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 fiscal year ended December 31, 2023

OR

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

Commission file number: 001-39580

IMMUNOME, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0694340**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
18702 N. Creek Parkway, Suite 100 Bothell, WA	**98011**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (610) 321-3700

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, $0.0001 Par Value	**IMNM**	**The Nasdaq Capital Market**

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically; every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.0405 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐	Non-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.
Yes ☐ No ☒

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

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

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant was approximately $75.5 million based on the closing price reported by NASDAQ on June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter). For purposes of making this calculation only, the registrant has defined affiliates as including all executive officers, directors and beneficial owners of more than 10% of the common stock of the registrant.

The number of outstanding shares of the Registrant's Common Stock as of March 26, 2024 was 59,694,243.

Documents Incorporated by Reference

Portions of the Registrant's definitive proxy statement on Schedule 14A for the 2024 Annual Meeting of Stockholders to be filed with Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference into Part III, Items 10-14 of this Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Annual Report on Form 10-K for the fiscal year ended December 31, 2023, or this Annual Report, may include "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to considerable risks and uncertainties. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Annual Report, other than statements of historical fact, are forward-looking statements. You can identify forward-looking statements by the use of words such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "suggest," "target," "will," "would" and similar statements of a future or forward-looking nature and identify forward-looking statements. In particular, forward-looking statements contained in this Annual Report relate to, among other things, the process of discovering, developing and commercializing medicines that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such medicines. We caution you that the foregoing may not encompass all of the forward-looking statements made in this Annual Report. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

Forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. There are or will be important factors that could cause actual results to differ materially from those indicated in these statements. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

This Annual Report also contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

You should read the following together with the more detailed information regarding our company, our common stock and our consolidated financial statements and notes to those statements appearing elsewhere in this Annual Report or incorporated by reference. The Securities and Exchange Commission, or SEC, allows us to "incorporate by reference" information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this Annual Report.

Risk Factor Summary

The risks described in the section titled "Risk Factors" immediately following this summary could impact our ability to realize the full benefits of our strengths or execute all or part of our strategy. Some of the more significant risks described in "Risk Factors" include the following:

Risks Related to Our Business

- We are a biopharmaceutical company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We have not yet demonstrated successful completion of clinical development, submitted a New Drug Application, obtained FDA approval for marketing, or successfully commercialized a drug product, and we may be unable to do so. Furthermore, AL102, which we recently acquired, is currently in Phase 3 development, but

such acquisition and prior clinical success is not indicative of our ability to obtain new drug application, or NDA, approval or successfully commercialize AL102.
- We will need to raise substantial additional funds to advance development of our development candidates and our discovery and ADC platforms, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize any of our development candidates.

Risks Related to Our Discovery, Development and Regulatory Approval of Development Candidates

- We may not be successful in our efforts to use and expand our discovery and ADC platforms to build and progress a pipeline.
- We may be unable to advance any of our development candidates into and through clinical development, obtain regulatory approvals and ultimately commercialize them, or we could experience significant delays in doing so.
- We may pursue particular programs or development candidates over others; these decisions may prove to be wrong and may adversely impact our business.
- We may fail to realize the business benefits anticipated as a result of completed or pending strategic transactions.
- Clinical trials are expensive, time-consuming and difficult to design and implement.
- Preliminary results from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and as the data undergo audit and verification procedures. Furthermore, clinical development has an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.
- If any of our development candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.
- Additional regulatory burdens and other risks and uncertainties in foreign markets may limit our growth.

Risks Related to Government Regulation

- We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or government enforcement actions; private litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; adverse publicity; and other consequences that could negatively affect our operating results and business.
- Health care legislative reform measures may have a material adverse effect on our business and results of operations.
- If we or our existing or potential future partners, manufacturers or other service providers fail to comply with health care laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our products and may harm our reputation.
- Even if we receive regulatory approval of our development candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.

Risks Related to Manufacturing, Commercialization and Reliance on Third Parties.

- If we choose to pursue collaborations and other strategic transactions, we may not be able to enter into such transactions on acceptable terms, if at all, which could adversely affect our development and commercialization activities, impact our cash position, increase our expense, and present significant distractions to our management.

- If third parties on which we intend to rely to conduct our current and future preclinical studies and clinical trials do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our programs could be delayed with material and adverse impacts on our business and financial condition.

Risks Related to Our Intellectual Property

- It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.
- If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future targeted therapeutics, or we could lose certain rights to grant sublicenses.
- Intellectual property rights of third parties could adversely affect our ability to commercialize our targeted therapeutics, and we might be required to obtain licenses from third parties to engage in development or marketing efforts, which may not be available on commercially reasonable terms or at all.

Risks Related to Our Business Operations and Industry

- We may be unable to successfully integrate the Immunome and Morphimmune businesses and realize the anticipated benefits of the Merger.
- Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Risks Related to Our Common Stock

- The market price of our common stock is expected to be volatile, and purchasers of our common stock could incur substantial losses.
- Our ability to use net operating loss carryforwards and other tax attributes may be limited.

PART I

Item 1. Business

General

We are a biopharmaceutical company focused on the development of targeted oncology therapies. We believe that the pursuit of novel or underexplored targets will be central to the next generation of transformative therapies. For that reason, we pursue therapeutics that we believe have best-in-class or first-in-class potential. Our goal is to establish a broad pipeline of preclinical and clinical assets which we can efficiently develop through successive value inflection points. To support that goal, we pair business development activity with significant investment in our internal discovery programs.

Our named pipeline comprises one clinical and three preclinical assets. Our clinical asset is AL102, an investigational gamma secretase inhibitor, or GSI, currently under evaluation in a Phase 3 trial for the treatment of desmoid tumors. We acquired AL102 and related assets pursuant to an Asset Purchase Agreement, or the Ayala Purchase Agreement, with Ayala Pharmaceuticals, Inc., or Ayala, that we entered into on February 5, 2024, and the

transaction closed on March 25, 2024. Based on our evaluation of Phase 2 data, we believe that AL102 has the potential, if approved, to establish a new standard of care for patients with desmoid tumors.

Our preclinical pipeline is centered on IM-1021, a receptor tyrosine kinase-like orphan receptor 1, or ROR1, antibody-drug conjugate, or ADC; IM-3050, a fibroblast activation protein, or FAP, targeted radioligand therapy, or RLT, candidate; and IM-4320, an anti-IL-38 immunotherapy candidate. We anticipate submitting investigational new drug applications, or INDs, for IM-3050 and IM-1021 in the first quarter of 2025 and for IM-4320 at a later date. We believe that each of these drugs has the potential to improve outcomes for patients across multiple indications.

Our business model is built upon our expertise in discovering and developing targeted therapies as well as our ability to evaluate and acquire high- potential assets. We believe that the successful track record of our leadership team will make us more attractive to companies selling assets, especially early-stage biotechnology companies that lack resources to efficiently develop their assets.

Our perspective is that the most important considerations when acquiring an asset are the quality of its preclinical or clinical data and the economic terms on which it can be acquired. Accordingly, we are willing to consider assets across multiple modalities, including ADCs, RLTs, naked antibodies, small molecules and more. We believe that effectively pursuing a novel target requires selecting a modality that is appropriate to the target biology.

At present, our internal discovery efforts are centered on ADCs and RLTs. We believe that a broad toolbox of linkers and payloads is necessary to design and develop a broad pipeline of ADCs, as different targets may require different payloads to achieve optimal efficacy and therapeutic index. The novel linker-payload unit we exclusively licensed from Zentalis Pharmaceuticals, Inc., or Zentalis, is an important component of this toolbox, and we have efforts underway to develop additional linkers and payloads. We also believe that the incorporation of albumin binders into radioligand therapies provides a differentiated approach that can increase the dose of radiation absorbed by patient tumors.

Our discovery platform provides us with a proprietary hybridoma technology to immortalize memory B cells isolated from oncology patient samples. This enables the production of sufficient quantities of antibodies to perform high-throughput functional screening, allowing for the recognition of antibodies and targets whose role in cancer was not previously appreciated. In January 2023, we announced an agreement with AbbVie under which AbbVie paid us $30 million upfront for access to up to 10 targets identified through our discovery platform.

On October 2, 2023, we completed a merger with Morphimmune Inc, or the Merger. As a result of the Merger, our corporate strategy has shifted significantly. At the close of the Merger, Clay Siegall, Ph.D. became our President and Chief Executive Officer. Three additional Morphimmune Inc, or Morphimmune, executives joined our leadership at the time of the Merger and, since that time, we have continued to expand our executive management team. We believe that these new hires, in combination with our existing management, have the experience and skills necessary to execute our post-Merger strategy.

Immunome Pipeline

AL102 (Gamma Secretase Inhibitor)

On February 5, 2024, we entered into the Ayala Purchase Agreement with Ayala, pursuant to which we acquired assets including the rights to AL102, a GSI, currently under evaluation in a Phase 3 trial for the treatment of desmoid tumors. We closed the transaction contemplated by the Ayala Purchase Agreement, including the purchase of AL102, on March 25, 2024.

Our interest in AL102 was largely a response to Phase 2 data, a preliminary version of which was shared by Ayala at European Society for Medical Oncology congress, or ESMO, in October 2023. Ayala's data showed an objective response rate, or ORR, of 64% in the intent-to-treat population and 75% among evaluable patients. Other measures of response, including tumor volume as measured by MRI and cellularity as estimated via T2 imaging, also showed deep responses.

Disease background

Desmoid tumors, also known as aggressive fibromatosis or desmoid-type fibromatosis, are debilitating, painful and aggressive non-metastatic soft tissue tumors that are prone to recurrence. Depending on where in the body they occur, desmoid tumors can cause debilitating pain, deformity and, in some cases, life threatening organ damage. These tumors are rare, with approximately 1,000-1,650 patients diagnosed each year and approximately 5,500-7,000 actively managed patients in the United States. They typically occur in people between the ages of 15 and 60 and are most common in early adolescence, with a peak around 30 years of age, and they are more common in women than men.

Desmoid tumors arise in connective tissue and can occur anywhere in the body where connective tissue is found. These tumors are locally aggressive, which means that while they do not metastasize to other parts of the body, they can grow into the surrounding or adjacent tissue. While some people with desmoid tumors do not experience symptoms, others may experience pain, swelling, difficulty sleeping, and reduced mobility. Symptoms largely depend on the location of the tumor and the extent of invasion or compression of surrounding tissue. The pain and physical limitations associated with desmoid tumors lead to high clinical burdens and reduced quality of life. Additionally, a study conducted in Denmark found that patients with desmoid tumors have substantially higher healthcare resource utilization compared with matched patients at 1- and 3- years post-diagnosis, including increases in both in-patient and out-patient visits as well as days of hospitalization.

The vast majority (85-90%) of desmoid tumors are sporadic and result from somatic mutations in the CTNNB1 gene, which encodes β-catenin protein. Desmoid tumors may also result from germline mutation of the APC gene, which is also associated with familial adenomatous polyposis, that leads to accumulation of β-catenin in the nucleus and drives overexpression of its target genes. Risk factors for developing desmoid tumors in patients with these mutations include trauma (especially abdominal surgery), estrogen, and pregnancy.

Desmoid tumors exhibit a variable clinical course, but evidence suggests that the initial period of tumor growth is followed by a long period during which the tumor is stable or may even regress. The recurrence rate of desmoid tumors is associated with tumor location and underlying genetic mutation. For example, tumors on the extremities have recurrence rates of up to 77% and intra-abdominal tumors recur much more frequently than extra-abdominal tumors in patients with familial adenomatous polyposis. Risk factors for the initial development of desmoid tumors can also increase the risk of recurrence.

Prior to the November 2023 U.S. Food & Drug Administration, or FDA, approval of the GSI nirogacestat for the treatment of adult patients with progressing desmoid tumors who require systemic treatment, the treatment landscape for desmoid tumors included watchful waiting, surgery, radiation therapy, low-dose or conventional chemotherapy, or tyrosine kinase inhibitors. Treatment considerations include tumor progression, symptoms, risk of morbidity, surgical risk, and the need for a fast response. Active surveillance is now the preferred management approach for patients whose tumors are in non-critical anatomic locations. We believe GSIs may ultimately capture much of the market for first-line desmoid tumor therapy.

Mechanism of action

AL102 is an investigational, oral, once-daily GSI. GSIs alter signaling through the Notch pathway, which is involved in embryonic development and the renewal and maintenance of adult tissues. Notch plays a critical role in the proliferation, survival, migration, invasion, and metastasis of cancer cells, which contribute to the development and progression of cancer. Notch also contributes to resistance to cancer therapeutics. Gamma secretase-mediated cleavage of Notch releases the Notch intracellular domain which travels to the nucleus and activates the genes that mediate oncologic behavior. Inhibition of gamma secretase by AL102 blocks this cleavage and inhibits Notch pathway activation.

Clinical development

Prior to the initiation of the Phase 3 trial of AL102 in desmoid tumors (RINGSIDE Part B), AL102 clinical activity was observed in two clinical trials that enrolled adult desmoid tumor patients. A Phase 1 dose-escalation clinical trial was conducted by Bristol-Myers Squibb, or BMS, in patients with solid tumors. In this trial, one patient with desmoid fibromatosis was enrolled. This patient demonstrated tumor shrinkage of 16.5% while on study. Based on these data and responses demonstrated with other GSIs, Ayala designed a seamless Phase 2/3 study called RINGSIDE to specifically evaluate the activity of AL102 in patients with progressing desmoid tumors who required therapy. RINGSIDE Part A enrolled 42 patients at three different dosing regimens of AL102: 2 mg once a day for two days every week, 4 mg once a day for two days every week or 1.2 mg once a day daily. Overall, the ORR in evaluable patients as measured by RECIST v1.1 by an independent radiologist was 61% for all doses tested. The 1.2 mg daily dosing cohort had an ORR of 75% in

the evaluable population. AL102 was well tolerated overall with a safety profile consistent with that reported with other GSIs. These data were reported at ESMO in 2023.

Overview of Treatment-Emergent Adverse Events for AL102 and Nirogacestat				
Study Population, n	**AL102, 1.2mg QD RINGSIDE Part A (n=14)**		**Nirogacestat 150mg BID DeFi Trial (n=69)**	
Adverse Event	**Any Grade**	**Grade ≥3**	**Any Grade**	**Grade ≥3**
Diarrhea	13 (92.8)	2 (14.3)	58 (84)	11 (16)
Nausea	8 (57.1)	-	37 (54)	1 (1)
Fatigue	7 (50)	-	35 (51)	2 (3)
Alopecia	7 (50)	-	13 (19)	-
Dry skin	7 (50)	-	11 (16)	-
Stomatitis	7 (50)	1 (7.1)	20 (29)	3 (4)
Dermatitis acneiform	6 (42.9)	-	15 (22)	-
Dry mouth	6 (42.9)	-	NR	NR
Hypophosphatemia	6 (42.9)	-	29 (42)	2 (3)
Rash maculo-papular	5 (35.7)	-	22 (32)	4 (6)
Aspartate aminotransferase increased	4 (28.6)	-	11 (16)	-
Months on the study, mean (range), months		16.6 (1-21.6)		20.6 (0.3 - 33.6)

Phase 3 RINGSIDE Part B trial in desmoid tumors

Based upon the clinical activity observed in RINGSIDE Part A at the dose of 1.2 mg given once daily, and following consultation with the FDA, the phase 3 randomized registration trial, RINGSIDE Part B (NCT04871282) was initiated by Ayala in November 2022. Enrollment was completed in February of 2024.

RINGSIDE Part B is a registrational Phase 3, global, double-blind, randomized, placebo-controlled clinical trial, conducted at 61 clinical sites in North America, Europe, Asia and Australia. It will evaluate the efficacy, safety and tolerability of AL102 compared to placebo in patients with progressing desmoid tumors. One hundred fifty-six patients with histologically confirmed desmoid tumors with progressive disease (defined as tumor growth of at least 20% within the past 12 months as measured by RECIST v1.1) were enrolled. Patients were either treatment-naïve with desmoid tumors not amenable to surgery or had refractory or recurrent disease after at least one line of therapy. Patients in the study were randomized to receive either AL102 at a dose of 1.2 mg given once daily or placebo and evaluated for tumor progression using RECIST v1.1. Patients who progress while on study are eligible to enter an open-label extension whereby they may receive AL102 at a dose of 1.2 mg once daily until disease progression or unacceptable toxicity. The primary endpoint of RINGSIDE Part B is progression free survival with secondary endpoints of ORR, duration of response and specific patient-reported outcomes.

We expect to publish topline data for RINGSIDE Part B in the first quarter of 2025. In parallel, we are evaluating and performing the additional manufacturing and pharmacology work required to support an NDA submission.

IM-1021 (ROR1 ADC)

On January 8, 2024, we announced that we had entered into an exclusive, worldwide license agreement with Zentalis, or the Zentalis License Agreement, under which we licensed from Zentalis ZPC-21 (now IM-1021), a preclinical-stage ADC targeting ROR1. ROR1 has an oncofetal expression pattern, with little or no expression in healthy tissue, and it is expressed on solid and liquid tumors. We believe ROR1 has been validated as an ADC target through clinical trials of a competitor ADC in multiple B-cell malignancies.

ROR1 as a therapeutic target in multiple oncology indications

ROR1 is expressed during normal embryonic and fetal development but is largely absent in most mature tissues. While low ROR1 expression is seen in some adult tissues (adipose, pancreas, lung, and a subset of intermediate B cells), high expression has been observed in a variety of blood malignancies and solid tumors. High expression of ROR1 was initially detected in B-cell chronic lymphocytic leukemia, or CLL, and subsequently identified in acute lymphocytic leukemia, non-Hodgkin lymphomas, and myeloid malignancies. Strong expression of ROR1 has also been reported in >30% of primary colon, lung, and pancreatic tumor samples, with more moderate expression seen in the majority of ovarian, lymphoma, skin, testicular, uterine, prostate, and adrenal cancers. Given this pattern of expression, ROR1 may have clinical utility as a therapeutic target in multiple solid and liquid tumor indications, including diseases with large patient populations and high unmet need.

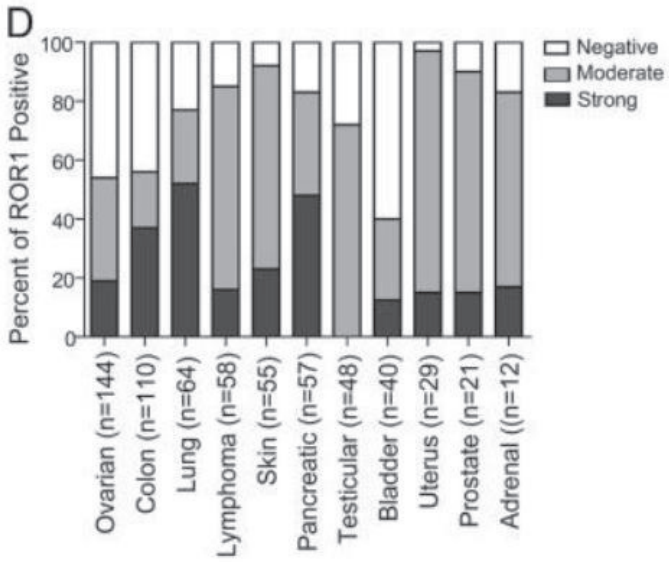
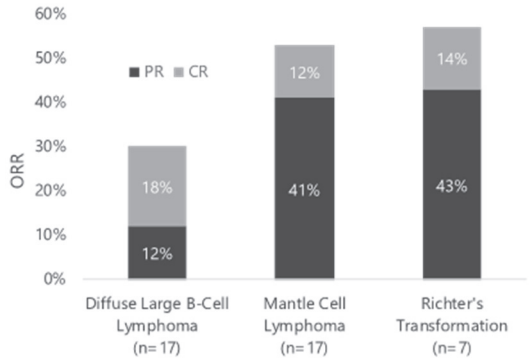


Figure 1. ROR1 expression in different cancer indications

ROR1 is an ADC target with demonstrated clinical activity. Clinical data from two competitor programs support the potential of ROR1-targeted ADCs. MK-2140 (formerly known as VLS-101) is a ROR1-targeted ADC which is currently being evaluated in four phase 2 trials for B-cell malignancies. In a Phase 1 dose escalation study of MK-2140 in heavily pre-treated patients (median prior lines of therapy = 4, range 1-9), objective tumor responses were observed in patients with mantle cell lymphoma, or MCL, or diffuse large B-cell lymphoma, or DLBCL, but not in patients with CLL,

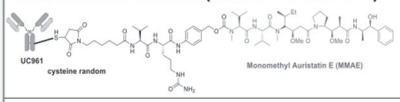
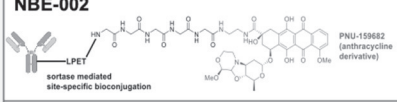
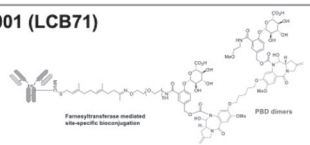
follicular lymphoma, Richter's transformation lymphoma, or RTL, or marginal zone lymphoma. Fourteen-month follow-up data from this trial in patients with DLBCL, MCL, or RTL showed an ORR of 29%, 53%, and 57%, respectively.



