultimate use of the loss carryforwards and tax credits, the Company has established a valuation allowance to fully reserve these tax benefits.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2022 and 2021 are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 115,047	\$ 264,773
Research and development tax credit carryforwards	103,155	92,832
Property and other intangible assets	1,452	1,150
Deferred revenue	14,561	25,153
Stock-based compensation	18,783	12,195
Operating lease liability	4,421	5,170
Other liabilities	3,144	1,737
Royalty sale	8,393	10,247
Sec 174 R&E capitalization	68,150	—
Total deferred tax assets	<u>\$ 337,106</u>	<u>\$ 413,257</u>
Deferred tax liabilities:		
Operating lease right of use asset	(2,967)	(3,386)
Royalty sale transaction costs	(107)	(158)
Total deferred tax liabilities	<u>\$ (3,074)</u>	<u>\$ (3,544)</u>
Valuation allowance	(334,032)	(409,713)
Net deferred tax assets/(liabilities)	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. The Company has determined that it is not more-likely-than-not that the tax benefits related to the federal and state deferred tax assets will be realized for financial reporting purposes. Accordingly, the deferred tax assets have been fully reserved at December 31, 2022 and 2021. The valuation allowance decreased by \$75.7 million during the year ended December 31, 2022.

Utilization of the NOL and credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future as provided by Sections 382 and 383 of the Internal Revenue Code of 1986, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and credit carry forwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, it has raised capital through the issuance of capital stock on several occasions (both pre and post initial public offering) which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. The Company completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since its formation and determined no ownership change occurred under Section 382 as of December 31, 2022. The Company has not completed a detailed Research and Development Credit Study (including the Orphan Drug Credit); accordingly, a portion of the tax credit carryforward may not be available to offset future income.

The Company accounts for uncertain tax positions under the recognition and measurement criteria of ASC 740-10. For those tax positions for which it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon settlement with a taxing authority that has full knowledge of all relevant information. If the Company does not believe that it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized. As of December 31, 2022 and 2021, no uncertain tax positions have been recorded. Interest and penalties related to the settlement of uncertain tax positions, if any, will be reflected in income tax expense. The Company did not recognize any interest and penalties associated with

unrecognized tax benefits in the accompanying consolidated financial statements. The Company does not expect any material changes to the unrecognized benefits within 12 months of the reporting date. Due to existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate.

The statute of limitations for assessment by the Internal Revenue Service, or IRS, and state tax authorities is open for tax years ending after December 31, 2018, although carryforward attributes that were generated prior to 2018 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period.

J. Capital Stock

Common Stock Reserved

At December 31, 2022, the Company had reserved 56.0 million shares of authorized common stock for the future issuance of shares under the 2018, ESPP, and Inducement Plans. See "Stock-Based Compensation" in Note B for a description of the 2018, ESPP, and Inducement Plans. Additionally, the Company has reserved 32.8 million shares of authorized common stock for future issuance pursuant to pre-funded warrant agreements, the details of which are discussed below.

Pre-Funded Warrants

In August 2021, the Company entered into a Securities Purchase Agreement (SPA) with RA Capital Healthcare Fund, L.P. (RA Capital), pursuant to which the Company agreed to sell to RA Capital a pre-funded warrant to purchase up to 5,434,782 shares of common stock for \$5.51 per share of common stock underlying the pre-funded warrant. The per share exercise price of the pre-funded warrant is \$0.01. The private placement resulted in aggregate gross proceeds of \$29.9 million, before \$0.2 million of transaction costs.

In connection with a public offering in December 2021, the Company issued pre-funded warrants to purchase 16,000,000 and 11,363,636 shares of common stock to RA Capital and Redmile Group, LLC, respectively, for \$6.59 per share of common stock underlying the pre-funded warrants, which, together with the per share exercise price of \$0.01, is equal to \$6.60, the public offering price of the shares of common stock in the offering. RA Capital and Redmile Group, LLC are each considered related parties pursuant to ASC 850, *Related Party Disclosures*.

The pre-funded warrants' fundamental transaction provision does not provide the warrant holders with the option to settle any unexercised warrants for cash in the event of any fundamental transactions; rather, in all fundamental transaction scenarios, the warrant holder will only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the shareholders of the Company in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof. The pre-funded warrants also include a separate provision whereby the exercisability of the warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 9.99% of the Company's common stock. This threshold is subject to the holder's rights under the pre-funded warrants to increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to the Company.

The Company has assessed the pre-funded warrants for appropriate equity or liability classification pursuant to the Company's accounting policy described in Note B, "Summary of Significant Accounting Policies." During this assessment, the Company determined the pre-funded warrants are freestanding instruments that do not meet the definition of a liability pursuant to ASC 480 and do not meet the definition of a derivative pursuant to ASC 815. The pre-funded warrants are indexed to the Company's common stock and meet all other conditions for equity classification under ASC 480 and ASC 815. Based on the results of this assessment, the Company concluded that the pre-funded warrants are freestanding equity-linked financial instruments that meet the criteria for equity classification under ASC 480 and ASC 815. Accordingly, the pre-funded warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. The Company also determined that the pre-funded warrants should be included in the determination of basic and diluted earnings per share in accordance with ASC 260, *Earnings per Share*.

Stock Options

As of December 31, 2022, the 2018 Plan and the Inducement Plan were the only employee share-based compensation plans of the Company under which grants can be made. During the year ended December 31, 2022, holders of options issued under the option plans exercised their rights to acquire an aggregate of 313,000 shares of common stock at prices ranging from \$2.31 to \$5.25 per share. The total proceeds to the Company from these option

exercises were \$1.2 million. Additionally, during 2022 and pursuant to the Company's ESPP, approximately 178,000 shares of common stock were issued to participating employees generating \$0.7 million of proceeds to the Company.

2004 Non-Employee Director Compensation and Deferred Share Unit Plan

Under the 2004 Non-Employee Director Compensation and Deferred Share Unit Plan, or the 2004 Director Plan, as amended, between 2004 and 2009 non-employee directors were paid their annual retainers in the form of deferred stock units, based on the fair market value of the Company's common stock on the last date of the Company's fiscal year prior to the year for which services were rendered, and in cash, with the option, at their discretion, to have all or a portion of the cash portion paid in additional deferred stock units. All deferred stock units awarded under the 2004 Director Plan have vested and are redeemed on the date a director ceases to be a member of the Board, at which time such director's deferred stock units will be settled in shares of common stock of the Company issued under the 2006 Plan at a rate of one share for each vested unit.

Compensation Policy for Non-Employee Directors

In September 2009, the Board adopted a new Compensation Policy for Non-Employee Directors, which superseded the 2004 Plan and made certain changes to the compensation of its non-employee directors. The Compensation Policy for Non-Employee Directors, as amended as of December 2022, consists of three elements: cash compensation; deferred stock units; and stock options.

Cash Compensation

Each non-employee director receives annual meeting fees which are paid in quarterly installments in, at each director's election, either cash or deferred stock units.

Deferred Stock Units

Pursuant to the Compensation Policy for Non-Employee Directors, as amended, non-employee directors receive deferred stock units upon initial election to the Board and annually thereafter. Vested deferred stock units are redeemed on the date a director ceases to be a member of the Board, at which time such director's deferred stock units will generally be settled in shares of the Company's common stock issued under our 2018 Plan (or its predecessor plans, depending on the grant date of the deferred stock units) at a rate of one share for each vested deferred stock unit then held. Any deferred stock units that remain unvested at that time will be forfeited.

Pursuant to the Compensation Policy for Non-Employee Directors, as amended, the Company recorded:

- \$0.7 million in compensation expense during the year ended December 31, 2022 related to the grant of 148,000 deferred share units and 100,000 deferred share units previously granted;
- \$0.7 million in compensation expense during the year ended December 31, 2021 related to the grant of 166,000 deferred share units and 52,000 deferred share units previously granted; and
- \$0.3 million in compensation expense during the year ended December 31, 2020 related to the grant of 127,000 deferred share units and 15,000 deferred share units previously granted.

Effective 2023, non-employee directors will opt to receive deferred stock units, restricted stock units, and/or shares upon initial election and annually thereafter.

Stock Options

Pursuant to the Compensation Policy for Non-Employee Directors, as amended, non-employee directors also receive stock option awards upon initial election to the Board and annually thereafter. The directors received a total of 321,622, 352,000, and 300,000 options in the years ended December 31, 2022, 2021, and 2020, and the related stock compensation expense is included in the amounts discussed in the "Stock-Based Compensation" section of footnote B above.