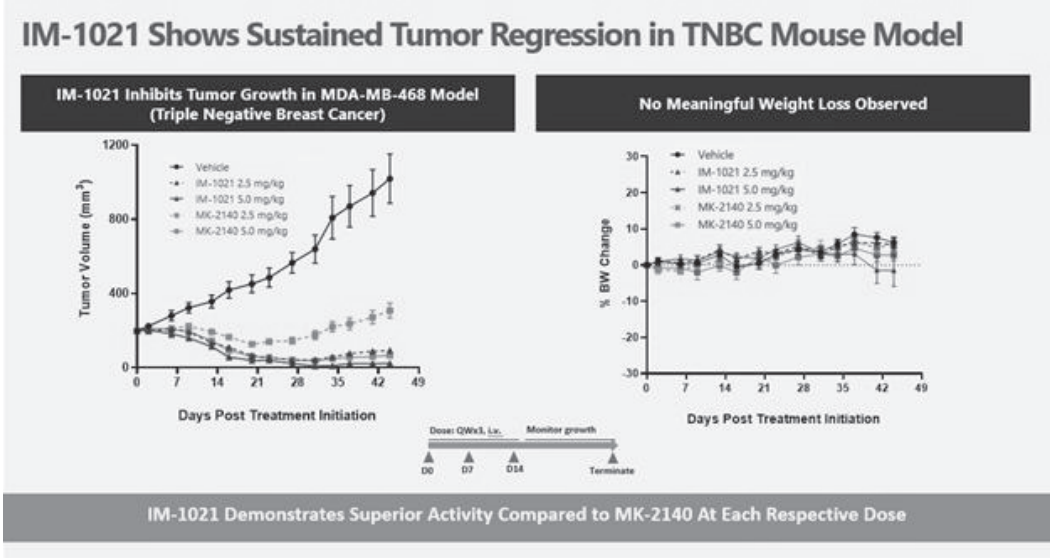
Six-month efficacy data from 20 patients with relapsed/refractory DLBCL in a Phase 2 trial of MK-2140 demonstrate an ORR by investigator review of 30%, including two patients with complete responses, or CR, four patients with partial responses, or PR, and 5 patients with stable disease, or SD.

IM-1021 is designed to overcome the challenges to developing a successful ADC for ROR1

Although ROR1 is expressed in diverse malignancies, its expression levels are relatively low compared with the targets of other ADC therapies. This moderate-to-low expression and slow internalization of ROR1 present challenges to developing a successful ADC for the treatment of ROR1-positive solid tumors. IM-1021 embodies our approach to overcoming these challenges. It incorporates a ROR1 antibody that is designed to promote internalization; a cleavable, undisclosed linker is used to conjugate the payload to the ROR1 antibody via cysteine conjugation; and a proprietary camptothecin derivative (a topoisomerase I inhibitor) that is designed to maximize the potential bystander effect and supports a drug-antibody ratio, or DAR, of 8. We believe that this combination of attributes may potentially provide IM-1021 with an improved therapeutic index compared with other ROR1-targeted ADCs in development.

Name	Linker / DAR	Payload	Development Status
Zilovertamab Vedotin (MK-2140 / VLS-101) 	MC-VC-PAB Cysteine conjugation Cleavable through Val-Cit DAR 4	**MMAE**: Tubulin Inhibitor	**Phase 2 completed; no further updates**
NBE-002 	Peptide linker containing GGGG Sortase-mediated conjugation Cleavable DAR 4	**PNU (Anthracycline derivative):** DNA intercalator	**Discontinued**
CS5001 (LCB71) 	Glucuronidase cleavable linker Farnesyltransferase conjugation Cleavable DAR 2	**Pyrrolobenzodiazepine (PBD-dimer) prodrug:** DNA crosslinker	**Phase 1 Ongoing**
IM-1021 (Formerly ZPC-21) Structure Omitted	Undisclosed linker Cysteine conjugation Cleavable DAR 8	**Camptothecin Derivative:** Topoisomerase I inhibitor	**IND expected 1Q 2025**

In preclinical studies, IM-1021 showed sustained tumor regression in a mouse model triple-negative breast cancer, or TNBC. In this model, IM-1021 dosed weekly for three weeks at 2.5 mg/kg or 5.0 mg/kg demonstrated superior reductions in tumor volume compared with the same respective dose of a competitor, vedotin payload ROR1 ADC, with no meaningful weight loss observed.



Subject to obtaining an IND, our IM-1021 clinical strategy is designed to efficiently evaluate dose escalation in patients with solid tumors or lymphoma, followed by potential expansion of the solid tumor clinical program into targeted indications, potentially including non-small cell lung cancer, breast prostate, pancreatic, and gastric cancer, and expansion of the lymphoma program into diffuse large B-cell lymphoma and mantle cell lymphoma. Concurrent with the dose escalation and expansion studies, we plan to conduct non-clinical studies evaluating IM-1021 in combination with other therapies, particularly in B-cell malignancies, and to evaluate and develop potential companion diagnostics that could help identify patients most likely to respond to IM-1021. Our strategy is to pursue pivotal clinical studies in indications that have shown compelling clinical outcomes in earlier-stage trials, present significant commercial opportunities, have the potential for enhanced outcomes using a companion diagnostic, and offer potential for accelerated approval.

We expect to submit an IND for the IM-1021 program to the FDA in the first quarter of 2025.

IM-3050 (FAP Radioligand Therapy)

Through our merger with Morphimmune, we acquired IM-3050, a FAP-targeted Lu-177 RLT development candidate for the treatment of solid tumors. FAP, or fibroblast activation protein, serves as a tumor-specific marker due to its broad expression on cancer associated fibroblasts. Cancer-associated fibroblasts are the most common tumor stromal cell, with expression in 75% of solid tumors. IM-3050 is designed to deliver radioactive ^{177}Lu directly to FAP-expressing cells, where the "bystander" effect of the radiation may damage or kill nearby tumor cells. We believe this RLT approach could overcome the limitations, such as poor internalization and low expression on tumor cells, that make FAP an unsuitable target for ADCs.

FAP is expressed in a wide variety of solid tumors

Tumors contain a large number of non-cancerous cells, generally referred to as the tumor stroma, that interact closely with tumor cells and contribute to tumorigenesis. Cancer-associated fibroblasts, or CAFs, and extracellular fibrosis can contribute up to 90% of the gross tumor mass, leaving original tumor cells in the minority. Many CAFs differ from normal fibroblasts by their expression of FAP.

A retrospective analysis of images obtained from PET/CT imaging using 68Ga-FAPI, a FAP-targeted radiodiagnostic, found tumor-specific uptake across fifteen types of solid tumors with the highest uptake in lung, breast and esophageal cancers, cholangiocellular carcinoma and sarcoma.

FAP is a membrane-bound serine protease that promotes tumor development and metastasis by influencing extracellular matrix remodeling, intracellular signaling, angiogenesis, epithelial-to-mesenchymal transition, and immunosuppression. The broad distribution of FAP across tumor types and the specificity of its expression in tumors make it an attractive target for the development of therapeutics and diagnostics.

FAP-specific inhibitors, such as talabostat, also known as BXCL701, have been investigated in clinical trials since at least 2005; however, none have been approved by the FDA to treat cancer. Other product candidates that have been investigated in the clinic have used FAP to target PET tracers for tumor imaging and cytotoxic molecules and radionuclides as antitumor agents.

Emerging field of targeted radiotherapies

Two targeted radiotherapies have been approved by the FDA in the past few years: Luthera® for gastroenteropancreatic neuroendocrine tumors, or GEP-NETs, that express the somatostatin receptor; and Pluvicto® for metastatic castration-resistant prostate cancer, or mCRPC. There has also been strong interest from pharmaceutical companies in acquiring radiotherapies, exemplified by the $4.1 billion dollar acquisition of RayzeBio, Inc. by BMS in 2024; the $2.1 billion acquisition of Endocyte, Inc. by Novartis AG in 2018; a $260 million upfront payment from Lantheus Holdings, Inc. to license two radiotherapeutics from Point Biopharma, Inc.; and a $50 million upfront payment from Novartis AG to license FAP-2286, a FAP-targeted radiotherapy Phase 1 clinical candidate originally developed by Clovis Oncology, Inc.

Published clinical results from IM-3050 competitor product candidates have demonstrated both the potential therapeutic benefits of this class of therapeutics and the limitations of current candidates. Among eleven patients with advanced or metastatic solid tumors treated with ^{177}Lu-FAP-2286, one patient achieved a PR after six treatments, and that patient's disease did not progress for more than 12 months after their first dose. However, most patients did not achieve a PR, highlighting the potential for FAP-targeted therapies with improved activity.

Our approach

IM-3050, our lead FAP-targeted RLT, has four functional domains:

- A small molecule FAP-specific ligand
- A linker tuned to drive tumor-specific uptake
- An albumin-binding domain to improve tumor retention
- A chelator to deliver the radionuclide

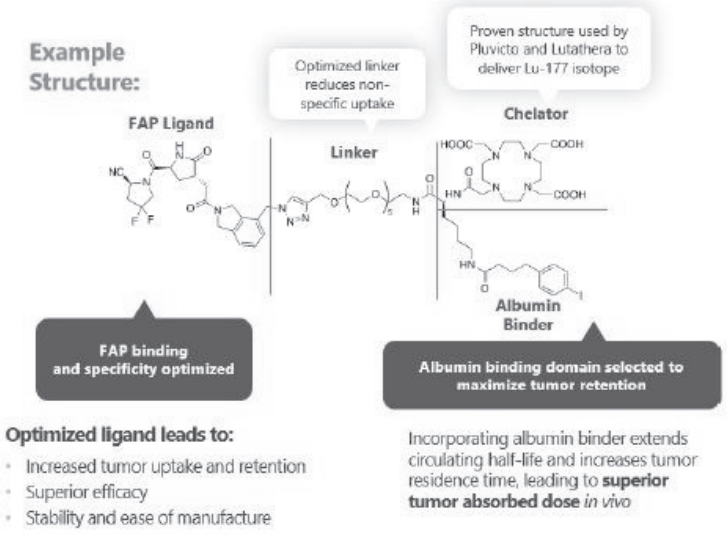


Figure 3. Immunome approach

Over the last two years, we have evaluated over 80 FAP-targeted RLTs that use different combinations of ligands, linkers, and albumin binders while still maintaining the four-domain structure.

An example of the impact that a change in a single domain can impart on the therapeutic potential of the product candidate is the effect of specific albumin-binding domains. The inclusion of albumin-binding domains has previously been used to improve the pharmacokinetics of biologics and small molecules that bind to albumin and have been shown to extend their half-life in circulation. We have conducted preclinical studies demonstrating that incorporating albumin binders into RLTs improved biodistribution and *in vivo* pharmacokinetic profiles. Strong albumin binding led to greater than five-fold increased tumor absorbed dose in an in vivo 4T1 tumor model without significantly increasing exposure in healthy organs including the liver and kidneys. Increased albumin binding affinity also led to increased circulating half-life of potential FAP RLT product candidates in serum when administered intravenously. The increase in circulating half-life is correlated with an increase in tumor-specific uptake and retention.

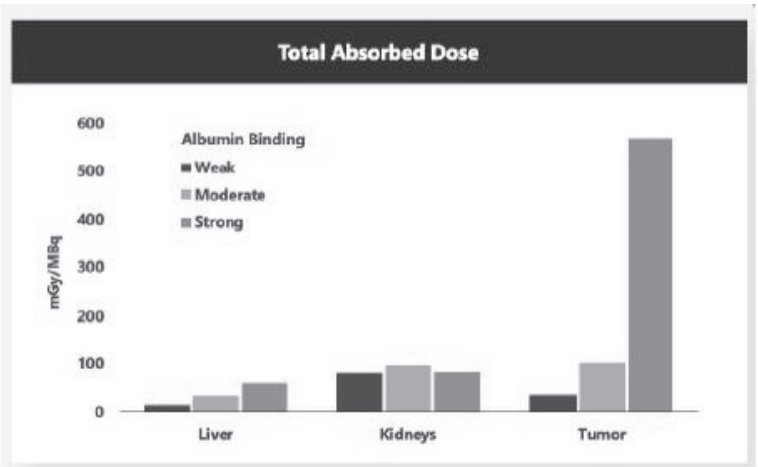


Figure 4. Albumin binding correlated with absorbed radiation dose

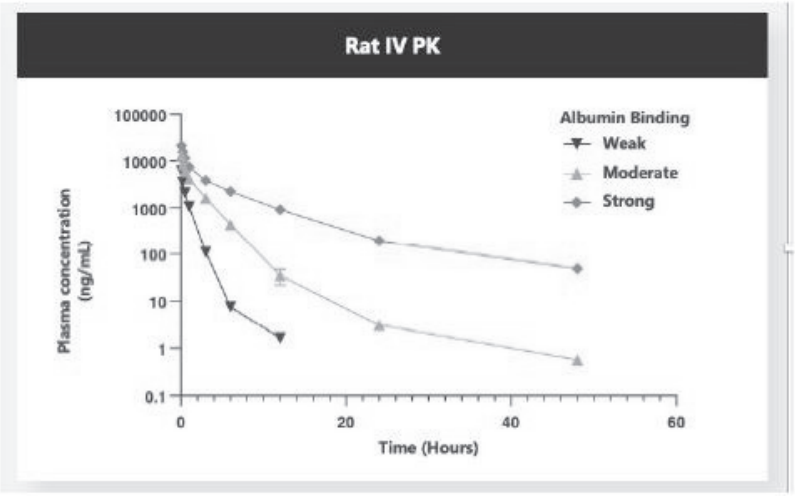


Figure 5. Albumin binding correlated with higher and prolonged plasma concentrations

We selected IM-3050 as a lead candidate following evaluation of factors like binding affinity, specificity for FAP, radiostability, *in vivo* tumor retention, preclinical activity and preclinical tolerability. Use of 177Lu-IM-3050 in a mouse model of glioblastoma demonstrated substantial tumor regression with no meaningful weight loss observed.

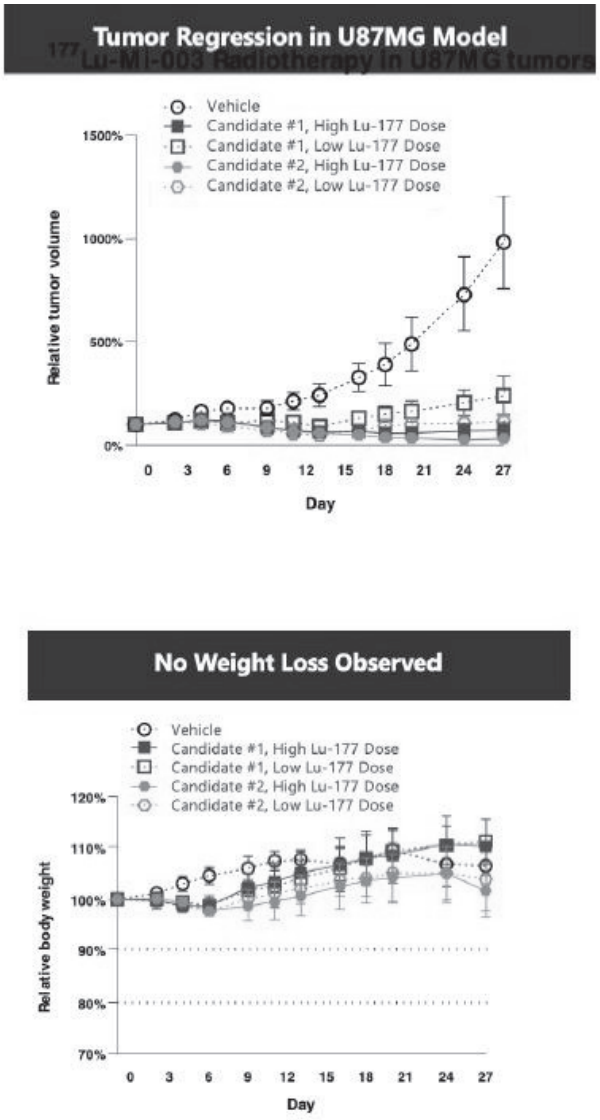


Figure 6A and 6B. Sustained tumor regression in a mouse model of glioblastoma with no weight loss observed

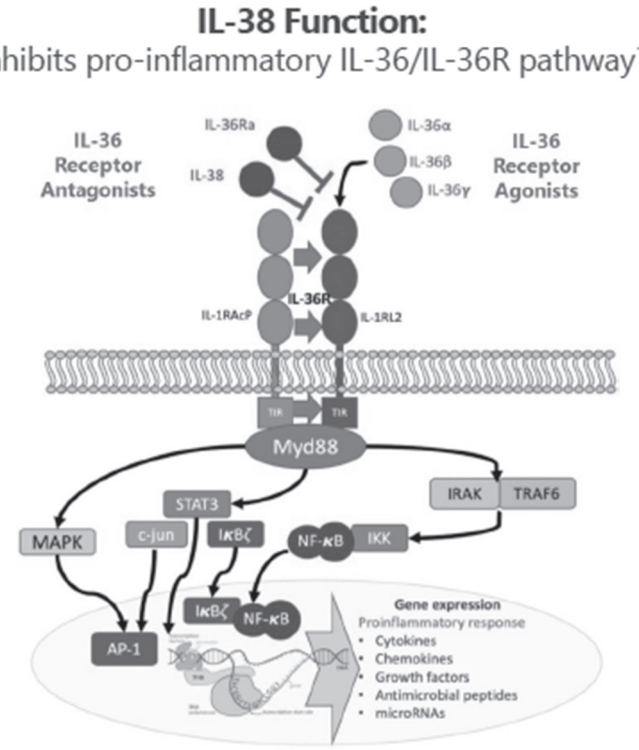
We expect to submit an IND for this program to the FDA in the first quarter of 2025.

IM-4320 (Anti-IL-38 Immunotherapy)

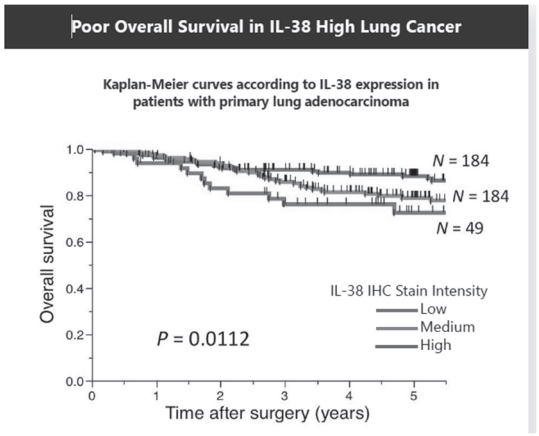
We initiated our anti-IL-38 immunotherapy program on the basis of data generated by our proprietary memory B cell hybridoma screening technology. IL-38 was identified as the target of an antibody isolated from a hybridoma library generated from the memory B cells of a patient with squamous head and neck cancer. Our query of public and proprietary databases of cancer gene expression revealed over-expression of IL-38 in multiple solid tumors. Furthermore, in some tumor types, we observed a correlation between high IL-38 expression and low levels of tumor-infiltrating immune effector cells, a hallmark of immune suppression, suggesting a role for IL-38 as an immune modulator.

IL-38 is an immunosuppressive cytokine and is a novel potential immuno-oncology target

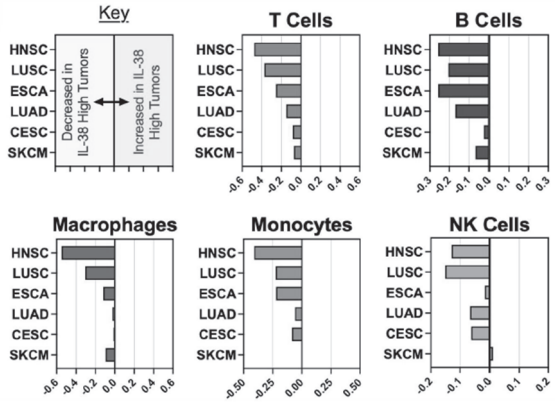
IL-38 is one of the eleven members of the IL-1 family of cytokines. IL-38 functions as an antagonist for IL-36R and IL-1 receptor accessory protein-like 1, or IL1RAPL1, limiting the activation of innate immune cells, and inhibiting the secretion of chemotactic and stimulatory factors that are critical for the induction of adaptive immunity.



In the context of cancer, overexpression of IL-38 results in the acceleration of tumor growth in the Lewis Lung model of lung cancer in vivo and reduced intra-tumoral T cell infiltrates. In lung adenocarcinoma patients, high IL-38 expression is associated with poor prognosis, correlates with PD-L1, and negatively correlates with CD8+ T cell density by histology. While the cellular source of IL-38 is unclear, the release of IL-38 is observed in vitro following apoptosis of tumor cells, suggesting that IL-38 may function as a negative feedback loop to suppress intra-tumoral immunity.



IL-38 mRNA expression data from The Cancer Genome Atlas, or TCGA, show that IL-38 expression is significantly higher in head and neck squamous carcinoma, or HNSC, compared to normal tissues. IL-38 transcripts were also detectable in multiple squamous tumor types among the 30 types tested. Notably, carcinomas with squamous cell morphology have exhibited the highest IL-38 expression and highest frequency of IL-38 positive patient samples. Results of the mRNA expression analysis were further confirmed by screening primary tumor samples from patients with HNSC, lung cancer (adenocarcinoma and squamous cell carcinoma), and cervical squamous cell carcinoma for the presence of IL-38 protein, which was found to be present in the majority of samples.



In addition to the studies noted above demonstrating that overexpression of IL-38 is associated with reduced intra-tumoral immunity, the potential for IL-38 as an immuno-oncology, or I/O, target is supported by data showing that down-regulation of IL-38 promotes activation of the innate immune system. For example, IL-38 knockout mice exhibited increased pro-inflammatory cytokine levels and delayed tumor growth. Moreover, the IL-38 pathway has been validated as a therapeutic target for treating psoriasis, a disease in which low levels of IL-38 promote a pro-inflammatory immune state. Spesolimab-sbzo, an antibody therapy that received FDA approval in 2022 for the treatment of adults with generalized pustular psoriasis, binds to IL36R and prevents the binding of other ligands that can induce downstream immune activation.

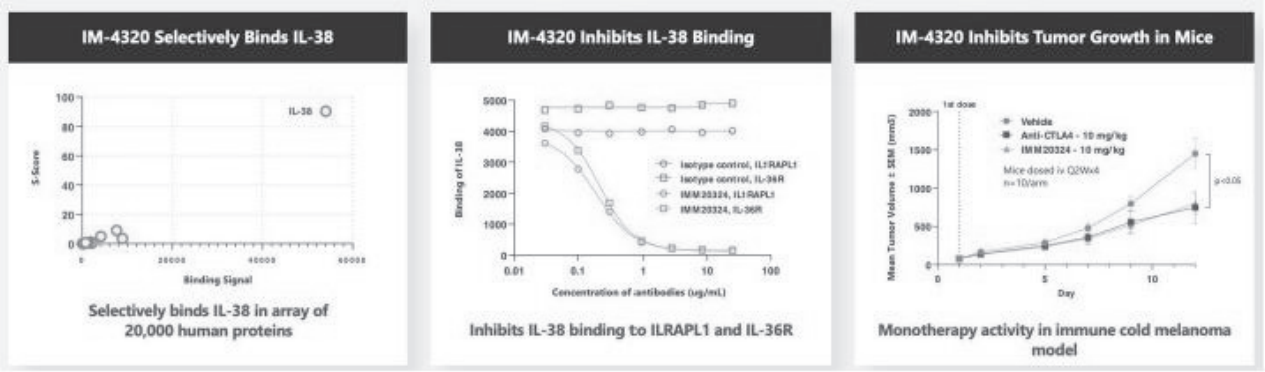
We believe these findings provide compelling evidence that IL-38 inhibition has potential as a novel I/O strategy. While immune checkpoint inhibitors that target T-cells, such as anti-CTLA-4, anti-PD-1 and anti-PD-L1, show great promise in diverse cancer indications, most patients receiving these therapies do not experience meaningful or sustained clinical responses. This is believed to be due to limited infiltration of immune cells, low tumor mutational burden, or the absence of a sustained immune response to the tumor. IL-38 inhibition may reverse the inhibitory mechanisms that regulate innate immune cells, providing a novel approach to leveraging the immune system to treat cancer.

Development of IM-4320 as a potential I/O therapy

To pursue IL-38, we generated anti-IL-38 antibodies and evaluated them for therapeutic potential. Through these evaluations, we found that:

- An anti-IL-38 antibody demonstrated a favorable pharmacokinetic profile and was well-tolerated in non-tumor-bearing mice.
- An anti-IL-38 antibody induced complete tumor regression in a subset of EMT6 tumor-bearing mice (a breast tumor model) and protects against tumor rechallenge.
- An anti-IL-38 antibody inhibited tumor growth in the B16.F10 syngeneic mouse model of melanoma and induced immunostimulatory chemokine expression in the tumor microenvironment.

We believe that IM-4320, our lead anti-IL-38 antibody, shows *in vivo* anti-tumor activity consistent with an active I/O agent. Our data indicate that IM-4320 selectively binds to IL-38, inhibiting its binding ILRAPL1 and IL-36R. Furthermore, it inhibited tumor growth in an immune cold melanoma model.



We intend to submit an IND for this program to the FDA subsequent to our anticipated IND submissions for IM-3050 and IM-1021.

ADC Strategy

We are pursuing a target-driven development strategy intended to establish a broad pipeline of next-generation ADCs focused on oncology indications with high unmet need. We are working to identify novel or under-explored targets that we believe will enable the development of first-in-class ADCs. We also are working to identify clinically validated ADC targets for which competitor programs have shown suboptimal efficacy and/or safety, with the goal of advancing best-in-class ADCs against these targets that overcome these limitations. Our ability to achieve these goals is predicated on our deep understanding of ADC target biology and our ability to deploy a broad toolbox of antibodies, linkers, and payloads in combinations that best match this biology.

Our development process is intended to efficiently advance ADC pipeline candidates through clinical proof-of-concept. We believe that key steps in this process include:

- Optimize the antibody portion of the ADC for binding and internalization
- Incorporate proven or novel linkers
- Select payloads that provide consistent cytotoxic effects
- Optimize ADC pharmacology for clinical activity

- Enable early go/no-go decisions via well-designed clinical trials

We believe that identifying appropriate targets is a key challenge of ADC development. One piece of evidence for this is the concentration of current ADC development activity, with 54% of active ADC clinical programs focused on the same ten targets as of November 2023.

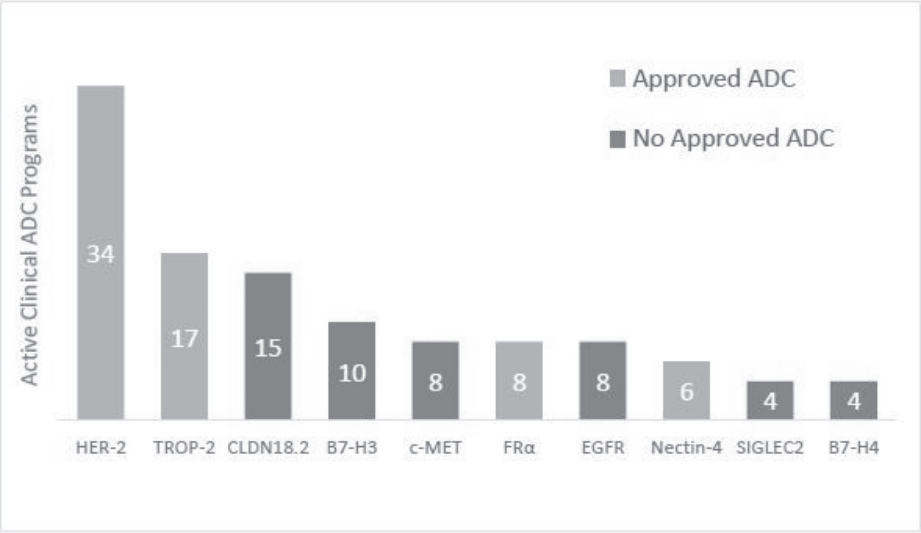


Figure 7. Active clinical ADC programs by target

We believe there are several downsides to pursuing these targets, including:

- Potential difficulty in overcoming limitations of existing ADCs against these targets due to heterogeneity of target expression on tumor cells and/or the likelihood that changes in payload and/or linker technology will yield only incremental gains in efficacy.

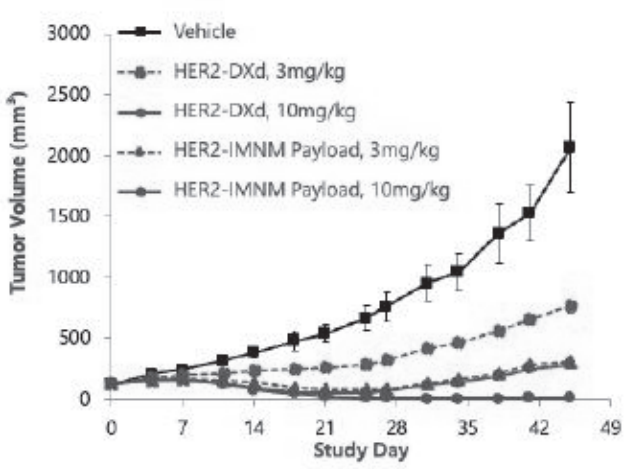
- Challenging development and commercialization pathways

- Lower unmet patient need

Given these downsides, we are systematically evaluating novel targets that we believe will have first-in-class potential using multiple target and antibody sources. We have already identified more than 30 novel targets through our discovery platform and, subject to satisfaction of the closing terms of the definitive asset purchase agreement with Atreca, Inc., or Atreca, announced December 26, 2023, we will have access to more than 25 additional antibodies that may support the development of ADCs against novel or underexplored targets. We also screen public and proprietary expression databases to identify other potential targets for ADC development. Potential targets identified through this systematic approach are evaluated for differential expression on tumor cells compared with normal cells and additional factors.

We believe that our proprietary camptothecin derivative/topoisomerase I inhibitor payload provides a significant opportunity to develop ADCs. We have exclusively licensed this payload, which is in the same class as another camptothecin derivative (deruxtecan) used in an FDA-approved ADC targeting HER2, from Zentalis. This proprietary payload is designed to have enhanced ADME properties, including the potential for greater *in vivo* potency, increased permeability that may lead to superior bystander effects, and faster clearance that may improve tolerability after cleavage. We have conducted studies in the JIMT-1 breast cancer model demonstrating that a HER2 ADC constructed

with our proprietary payload provided improved activity compared with a deruxtecan-containing HER2 ADC when dosed intravenously weekly for three weeks.



We believe that camptothecin derivatives are well-suited for ADCs targeting solid tumor because they achieve a higher DAR and higher clinical doses. Additionally, a third-party comparison of two FDA-approved HER2 ADCs that contain the same antibody (trastuzumab) but different payloads showed that percentage of patients with progression-free survival was significantly higher for the ADC containing the camptothecin derivative.

In addition to our portfolio of targets, antibodies, and payloads, we also have access to novel linker technologies under our exclusive worldwide license agreement with Zentalis.

Immunome Discovery Platform

Immunome's discovery platform provides a proprietary approach to identifying cancer-associated targets. Although many of these targets are known in scientific literature, many of them were not previously known to be associated with cancer.

The workflow for our discovery platform is as follows:

Patient Sampling: Our discovery process begins with obtaining a patient's lymph node, tumor or blood sample and then purifying and expanding the memory B cell population. In oncology, patients sampled include those who are treatment naïve, treated with standard regimens, or have been treated with immunotherapies.

Patient Response: We fuse and immortalize thousands of these patient-derived memory B cells using proprietary methods, capturing them as hybridomas, each of which typically express an individual antibody in quantities sufficient for extensive functional screening.

Antibody Screening: For oncology, we screen individual antibodies by assessing their binding to intact cancer cells or normal cells, or by assessing their binding to a large number of different extracts of authentic tumor samples and cancer cell lines. Using our proprietary approach, we can screen up to 18,400 antibodies on a single array. Hybridomas producing antibodies that show both high-affinity binding, by typically binding at single digit nanomolar concentrations, and specific binding, by showing much higher binding to a subset of tumor cells compared to normal cells, are designated as screening "hits." Hybridomas producing those hits can be sequenced, their immunoglobulin genes can be cloned into expression vectors, and the individual antibodies can then be produced recombinantly.

Antibody Validation: The next step in our process is to identify the specific antigen to which the antibody appears to bind with high affinity and specificity. We use one of two complementary approaches for this activity: the first

method involves an assessment of antibody binding to known human proteins spotted on a protein microarray with high selectivity. If the target is not represented on the array or no specific binding is seen, we attempt to use the antibody to "pull out" the antigen from its source using immunoprecipitation, and then identify the antigen sequence using mass spectrometry. Using these two approaches we are largely successful in identifying the antigen to which newly identified antibodies are binding. We then conduct experiments to assess whether the binding of the antibody to the specific antigen can produce a change in the biology of a cancer cell expressing the target, which we refer to as target validation. Additional tests, such as measurements of changes in cell growth, cell survival, cell migration, or internalization of the antigen after it has been bound by the antibody, are used to further assess the potential that the antibody could be of therapeutic interest.

Our Management Team

We are led by Clay Siegall, Ph.D., President and Chief Executive Officer. Dr. Siegall previously served as CEO of Seagen, Inc., which he co-founded in 1997 and led for nearly 25 years. During his tenure, Seagen earned FDA approvals for four cancer therapies. Pfizer purchased Seagen in December 2023. Dr. Siegall joined us in connection with our acquisition of Morphimmune, a preclinical biotechnology company led by Dr. Siegall, in October 2023.

In addition to Dr. Siegall, three members of our current management team joined us from Morphimmune in October 2023. Jack Higgins, Ph.D., our Chief Scientific Officer, held the same role at Morphimmune. He was previously the Chief Development Sciences Officer at Molecular Templates, Inc., where he led discovery and development efforts for multiple clinical candidates and co-invented the company's Engineered Toxin Body platform. Bruce Turner, MD, Ph.D., our Chief Strategy Officer, held the same role at Morphimmune and previously founded several biotechnology companies including Xanadu Bio, Inc. and Gennao Bio, Inc. Max Rosett, our Executive Vice President, Operations, and Interim Chief Financial Officer, served as Acting Chief Operating Officer at Morphimmune. Mr. Rosett previously served as a Principal at Research Bridge Partners, where he led Research Bridge Partners' investment in Morphimmune's Series A financing.

Bob Lechleider, M.D. serves as our Chief Medical Officer. Dr. Lechleider was most recently the Chief Medical Officer of OncoResponse, Inc. and previously worked with Dr. Siegall at Seagen, where he was responsible for directing the development of early and late-stage portfolios. Phil Roberts serves as our Chief Technical Officer. Mr. Roberts previously served as SVP, Technical Operations at Mirati Therapeutics, Inc., where he led the CMC development of Krazati, Mirati's first approved product. Sandra Stoneman, J.D., serves as our Chief Legal Officer. She joined us from Duane Morris LLP, where she was an equity partner. Kinney Horn serves as our Chief Business Officer. He previously served in the same role at Olema Oncology, Inc. and spent more than 15 years at Genentech, Inc.

Strategic Transactions

Acquisition of Assets from Ayala Pharmaceuticals, Inc.

On February 5, 2024, we entered into the Ayala Purchase Agreement with Ayala, pursuant to which we acquired Ayala's AL101 and AL102 programs and assumed certain of Ayala's liabilities associated with the acquired assets, or the Ayala Asset Purchase. The Ayala Asset Purchase closed on March 25, 2024, or the Ayala Closing. At the Ayala Closing we (i) paid Ayala $20,000,000, less certain adjustments, (ii) issued Ayala 2,175,489 shares of Company common stock, or the Ayala Shares, with the shares valued at the trailing 30-day volume-weighted average price and (iii) assumed specified liabilities. Pursuant to the Ayala Purchase Agreement, we are obligated to pay Ayala up to $37,500,000 in development and commercial milestones. No legal entities or employees were acquired from Ayala.

The Ayala Purchase Agreement also provides that until the six-month anniversary of the Ayala Closing, Ayala will hold and not sell 50% of the Ayala Shares, subject to certain exceptions. Further, Ayala has agreed, subject to certain exceptions, that until the one-year anniversary of the Ayala Closing, any transfer of the Ayala Shares by Ayala that exceed 15% of the average daily trading volume of our stock over the five-trading day period ending on the trading day immediately prior to such trading date shall be made pursuant to a block trade or other disposition through a market participant designated by us.

We have agreed to use our commercially reasonable efforts to (x) file a resale registration statement with the SEC registering the Ayala Shares for resale on or before the date seven days following the earlier of (i) April 1, 2024 and (ii) the date of this Annual Report and (y) cause such resale registration statement to be declared effective as soon as practicable after the filing thereof but no later than 90 calendar days after the filing thereof or by five trading days from when we are notified that the SEC will not review the resale registration statement or that it will not be subject to further review.

Merger with Morphimmune

On October 2, 2023, we completed our merger with Morphimmune. Under the terms of the Agreement and Plan of Merger and Reorganization dated as of June 28, 2023, or the Merger Agreement, among us, Morphimmune and Ibiza Merger Sub, Inc., a wholly owned subsidiary of the Company, or Merger Sub, Morphimmune merged with and into Merger Sub, with Morphimmune surviving as a wholly-owned subsidiary of us, or the Merger. In connection with the Merger, on October 2, 2023, we issued and sold 21,690,871 shares of our common stock pursuant to the subscription agreements in a Private Investment in Public Equity, or PIPE, transaction which provided us with gross proceeds of $125.0 million.

Acquisition of Assets from Atreca, Inc.

On December 22, 2023, we entered into an asset purchase agreement with Atreca, pursuant to which we will acquire certain antibody-related assets and materials for an upfront payment of $5.5 million and up to $7.0 million in clinical development milestones. The closing of the transaction is subject to customary conditions, including the approval of Atreca's stockholders. We expect the closing to occur in the second quarter of 2024.

Strategic Collaborations, License Agreements and Other Material Agreements

BMS License Agreement

In connection with the Ayala Closing, we assumed the License Agreement dated as of November 29, 2017, with BMS, as amended by that certain First Amendment to License Agreement dated as of May 4, 2020, or the BMS License.

Under the BMS License, BMS has granted us a worldwide, non-transferable, exclusive, sublicensable license under certain patent rights and know-how controlled by BMS to research, discover, develop, make, have made, use, sell, offer to sell, export, import and commercialize AL101 and AL102, or the BMS Licensed Compounds, and products containing AL101 or AL102, or the BMS Licensed Products, for all uses including the prevention, treatment or control of any human or animal disease, disorder or condition.

Under the BMS License, we are obligated to use commercially reasonable efforts to develop at least one BMS Licensed Product. We have sole responsibility for, and bear the cost of, conducting research and development and preparing all regulatory filings and related submissions with respect to the BMS Licensed Compounds and/or BMS Licensed Products. Ayala has assigned and transferred to us all INDs for the BMS Licensed Compounds originally assigned by BMS to Ayala. We are also required to use commercially reasonable efforts to obtain regulatory approvals in certain major market countries for at least one BMS Licensed Product, as well as to affect the first commercial sale of and commercialize each BMS Licensed Product after obtaining such regulatory approval. Immunome has sole responsibility for, and bears the cost of, commercializing BMS Licensed Products. For a limited period of time, we may not engage directly or indirectly in the clinical development or commercialization of a Notch inhibitor molecule that is not a BMS Licensed Compound.

We are obligated to pay BMS up to approximately $142 million in the aggregate upon the achievement of certain clinical development and regulatory milestones by products containing the BMS Compounds. Furthermore, we are obligated to pay up to $50 million per BSM Licensed Product containing a BMS Compound upon the achievement of certain commercial milestones for that product. In addition, we are obligated to pay BMS tiered royalties ranging from a high single-digit to a low teen percentage on worldwide net sales of all BMS Licensed Products.

BMS has the right to terminate the BMS License in its entirety upon written notice to us (a) for insolvency-related events involving us, (b) for our material breach of the BMS License if such breach remains uncured for a defined period of time, (c) for our failure to fulfil our obligations to develop or commercialize the BMS Licensed Compounds and/or BMS Licensed Products not remedied within a defined period of time following written notice by BMS, or (d) if we or our affiliates commence any action challenging the validity, scope, enforceability or patentability of any of the licensed patent rights. We have the right to terminate the BMS License (a) for convenience upon prior written notice to BMS, the length of notice dependent on whether a BMS Licensed Product has received regulatory approval, (b) upon immediate written notice to BMS for insolvency-related events involving BMS, (c) for BMS's material breach of the BMS License if such breach remains uncured for a defined period of time, or (d) on a BMS Licensed Compound-by-BMS Licensed Compound and/or BMS Licensed Product-by-BMS Licensed Product basis upon immediate written notice to BMS if we reasonably determine that there are unexpected safety and public health issues relating to the applicable BMS Licensed Compounds and/or BMS Licensed Products. Upon termination of the BMS License in its entirety by us for convenience or by BMS, we grant an exclusive, non-transferable, sublicensable, worldwide license to BMS under certain of our patent rights that are necessary to develop, manufacture or commercialize BMS Licensed Compounds or BMS Licensed Products. In exchange for such license, BMS must pay us a low single-digit percentage royalty on net sales of the BMS Licensed Compounds and/or BMS Licensed Products by it or its affiliates, licensees or sublicensees, provided that the termination occurred after a specified developmental milestone for such BMS Licensed Compounds and/or BMS Licensed Products.

Zentalis License Agreement

In January 2024, we entered into the Zentalis License Agreement with Zentalis, pursuant to which we received an exclusive, worldwide, royalty-bearing, sublicensable license under certain intellectual property relating to Zentalis' proprietary ADC platform technology, ROR1 antibodies and ADCs targeting ROR1 to exploit products covered by or incorporating the licensed intellectual property rights. Under the Zentalis License Agreement, we are required to use commercially reasonable efforts to develop an ADC targeting ROR1, two additional ADCs, and commercialize any product that receives regulatory approval.

Under the Zentalis License Agreement, we paid to Zentalis upfront consideration totaling $15 million in cash and $20 million in shares of our common stock, with the shares valued at the trailing 30-day volume-weighted average price. We are obligated to pay Zentalis an aggregate of up to $150 million in development and regulatory milestones on the first product containing an ADC targeting ROR1, or a ROR1 ADC Product, to achieve such milestones and commercial milestones on ROR1 ADC Products. We are also obligated to pay to Zentalis mid-to-high single digit royalties on ROR1 ADC Products. In addition, we are obligated to pay Zentalis $25 million in development and regulatory milestones for the first product from each of the first five additional development programs using the licensed platform technology to generate products, and mid-single digit royalties on products from each such program. Our royalty payment obligation will commence, on a product-by-product and country-by-country basis, on the first commercial sale of such product in such country and will expire on the latest of (a) the ten (10)-year anniversary of such first commercial sale for such product in such country, (b) the expiration of regulatory exclusivity for such product in such country, and (c) the expiration of the last-to-expire valid claim of a licensed patent covering such product in such country.