K. Leases

Leases

The Company currently has one real estate lease with CRP/King 830 Winter L.L.C. for the rental of approximately 120,000 square feet of laboratory and office space at 830 Winter Street, Waltham, Massachusetts through March 2026. The Company uses this space for its corporate headquarters and other operations. The Company may extend the lease for two additional terms of five years and is required to pay certain operating expenses for the leased

premises subject to escalation charges for certain expense increases over a base amount. The Company also has a lease agreement through March 2027 for the rental of copier equipment.

Lease expense for operating lease payments is recognized on a straight-line basis over the lease term, which for each of the years ended December 31, 2022, 2021, and 2020 was \$4.0 million and is included in operating expenses in the consolidated income statements. Cash paid against operating lease liabilities in each of the years ended December 31, 2022 and 2021 was \$5.3 million. As of December 31, 2022, the Company's ROU assets and lease liabilities for operating leases totaled \$10.2 million and \$15.2 million, respectively, and the weighted average remaining term of the operating leases is approximately 3.25 years. The weighted average discount rate for the operating lease liability is approximately 11%. A 100-basis point change in the incremental borrowing rate would result in less than a \$1 million impact to the ROU assets and liabilities recorded.

The maturities of operating lease liabilities discussed above are as follows (in thousands):

2023	\$	5,503
2024		5,522
2025		5,543
2026		1,429
2027		13
Total lease payments		18,010
Less imputed interest		(2,766)
Total lease liabilities	\$	<u>15,244</u>

In addition to the amounts in the table above, the Company is also responsible for variable operating costs and real estate taxes approximating \$3.8 million per year through March 2026.

Sublease Income

In 2020, the Company executed four agreements to sublease a total of approximately 65,000 square feet of the Company's leased space at 830 Winter Street, Waltham, Massachusetts through March 2026. During the years ended December 31, 2022 and 2021, the Company recorded \$1.1 million and \$4.9 million of sublease income, respectively, inclusive of the sublessees' proportionate share of operating expenses and real estate taxes for the period. The decrease in the current year period is driven by amortization of the lease incentive discussed further below.

In June 2022, in order to reclaim laboratory and office space, the Company modified one of its sublease agreements to terminate the sublease early. Pursuant to the amended sublease agreement, the Company is required to pay the sublessee \$4.0 million as a lease incentive, of which \$1.8 million was paid in June 2022 and the remainder was paid at the end of the sublease term in early January 2023. No other terms from the original sublease agreement were modified. In accordance with ASC 842, *Leases*, the \$4.0 million lease incentive was recognized on a straight-line basis over the remaining sublease term. Additionally, in November 2022, the Company modified a separate sublease agreement to terminate the sublease on January 31, 2023. There was no lease incentive included and no other terms from the original sublease agreement were modified. As a result of the early termination of the two sublease agreements, the Company will forego \$4.6 million in minimum future rental payments. The Company assessed the underlying right-of-use asset and determined there was no impairment.

One of the two remaining sublease agreements includes an early termination option after certain periods of time for an agreed-upon fee. Assuming no early termination option is exercised, the Company will receive \$5.7 million in minimum rental payments over the remaining term of the subleases, which is not included in the operating lease liability table above. The sublessees are also responsible for their proportionate share of variable operating expenses and real estate taxes.

L. Commitments and Contingencies

Manufacturing Commitments

As of December 31, 2022, the Company has noncancelable obligations under several agreements related to in-process and future manufacturing of antibody and cytotoxic agents required for supply of the Company's product candidates totaling \$17.9 million, which will be paid in 2023. Additionally, pursuant to commercial agreements for future production of antibody, the Company's noncancelable commitments total \$43.7 million at December 31, 2022.

License Commitment

In October 2021, as a result of a dispute regarding terms of a 2012 license agreement with a contract manufacturing vendor, the Company and vendor amended their agreement to replace certain annual fees and potential royalties payable by the Company on future sales of ELAHERE with capped development and sales-based milestone payments totaling \$18.0 million, of which \$6.0 million and \$3.0 million was recorded as research and development expense during the years ended December 31, 2022 and 2021, respectively.

Litigation

The Company is not party to any material litigation.