The Zentalis License Agreement will continue until the expiration of all royalty payment obligations. The Zentalis License Agreement may be terminated early by (a) either party in its entirety upon (i) the other party's uncured material breach, subject to a notice and cure period, (ii) any insolvency event of the other party or (iii) prolonged force majeure, (b) us, either in its entirety or in part, for convenience upon a specified period prior written notice, or (c) Zentalis (i) in its entirety if we challenge one of the licensed patents or (ii) fail to meet certain development activity benchmarks within specified time periods.

Collaboration with AbbVie

On January 4, 2023, we entered into a collaboration and option agreement, or the Collaboration Agreement, with AbbVie Global Enterprises Ltd., or AbbVie, pursuant to which we will use our discovery platform to discover and

validate targets derived from patients with three specified tumor types, and antibodies that bind to such targets, which may be the subject of further development and commercialization by AbbVie. The research term is at least 66 months, subject to extension in certain circumstances by specified extension periods. Pursuant to the terms of the Collaboration Agreement, with respect to each novel target-antibody pair that we generate that meets certain mutually agreed criteria (each, a Validated Target Pair or VTP), we granted to AbbVie an exclusive option (up to a maximum of 10 in total) to purchase all rights in and to such Validated Target Pair, for all human and non-human diagnostic, prophylactic and therapeutic uses throughout the world, including without limitation the development and commercialization of certain products derived from the assigned Validated Target Pair and directed to the target comprising such VTP (Products). No rights are granted by us to AbbVie under any of our technology covering our discovery platforms. Until the expiration of the research term, we are not permitted to conduct any activities in connection with targets or antibodies derived from patients with the specified tumor types, whether independently or with other third parties, except in limited circumstances with respect to certain target-antibody pairs that are no longer subject to the collaboration with AbbVie. In addition, during the term of the Collaboration Agreement, we are not permitted to develop products directed to targets that are included in VTPs purchased by AbbVie, or to which AbbVie still has rights under the Collaboration Agreement, whether independently or with other third parties.

Under the Collaboration Agreement, AbbVie paid us an upfront payment of $30.0 million, and will make certain additional platform access payments in the aggregate amount of up to $70.0 million based on our use of our discovery platform in connection with activities under each stage of the research plan, and delivery of VTPs to AbbVie. AbbVie will also pay an option exercise fee in the low single digit millions for each of the up to 10 VTPs for which it exercises an option. If AbbVie progresses development and commercialization of a Product, AbbVie will pay us development and first commercial sale milestones of up to $120.0 million per target, and sales milestones based on achievement of specified levels of net sales of Products of up to $150.0 million in the aggregate per target, in each case, subject to specified deductions in certain circumstances. On a Product-by-Product basis, AbbVie will pay us tiered royalties on net sales of Products at a percentage in the low single digits, subject to specified reductions and offsets in certain circumstances. AbbVie's royalty payment obligation will commence, on a Product-by-Product and country-by-country basis, on the first commercial sale of such Product in such country and will expire on the earlier of (a) (i) the ten (10)-year anniversary of such first commercial sale for such Product in such country, or (ii) solely with respect to a Product that incorporates an antibody comprising a VTP (or certain other antibodies derived from such delivered antibody), the expiration of all valid claims of patent rights covering the composition of matter of any such antibody (whichever out of (i) or (ii) is later), and (b) the expiration of regulatory exclusivity for such Product in such country. We are potentially eligible to receive up to $2.8 billion from AbbVie under the Collaboration Agreement from the sources described above.

The Collaboration Agreement will expire upon the expiration of the last to expire royalty payment obligation with respect to all Products in all countries, subject to earlier expiration if all option exercise periods for all Validated Target Pairs expire without AbbVie exercising any option. In addition, the research term will terminate if AbbVie does not elect to make certain platform access payments at specified points during the research term, in order for the Company to continue the target discovery activities under the collaboration. The Collaboration Agreement may be terminated by (a) either party upon the other party's uncured material breach, or upon any insolvency event of the other party, (b) AbbVie for convenience upon a specified period prior written notice, or (c) AbbVie for the Company's breach of representations and warranties with respect to debarment or compliance with anti-bribery and anti-corruption laws. If AbbVie has the right to terminate the Collaboration Agreement for our uncured material breach or a breach of representations and warranties with respect to debarment or compliance with anti-bribery and anti-corruption laws, AbbVie may elect to continue the Collaboration Agreement, subject to certain specified reductions applicable to certain of AbbVie's payment obligations (with a specified floor on such reductions).

Whitehead Patent License Agreement

In June 2009, we entered into an exclusive patent license agreement, or the Whitehead Agreement, with the Whitehead Institute for Biomedical Research, or Whitehead, and the Massachusetts Institute of Technology, or MIT, as licensing agent for Whitehead, pursuant to which we obtained from MIT and Whitehead a royalty-bearing exclusive license under certain patent rights of Whitehead and a royalty-bearing non-exclusive license under certain biological and chemical material of Whitehead that relate to our discovery platform. The foregoing license recently expired in accordance with its terms.

On November 17, 2022, we entered into a Letter Agreement, or Letter Agreement, with Whitehead, which became effective on January 4, 2023, upon the satisfaction of the conditions described therein. The Letter Agreement supplements the Whitehead Agreement. Pursuant to the Letter Agreement, certain payments received by us from the Collaborator (as defined in the Letter Agreement) (i.e., a corporate partner, as defined in the License Agreement) would be excluded from our payment obligations to Whitehead. Further, we will make certain payments to Whitehead (i) as Net Sales (as defined in the License Agreement) as long as we receive those payments from the Collaborator on a specified number of products purchased by the Collaborator and (ii) upon the achievement of certain milestones whether by us or the Collaborator.

License Agreement with Purdue Research Foundation

In January 2022, Morphimmune entered into a Master License Agreement, or the Purdue License Agreement, with Purdue Research Foundation, or PRF. Under the Purdue License Agreement, PRF granted Morphimmune a royalty-bearing, transferable, worldwide, exclusive license, sublicensable through multiple tiers, under certain patents and technology owned by PRF relating to, among other subject matter, drugs to target FAP, to research, develop, manufacture, and commercialize products covered by the licensed patents in all fields of use with limited exceptions. The license is subject to certain rights of the U.S. government and rights retained by PRF (i) to practice and to license any government agencies, universities or other educational institutions to practice, make, and use the intellectual property licensed to Morphimmune on a royalty-free basis for non-commercial uses, (ii) to conduct activities required under sponsored research agreements with Morphimmune and (iii) to disseminate and publish materials and scientific findings from PRF's research related to the intellectual property licensed to Morphimmune. Morphimmune is obligated to use commercially reasonable efforts to develop and commercialize the licensed products in accordance with a development and commercialization plan and to achieve agreed development milestones according to a specified timeline. PRF is obligated to prosecute and maintain the licensed patents at Morphimmune's cost and expense.

Under the Purdue License Agreement, Morphimmune paid PRF a one-time upfront payment of $200,000 upon execution and $100,000 on each of the first and second anniversary of the effective date of the Purdue License Agreement. During the period commencing on the date of first commercial sale of a licensed product and ending upon the date of expiration of the last valid claim of the licensed patents covering such licensed product in a country, referred to as the royalty term, Morphimmune will pay PRF an earned unit royalty of a low single-digit percentage on gross receipts from sale of the licensed product, and beginning with the first sale of a licensed product, a tiered minimum annual royalty from the low to mid six-digit figure range less the unit royalties due for the annual period. Upon the achievement of specified development and commercialization milestones, Morphimmune will pay PRF the milestone payments as specified in the Purdue License Agreement, which may be up to $3.75 million in the aggregate. Morphimmune is also required to pay PRF an annual maintenance fee ranging from a low five-digit figure to a low six-digit figure prior to first sale of a licensed product and a low double-digit percentage of sublicense income received for sublicenses of licensed intellectual property, with such percentage depending upon the timing of execution of the sublicense.

The Purdue License Agreement expires on a licensed product-by-licensed product and country-by-country basis, upon expiration of the royalty term for such licensed product for the applicable country. Morphimmune may terminate the Purdue License Agreement upon at least one month's prior written notice to PRF. PRF may terminate the Purdue License Agreement and the licenses granted thereunder if Morphimmune fails to cure a payment default or other material breach of the Purdue License Agreement after written notice from PRF, or if Morphimmune becomes insolvent.

Manufacturing

For certain early research and development activities, we may produce materials at the laboratory scale necessary to support those activities. For other early-stage activities and for all later stage work, such as IND-enabling studies and safety assessment and clinical assessment, we use third-party manufacturers to produce necessary antibodies, linkers, payloads, ADCs, small molecules, and, in the case of radioligand therapies, cold and chelated forms of the compound. We use third-party manufacturers to produce all materials (including intermediates or reagents) necessary to advance our four named programs. We do not have, and we do not currently plan to acquire or develop the infrastructure, facilities or capabilities to conduct these manufacturing activities ourselves. We intend to continue to utilize third-party

manufacturers to produce, package, label, test and release product for clinical and non-clinical testing and for future commercial use, as needed. We expect to continue to rely on such third parties to manufacture our products for the foreseeable future. Our expected future contractual manufacturing organizations will each have successful track records of producing products for other companies under applicable compliance regulations, such as cGMP compliance in the case of the FDA.

Competition

The development and commercialization of new product candidates is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop therapies for the treatment of cancer, which is highly competitive with rapidly changing standards of care. As such, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We expect to compete with oncology companies advancing antibodies, ADCs, small molecules, targeted radiotherapies, and other therapeutic modalities. We are aware of competitors who are pursuing antibody-based discovery approaches, including, but not limited to, AbCellera Biologics, Inc.; Adaptive Biotechnologies Corporation, or Adaptive; AIMM Therapeutics B.V.; IGM Biosciences, Inc.; and OncoReponse, Inc. We also expect to compete with companies pursuing targeted radiotherapies, including, but not limited to, RayzeBio, Fusion Pharmaceuticals, POINT Biopharma, Aktis Oncology, Actinium Pharmaceuticals, and Yantai LNC Biotechnology. In addition, we expect to compete with large, multinational pharmaceutical companies that discover, develop and commercialize antibodies, ADCs, small molecules, targeted radiotherapies, and other therapeutics for use in treating cancer such as Immunogen (acquired by AbbVie Inc.), AstraZeneca; Amgen; Bayer AG, BMS; Eli Lilly and Company; Genentech, Inc. (a member of Roche group); Merck & Co. Inc.; Novartis; Seagen (acquired by Pfizer) and Johnson & Johnson. If any future product candidates identified through our current lead programs are eventually approved for sale, they will likely compete with a range of treatments that are either in development or currently marketed for use in those same disease indications.

With respect to AL102, we expect to compete with companies advancing treatment of desmoid tumors, including but not limited to, SpringWorks Therapeutics, Inc. In November 2023, Springworks received FDA approval for its oral gamma secretase inhibitor, OGSIVEO® (nirogacestat), for the treatment of adult patients with progressing tumors who require systemic treatment. Desmoid tumors treatments also include surgery, hormonal therapy, targeted therapy and chemotherapy.

There are several other companies developing FAP-targeted radioligand therapies which may represent the most direct competition to our IM-3050 program. Novartis is advancing a FAP-targeted radioligand therapy (177Lu-FAP-2286) that was acquired from Clovis Oncology and is currently in Phase 1/2. In December 2023, Eli Lilly and Company acquired POINT Biopharma, which is developing a FAP-targeted radioligand therapy (PNT2004) that is currently in Phase 1. Yantai LNC Biotechnology has also initiated a Phase 1 trial for another FAP-targeted radioligand therapy (LNC1004.) Additionally, our IM-3050 program faces competition from competitors who may have superior access to a consistent supply of radioactive isotopes.

In January 2023, we exclusively licensed a preclinical ROR1 ADC program from Zentalis with the potential to address hematologic and solid tumor indications. There are several other companies developing antibodies, ADCs, and CAR-T therapies targeting ROR1, and they may represent the most direct competition to our ROR1 ADC program. Merck has an ADC program (Zilovertamab vedotin) in a Phase 2/3 clinical trial for B-cell lymphoma. CStone Pharaceuticals, Inc. has an ADC program in a Phase I trial. Companies advancing clinical ROR1-CAR T therapy programs include Octernal Therapeutics (ONCT-808) in a Phase 1/2 in B-cell malignancies, and Lyell Immunopharma (LYL797) in a Phase 1 trial.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical studies, obtaining regulatory approvals and marketing approved

products than we have. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, these larger companies may be able to use their greater market power to obtain more favorable supply, manufacturing, distribution and sales-related agreements with third parties, which could give them a competitive advantage over us.

Further, as more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in that class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, or if the approval of other agents for an indication or patient population significantly alters the standard of care with which we tested our product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and subject enrollment for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our current or future products or programs.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally, acquired or licensed from third parties. We will also seek to rely on regulatory protection afforded through orphan drug designations, inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We utilize various types of intellectual property assets to provide multiple layers of protection. For example, we seek a variety of patents to protect our inventions including, for example, compositions of matter and uses in treatment and diagnostic and methods for novel antibodies, including methods of treatment for diseases expressing novel targets. We believe our current layered patent estate, together with our efforts to develop and patent next generation technologies, provides us with substantial intellectual property protection.

As of March 28, 2024, we own or exclusively in-license (a) 139 issued or granted patents, including 6 issued U.S. patents, 74 EP validations, 2 Australian patents, 2 Canadian patents, 2 Chinese patents, 3 Indian patents, 2 Japanese patents, and 2 Korean patents; (b) 3 pending U.S. provisional patent applications; (c) 3 pending PCT applications; (d) 19 pending U.S. non-provisional patent applications; and (e) 148 pending foreign patent applications, including 10 in Australia, 12 in Canada, 12 in China, 15 in Europe, 7 in India, 11 in Japan and 10 in Korea, all across 24 patent families, covering our IM-4320 (IL-38), IM-1021 (ROR1), IM-3050 (FAP), AL102 and AL101 product candidates. Our portfolio includes issued and/or pending claims directed to the composition of matter and methods of use for IM-4320, IM-1021, IM-3050, AL102 and AL101. Patent applications covering IM-4320, if issued, are expected to expire between 2040 and 2042, absent any patent term extensions or adjustments and without accounting for terminal disclaimers. Patent applications covering IM-1021, if issued, are expected to expire in 2042, absent any patent term extensions or adjustments and without accounting for terminal disclaimers. Patent applications covering IM-3050, if issued, are expected to expire in 2045, absent any patent term extensions or adjustments and without accounting for terminal disclaimers. The US composition of matter patent covering AL102 will expire in 2038, which includes 5 years of expected patent term extension. Patent applications covering AL102 and various derivatives, if issued, are expected to expire between 2033-2043, absent any patent term extensions or adjustments and without accounting for terminal

disclaimers. The US composition of matter patent covering AL-101 will expire in 2037, which includes 5 years of expected patent term extension; patent applications covering AL-101, if issued, are expected to expire between 2032-2042, absent any patent term extensions or adjustments and without accounting for terminal disclaimers. We recognize that the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, which may affect the validity, enforceability and expiration of the aforementioned patents and patent applications.

Our commercial success will depend in significant part upon obtaining and maintaining patent protection and trade secret protection for our targeted therapeutics and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents, or any patents granted to us in the future will be commercially useful in protecting our targeted therapeutics, current programs and processes. For this and more comprehensive risks related to our intellectual property, please see the section titled "Risk Factors — Risks Related to Our Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may potentially be lengthened by patent term adjustment, or PTA, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, or PTE, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits PTE of up to five years beyond the expiration of the patent. The length of the PTE accorded a patent is related to the length of time the drug is under regulatory review by the FDA. PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Further, only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions for extending the term of a patent that covers an approved drug are available in multiple European countries and other foreign jurisdictions. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We expect to seek patent term extensions to all of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. Patent term in the U.S. may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

In some instances, we file provisional patent applications directly in the USPTO. Provisional patent applications are designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the non-provisional patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the earliest non-provisional application filing date. This system allows us to obtain an early priority date, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in a subsequent non-provisional application. While we intend, as appropriate, to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such non-provisional patent applications will result in the issuance of patents that provide us with any competitive advantage.

We intend to file U.S. non-provisional applications and/or international Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional or non-provisional applications, when applicable. The PCT system allows for a single PCT application to be filed within 12 months of the priority filing date of a corresponding priority patent application, such as a U.S. provisional or non-provisional application, and to designate all of the 157 PCT contracting states in which national phase patent applications can later be pursued based on the PCT application. The PCT International Searching Authority performs a patentability search and issues a non-binding

patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to establish a patent application filing date in any of the member states and then seek patents through later-filed national-phase applications. No later than either 30 or 31 months from the earliest priority date of the PCT application, separate national phase patent applications can be pursued in any of the PCT member states, depending on the deadline set by individual contracting states. National phase entry can generally be accomplished through direct national filing or, in some cases, through a regional patent organization, such as the European Patent Organization. The PCT system delays application filing expenses, allows a limited evaluation of the chances of success for national/regional patent applications and allows for substantial savings in comparison to having filed individual countries rather than a PCT application in the event that no national phase applications are filed.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patent applications containing claims for protection of all commercially relevant uses of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We may periodically reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that coverage and value are obtained for our processes, and compositions, given existing patent law and court decisions. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy subject matter, written description, and enablement requirements of the various patent jurisdictions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our targeted therapeutics. We cannot predict whether the patent applications we are currently pursuing will be issued as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know-how, other proprietary information and/or continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent

applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention.

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or programs and targeted therapeutics.

For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors — Risks Related to Our Intellectual Property."

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of drugs and biologics. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our programs and development candidates.

U.S. Government Regulation of Biological Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, or biologics license applications, or BLAs, or the agency's issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

Nonclinical and Clinical Development

Nonclinical studies include laboratory evaluation of product chemistry and formulation and may involve *in vitro* testing or *in vivo* animal studies to assess the potential for toxicity, adverse events, and other safety characteristics of the program or development candidate, and in some cases to establish a rationale for therapeutic use. The conduct of nonclinical studies is subject to federal regulations and requirements, including good laboratory practice regulations for safety/toxicology studies.

The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, as well as other information, to the FDA as part of the IND application. Some long-term nonclinical testing as well as manufacturing process development and product quality evaluation, continues after the IND is submitted.

Human clinical trials in support of an NDA or BLA

Prior to beginning the first clinical trial with a program or development candidate, the sponsor must submit an IND to the FDA. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions related to the proposed clinical trial and places the IND on a clinical hold. In such a case, the IND sponsor must resolve all outstanding concerns or questions posed by the FDA before the clinical trial can begin. Submission of an IND therefore may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices, or GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent institutional review board, or IRB, for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, or DSMB, which provides authorization for whether a study may move forward at designated check points based on review of certain data from the study, to which only the DSMB has access, and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse reactions, findings from other studies suggesting a significant risk to humans exposed to the investigational product, findings from animal or in vitro testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Sponsors of clinical trials of certain FDA-regulated products must register and disclose certain clinical trial information to a public registry maintained by the National Institutes of Health, or NIH. In particular, information related to the investigational product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

For purposes of NDA or BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1 — The investigational product is initially introduced into healthy human subjects or directly into patients with the target disease or condition for certain therapies targeting severe or life-threatening diseases where the investigational product may be too inherently toxic to administer ethically to healthy volunteers. In either case, these studies are designed to test safety, dosage tolerance, absorption, metabolism, distribution and excretion of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to assess adverse events and potential side effects. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and, if appropriate, to provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the NDA or BLA; failure to exhibit due diligence with regard to conducting these Phase 4 clinical trials could result in withdrawal of approval for products. Concurrent with clinical trials, companies may complete additional nonclinical studies and develop additional information about the characteristics of the investigational product and must 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 candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. An NDA or BLA must contain sufficient evidence of the candidate's safety, purity, potency and efficacy for its proposed indication or indications. Data may come from company-sponsored clinical trials or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the NDA or BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended, or PDUFA, each NDA or BLA must be accompanied by a significant user fee, and the sponsor of an approved application is also subject to an annual program fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews it to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any application that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the application 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 reviews BLA to determine, among other things, whether the proposed product is safe, pure, and potent for its intended use, and whether the facility (or facilities) in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. 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 current good manufacturing practice, or cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Most such applications are meant to be reviewed within ten months from the date they are accepted for filing, and most applications for "priority review" products are meant to be reviewed within six months from the date the application is accepted for filing. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant deemed a major amendment to the application. The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making final decisions on approval.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, the FDA will typically inspect one or more clinical trial sites to assure that the clinical trials were conducted in compliance with good clinical practices, or GCP. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

After the FDA evaluates an NDA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies that the FDA identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional clinical or other data, additional clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may choose to either resubmit the NDA or BLA addressing all of the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA grants regulatory approval of a product, such approval is limited to the conditions of use (e.g., patient population, indication) described in the application and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the product with a risk evaluation and mitigation strategy, or REMS, to ensure the benefits of the product outweigh its risks and to assure the safe use of the drug or biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. 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 application without a REMS, if required. The FDA also may condition approval on, among other things, changes to proposed labeling (e.g., the addition of specific contraindications, warnings or precautions) or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need for such diseases or condition. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review

sections of the NDA or BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the application. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

In addition, the FDA may designate a drug or biologic as a "breakthrough therapy" upon a request made by the IND sponsor. A breakthrough therapy is a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, which are intended to expedite the development and review of an application for approval of a breakthrough therapy.

Finally, the FDA may designate an application for priority review if it is for a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over existing therapy. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on an original marketing application from ten months to six months from the date of filing.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Accelerated Approval Pathway

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, 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. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a program or

development candidate approved on this basis is typically subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to establish the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, may allow the FDA to withdraw approval of the drug. The FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website.

All promotional materials for products approved under the accelerated approval program are subject to prior review by the FDA.

Pediatric Trials

Under the Pediatric Research Equity Act, or PREA, an NDA or BLA or supplement thereto must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of such data or full or partial waivers. The FDCA requires that a sponsor who is planning to submit a marketing application for a drug or biologic product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA, if there is no such meeting, as early as practicable before the initiation of Phase 3 or Phase 2/3 clinical trials. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. Unless otherwise required by regulation, the PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. 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 the drug or biologic is no longer designated as an orphan drug. More than one program or development 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 product exclusivity. During the seven-year exclusivity period, the FDA may not approve any other applications to market a product containing the same active moiety for the same disease, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Thus, orphan drug exclusivity could block the approval of one of our potential products for seven years if a competitor obtains approval of the same product as defined by the FDA and we are not able to show the clinical superiority of our program or development candidate or if our program or development candidate's indication is determined to be contained within the competitor's product orphan indication. In addition, the FDA will not recognize

orphan drug exclusivity if a sponsor fails to demonstrate upon approval that the product is clinically superior to a previously approved product containing the same active moiety for the same orphan condition, regardless of whether or not the previously approved product was designated an orphan drug or had orphan drug exclusivity. A product that has received orphan drug designation may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received the designation. Orphan exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same product for a different disease or condition.

Post-Approval Requirements

Any products that we may manufacture or distribute pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, reporting of adverse experiences with the product, periodic reporting requirements, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, as well as advertising and promotion requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as off-label use), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the Internet. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval of a new application or supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals, including the requirement for a REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or 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.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the quality and long-term stability of the product. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our programs and development candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities before any product is approved and our commercial products can be manufactured. Third-party manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers, including third-party manufacturers, and other entities involved in the manufacture and distribution of approved biologics 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. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturing organizations, or CMOs, 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 cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or sponsor of an approved NDA or BLA, including, among other things, voluntary recall and regulatory sanctions as described below.

The FDA may withdraw approval if compliance with regulatory requirements and 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, or failure to comply with regulatory requirements, could result in adverse consequences to the Company. Examples of these consequences include, without limitation, the following: may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program; complete withdrawal of the product from the market or other limits on marketing or manufacture of the product; imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biopharmaceutical products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Pediatric exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly responds to a Written Request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic without such alteration or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product 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 studies 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.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

Hatch-Waxman exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data 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, or ANDA, or an NDA submitted under Section 505(b)(2) (505(b)(2) NDA) submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, 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 innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. 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.

FDA Regulation of Companion Diagnostics

We believe that certain of our product candidates may require an in vitro diagnostic to identify appropriate patient populations for investigation and/or use of our product candidates. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA. Most companion diagnostics for oncology product candidates utilize the PMA pathway.

If use of companion diagnostic is deemed essential to the safe and effective use of a drug product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for “In Vitro Companion Diagnostic Devices.” According to the guidance, for novel product candidates, a companion diagnostic device and its corresponding drug candidate should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device may be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. In which case, the sponsor of the diagnostic device will be required to submit and obtain approval of an IDE application, and subsequently comply with the IDE regulations. However, according to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of applicable IDE regulations and the IND regulations. The guidance provides that, depending on the details of the study plan and degree of risk posed to subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

The FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic simultaneously with approval of the therapeutic. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its

components regarding, among other things, device design, manufacturing and labeling. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

If the FDA's evaluation of the PMA application is favorable, the FDA may issue an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If and when the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

After a device is commercialized, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Other U.S. Health Care Laws and Compliance Requirements

Although we currently do not have any products on the market, our business operations and current and future arrangements with investigators, health care professionals, consultants, third-party payors and customers may be subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, (such as the Office of Inspector General and the Health Resources and Service Administration), the Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal health care programs. The term remuneration has been interpreted broadly to include anything of value. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers and purchasers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Further, courts have found that if “one purpose”

of remuneration is to induce referrals, the federal Anti-Kickback statute is violated. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices, including our arrangements with physicians, may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

The federal false claims and civil monetary penalty laws, including the False Claims Act, or FCA, which can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal health care programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other health care companies have been, and continue to be, prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. A violation of the Anti-Kickback Statute makes any claim submitted as a result of the violation of the Anti-Kickback Statute a false claim under the FCA. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any health care benefit program, including private third-party payors, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Like the federal Anti-Kickback Statute, under HIPAA, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that our products are approved by and sold in a foreign country, we may be subject to similar foreign laws.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health care clearinghouses, and health plans, known as covered entities, as well as independent contractors, or agents of covered entities that create, receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates. Among other things, the passage of HITECH made HIPAA's privacy and security standards directly applicable to business associates and their covered subcontractors. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the Patient Protection and Affordable Care Act, or ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians, as broadly defined by such law, certain advanced non-physician health care practitioners, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of,

such individuals or entities, and to report annually certain ownership and investment interests held by physicians and their immediate family members. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other health care entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable health care laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state health care laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and integrity oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The complex compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a health care company may run afoul of one or more of the requirements.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any programs or development candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state health care programs, private managed care providers, health insurers and other organizations. Coverage and adequate reimbursement from governmental health care programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Third-party payors decide which therapeutics they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is a covered benefit under its health plan, safe, effective and medically necessary, appropriate for the specific patient, cost-effective and neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, we cannot be sure that the level of reimbursement will be adequate. Coverage may also be

more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Limited coverage and less than adequate reimbursement may reduce the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies, and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and biologics, as well as drugs and biologics administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our programs and development candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Additionally, in the United States there is no uniform policy among third-party payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, one third-party payor's determination to provide coverage for a product does not ensure that other payors will also provide coverage for the product. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any program or development candidate that we successfully develop.

Many pharmaceutical manufacturers must calculate and report certain price reporting metrics, such as average sales price and best price, to the government, such as average sales price and best price. These prices for drugs or biologics may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or biologics from countries where drugs may be sold at lower prices than in the United States. Further, certain of our products, if approved, may be administered by a physician. Under currently applicable U.S. law, certain products that are not self-administered by the patient (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain drug and biological products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs or biologicals, the manufacturer is required to participate in other government health care programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires biopharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient therapeutic products furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular program or development candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any programs or development candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations,

and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on health care pricing. The downward pressure on the rise in health care costs has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Health Care Reform

In the United States and some jurisdictions outside the United States, there have been, and continue to be, proposed legislative and regulatory changes to the current health care systems that could prevent or delay marketing approval of programs and development candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell programs and development candidates for which marketing approval is obtained. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product and therapeutic candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access.

For example, the ACA was enacted in March 2010 and has had a significant impact on the health care industry in the United States. The ACA expanded coverage for the uninsured while at the same time containing overall health care costs. With regard to biopharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. Additionally, the Creating and Restoring Equal Access to Equivalent Samples Act, or CREATES Act, was enacted on December 20, 2019 to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on any of our future commercial products are unknown.

Following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court dismissed a challenge on procedural groups that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Further legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA that affect health care expenditures. These changes include aggregate reductions to Medicare payments to providers pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

In addition, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. On August 29, 2023, the list of the first ten drugs that will be subject to price negotiations was published, although the Medicare drug price negotiation program is currently subject to legal challenges. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs as implemented. These provisions take effect progressively starting in fiscal year 2023. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Additionally, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, including any future drug products for which we secure marketing approval.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees and Human Capital Resources

As of December 31, 2023, we had 55 full-time employees, including 38 who hold advanced degrees. Of these 55 employees, 26 were engaged in research and development activities and 29 were engaged in general and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, and retaining a diverse pool of qualified talent as well as training, incentivizing, and integrating our new and existing employees, advisors, and consultants. We offer a competitive total rewards package, updated in 2024 based on market research. We incentivize high performers through an annual bonus program based on our company and individual performance for which all employees are eligible. We also offer equity incentive plans, the purpose of which are to attract, retain and reward employees through the granting of share-based compensation awards, with the intention of increasing stockholder value and the success of our company by motivating team members.

Facilities

We currently lease approximately 11,000 square feet of office and laboratory space in Exton, Pennsylvania under a lease that expires on March 31, 2025. We currently lease approximately 14,000 square feet of office and laboratory space in Bothell, Washington under a lease that expires on October 31, 2028. We believe the leased spaces are sufficient to meet our immediate facility needs, and that any additional space we may require will be available on commercially reasonable terms.

Corporate and Other Information

We were incorporated in the state of Pennsylvania on March 2, 2006, and converted to a Delaware corporation on December 2, 2015. Our principal executive offices are located at 18702 North Creek Parkway, Suite 100, Bothell WA 98011, and our telephone number is (610) 321 3700. Our corporate website is www.immunome.com and we regularly post copies of our press releases as well as additional information about us on our website. Information contained on, or accessible through, our website shall not be deemed incorporated into, and is not a part of, this Annual Report. We have included our website in this Annual Report solely as an inactive textual reference.

All brand names or trademarks appearing in this Annual Report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this Annual Report is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Item 1A. Risk Factors

As noted throughout this Annual Report, an investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as other information included in this Annual Report as well as our other public filings with the SEC before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and/or prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report and those we may make from time to time. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. You should consider all of the risk factors described when evaluating our business.

Risks Related to Our Business

We are a biopharmaceutical company with a history of losses. We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a biotechnology company with a history of losses. Since our inception, we have devoted substantially all of our resources to research and development, raising capital, pursuing strategic transactions, building our management team and building our intellectual property portfolio, and we have incurred significant operating losses. As of December 31, 2023, we had an accumulated deficit of $222.8 million. Our net loss was $106.8 million and $36.9 million for the years ended December 31, 2023 and 2022, respectively. Substantially all our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. In 2023, the net loss included $80.8 million of in-process research and development (IPR&D) expense in relation to our acquisition of Morphimmune, which occurred in October 2023. To date, we have not generated any revenue from product sales, and we have not identified or sought or obtained regulatory approval for the marketing or sale of any product. Furthermore, we may not generate any revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development activities and the regulatory approval process for our development candidates.

We expect our net losses to increase substantially as we continue our operations; however, the amount of our future losses is uncertain. Our ability to achieve or sustain profitability, if ever, will depend on, among other things, successfully identifying and developing our development candidates, obtaining regulatory approvals for marketing and commercialization, manufacturing on commercially reasonable terms, performance as anticipated by our vendors, entering into additional potential future strategic partnerships and performing and meeting milestones on strategic partnerships, establishing a sales and marketing organization or suitable third-party alternatives for any approved product and raising sufficient funds to finance business activities. If we, or our present or potential future partners, are unable to commercialize one or more of our programs or development candidates, or if sales revenue from any program or development candidate that receives approval is insufficient, we will not achieve or sustain profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We have a limited operating history, which may make it difficult to evaluate our drug development capabilities and predict our future performance.

Other than our recent acquisition of AL102, a product candidate in late-stage clinical trials, we have not initiated clinical trials for any of our drug candidates. We have no drugs approved for commercial sale and have not generated any revenue from drug sales. Our ability to generate drug revenue, which may not occur for the foreseeable future, if ever, will depend on the successful development and eventual commercialization of our drug candidates, which may never occur. We may never be able to develop or commercialize a marketable drug.

Our current and future drug candidates require additional discovery research, preclinical development, clinical development, regulatory approval in multiple jurisdictions to market, manufacturing validation, obtaining current good manufacturing practice, or cGMP, manufacturing supply, capacity and expertise, building of a commercial and distribution organization, substantial investment and significant marketing efforts before we generate any revenue from drug sales.

Our limited operating history may make it difficult to evaluate our drug candidates and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early clinical-stage companies in evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our drug candidates, including AL102, we will need to transition from a company with a research focus to a company capable of supporting clinical development and if successful, commercial activities. We may not be successful in such a transition.

We have not yet demonstrated successful completion of clinical development, submitted a New Drug Application, obtained FDA approval for marketing, or successfully commercialized a drug product, and we may be unable to do so. Furthermore, AL102, which we recently acquired, is currently in Phase 3 development, but such acquisition and prior clinical success is not indicative of our ability to obtain new drug application, or NDA, approval or successfully commercialize AL102.

As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product, conduct sales and marketing activities necessary for successful commercialization, or arrange for a third party to do any of the foregoing on our behalf. Prior to obtaining approval to commercialize a product candidate in the United States or elsewhere, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. In 2022, we advanced IMM-BCP-01 into Phase 1 clinical trials for the treatment of SARS-CoV-2, but we since decided to cease further development of IMM-BCP-01 until we identify a partner to continue trials and further development. As such, AL102 is currently our only clinical trial candidate. We acquired this asset and have not yet conducted or completed any clinical trials for our current development candidates previously. We also have limited experience as a company in preparing and submitting marketing applications and have not previously submitted an NDA or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA or other comparable foreign regulatory authorities and cannot be certain how many additional clinical trials of our development candidates will be required or how such additional trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of an application for and obtaining regulatory approval of any of our development candidates. Notably, AL102's prior development was not conducted by us. As a result, our assumptions about AL102's development potential are based in large part on the data generated from clinical trials conducted by Ayala and we may observe materially and adversely different results in ongoing or future clinical trials. In addition, results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for AL102 is promising, compliance or data integrity issues may later arise and even if not, the data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. Marketing approval of AL102 or any other applications that we may submit may be delayed by several years or may require us to expend significantly more resources than we have available.

In addition, even if we were to obtain marketing approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a post-marketing risk management strategy such as a Risk Evaluation and Mitigation Strategy, or REMS, or the equivalent in another jurisdiction. Regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for AL102 or our earlier-stage product candidates.

We will need to raise substantial additional funds to advance development of our development candidates and our discovery and ADC platforms, and we cannot guarantee that we will have sufficient funds available in the future to develop and commercialize any of our development candidates.

The research and development of biotechnology products is capital-intensive. If our development candidates continue to advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop and acquire our development candidates and will require significant funds to continue to advance our discovery and ADC platforms and conduct further research and development, including preclinical studies and clinical trials, to seek regulatory approvals and to manufacture and market products, if any, that are approved for commercial sale. In addition, we incur additional costs associated with operating as a public company.

Based on our current operating plan, we expect that our existing cash, cash equivalents and marketable securities at December 31, 2023, in combination with the proceeds from the 2024 Financing, will enable us to fund our current and planned operating expenses and capital expenditures for at least 12 months from the filing date of this Annual Report on Form 10-K. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of biotechnology products is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities.

Any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and, if approved, commercialize our current and any future development candidates. Additional funding may not be available on acceptable terms, or at all. As a result of actual or anticipated changes in interest rates and economic inflation and the impact of the Russia/Ukraine conflict and Israel-Hamas conflict, the global credit and financial markets have experienced and may in the future experience extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, and uncertainty about economic stability. If the equity and credit markets deteriorate, including as a result of recent or future bank failures, it may make any necessary debt or equity financing more difficult to obtain in a timely manner on favorable terms or at all.

The timing and amount of our operating expenditures will depend largely on factors outside of our control, some of which are discussed in this section, including the following:

- the scope, number, timing and progress of preclinical and clinical development activities;
- the price and pricing structure that we are able to obtain from our third-party contract manufacturers to manufacture our preclinical study and clinical trial materials and supplies and other vendors relevant to advancement of our programs;
- our ability to maintain our current licenses, conduct our research and development programs and establish new strategic partnerships and collaborations;
- the costs involved in obtaining, maintaining, enforcing and defending patents and other intellectual property rights and the resources needed to pursue regulatory approvals;
- the Merger and the costs related to the integration of business, operations, networks, systems, technologies, policies and procedures; and
- our efforts to enhance operational systems, secure sufficient laboratory space and hire additional personnel, including personnel to support development of our programs and development candidates and satisfy our obligations as a public company.

To date, we have primarily financed our operations through the sale of equity securities and convertible debt, and through our collaborations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, additional collaborations, strategic alliances, licensing arrangements, government contracts and other arrangements. We cannot assure you that we will be successful in acquiring additional funding at levels sufficient to fund our operations on terms favorable to us or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. Because of the numerous risks and uncertainties associated with the development and commercialization of our development candidates and the extent to which we may enter into collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials. To the extent that we raise additional capital through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights, future revenue streams or research programs or to grant licenses on terms that may not be as favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We do not expect to realize revenue from product sales (either directly or through our collaborators) in the foreseeable future, if at all, unless and until our drug candidates complete clinical testing, are approved for commercialization and are successfully marketed.

Risks Related to Our Discovery, Development and Regulatory Approval of Development Candidates

We may not be successful in our efforts to use and expand our discovery and ADC platforms to build and progress a pipeline.

A key element of our strategy is to use and expand our discovery and ADC platforms to build a pipeline and progress the pipeline through preclinical and clinical development for the treatment of various diseases. Our scientific research that forms the basis of our discovery and ADC platforms is ongoing. Further, the scientific evidence to support the feasibility of discovering and developing products based on our technologies has not been established. In addition, our discovery and ADC platforms are not proven to be superior to competing technologies. Even if we are successful in building our pipeline, the development candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from regulatory authorities or achieve market acceptance. If we or our collaborators do not successfully develop and commercialize development candidates, we will not be able to generate product revenue.

We may be unable to advance any of our development candidates into and through clinical development, obtain regulatory approvals and ultimately commercialize them, or we could experience significant delays in doing so.

Some of our candidates are in the early stages of development efforts and we will need to continue to progress our development candidates through preclinical studies and submit INDs to the FDA or appropriate regulatory documents to applicable foreign authorities prior to initiating their clinical development. Additionally, we acquired AL102, a Phase 3 clinical asset, which requires additional clinical data before we can submit an NDA to the FDA and other applicable foreign authorities before we can receive regulatory approval, if at all. We have no products on the market that have gained regulatory approval. Our ability to generate revenue and achieve and sustain profitability depends on our ability to continue to identify programs and nominate development candidates, advance them into preclinical and clinical development and obtain regulatory approvals for and successfully commercializing them, either alone or through a collaboration.

Before obtaining regulatory approval for the commercial distribution of any programs or development candidates, we, either alone or with or through a collaborator, must conduct extensive preclinical studies, followed by clinical trials

to demonstrate their safety and efficacy in humans. We cannot be certain of the timely completion or outcome of our research and development activities or our planned clinical studies and cannot predict if the FDA or other regulatory authorities will ultimately support the further advancement of our development candidates. Most of our development candidates are in the early stages of development, other than AL102, which is a Phase 3 clinical asset, and we are subject to the risks of failure inherent in the development of candidates based on novel approaches, targets and mechanisms of action.

In November 2021, we submitted an IND for the IMM-BCP-01 program to the FDA. In March 2022, the FDA communicated that the clinical study can be initiated for our antibody cocktail for the treatment of SARS-CoV-2 following a brief clinical hold, and we initiated the Phase 1b study of IMM-BCP-01 in patients infected with SARS-CoV-2 in June 2022. On January 6, 2023, we announced that we successfully completed dosing of the first cohort of patients in a Phase 1b trial with no significant treatment-related adverse events. We decided to seek a partner in order to continue the trial and for any further development activities. No assurance can be given that we will be able to find a suitable partner for IMM-BCP-01, that any potential partner will offer us satisfactory partnering terms or that any such partner will have success in its development and commercialization efforts.

We anticipate submitting INDs for IM-3050 and IM-1021 in the first quarter of 2025 and for IM-4320 at a later date. However, there can be no assurance that we will be able to do so as anticipated or that we will not face regulatory or other hurdles, including the requirement to provide additional data.

If we do not advance IM-4320, IM-1021 or IM-3050 to IND as anticipated, we may incur significant delays and expense identifying another development candidate, if any. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays, and difficulties frequently encountered by biotechnology companies such as ours.

We may not have the financial resources to continue development of, or to enter into new collaborations for, our development candidates. This may be exacerbated by one or more of the following:

- negative or inconclusive results from our preclinical studies or clinical trials or the preclinical studies or clinical trials of others for development candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- product-related side effects experienced by participants in our clinical trials or by individuals using drugs or therapeutic antibodies similar to ours;
- product-related side effects experienced by participants in our clinical trials or by individuals using drugs or therapeutic antibodies similar to ours;
- delays in IND submissions or comparable foreign applications, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- inadequate supply or quality of components or materials or other supplies necessary for the conduct of our preclinical studies or clinical trials;
- poor effectiveness of our development candidates during preclinical studies or clinical trials;
- capital expenditures used to expand our current pipeline;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial or manufacture site; failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all; or
- the FDA or other regulatory agencies interpreting our data differently than we do.