M. Related Party Transactions

The Company's chief executive officer has served as a director on the board of directors of Ergomed PLC since June 2021. During the year ended December 31, 2022, the Company executed agreements with Ergomed Clinical Research, Inc. and PrimeVigilance USA, Inc., subsidiaries of Ergomed PLC, for clinical trial and pharmacovigilance-related services. Ergomed Clinical Research, Inc. and PrimeVigilance USA, Inc. are each considered related parties pursuant to ASC 850, *Related Party Disclosures*. In the year ended December 31, 2022, the Company made payments totaling \$5.0 million to Ergomed Clinical Research, Inc. Payments made pursuant to the agreement with PrimeVigilance USA, Inc. during the year ended December 31, 2022 were not material to the Company's consolidated statement of operations.

The Company's Executive Vice President of Research, Development, and Medical Affairs joined the Company on December 29, 2022. He has served as a director on the board of directors of Magenta Therapeutics since August 2022. In 2020, the Company and Magenta executed a Material Transfer and Evaluation Agreement, and subsequently executed an exclusive development and commercialization license to the Company's IGN ADC technology to a specified target in November 2022. Pursuant to the agreements, the Company received an aggregate \$6.0 million in license fees during the years ended December 31, 2022 and 2021.

N. Employee Benefit Plans

The Company has a deferred compensation plan under Section 401(k) of the Internal Revenue Code (the 401(k) Plan). Under the 401(k) Plan, eligible employees are permitted to contribute, subject to certain limitations, up to 100% of their gross salary and the Company's matching contribution is 50% of the first 6% of the eligible employees' contributions. In the years ended December 31, 2022, 2021 and 2020, the Company's contributions to the 401(k) Plan totaled \$1.0 million, \$0.5 million, and \$0.4 million, respectively.

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

None.

Item 9A. *Controls and Procedures*

1. Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of the end of such period, our disclosure controls and procedures were adequate and effective.

2. Internal Control Over Financial Reporting

(a) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management, and other personnel 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 in the U.S. and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our 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. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in 2013.

Based on this assessment, management has concluded that, as of December 31, 2022 our internal control over financial reporting is effective.

Ernst & Young LLP, our independent registered public accounting firm, has issued a report on the effectiveness of our internal control over financial reporting as of December 31, 2022. This report appears immediately below.

(b) *Attestation Report of the Independent Registered Public Accounting Firm*

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of ImmunoGen, Inc.

Opinion on Internal Control over Financial Reporting

We have audited ImmunoGen, Inc.'s internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, ImmunoGen, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated March 1, 2023 expressed an unqualified opinion thereon that included an explanatory paragraph regarding the Company's ability to continue as a going concern.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 1, 2023

(c) *Changes in Internal Control Over Financial Reporting*

During the three months ended December 31, 2022, we implemented certain internal controls in connection with our product launch. There were no other changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

3. *Limitations on the Effectiveness of Controls*

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or its internal control over financial reporting will prevent all error and all fraud. 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. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within an organization have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake.

Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. *Other Information*

None

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

Not applicable

PART III

The information called for by Part III of Form 10-K (Item 10—Directors, Executive Officers and Corporate Governance of the Registrant, Item 11—Executive Compensation, Item 12—Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, Item 13—Certain Relationships and Related Transactions, and Director Independence, and Item 14—Principal Accounting Fees and Services) is incorporated by reference from our proxy statement related to our 2022 annual meeting of shareholders, which will be filed with the Securities and Exchange Commission not later than May 2, 2022 (120 days after the end of the year covered by this report).

PART IV

Item 15. *Exhibits, Financial Statement Schedules*

(a) Documents filed as part of this Report:

(1) See the financial statements of ImmunoGen, Inc. at Item 8 of this report.

(2) Financial Statement Schedules:

Schedules not included herein are omitted because they are not applicable, or the required information appears in the accompanying Consolidated Financial Statements or Notes thereto.