Further, we and any existing or potential future partners may never receive necessary marketing and commercialization approvals from regulatory authorities. Even if we or a potential future partner obtains regulatory approval, the approval may be delayed, or may be for targets, disease indications or patient populations not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or a potential future partner may be subject to post-marketing testing requirements to maintain regulatory approval.

We may pursue particular programs or development candidates over others; these decisions may prove to be wrong and may adversely impact our business.

In the natural course of progressing our development candidates, we may make decisions about prioritization that may prove to be incorrect. In addition, because we have limited financial and other resources, we may be limited in our ability to pursue all potential development candidates of interest, including IM-4320, IM-1021, IM-3050 and AL102, even if we would otherwise choose to do so if these limitations did not exist. For these reasons, we may fail to capitalize on viable opportunities. If we do not accurately evaluate the commercial potential or target market for a program or development candidate, we may relinquish valuable rights to it through partnership, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

We may fail to realize the business benefits anticipated as a result of completed or pending strategic transactions.

The success of our business strategy to pursue acquisitions of assets will depend, in part, on our ability to successfully integrate, develop and advance the acquired assets. If we are unable to do so following the consummation of such transaction, the anticipated benefits of such transaction may not be realized fully or at all, or may take longer to realize than expected. Any failure to timely realize the anticipated benefits of our strategic transaction could have a material adverse effect on our business, operating results, financial condition and stock price. Furthermore, in connection with the consummation of such transactions, we may become responsible for unknown or contingent liabilities. These liabilities could include, among others, exposure to unexpected compliance and regulatory violations and issues, clinical trial design or contract manufacturing and supply issues or delays that may impact the timing to submit applications for regulatory approval, unanticipated obligations to vendors and other creditors and other problems that could result in significant costs and delays to us.

All these factors could decrease or delay the expected accretive effect of the transactions, negatively impact our stock price, or have a material adverse effect on our business, financial condition and results of operations.

As a targeted radioligand therapy, our IM-3050 program may face additional and potentially unpredictable challenges.

Lutetium-177 (177Lu), or Lu-177, oncology therapy is relatively new, only two Lu-177 therapies have been approved in the United States or the European Union and only a limited number of clinical trials of products based on Lu-177 therapies have commenced. As such, it is difficult to accurately predict the developmental challenges we may incur in advancing IM-3050 through candidate nomination, preclinical studies and clinical trials, if at all. The IM-3050 program is subject to risks described above as well as others that may include:

- interruptions to our ability to obtain sufficient supply of Lu-177 for our preclinical needs and potential future clinical and commercial needs;

- we may not be able to find suitable vendors, including contract research organizations, or CROs and clinical manufacturing organizations, for our development due to the limited number of suppliers qualified to work with radioactive material, or we may develop sole-source relationships with vendors, which may present additional risks inherent to a sole-source relationship;

- if we initiate a clinical trial, our ability to recruit patients may be negatively impacted by the limited number of sites that can administer radioligand therapies;

- if our product is successfully approved for commercial sale, our revenue may be negatively impacted by the limited number of sites that can administer radioligand therapies; and

- due to the short half-life of Lu-177, we may incur significant expense developing the means required to effectively and timely distribute drug products to clinical sites and, if approved, to sites for administration to patients.

There is no guarantee that our collaboration with AbbVie Global Enterprises Ltd., or AbbVie, will result in the successful discovery and validation of targets for further development and commercialization by AbbVie.

Related to the AbbVie collaboration and option agreement entered into on January 4, 2023, or the Collaboration Agreement, there is no guarantee that our discovery platform will successfully discover and validate targets, or that such targets may become the subject of further successful development and commercialization by AbbVie. Additionally, if there is any conflict, dispute, disagreement, or issue of nonperformance between us and AbbVie regarding our rights or obligations under the Collaboration Agreement, AbbVie may have a right to terminate the agreement or reduce the payments due to us thereunder.

We have obtained rights to use human samples in furtherance of our research and development. However, if we failed to obtain appropriate permission to use these samples or exceed the scope of the permissions given, our program could be adversely affected.

With respect to certain of our development candidates, our discovery process involves gathering tissue samples from humans. While we attempt to ensure that we and our vendors have obtained these samples with all necessary permissions, there is a risk that one or more individuals from whom samples were collected, or their representatives may assert that we have either failed to obtain appropriate permission or exceeded the scope of permission granted. In such circumstances, we could be required to pay monetary damages, to pay a continuing royalty on any products created or invented by analyzing the person's sample or even to cease using the sample and any and all materials derived from or created through analysis of the sample, any of which could result in a change to our business plan and materially harm our business, financial condition, results of operations and prospects. Further, in some cases, these penalties could materially impact the performance, availability, or validity of studies conducted by us or on our behalf. Even in the absence of violations resulting in penalties, regulatory and other authorities may refuse to authorize the conduct or to accept the results of studies for regulatory or ethical reasons, which could impact our ability to progress our program into or through clinical trials, and peer-reviewed journals may refuse to publish scientific findings, which could limit our ability to disseminate information related to this program.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For example, we will incur additional expenses as a result of acquiring AL102 and implementing its Phase 3 clinical trial. Additionally, because our other development candidates are based on new technologies and discovery approaches, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat study participants and to treat potential side effects that may result from our development candidates may be significant. Accordingly, our clinical trial costs are likely to be high and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preliminary results from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and as the data undergo audit and verification procedures. Furthermore, clinical development has an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

From time to time, we may publish preliminary results from our preclinical studies and clinical trials. Interim results from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as enrollment continues and more data becomes available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published or publish. As a result, preliminary and interim data should be viewed with caution until the final data is available. Differences between preliminary or interim data and final data could significantly affect our business prospects.

It is impossible to predict when or if any of our programs or development candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities, we must, as applicable, complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of any of our development candidates may not be predictive of the results of later-stage clinical trials. In addition, development candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of pharmaceutical companies have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials. In addition, AL102's prior development was not conducted by us, and we did not conduct any of the preclinical studies for the ROR1 ADC that we in-licensed from Zentalis. As a result, our assumptions about the potential of these programs are based in large part on the data generated in preclinical studies and clinical trials conducted by these third parties. Results from nonclinical studies and clinical trials can be interpreted in different ways. We may observe materially and adversely different results in any ongoing or future preclinical studies or clinical trials, or later discover errors or other issues with the data generated by these third parties.

We do not know whether planned preclinical studies and clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll participants on time or be completed on schedule, if at all. Our development programs may be delayed for a variety of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- delays in developing suitable assays for screening participants for eligibility for trials with respect to certain development candidates;
- delays in reaching agreement with the FDA, European Medicines Agency or other regulatory authorities as to the design or implementation of our clinical trials;
- reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board, or IRB, approval at each clinical trial site;
- recruiting suitable participants to participate in a clinical trial and having participants complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;

- failure to perform in accordance with the FDA's good clinical practice, or GCP requirements, or applicable regulatory guidelines in other countries;

- any unresolved ethical issues associated with enrolling patients in clinical trials in lieu of prescribing existing treatments that have established safety and efficacy profiles;

- addressing participant safety concerns that arise during the course of a trial, including occurrence of adverse events that are viewed to outweigh potential benefits;

- external factors such as an epidemic or pandemic which prevent execution of the study(ies) or recruitment of subjects to a trial or trials; or

- having inadequate supply or quality of components or materials or other supplies necessary for the conduct of our preclinical studies or clinical trials.

Furthermore, we expect to rely on CROs, clinical trial sites and other vendors to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

Clinical trials may be suspended or terminated by us, our partners, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trials or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, inability to recruit appropriate subjects or an adequate number of subjects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of any of our programs, the commercial prospects will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval.

If we encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for our programs or development candidates if we are unable to locate and enroll a sufficient number of eligible participants to participate in these trials as required by the FDA or other regulatory authorities. The enrollment of participants depends on many factors, including:

- the severity of the disease under investigation;

- the eligibility criteria defined in the clinical trial protocol and the size of the population required for analysis of the trial's primary endpoints;

- the existence of approved therapies, or ones available under Emergency Use Authorizations, for treating similar populations may limit recruitment into the clinical trial;

- the willingness or availability of eligible individuals to participate in our clinical trials;

- the proximity and availability of clinical trial sites;

- the referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- perceptions as to the potential advantages of the candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain participant consents; and
- the risk that those enrolled in clinical trials will drop out of the trials before completion.

In addition, our future clinical trials will compete with other clinical trials for development candidates that are in the same therapeutic areas as those being pursued by us, and this competition will reduce the number and types of participants available to us, because some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of participants who are available for our clinical trials at such clinical trial sites. Additionally, because we anticipate that some of our oncology clinical trials will be in patients with advanced solid tumors, the patients are typically in the late stages of the disease and may experience disease progression or adverse events independent from our development candidates, making them unevaluable for purposes of the trial and requiring additional enrollment. Delays in enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our pipeline.

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.

The development and commercialization of new product candidates is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop therapies for the treatment of cancer, which is highly competitive with rapidly changing standards of care. As such, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We expect to compete with oncology companies advancing antibodies, ADCs, small molecules, targeted radiotherapies, and other therapeutic modalities. We are aware of competitors who are pursuing antibody-based discovery approaches, including, but not limited to, AbCellera Biologics, Inc.; Adaptive Biotechnologies Corporation, or Adaptive; AIMM Therapeutics B.V.; IGM Biosciences, Inc.; and OncoReponse, Inc. We also expect to compete with companies pursuing targeted radiotherapies, including, but not limited to, RayzeBio, Fusion Pharmaceuticals, POINT Biopharma, Aktis Oncology, Actinium Pharmaceuticals, and Yantai LNC Biotechnology. In addition, we expect to compete with large, multinational pharmaceutical companies that discover, develop and commercialize antibodies, ADCs, small molecules, targeted radiotherapies, and other therapeutics for use in treating cancer such as Immunogen (acquired by AbbVie Inc.), AstraZeneca; Amgen; Bayer AG, BMS; Eli Lilly and Company; Genentech, Inc. (a member of Roche group); Merck & Co. Inc.; Novartis; Seagen (acquired by Pfizer) and Johnson & Johnson. If any of our current or future product candidates are eventually approved for sale, they will likely compete with a range of treatments that are either in development or currently marketed for use in those same disease indications.

With respect to AL102, we expect to compete with companies advancing treatments for desmoid tumors, including but not limited to, SpringWorks Therapeutics, Inc. In November 2023, Springworks received FDA approval for its oral gamma secretase inhibitor, OGSIVEO® (nirogacestat), for the treatment of adult patients with progressing tumors who

require systemic treatment. Desmoid tumors treatments also include surgery, hormonal therapy, targeted therapy and chemotherapy.

There are several other companies developing FAP-targeted radioligand therapies which may represent the most direct competition to our IM-3050 program. Novartis is advancing a FAP-targeted radioligand therapy (177Lu-FAP-2286) that was acquired from Clovis Oncology and is currently in Phase 1/2. In December 2023, Eli Lilly and Company acquired POINT Biopharma, which is developing a FAP-targeted radioligand therapy (PNT2004) that is currently in Phase 1. Yantai LNC Biotechnology has also initiated a Phase 1 trial for another FAP-targeted radioligand therapy (LNC1004.) Additionally, our IM-3050 program faces competition from competitors who may have superior access to a consistent supply of radioactive isotopes.

In January 2023, we exclusively licensed a preclinical ROR1 ADC program from Zentalis with the potential to address hematologic and solid tumor indications. There are several other companies developing antibodies, ADCs, and CAR-T therapies targeting ROR1, and they may represent the most direct competition to our ROR1 ADC program. Merck has an ADC program (Zilovertamab vedotin) in a Phase 2/3 clinical trial for B-cell lymphoma. CStone Pharmaceuticals, Inc. has an ADC program in a Phase I trial. Companies advancing clinical ROR1-CAR T therapy programs include Octernal Therapeutics (ONCT-808) in a Phase 1/2 in B-cell malignancies, and Lyell Immunopharma (LYL797) in a Phase 1 trial.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, performing preclinical studies, conducting clinical studies, integrating assets into their portfolio, obtaining regulatory approvals and marketing approved products than we have. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, these larger companies may be able to use their greater market power to obtain more favorable supply, manufacturing, distribution and sales-related agreements with third parties, which could give them a competitive advantage over us.

Further, as more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in that class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, or if the approval of other agents for an indication or patient population significantly alters the standard of care with which we tested our product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and subject enrollment for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our current or future products or programs.

The market may not be receptive to our development candidates, and we may not generate any revenue from their sale, partnering or licensing.

Even if regulatory marketing approval is obtained, we may not generate or sustain revenue from sales of the corresponding product. Market acceptance will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals and the terms of such approvals;

- safety and efficacy;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration;
- the availability of coverage and adequate government and third-party payor reimbursement and the pricing of our products, particularly as compared to alternative treatments; and
- availability of alternative effective treatments for the disease indications that our programs or development candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any program or development candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If the market opportunities for our development candidates are smaller than we believe they are, our future product revenues may be adversely affected, and our business may suffer.

Our understanding of the number of people who suffer from certain types of medical conditions that may be able to be treated by our current and future potential development candidates is based on estimates. These estimates may prove to be incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment. Additionally, patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition. In particular, the treatable population for various oncology indications may further be reduced if our estimates of addressable populations are erroneous or sub-populations of patients do not derive benefit from our development candidates.

Further, there are several factors that could contribute to making the actual number of participants in clinical studies less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

If we or others identify undesirable side effects caused by any of our current or future development candidates undergoing clinical trials, our ability to market and derive revenue from the program or development candidate could be compromised.

Undesirable side effects caused by any development candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could order us to cease further development of or deny approval of a development candidate for any or all targeted indications. Such side effects could also affect recruitment or the ability of enrolled participants to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business and financial condition and impair our ability to generate revenues.

Further, clinical trials by their nature utilize a sample of the potential population. With a limited number of participants and limited duration of exposure, rare and severe side effects of a program or development candidate may only be uncovered when a significantly larger number of participants are exposed to the development candidate or when participants are exposed for a longer period of time.

In the event that any of our development candidates receive regulatory approval and we or others identify undesirable side effects caused by one of these products, any of the following adverse events could occur, which could result in the loss of significant revenue to us and materially and adversely affect our results of operations and business:

- regulatory authorities may withdraw their approval of the product, seize the product or impose additional restrictions on the marketing of the particular product or the manufacturing processes for the product or any component thereof;

- we may be required to recall the product, change the way the product is administered, conduct additional preclinical studies or clinical trials or change the labeling of the product;

- we may be sued, subject to fines, injunctions or the imposition of civil or criminal penalties; and

- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication or a limitation on the indications for use or impose restrictions on the distribution in the form of a REMS in connection with approval.

If any of our development candidates is approved for marketing and commercialization in the future and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.

We currently have no sales, marketing or distribution capabilities, which are necessary in order to commercialize each program and development candidate that gains FDA approval. It would be expensive and time-consuming to build these capabilities or enter into strategic partnerships with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market any approved products or decide to co-promote products with partners, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business and results of operations could be materially and adversely affected.

A Fast Track Designation from the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive regulatory approval.

The FDA has granted Fast Track designation for AL102 for progressing desmoid tumors. We intend to seek such designation for some or all of our additional product candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, drugs and biologic are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a biologics license application, or biologics license applications, or BLA, or NDA is submitted, the application may be eligible for priority review. An NDA or BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted. If the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA, as applicable, and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation for any of our product candidates, such product candidates may not experience a faster

development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that AL102 or any other product candidate that may be granted Fast Track designation will receive regulatory approval in the United States. Many product candidates that have received Fast Track Designation have ultimately failed to obtain regulatory approval.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, 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. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, President Biden signed an omnibus appropriations bill to fund the U.S. government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things, provided FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of any feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for any of our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for any of our product candidates would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may fail to obtain orphan drug designations from the FDA for our product candidates, and even if we obtain such designations, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States, may designate biologics or drugs designed to address relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may grant

orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States, where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding for clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

In November 2023, the FDA granted Orphan Drug Designation to AL102 for the treatment of desmoid tumors, and we may seek additional Orphan Drug Designations for our other product candidates. There can be no assurances that we will be able to obtain such designations. Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that product candidate. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active ingredients may be approved for the same disease or condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug or biologic for the same disease or condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care, or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development or regulatory review time of a drug nor gives the drug or biologic any advantage in the regulatory review or approval process.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain such diagnostic, which would be subject to regulatory approval requirements. The process of obtaining or creating a diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains regulatory approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

Additional regulatory burdens and other risks and uncertainties in foreign markets may limit our growth.

Our future growth may depend, in part, on our ability to engage in development and commercialization efforts in foreign markets for which we may rely on strategic partnership with third parties. We will not be permitted to market or promote any program or development candidate before we receive regulatory approval from the applicable regulatory authority in a foreign market, and we may never receive such regulatory approval. To obtain separate regulatory approval in foreign markets, we generally must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of a program or development candidate, and we cannot predict success in these jurisdictions. If we obtain approval of any of our programs or development candidates and ultimately commercialize any such program or development candidate in foreign markets, we would be subject to risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries. Pricing flexibility may be limited in foreign markets which may further limit revenue.

Our business entails a significant risk of product liability, which may not be sufficiently covered by our insurance.

As we continue to engage in preclinical studies and clinical trials, we will be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of antibody treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, our partners or we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or government enforcement actions; private litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; adverse publicity; and other consequences that could negatively affect our operating results and business.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data, Due to these data processing activities, we and our current and potential collaborators are subject to numerous data privacy and security obligations, such as federal, state, local and foreign laws and regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations related to data privacy and security.

In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws (*e.g.*, the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, state data breach notification laws, state health information privacy laws, federal and state consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act), and other similar laws (*e.g.*, wiretapping laws), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. For example, HIPAA imposes specific requirements relating to the privacy, security, and transmission of

individually identifiable protected health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, or other data privacy and security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose protected health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. However, determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. Many state laws govern the data privacy and security of personal information and data in specified circumstances, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal information. As applicable, such rights may include the right to access, correct, or delete certain personal information, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal information, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or CPRA, and collectively, CCPA, applies to personal information of consumers, business representatives, and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices about such businesses' data collection, use and sharing practices, and provide such consumers certain rights concerning their personal information, such as ways to opt-out of certain sales or transfers of personal information and other processing activities, and the right to access, correct, or delete certain personal information. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, and collectively, GDPR, impose strict requirements for processing personal information. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Compliance with foreign data privacy and security laws and regulations, such as the GDPR, should it become applicable to us, could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions.

Our employees and personnel have used, and may in the future use, generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

We also have used, and may in the future use, AI and machine learning, or ML, technologies to assist us in making certain decisions, which is regulated by certain data privacy and security laws. Due to inaccuracies or flaws in the inputs, outputs, or logic of the AI/ML, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups, and, we are, or may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain data privacy and security laws, such as the CCPA, require our customers to impose specific contractual restrictions on their service providers. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose personal information.

We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal information on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. Failure to comply with U.S. and foreign data privacy and security laws and regulations could result in government enforcement actions (*e.g.*, investigations, fines, penalties, audits, inspections, and similar); litigation (including class claims) or mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. Claims that we have violated individuals' privacy rights, failed to comply with data privacy and security laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business. Plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of the aforementioned events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Health care legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain health care costs. For example, in March 2010, the Patient Protection and Affordable Care Act, or ACA, was signed into law. This legislation changed the system of health care insurance and benefits and was intended to broaden access to health care coverage, enhance remedies against fraud and abuse, add transparency requirements for the health care and health insurance industries, impose taxes and fees on the health care industry, impose health policy reforms, and control costs. This law also contains provisions that would affect companies in the pharmaceutical industry and other health care related industries by imposing additional costs and changes to business practices. Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by the U.S. Congress. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates

the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. The uncertainty around the future of the ACA and other health reform measures, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. We continue to evaluate the effect that the ACA and any other health reform measures could have on our business. Additional federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug and biologic pricing and reimbursement. Such reforms could have an adverse effect on anticipated revenues from development candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop development candidates.

Further, among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, the Centers for Medicare & Medicaid Services, or CMS, began to implement the program in which a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product’s price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, the CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. On August 29, 2023, the list of the first 10 drugs that will be subject to price negotiations was published, although the Medicare drug price negotiation program is currently subject to legal challenges. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has and will continue to issue and update guidance as these programs are implemented. The IRA permits the U.S. Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

Further, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Additionally, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida’s Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

Those new laws and initiatives may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our future customers and accordingly, our financial operations. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for our development candidates or additional pricing pressures, or otherwise adversely impact our operations.

If we or our existing or potential future partners, manufacturers or other service providers fail to comply with health care laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our products and may harm our reputation.

Health care providers and third-party payors, among others, will play a primary role in the prescription and recommendation of any programs or development candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, providers and customers, among others, may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our development candidates for which we obtain marketing approval. These laws and regulations, include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws, including the federal False Claims Act, which prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, including: allegedly providing free items and services, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to government healthcare programs for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Drug Rebate Program to reduce liability for Medicaid rebates. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, of any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless or the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule which impose requirements relating to the privacy, security and transmission of individually identifiable

health information on certain health care providers, health care clearinghouses, and health plans, known as covered entities, as well as independent contractors, or agents of covered entities that create, receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates, and their covered subcontractors;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, created as part of the ACA, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous local, state and foreign laws and regulations such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws that require biotechnology companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws require the registration or pharmaceutical sales representatives.