(3) Exhibit Index

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit Number
			Form	Filing Date with SEC	
3.1	Restated Articles of Organization, as amended		10-Q	August 5, 2020	3.1
3.1(a)	Articles of Amendment		10-Q	January 30, 2013	3.1
3.1(b)	Articles of Amendment		10-Q	August 4, 2017	3.1
3.1(c)	Articles of Amendment		10-Q	August 5, 2020	3.1(c)
3.1(d)	Articles of Amendment		10-Q	August 1, 2022	3.1(d)
3.2	Amended and Restated By-Laws		8-K	June 20, 2016	3.1
4.1	Article 4 of Restated Articles of Organization, as amended (see Exhibit 3.1)				
4.2	Form of Common Stock certificate		S-1	November 15, 1989 (File No. 33-31219)	4.2
4.3	Description of Securities	X			
4.4	Form of Pre-Funded Warrant issued August 12, 2021		8-K	August 12, 2021	4.1
4.5	Form of Pre-Funded Warrant issued December 6, 2021		8-K	December 3, 2021	4.1
10.1	Lease Agreement, dated as of July 27, 2007, by and between Intercontinental Fund III 830 Winter Street LLC, landlord, and the Registrant		10-Q	November 7, 2007	10.2
10.1(a)	First Amendment to Lease Agreement dated as of December 9, 2013, by and between Intercontinental Fund III 830 Winter Street LLC, landlord, and the Registrant		10-Q	February 5, 2014	10.1
10.1(b)	Second Amendment to Lease Agreement dated as of April 28, 2014, by and between Intercontinental Fund III 830 Winter Street LLC, landlord, and the Registrant		10-Q	May 2, 2014	10.1
10.1(c)	Third Amendment to Lease Agreement dated as of December 14, 2015 by and between CRP/King 830 Winter, L.L.C., landlord, and the Registrant		10-Q	February 4, 2016	10.1
10.1(d)	Fourth Amendment to Lease Agreement dated as of April 6, 2018 by and between CRP/King 830 Winter, L.L.C., landlord, and the Registrant		10-Q	May 9, 2018	10.2
10.2**	Collaboration and License Agreement effective as of October 19, 2020 by and between the registrant and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., a subsidiary of Huadong Medicine Co., Ltd.		10-K	March 1, 2021	10.6
10.3**	License Agreement as of February 14, 2022 by and between the Registrant and Eli Lilly and Company		10-Q	May 6, 2022	10.1
10.10†	2006 Employee, Director and Consultant Equity Incentive Plan, as amended and restated through November 11, 2014		8-K	November 13, 2014	10.1
10.10(a)†	Form of Incentive Stock Option Agreement for Executives under 2006 Plan		S-8	November 15, 2006	99.4
10.10(b)†	Form of Non-Qualified Stock Option Agreement for Executives under 2006 Plan		S-8	November 15, 2006	99.5
10.10(c)†	Form of Non-Qualified Stock Option Agreement for Directors under 2006 Plan		10-Q	October 29, 2010	10.1
10.10(d)†	Form of Director Deferred Stock Unit Agreement		10-Q	October 29, 2010	10.1
10.10(e)†	Form of Incentive Stock Option Agreement for all employees (including executives)		10-K	August 29, 2012	10.14(g)
10.10(f)†	Form of Non-Qualified Stock Option Agreement for all employees (including executives)		10-K	August 29, 2012	10.14(h)
10.10(g)†	Form of Non-Qualified Stock Option Agreement for Directors		10-K	August 29, 2012	10.14(i)
10.10(h)†	Form of Incentive Stock Option for all employees (including executives)		8-K	April 26, 2016	10.1
10.10(i)†	Form of Non-Qualified Stock Option Agreement for all employees (including executives)		8-K	April 26, 2016	10.2