Ensuring that our future business arrangements with third parties comply with applicable health care laws and regulations could involve substantial costs. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a health care company may run afoul of one or more of the requirements. It is possible that governmental authorities will conclude that our business practices, including certain advisory agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including criminal and civil monetary penalties, damages, fines, individual imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government health care programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We intend to develop and implement a comprehensive corporate compliance program prior to the commercialization of our development candidates. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. Moreover, federal, state or foreign laws or regulations are subject to change, and while we, our collaborators, manufacturers and/or service providers currently may be compliant, that could change due to changes in interpretation, prevailing industry standards or for other reasons.

Any programs or development candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a program or development candidate ahead of our competitors, our development candidates may face competition from biosimilar or generic products. In the United States, our antibody-based programs and development candidates are expected to be regulated by the FDA as biological products, and we intend to seek approval for these development candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our programs and development candidates.

We believe that any of our development candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our development candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient's specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off-label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity for which our development candidates may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved. If competitors are able to obtain marketing approval for biosimilars referencing our development candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our development candidates may have received approval.

If the FDA, the European Medicines Agency, or EMA, or other comparable foreign regulatory authorities approve generic versions of any of our small molecule drug candidates that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of those products, the sales of our products, if approved, could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the sponsor generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed

drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The Federal Food, Drug and Cosmetic Act provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the sponsor may submit its application four years following approval of the reference listed drug.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our small molecule product candidates are approved, even if we still have patent protection for such products. Competition that our products could face from generic versions of our products could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact 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, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the 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 necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Even if we receive regulatory approval of our development candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.

If our development candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities must comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing applications, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our development candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the program and development candidate. The FDA may also require a REMS program as a condition of approval of our development candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our development candidates, we will have to comply with requirements, including submissions of safety and other post-marketing information and reports, and registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval.

The FDA strictly regulates marketing, labeling, advertising, and promotion of 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. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. 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;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, 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; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our development candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Even if we are able to commercialize any program or development candidate, the program and development candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our development candidates or assure that coverage and reimbursement will be available for any product that we may develop. The regulations that govern marketing approvals, pricing and reimbursement for new drug and biological products vary widely from country to country. Some countries require approval of the sale price of a drug or biologic before it can be marketed. In many countries, the pricing review period begins after marketing or product approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. We are monitoring these regulations as several of our programs move into later stages of development, including AL102 which is in Phase 3 clinical development; however, a majority of our programs are currently in the earlier stages of development and we will not be able to assess the impact of price regulations for a number of years. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that could delay our commercial launch of the product and negatively impact any potential revenues we may be able to generate from the sale of the product in that country and potentially in other countries due to reference pricing.

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement/payment for these products and related treatments will be available from government health administration authorities, private payors and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary and/or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. At this time, we are unable to determine their cost effectiveness or the likely level or method of reimbursement for our development candidates. Increasingly, third-party payors, such as government and private insurance plans, are requiring that biotechnology companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts paid for biotechnology products. If the price we are able to charge for any products we develop, or the payments provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

We currently expect that any drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U.S. law, certain therapeutic products that are not usually self-administered (such as most injectable drugs and biologics) may be eligible for coverage under the Medicare Part B program if:

- they are incident to a physician's services;
- they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and
- they have been approved by the FDA and meet other requirements of the statute.

There may be significant delays in obtaining coverage for newly approved biologics, and coverage may be more limited than the indications for which the biologic is approved by the FDA or comparable foreign regulatory authorities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to pay all or part of the costs associated with their prescription medications. Patients are unlikely to use our products unless coverage is provided, and payment is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate payment is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Moreover, eligibility for coverage does not imply that any of our products, if approved, will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs or biologics, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments

for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or biologics may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for drug or biologic products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug and biologic products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, we or our collaborators may develop companion diagnostic tests for use with our current and future potential development candidates. We or our collaborators will be required to obtain coverage and reimbursement for these tests separately and apart from the coverage and reimbursement we may seek for our current and future potential development candidates. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new products we develop and for which we obtain regulatory approval could adversely affect our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

A number of legislative and regulatory changes in the health care system in the United States and other major health care markets have been proposed and/or adopted in recent years, and such efforts have expanded substantially in recent years. We believe that the efforts of governments and third-party payors to contain or reduce the cost of health care and legislative and regulatory proposals to broaden the availability of health care will continue to affect the business and financial condition of pharmaceutical and biotechnology companies.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm our business.

We are subject to the Foreign Corrupt Practices Act, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We adopted a Code of Business Conduct and Ethics and implemented training programs, policies and procedures to ensure compliance with such code. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Risks Related to Manufacturing, Commercialization and Reliance on Third Parties

If we choose to continue to pursue collaborations and other strategic transactions, we may not be able to enter into such transactions on acceptable terms, if at all, which could adversely affect our development and commercialization activities, impact our cash position, increase our expenses, and present significant distractions to our management.

We have, and may continue to consider strategic transactions, such as the Ayala Asset Purchase, our Collaboration Agreement with AbbVie, the Zentalis License Agreement, acquisitions of companies like the merger with Morphimmune, other asset purchases, collaborations, joint ventures and out- or in-licensing. The competition for partners is intense, and the negotiation process is time-consuming and complex. If we desire to enter into strategic transactions but are not able to do so, we may not have access to the required liquidity or expertise to further develop our development candidates and our discovery and ADC platforms. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, but we may not be able to realize the benefit of acquiring such assets. Conversely, any new collaboration that we do enter into may be on terms that are not optimal for us. These transactions would entail numerous operational and financial risks, including:

- exposure to unknown liabilities and higher-than-expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses; and

- disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, programs or technologies, including impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and our business could be materially harmed by such transactions. Conversely, any failure to enter into any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our development candidates and have a negative impact on the competitiveness of any program or development candidate that reaches market.

In addition, to the extent that any of our current or potential future partners were to terminate a collaboration agreement, we may be forced to independently develop our development candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and maintaining, enforcing and defending intellectual property rights, or, in certain instances, abandoning any program or development candidate altogether, any of which could result in a change to our business plan and materially harm our business, financial condition, results of operations and prospects.

If third parties on which we intend to rely to conduct our current and future preclinical studies and clinical trials do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our programs could be delayed with material and adverse impacts on our business and financial condition.

We intend to rely on third-party clinical investigators, CROs, clinical data management organizations and consultants to design, conduct, supervise and monitor certain preclinical studies and any clinical trials, including the Phase 3 clinical trial of AL102. Because we intend to rely on these third parties and will not have the ability to conduct certain preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of such preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third

parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

The FDA requires certain preclinical studies to be conducted in accordance with good laboratory practices and clinical trials must be conducted in accordance with GCPs, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our clinical trials could have a material and adverse impact on our commercial prospects and may impair our ability to generate revenue.

Because we may rely on third parties for manufacturing, supply and testing, some of which may be sole source vendors, for preclinical and clinical development materials and commercial supplies, our supply may become limited or interrupted or may not be of satisfactory quantity or quality.

We may rely on third-party contract manufacturers for our preclinical and future clinical trial product materials and commercial supplies, including our Phase 3 clinical trial of AL102. We do not intend to produce any meaningful quantity of materials needed for preclinical and clinical development through our internal resources, and we do not currently own manufacturing facilities for producing such supplies. While we intend to try to avoid sole-source arrangements with any of our manufacturing, supply and testing vendors, it may not always be possible to do so. We cannot assure you that our preclinical or future clinical development product supplies and commercial supplies will not be limited or interrupted, especially with respect to any sole source third-party manufacturing and supply partners or will be of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a program or development candidate is subject to FDA and other regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP. In the event that any of our future manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, or at all. In some cases, the technical skills or technology required for manufacture may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our materials. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop in a timely manner or within budget.

If we are unable to obtain or maintain third-party manufacturing for any program or development candidate, or to do so on commercially reasonable terms, we may not be able to complete our development and commercialization efforts successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials;
- delay in submitting regulatory applications, or receiving regulatory approvals;
- loss of the cooperation of a potential future partner;

- subjecting third-party manufacturing facilities or our potential future manufacturing facilities to additional inspections by regulatory authorities;

- requirements to cease distribution or to recall batches; and

- in the event of approval to market and commercialize a product, an inability to meet commercial demands.

We may be unable to successfully scale manufacturing in sufficient quality and quantity, which would delay or prevent us from completing our development and commercialization efforts, if any.

In order to conduct our research and development efforts, including clinical trials, for our development candidates, we will need to manufacture large quantities. If any programs or development candidates are commercialized, we will need to scale up manufacturing efforts even further. We currently expect to continue to use third parties for our manufacturing needs, as we do not currently have, nor do we currently intend to establish, our own manufacturing capacity. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any program or development candidate in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and our manufacturers may fail to perform under their contracts with us, which could result in an unexpected need to change manufacturers. If we or our manufacturing partners are unable to successfully scale the manufacture at any stage, in sufficient quality and quantity, the development, testing and clinical trials of that program or development candidate may be delayed or infeasible, and regulatory approval or commercial launch of any potential resulting product may be delayed or not obtained, which could significantly harm our business.

Our significant reliance on third-party vendors could impair our ability to implement our business plan.

We rely on, and expect to continue to rely on, third-party vendors for many aspects of our business. We depend on these third parties, and likely will continue to depend on them, to perform their obligations in a timely manner consistent with contractual and regulatory requirements. We also at times need to rely, and may continue to need to rely, on certain vendors as our sole source for research, development, manufacturing or other services. Establishing additional or replacement sole source vendors, if required, may not be accomplished quickly. In addition, these vendors may now or in the future partner with and conduct services for third parties developing in enabling technologies that are competitive with our discovery and ADC platforms and/or current or future development candidates. If we are unable to make arrangements with a vendor for a particular need, or maintain our relationship with that vendor, on commercially reasonable terms, we may not be able to develop and commercialize our programs or development candidates successfully or operate our business as we intend, which could harm our business, result of operations, financial condition and prospects.

A cyber-attack or breach of our information technology systems, or those of the third parties upon which we rely, could cause adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; and other adverse consequences.

In the ordinary course of business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, process, proprietary, confidential, and sensitive data, including our clinical trial data or personal information, or collectively, sensitive data.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of

these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to conduct our business as presently conducted.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties upon which we rely experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties upon which we rely fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information security systems (such as our hardware and/or software, including that of third parties upon which we rely), but we may not be able to detect, mitigate, and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to conduct our business as presently conducted. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal information); litigation (including class claims) and mass arbitration demands; indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); disputes with physicians and other healthcare providers, clinical trial participants and our partners; increases in operating expenses; expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

Further, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Our current laboratory operations are concentrated in two locations, and we or the third parties upon whom we depend on may be adversely affected by natural or other disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current business operations are concentrated in the greater Seattle and Philadelphia areas. Any unplanned event, such as flood, fire, explosion, extreme weather condition, medical epidemics, including any potential effects from a pandemic, such as power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities or the manufacturing facilities of our third-party contract manufacturers, or lose our repository of blood-based and other valuable laboratory samples, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development efforts or interruption of our business operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our locations, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. In addition, terrorist acts or acts of war targeted at the United States, and specifically the greater Seattle and Philadelphia areas, could cause damage or disruption to us, our employees, facilities, partners and suppliers. The disaster recovery and business continuity plan we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business and financial condition.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our success will depend in part on obtaining and maintaining patent protection and trade secret protection for our discovery and ADC platforms and targeted therapeutics, as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our technologies from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and have in recent years been the subject of much litigation. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Over the past decade, U.S. federal courts have increasingly invalidated pharmaceutical and biotechnology patents during litigation often based on changing interpretations of patent law. Further, the determination that a patent application or patent claim meets all the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the U.S. Patent and Trademark office, or USPTO, or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. We cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our own patent portfolio.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art publications or patent literature, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patent portfolio in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our targeted therapeutics and/or materially harm our business.

In addition to challenges during litigation, third parties can challenge the validity of our patents in the United States using post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent filed March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which may result in a loss of the challenged patent right to us.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our targeted therapeutics programs;

- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) claims will have sufficient scope to protect any one of our targeted therapeutics, provide us with commercially viable patent protection or provide us with any competitive advantages;

- if our pending applications issue as patents, they may be challenged by third parties as invalid or unenforceable under United States or foreign laws;

- we may not successfully commercialize our targeted therapeutics, if approved, before our relevant patents expire;

- we may not be the first to make the inventions covered by our patent portfolio; or

- we may not develop additional proprietary technologies or targeted therapeutics that are separately patentable.

In addition, to the extent that we are unable to obtain and maintain patent protection for our targeted therapeutics, or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of any of our targeted therapeutics for follow-on indications.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

In order to obtain and maintain our patents, we are required to pay application fees, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents or applications to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and in-licensed patents or applications and any patent rights we may own or in-license in the future. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these requirements, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future targeted therapeutics.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international Patent Corporation Treaty filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new commercial products arising from our discovery and ADC platforms, patents protecting such products might expire before or shortly after such products are commercialized.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension, or PTE, of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of an enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining

term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication - in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. We anticipate applying for PTE in the United States. Similar extensions may be available in other countries where we are prosecuting patents, and we likewise anticipate applying for such extensions.

The granting of a PTE is not guaranteed and is subject to numerous requirements. We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. In addition, to the extent we wish to pursue a PTE based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current or any future targeted therapeutics.

The U.S. Congress is responsible for passing laws establishing patentability standards. As with any laws, implementation is left to federal agencies and the federal courts based on their interpretations of the laws. Interpretation of patent standards can vary significantly within the USPTO and across the various federal courts, including the U.S. Supreme Court. Recently, the U.S. Supreme Court has ruled on several patent cases, generally limiting the types of inventions that can be patented. Further, there are open questions regarding interpretation of patentability standards that the U.S. Supreme Court has yet to decisively address. Absent clear guidance from the U.S. Supreme Court, the USPTO has become increasingly conservative in its interpretation of patent laws and standards.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, the legal landscape in the United States has created uncertainty with respect to the value of patents. Depending on any actions by the U.S. Congress, and future decisions by the lower federal courts and the U.S. Supreme Court, along with interpretations by the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The U.S. Supreme Court has ruled on several patent cases in recent years; these cases often narrow the scope of patent protection available to inventions in the biotechnology and pharmaceutical spaces. For example, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, or *Myriad*, the Supreme Court ruled that a "naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," and invalidated Myriad Genetics' claims on the isolated BRCA1 and BRCA2 genes. To the extent that any of our patent application claims are deemed to be directed to natural products, or to lack an inventive concept above and beyond an isolated natural product, a court may decide the claims are directed to patent-ineligible subject matter and are invalid. The application of *Myriad* to biotechnology inventions has continued to develop and may continue to change over time. Subsequent rulings in cases or guidance or procedures issued by the USPTO relating to patent eligibility may have a negative impact on our business.

In *Amgen Inc. v. Sanofi*, or *Amgen*, the U.S. Supreme Court held that certain of Amgen's patent claims defined a class of antibodies by their function of binding to a particular antigen. The Court further wrote that because the patent claims defined the claimed class of antibodies only by their function of binding to a particular antigen, a skilled artisan would have to use significant trial and error to identify and make all of the molecules in that class. The Court ultimately held that Amgen failed to properly enable its patent claims. Certain claims of our patent portfolio relate to broad classes of therapeutic agents, antibodies or antigen binding fragments. To the extent that a court finds that the skilled artisan would need significant trial and error to identify all the species in that class, the court may find the claims invalid under *Amgen*. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that

would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Further, a new court system recently became operational in the European Union. The Unified Patent Court, or UPC, began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the European Union. The broad geographic reach of the UPC could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of our European patents. Patent owners have the option to opt-out their European patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. We have decided to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be subject to the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting, enforcing and defending patents protecting our current or future targeted therapeutics in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our targeted therapeutics.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and Europe. Many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our owned and in-licensed patents or the marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our owned or in-licensed intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business. Such proceedings could also put our owned or in-licensed patents at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits or other adversarial proceedings that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our and our licensors' efforts to enforce such intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of its patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business prospects may be materially adversely affected.

Proceedings to enforce our patent rights, whether successful or not, could result in substantial costs and divert our efforts and resources from other aspects of our business. Further, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly; put our pending patent applications at risk of not issuing; and provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our targeted therapeutics, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products, if approved. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

In order to protect our competitive position around our future products, we may become involved in lawsuits to enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and which may result in our patents being found invalid or unenforceable.

Competitors may seek to commercialize competitive products to our current or future targeted therapeutics. In order to protect our competitive position, we may become involved in lawsuits asserting infringement of our patents, or misappropriation or other violations of our intellectual property rights. Litigation is expensive and time-consuming and would likely divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

If we or our licensors file a patent infringement lawsuit against a perceived infringer, such a lawsuit could provoke the defendant to counterclaim that we infringe their patents and/or that our patents are invalid and/or unenforceable. In patent litigation in the United States, it is commonplace for a defendant to counterclaim alleging invalidity and/or unenforceability. In any patent litigation there is a risk that a court will decide that the asserted patents are invalid or unenforceable, in whole or in part, and that we do not have the right to stop the defendant from using the invention at issue. With respect to a counterclaim of invalidity, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. There is also a risk that, even if the validity of such patent is upheld, the court will construe the patent claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. If any of our patents are found invalid or unenforceable, or construed narrowly, our ability to stop the other party from launching a competitive product would be materially impaired. Further, such adverse outcomes could limit our ability to assert those patents against future competitors. Loss of patent protection would have a material adverse impact on our business.

Even if we establish infringement of any of our patents by a competitive product, a court may decide not to grant an injunction against further infringing activity, thus allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay us a “reasonable royalty” as determined by the court, and/or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity and/or competition from a related product would have a material adverse impact on our business.

Litigation often involves significant amounts of public disclosures. Such disclosures could have a materially adverse impact on our competitive position or our stock prices. During any litigation we would be required to produce voluminous records related to our patents and our research and development activities in a process called discovery. The discovery process may result in the disclosure of some of our confidential information. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common stock.

Litigation is inherently expensive, and the outcome is often uncertain. Any litigation likely would substantially increase our operating losses and reduce our resources available for development activities. Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially

greater financial resources. As a result, we may conclude that even if a competitor is infringing any of our patents, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

If in the future, we in-license any patent rights, we may not have the right to file a lawsuit for infringement and may have to rely on a licensor to enforce these rights for us. If we are not able to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

Concurrently with an infringement litigation, third parties may also be able to challenge the validity of our patents before administrative bodies in the United States or abroad. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our products, potentially negatively impacting any concurrent litigation.

We may need to acquire or license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our targeted therapeutics. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our current and future targeted therapeutics.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development. If we are unable to acquire such intellectual property outright, or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, our ability to commercialize any of our targeted therapeutics, if approved, would likely be delayed or we may have to abandon development of that targeted therapeutic and our business and financial condition could suffer. Further, we may be required to expend significant time and resources to redesign our targeted therapeutics or the methods for manufacturing them, or to develop or license replacement technology, all of which may not be commercially or technically feasible. In such events, there could be a material adverse effect on our ability to commercialize and on our business, financial condition, results of operations and prospects.

If we in-license additional targeted therapeutics in the future, we might become dependent on proprietary rights from third parties with respect to those targeted therapeutics. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to our ability to develop and commercialize any targeted therapeutics subject to such licenses. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, including with respect to the use, field or territory of the licensed intellectual property, thereby giving our competitors and other third parties access to the same intellectual property licensed to us. In-licensing intellectual property rights could require us to make substantial licensing and royalty payments. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings. If any in-licensed patents are invalidated or held unenforceable, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products.

We may not have the right to control the prosecution, maintenance, enforcement or defense of patents and patent applications that we license from third parties. In such cases, we would be reliant on the licensor to take any necessary actions. We cannot be certain that such licensor would act with our best interests in mind, or in compliance with applicable laws and regulations, or that their actions would result in valid and enforceable patents. For example, it is possible that a licensor's actions in enforcing and/or defending a patent licensed by us may be less vigorous than had we conducted them ourselves. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of licensed technology in relation to our development and commercialization of our targeted therapeutics and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected targeted therapeutics.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we may own or in-license now or in the future, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and potential future licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future targeted therapeutics, or we could lose certain rights to grant sublicenses.

We are reliant upon in-licenses to certain patent rights and proprietary technology from third parties, such as BMS, Zentalis, Thomas Jefferson University, or TJU, and Purdue University, or Purdue, that are or may become important or necessary to our discovery and ADC platforms or targeted therapeutics pipeline.

Our current license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution, and enforcement or other obligations on us. In addition, our license agreements with Zentalis, BMS, TJU and Purdue each require us to bear the costs of filing and maintaining patent applications. If we are in breach of our license agreements, we may be required to pay damages and the licensor may have the right to terminate the license. License termination could result in a material adverse effect on our ability to use our discovery and ADC platforms and/or targeted therapeutics and our ability to develop, manufacture, and sell products that are discovered using or are covered by the licensed technology or could enable a competitor to gain access to the licensed technology.