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit Number
			Form	Filing Date with SEC	
10.11†	2016 Employee, Director and Consultant Equity Incentive Plan, as amended and restated through June 13, 2017		8-K	June 16, 2017	10.1
10.11(a)†	Form of Incentive Stock Option Agreement under the 2016 Plan		8-K	December 13, 2016	10.2
10.11(b)†	Form of Non-Qualified Stock Option Agreement for Employees under the 2016 Plan		8-K	December 13, 2016	10.3
10.11(c)†	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors		8-K	December 13, 2016	10.4
10.11(d)†	Form of Deferred Stock Unit Agreement for Non-Employee Directors		8-K	December 13, 2016	10.5
10.12†	Amended and Restated 2018 Employee, Director and Consultant Equity Incentive Plan		8-K	June 17, 2022	10.1
10.12(a)†	Form of Incentive Stock Option Agreement under the 2018 Plan		8-K	June 22, 2018	10.2
10.12(b)†	Form of Non-Qualified Stock Option Agreement for Employees under the 2018 Plan		8-K	June 22, 2018	10.3
10.12(c)†	Form of Restricted Stock Unit Agreement under the 2018 Plan, as amended February 3, 2023	X			
10.12(d)†	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors, as amended December 15, 2022	X			
10.12(e)†	Form of Deferred Stock Unit Agreement for Non-Employee Directors		8-K	June 22, 2018	10.6
10.12(f)†	Form of Restricted Stock Unit Agreement for Non-Employee Directors as of December 15, 2022	X			
10.12(g)†	Form of Performance-Based Stock Option Agreement dated February 7, 2020		10-K	March 11, 2020	10.11(f)
10.13†	Amended and Restated 2018 Employee Director and Consultant Equity Incentive Plan		8-K	June 17, 2021	10.1
10.14†	Employee Stock Purchase Plan, as amended through September 27, 2019		10-Q	November 5, 2019	10.1
10.15†	2004 Non-Employee Director Compensation and Deferred Stock Unit Plan, as amended and restated on December 15, 2022	X			
10.16†	Form of Proprietary Information, Inventions and Competition Agreement between the Registrant and each of its executive officers		10-Q	February 8, 2007	10.15
10.17†	Change in Control Severance Agreement dated as of March 31, 2017 between the Registrant and Anna Berkenblit		10-Q	May 5, 2017	10.3
10.18†	Change in Control Severance Agreement dated as of March 31, 2017 between the Registrant and Mark J. Enyedy		10-Q	May 5, 2017	10.4
10.19†	Change in Control Severance Agreement dated as of January 5, 2021 between the Registrant and Renee Lentini	X			
10.20†	Change in Control Severance Agreement dated as of December 29, 2022 between the Registrant and Michael J. Vasconcelles	X			
10.21†	Change in Control Severance Agreement dated as of July 20, 2020 between the Registrant and Susan Altschuller, Ph.D.		10-Q	August 5, 2020	10.4
10.22†	Change in Control Severance Agreement dated as of June 1, 2020 between the Registrant and Stacy Coen		10-K	March 1, 2021	10.19
10.23†	Offer Letter dated as of December 29, 2022 between the Registrant and Michael J. Vasconcelles	X			
10.23(a)†	First Amendment to Offer Letter dated as of December 29, 2022 between the Registrant and Michael J. Vasconcelles	X			

Exhibit Number	Exhibit Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit Number
			Form	Filing Date with SEC	
10.24†	Compensation Policy for Non-Employee Directors, as amended through December 15, 2022	X			
10.25†	Severance Pay Plan for Vice Presidents and Higher, as amended through June 20, 2019		10-Q	August 7, 2019	10.1
10.26†	Summary of ImmunoGen Incentive Bonus Plan		8-K	February 20, 2018	10.1
10.27†	Inducement Equity Incentive Plan, as amended December 15, 2022	X			
10.27(a)†	Form of Non-Qualified Stock Option Agreement under the Inducement Equity Incentive Plan		8-K	December 20, 2019	10.2
10.27(b)†	Form of Restricted Stock Unit Agreement (Inducement Plan), as amended February 3, 2023	X			
10.27(c)†	Form of Performance-Based Stock Option Agreement (February 2020) under the Inducement Equity Incentive Plan		10-Q	August 5, 2020	10.2
10.28	Open Market Sale Agreement SM , dated December 18, 2020, by and between the Registrant and Jeffries LLC		8-K	December 18, 2020	10.1
21	Subsidiaries of the Registrant	X			
23	Consent of Ernst & Young LLP	X			
31.1	Certification of the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32	Certifications of principal executive officer and principal financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101	Financial statements from the annual report on Form 10-K of ImmunoGen, Inc. for the year ended December 31, 2022 formatted in inline XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations and Comprehensive Loss; (iii) the Consolidated Statements of Shareholder's Equity (Deficit); (iv) the Consolidated Statements of Cash Flows; and (v) the Notes to Consolidated Financial Statements	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X			

* Portions of this Exhibit were omitted, as indicated by [***], and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment.

** Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets [***] because the identified confidential portions (i) are not material and (ii) is the type of information the Registrant treats as private or confidential.

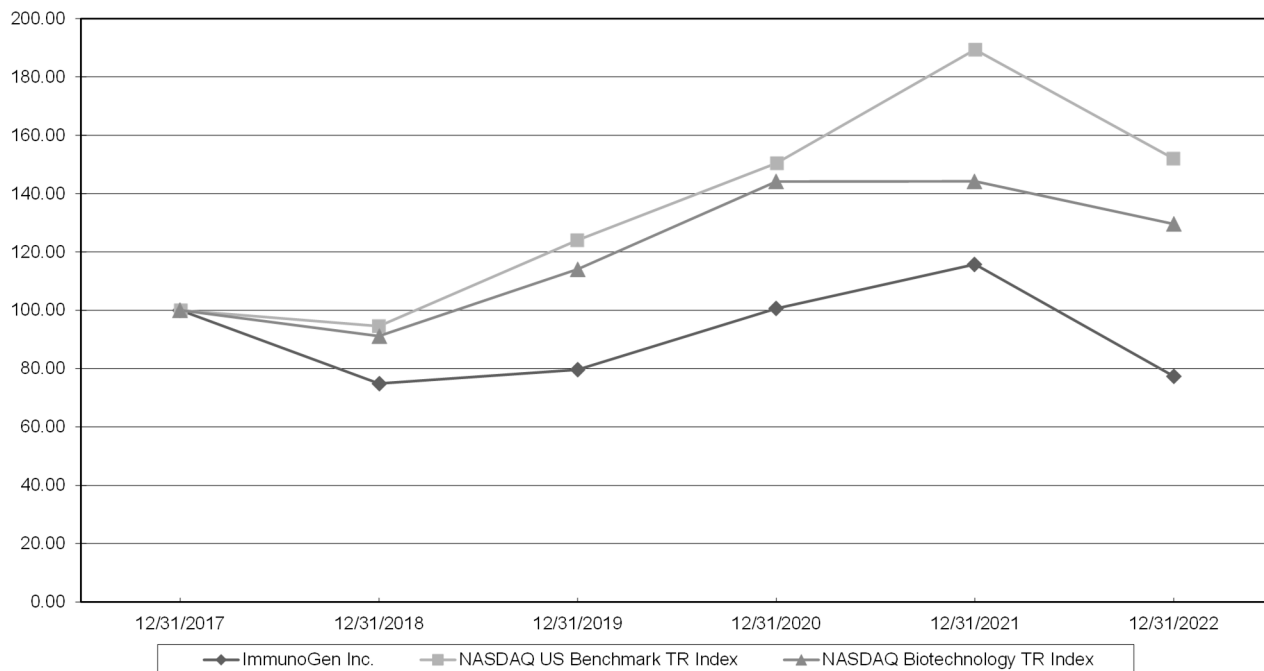
† Exhibit is a management contract or compensatory plan, contract or arrangement required to be filed as an exhibit to this report on Form 10-K.

Item 16. Form 10-K Summary

None

IMMUNOGEN, INC.
Stock Price Performance Graph

The graph and table below compare the annual percentage change in our cumulative total shareholder return on our common stock for the period from December 31, 2017 through December 31, 2022 (as measured by dividing (i) the sum of (A) the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and (B) the difference between our share price at the end and the beginning of the measurement period; by (ii) the share price at the beginning of the measurement period) with the total cumulative return of the NASDAQ US Benchmark TR Index and the NASDAQ Biotechnology TR Index during such period. We have not paid any dividends on our common stock, and no dividends are included in the representation of our performance. The stock price performance on the graph below is not necessarily indicative of future price performance.



	<u>Dec 2017</u>	<u>Dec 2018</u>	<u>Dec 2019</u>	<u>Dec 2020</u>	<u>Dec 2021</u>	<u>Dec 2022</u>
IMMUNOGEN, INC.	\$100.00	\$74.88	\$79.64	\$100.62	\$115.75	\$77.37
NASDAQ US BENCHMARK TR INDEX	\$100.00	\$94.56	\$124.03	\$150.41	\$189.36	\$152.00
NASDAQ BIOTECHNOLOGY TR INDEX	\$100.00	\$91.14	\$114.02	\$144.15	\$144.18	\$129.59

The above graph and table assume \$100 invested on December 31, 2017 with all dividends reinvested, in each of our common stock, the NASDAQ US Benchmark TR Index, and the NASDAQ Biotechnology TR Index.

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CORPORATE INFORMATION

EXECUTIVES

Mark J. Enyedy

President and Chief Executive Officer

Audrey M. Bergan

Senior Vice President, Chief Human Resources Officer

Anna Berkenblit, MD, MMsC

Senior Vice President, Chief Medical Officer

Daniel S. Char, JD

Senior Vice President, Chief Legal Officer

Stacy A. Coen

Senior Vice President, Chief Business Officer

Robert W. Herbst, PhD

Vice President, Technical Operations

Isabel Kalofonos

Senior Vice President, Chief Commercial Officer

Renee Lentini

Interim Chief Financial Officer, Chief Accounting Officer, and Vice President, Finance

Massimo Radaelli

Senior Vice President, General Manager International (Ex-US)

Mike J. Vasconcelles, MD

Executive Vice President, Research, Development, and Medical Affairs

Theresa G. Wingrove, PhD

Senior Vice President, Regulatory Affairs and Quality

AUDITORS

Ernst & Young LLP
Boston, MA

LEGAL COUNSEL

Ropes & Gray, LLP
Boston, MA

DIRECTORS

Stephen C. McCluski

Chairman of the Board, Former Senior Vice President and Chief Financial Officer, Bausch & Lomb, Inc.

Stuart A. Arbuckle

Executive Vice President and Chief Operating Officer, Vertex Pharmaceuticals, Inc.

Mark J. Enyedy

President and Chief Executive Officer, ImmunoGen, Inc.

Mark A. Goldberg, MD

Former Executive Vice President, Medical and Regulatory Strategy, Synageva BioPharma Corp.

Tracey L. McCain, Esq

Executive Vice President and Chief Legal and Compliance Officer, Blueprint Medicines Corporation

Dean J. Mitchell

Former Executive Chairman of the Board, Covis Pharma Holdings S.a.r.l.

Kristine Peterson

Former Chief Executive Officer, Valeritas, Inc.

Helen M. Thackray, MD

Chief Research and Development Officer, BioCryst Pharmaceuticals, Inc.

Richard J. Wallace

Former Senior Vice President Research and Development, GlaxoSmithKline plc

SHAREHOLDER INQUIRIES

Information about ImmunoGen can be found at www.immunogen.com. Inquiries related to the Company may be directed to the Investor Relations department at our headquarters. Communications related to stock and transfer requirements, including lost stock certificates and change of name or address, should be directed to the Transfer Agent.

ImmunoGen, Inc. | 830 Winter Street | Waltham, MA 02451 | 781-895-0600 | www.immunogen.com

VIRTUAL ANNUAL MEETING


9:00 AM ET on June 14, 2023

www.virtualshareholdermeeting.com/IMGN2023

No in-person meeting will be held.

STOCK TRANSFER AGENT AND REGISTRAR

Broadridge Corporate Issuer Solutions, Inc.
P.O. Box 1342
Brentwood, NY 11717
Phone: 855-697-4961
Fax: 215-553-5402
Email: shareholder@broadridge.com



We extend our sincere gratitude to the patients, families, and medical professionals who participate in our clinical trials as we work to meaningfully improve the lives of people with cancer.

immunogen

830 Winter Street
Waltham, MA 02451
781-895-0600
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Nasdaq: IMGN

The enclosed message to our shareholders includes forward-looking statements regarding ImmunoGen's current expectations related to the commercialization of ELAHERE; mirvetuximab soravtansine, pivekimab sunirine, IMG936, and IMG151 clinical trials, including the timing of initiating and receiving data from, as well as the likelihood of success of, the trials for these product candidates, including a trial that is intended to support full regulatory approval of ELAHERE; the potential of ELAHERE to become a standard of care; and the potential of ELAHERE to become a combination agent of choice. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this presentation. We undertake no obligation to update or revise any of these forward-looking statements. Factors that could cause future results to differ materially from such expectations include, but are not limited to: that top-line data may change as more patient data become available and are subject to audit and verification procedures; the difficulties inherent in the development of novel biopharmaceuticals; the results of the ongoing MIRASOL trial may fail to support full approval of ELAHERE and, if so, additional studies may be required; the risks and uncertainties inherent in the Company's development programs, including its preclinical and clinical studies and regulatory processes, their timing, expense, and results as well as the possibility that studies of the Company's development programs fail to confirm the hypotheses suggested by exploratory analyses or fail to satisfy the requirements for approval by one or more regulatory agencies; the Company's ability to financially support its development programs; additional market research and sources that may cause the Company's expectations of future market opportunities for its development programs to change; the risk that we may not be able to obtain adequate reimbursement for any approved products, including the potential for delays or additional difficulties for ELAHERE in light of the FDA granting accelerated approval; and the risks and uncertainties associated with the scale and duration of the COVID19 pandemic and resulting impact on ImmunoGen's industry and business. A review of these and other risks can be found in the "risk factors" set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 1, 2023, and other reports filed with the SEC and available at www.sec.gov and on our website at www.immunogen.com.