Under our current and future license agreements, we may not have all intellectual property rights necessary for developing, commercializing, and protecting our current or future targeted therapeutics.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. For example, pursuant to our license agreements with TJU and Purdue, while we may comment on patent applications and may lead enforcement of the patents and patent applications, the licensing institution is responsible for the preparation, filing, prosecution and maintenance and defense of the patents and patent applications. While we may provide input on patent strategy, including strategy relating to patent drafting and prosecution, we cannot be certain that the in-licensed patents and patent applications will be prepared, filed, prosecuted, maintained, and defended in a manner consistent with the best interests of our business. If our licensors and future licensors lose rights to licensed patents or patent applications, our right to develop and commercialize any of our targeted therapeutics that is the subject of such licensed rights could be materially adversely affected.

Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to disagreement regarding interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse impact on our business and ability to achieve profitability. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected targeted therapeutics, which could have a material adverse effect on our business and financial conditions.

Intellectual property rights of third parties could adversely affect our ability to commercialize our targeted therapeutics, and we might be required to obtain licenses from third parties to engage in development or marketing efforts, which may not be available on commercially reasonable terms or at all.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our targeted therapeutics without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to targeted therapeutics or components thereof, methods of manufacturing our targeted therapeutics or components thereof, and/or methods of use for the treatment of the disease indications for which we are developing our targeted therapeutics. If any third-party patents or patent applications are found to cover any of our targeted therapeutics, or their methods of use or manufacture, we may not be free to manufacture or market such targeted therapeutics as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all. We or our licensors, or any future strategic partners, may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights. In some instances, we may be required to indemnify our licensors for the costs associated with any such adversarial proceedings or litigation.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our targeted therapeutics, including patent infringement lawsuits in the U.S. or abroad. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture

or methods for treatment related to the composition, use or manufacture of our targeted therapeutics. Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our targeted therapeutics or elements thereof or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future targeted therapeutics unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current or future targeted therapeutics. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future targeted therapeutics. Additionally, claims in pending patent applications, subject to certain limitations, can be amended in a manner that could cover our targeted therapeutics. If a third-party infringement claim should successfully be brought, we may be required to pay substantial damages or be forced to abandon our current or future targeted therapeutics or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

Third parties may assert infringement claims against us based on patents that exist now or may arise in the future, regardless of the merit of such patents or infringement claims. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources, and we may not have sufficient resources to bring these actions to a successful conclusion.

While we perform periodic searches for relevant patents and patent applications with respect to our programs and development candidates, and uses thereof, we cannot guarantee the completeness or thoroughness of any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of any of our targeted therapeutics in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that any of our targeted therapeutics may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future.

Numerous third-party U.S. and foreign issued patents and pending patent applications exist which are related to our targeted therapeutics or components of our targeted therapeutics. For example, we are aware of patent portfolios related to compounds containing FAP targeting ligands that are owned by 3B Pharmaceuticals, Cornell University, Institute of Organic Chemistry and Biochemistry of the Czech Academy of Sciences, and Johns Hopkins University. There may also be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our targeted therapeutics.

If our defenses to such assertions of infringement were unsuccessful, we could be liable for a court-determined reasonable royalty on our existing sales and further damages to the patent owner (or licensee), such as lost profits. Such royalties and damages could be significant. If we are found to have willfully infringed the claims of a third party's patent, the third party could be awarded treble damages and attorney's fees. Further, if we are found to infringe, misappropriate or otherwise violate a third party’s intellectual property rights, we could be forced, including by court order, to cease

developing, manufacturing or commercializing the infringing product. We might, if possible, also be forced to redesign current or future targeted therapeutics so that we no longer infringe, misappropriate or violate the third-party intellectual property rights. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. If we were required to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. We cannot assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights, Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally, it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing a product or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effects on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations.

Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

Determinations of inventorship can be subjective. While we undertake to accurately identify correct inventorship of inventions made on our behalf by our employees, consultants and contractors, an employee, consultant or contractor may disagree with our determination of inventorship and assert a claim of inventorship. Any disagreement over inventorship could result in our being forced to defend our determination of inventorship in a legal action which could result in substantial costs and be a distraction to our senior management and scientific personnel.

While we typically require employees, consultants and contractors who may develop intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. In either case, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we are unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on our behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in our losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and/or being enjoined from clinical testing, manufacturing and marketing of the affected product candidate(s). Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. We may rely on trade secrets or confidential know-how to protect certain aspects of our technology, especially where patent protection is believed by us to be of limited value. We expect to rely on third parties for future manufacturing of our targeted therapeutics, and any future targeted therapeutics. We also expect to collaborate with third parties on the development of our targeted therapeutics and any future targeted therapeutics. As a result of the aforementioned collaborations, we must, at times, share trade secrets with our collaborators. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements.

Trade secrets or confidential know-how can be difficult to maintain as confidential. We protect and plan to protect trade secrets and confidential and unpatented know-how, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements prior to beginning research or disclosing proprietary information with parties, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants under which they are obligated to maintain confidentiality and to assign their inventions to us. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or securing title to an employee- or consultant-developed invention if a dispute arises, is difficult, expensive and time-consuming, and the outcome is unpredictable.

The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may be subject to claims by third parties that we or our employees or consultants have wrongfully used or disclosed their alleged trade secrets or other proprietary information.

Many of our current or former employees or consultants and our licensors' current or former employees or consultants, including our senior management, were previously employed at universities or biotechnology or biopharmaceutical companies, including some which may be competitors or potential competitors. Although we take commercially reasonable steps to ensure that our employees do not use the proprietary information, know-how or trade secrets of others in their work for us, including incorporating such intellectual property into our targeted therapeutics, we may be subject to claims that we or these employees have misappropriated the intellectual property of a third party. Litigation or arbitration may be necessary to defend against these claims.

If we fail in defending against such claims, in addition to paying monetary damages, we may sustain reputational damage, lose valuable intellectual property rights or key personnel or may be enjoined from using such intellectual property. Further, it may become necessary for us to obtain a license from such third party to commercialize any of our products. Such license(s) may not be available on commercially reasonable terms or at all. Any such proceedings and

possible aftermath would likely divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. A loss of key personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future targeted therapeutics, which could materially harm our business. Even if we are successful in defending against any such claims, litigation or arbitration could result in substantial costs and could be a distraction to our management.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products or formulations that are similar or competitive to our targeted therapeutics, but that are not covered by the claims of any patents that we own, license or control;
- we or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own, license or control;
- we or our licensors or strategic partners might not have been the first to file patent applications covering certain of our owned and in-licensed inventions;
- others may independently develop the same, similar, or alternative technologies without infringing, misappropriating or violating our owned or in-licensed intellectual property rights;
- it is possible that our owned or in-licensed pending patent applications will not lead to issued patents;
- others may have access to the same intellectual property rights licensed to us on a non-exclusive basis in the future;

- issued patents that we own, in-license, or control may not provide us with any competitive advantages, or may be narrowed or held invalid or unenforceable, including as a result of legal challenges;

- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;

- ownership of our patent portfolio may be challenged by third parties;

- patent enforcement is expensive and time-consuming and difficult to predict; thus, we may not be able to enforce any of our patents against a competitor; and

- the patents of third parties or pending or future patent applications of third parties, if issued, may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse impact on our business and financial condition.

Risks Related to Our Business Operations and Industry

We may be unable to successfully integrate the Immunome and Morphimmune businesses and realize the anticipated benefits of the Merger.

The completed transaction involved the merger of two companies which previously operated as independent companies. We will be required to devote significant management attention and resources to integrating our business practices and operations with those of Morphimmune in order to effectively realize synergies as a combined company, including leveraging anticipated synergies across technology platforms. Potential difficulties we may encounter in the integration process include the following:

- the inability to successfully combine the two businesses in a manner that permits us to realize the technology platform synergies anticipated to result from the Merger, which would result in the anticipated benefits of the Merger not being realized in the time frame currently anticipated or at all;

- the complexities associated with managing the larger combined businesses and integrating personnel from the two companies, while at the same time attempting to (i) continue pursuing pre-clinical and clinical development of existing development candidates, (ii) researching and developing new development candidates based on each company's respective platforms, and (iii) identifying and pursuing other potential strategic transactions or collaborations;

- the additional complexities of combining two companies with different histories, operating structures and technology foundations;

- the complexities associated with and integration issues relating to reconstituting our board of directors and changing our management team;

- the failure to successfully manage relationships with the combined supplier and vendor bases of the two companies;

- the failure to retain key employees of either of the two companies;

- potential unknown liabilities and unforeseen increased expenses, delays or regulatory conditions associated with the Merger; and

- performance shortfalls at one or both of the two companies as a result of the diversion of management's attention caused by completing the Merger and integrating the companies' operations.

For all these reasons, it is possible that the integration process could result in the distraction of our management, the disruption of our ongoing business or inconsistencies in our standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with current and potential future vendors, regulators, collaboration partners, and employees or to achieve the anticipated benefits of the Merger, or could otherwise adversely affect our business and financial results.

Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors, consultants and other specialized personnel. While we have written employment agreements with our management team and each of our key employees, those employment arrangements are at-will and could be terminated at any time. The loss of one or more members of our management team or other key employees, advisors or consultants could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. We do not currently maintain "key man" insurance on any of our executive officers.

The relationships that our key management team members have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our programs, development candidates and technologies and the specialized nature of the regulatory approval process. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. Our future success is also dependent on our ability to retain qualified advisors and consultants. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations.

As of December 31, 2023, we had 55 full-time employees. The continued operation of our business and execution of our plans will require material additional staffing within the next twelve months. We cannot provide assurance that we will be able to hire or retain adequate staffing levels to advance our discovery and ADC platforms, develop our programs or development candidates or run our operations or to accomplish our objectives.

We expect to continue to incur substantial expenses related to the completed Merger.

We expect to continue to incur substantial expenses in connection with the completed Merger and the related integration of businesses, operations, networks, systems, technologies, policies and procedures. While we have assumed that a certain level of transaction and integration expenses would be incurred, there are a number of factors beyond our control that could affect the total amount or the timing of our integration expenses. Many of the expenses that will be incurred, by their nature, are difficult to estimate accurately at the present time. Due to these factors, the transaction and integration expenses could be greater or could be incurred over a longer period of time than we currently expect.

We may experience difficulties in managing our growth and expanding our operations.

As our development candidates enter and advance through preclinical studies and any clinical trials, including our Phase 3 clinical trial of AL102, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. We may also experience difficulties in the discovery and development of new development candidates using our discovery and ADC platforms if we are unable to meet demand as we grow our operations. In the future, we also expect to have to manage additional relationships with collaborators, suppliers and other organizations. Our ability to manage our operations and future growth will require us

to continue to improve our operational, financial and management controls, reporting systems and procedures and secure adequate facilities for our operational needs. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

Our employees, principal investigators, vendors and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, vendors and commercial partners. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. For example, individuals conducting the non-interventional clinical studies that we sponsor through which we obtain antibodies for development into potential antibody-based therapeutics may violate applicable laws and regulations regarding personal information. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this 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 to be in compliance 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 material and adverse effect on our business and financial condition, including the imposition of significant criminal, civil, and administrative fines or other sanctions, such as monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded health care programs, such as Medicare and Medicaid, integrity obligations, reputational harm and the curtailment or restructuring of our operations.

Risks Related to our Common Stock

An active trading market for our common stock may not be sustained, which may make it difficult for you to sell your shares.

The trading market for our common stock on The Nasdaq Capital Market has been limited and an active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at a price that is attractive to you, or at all.

The market price of our common stock is expected to be volatile, and purchasers of our common stock could incur substantial losses.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of biotechnology, early-stage pharmaceutical and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to successfully develop and obtain regulatory approvals for our development candidates, and delays or failures to obtain such approvals;
- failure of any of our development candidates, if approved, to achieve commercial success;
- failure by us to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;

- changes in laws or regulations applicable to our development candidates;
- any inability to obtain adequate supply of our development candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed any projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- the effects of the Merger and our financing transactions, which materially increase our public float;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- failure to maintain compliance with the listing requirements of The Nasdaq Capital Market;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Certain of our executive officers, directors and large stockholders own a significant percentage of our outstanding capital stock. As a result of their share ownership, these stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. These stockholders' interests may not always coincide with our corporate interests or the interests of other stockholders, and these stockholders may exercise their voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including further development of our programs and development candidates, preparing IND filings, conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. In this regard, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 14, 2021, pursuant to which we may issue from time to time securities with an aggregate value of up to $200.0 million in one or more offerings at prices and terms to be determined at the time of sale. In October 2023, we completed our Merger and concurrent PIPE transaction for gross proceeds of approximately $125.0 million before deducting fees and offering expenses. An aggregate of 21,690,871 shares of our common stock at $5.75 per share were issued pursuant to the subscription agreements and have been registered for resale pursuant to a registration statement on Form S-3 filed with the SEC and made effective on November 27, 2023. In February 2024, we raised $230.0 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by us, through a public offering of our common stock. In connection with the closing of the public offering, we issued and sold 11,500,000 shares of our common stock. Additionally, we have and may issue shares of our common stock in connection with strategic transactions, including, for example, the Zentalis License and the Ayala Asset Purchase.

We issued 2,298,586 shares to Zentalis in connection with the Zentalis License and 2,175,489 shares to Ayala in connection with the Ayala Asset Purchase, both of which we are required to register for resale within seven days of the filing of this Annual Report. The shares issued to Zentalis and Ayala are subject a to (i) a six-month lock-up with respect to half of the shares and (ii) an orderly market disposition. Notwithstanding these contractual protections, any sales of these shares may cause our stock price to fall.

Additionally, on February 13, 2024, we filed an automatic shelf registration statement on Form S-3, pursuant to which we may issue from time-to-time securities in one or more offerings at prices and terms to be determined at the time of sale. If we sell shares of common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2020 Equity Incentive Plan, or 2020 Plan, our management is authorized to grant stock options to our employees, directors and consultants. The aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2020 Plan shall not exceed 8,080,286 shares. Additionally, the number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each year, beginning on January 1, 2021 and continuing through and including January 1, 2030, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall. Additionally, pursuant to Morphimmune Inc.'s 2020 Equity Incentive Plan, or the Morphimmune Plan, the aggregate number of shares that may be issued pursuant to stock awards under the Morphimmune Plan is 2,429,630 shares. We do not currently intend to issue any further awards under the Morphimmune Plan.

We are an "emerging growth company" and our election of reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this Annual Report. We could be an emerging growth company for up to five years following the completion of our initial public offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in this Annual Report and our other periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of an exemption that allows us to delay adopting new or revised accounting standards until such time as those standards apply to private companies. As a result, we will not be subject to the same new or revised accounting standards as other public companies that comply with the public company effective dates, including but not limited to the new lease accounting standard. We have also elected to take advantage of certain of the reduced disclosure obligations in this Annual Report and may elect to take advantage of other reduced reporting requirements in future filings. As a result of these elections, the information that we provide to our stockholders may be different than you might receive from other public reporting companies. However, if we later decide to opt out of the extended period for adopting new accounting standards, we would need to disclose such decision and it would be irrevocable.

Our ability to use net operating loss carryforwards and other tax attributes may be limited.

We have incurred losses during our history, and we do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. Under current law, U.S. federal net

operating loss, or NOL, carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including changes in connection with the Merger and potential changes due to other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

Capital appreciation, if any, will be a stockholder's sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be our stockholder's sole source of gain for the foreseeable future.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders, which our company is not obligated to call more than once per calendar year, be called only by the chairman of our board of directors, our chief executive officer, or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and (iv) any action asserting a claim against us or any of our directors, officers or other employees, governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits against us and our directors, officers, and other employees. While the Delaware courts have determined that such choice of forum provisions are facially valid, and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instances, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, both state and federal court, or other jurisdictions which could seriously harm our business, financial condition, results of operations, and prospects.

We could be subject to securities class action litigation or stockholder derivative litigation.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. Additionally, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face any litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

General Risk Factors

Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations.

The results of our operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The United States and global economies are facing growing inflation, higher interest rates and potential recession. Furthermore, a severe or prolonged economic downturn, including

a recession or depression or political disruption such as the war between Ukraine and Russia and the Israel-Hamas conflict could result in a variety of risks to our business, including weakened demand for our development candidates, if approved, relationships with any vendors or business partners located in affected geographies and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Furthermore, concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult to acquire financing on acceptable terms or at all. Any decline in available funding or access to cash and liquidity resources could, among other risks, adversely impact our and our vendors', collaborators' and other business relations' ability to meet operating expenses, financial obligations or fulfill other obligations, potentially resulting in breaches of financial and/or contractual obligations and/or result in violations of federal or state wage and hour laws. Any of these impacts could have material adverse impacts on our business operations, financial condition and results of operations.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II of this Annual Report.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation informally titled the Tax Cuts and Jobs Act; the Coronavirus Aid, Relief, and Economic Security Act; and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. The Biden administration and the U.S. Congress could also enact other tax law changes that could have an adverse effect on our operations, cash flows and results from operations and contribute to overall market volatility. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

If we unable to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are subject to requirements of the Sarbanes-Oxley Act, the regulations of The Nasdaq Capital Market, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include, among other things, that we maintain corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our consolidated financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Capital Market.

If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business, results of operations and financial condition and could cause a decline in the trading price of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. 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 an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to public company reporting and compliance initiatives.

As a public company listed on The Nasdaq Capital Market, we incur significant expenses for director and officer insurance, legal services, accounting services and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and The Nasdaq Capital Market have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits smaller “emerging growth companies” to implement many of these requirements over a longer period and up to five years from the pricing of our initial public

offering. We intend to continue to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costlier. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we are required to incur substantial costs to maintain our current levels of such coverage.

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research, development and manufacturing involve the use of hazardous and radioactive materials and various flammable and toxic chemicals. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous and radioactive materials and waste products. Although we believe our procedures for storing, handling and disposing of these materials in our facilities comply with the relevant guidelines of the Commonwealth of Pennsylvania, the State of Washington and the Occupational Safety and Health Administration of the U.S. Department of Labor, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for substantial resulting damages. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Our workers' compensation insurance may not provide adequate coverage against costs and expenses we may incur due to injuries to our employees resulting from the use of these materials. Our current environmental liability insurance covering certain of our facilities could be inadequate for all environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials and waste products. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature.

Our information technology and legal departments, in consultation with third party service providers, help (i) identify, assess and manage our cybersecurity threats and risks, and (ii) identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and our risk profile using various methods including, for example: analyzing reports of threats and actors, evaluating threats reported to us, performing security audits, and conducting vulnerability assessments.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response measures, disaster recovery/business continuity plans, risk assessments, encrypting sensitive data, network security controls, data segregation, access controls, physical security, asset management, tracking and disposal, systems monitoring, vendor risk management program, employee training, penetration testing, and dedicated cybersecurity staff. Additionally, we are in the process of developing an incident response plan and response policy.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, (1) our Vice President, Technology Enablement, who leads our information technology department and reports to Mr. Rosett, our Interim Chief Financial Officer and Executive Vice President, Operations, works with management and our third-party service providers to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business; and (2) our senior management, in consultation with our information technology department and third-party service providers, evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example: professional service firms, including legal counsel, cybersecurity consultants and cybersecurity software providers.

We use third-party service providers to perform a variety of functions throughout our business, such as contract research organizations, contract manufacturing organizations, hosting companies and application providers. We have a vendor management process to manage cybersecurity risks associated with our use of these providers. The process includes conducting a risk assessment of each vendor and imposing contractual obligations on such vendor with respect to the protection of our information. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including in the section titled "Risks Related to Manufacturing, Commercialization and Reliance on Third Parties."

Governance Related to Cybersecurity Risks

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain of our management, including Mr. Rosett, our Interim Chief Operating Officer and EVP, Operations, and our VP, Technology Enablement. Mr. Rosett has over 10 years of experience in the biotech and technology industry, including serving as a software engineer at Google. Our VP, Technology Enablement has over 25 years of experience in information technology in the biotech industry and has served in various roles of increasing importance related to information technology.

Mr. Rosett and our VP, Technology Enablement are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Mr. Rosett is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Mr. Rosett. Mr. Rosett and our VP, Technology Enablement work with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response and vulnerability management processes include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from management concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties

We currently lease approximately 11,000 square feet of office and laboratory space in Exton, Pennsylvania under a lease that expires on March 31, 2025. We currently lease approximately 14,000 square feet of office and laboratory space in Bothell, Washington, under a lease that expires on October 31, 2028. We believe our leased space is sufficient to meet our immediate facility needs, and that any additional space we may require will be available on commercially reasonable terms.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of the outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock has been publicly traded on The Nasdaq Capital Market under the symbol "IMNM" since October 2, 2020.

Holders

As of March 25, 2024, the Company had approximately 99 record holders of its common stock. A substantially greater number of holders are beneficial owners whose shares are held of record by banks, brokers and other nominees.

Dividends

The Company has not declared or paid any dividends since its inception, nor does it expect to pay dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved].

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" (Part I, Item 1A) section of this Annual Report, our actual results could differ materially from the results described in or implied by these forward-looking statements. You should carefully read the "Risk Factors" (Part I, Item 1A) section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a biopharmaceutical company focused on the development of targeted oncology therapies. We believe that the pursuit of novel or underexplored targets will be central to the next generation of transformative therapies. For that reason, we pursue therapeutics that we believe have best-in-class or first-in-class potential. Our goal is to establish a broad pipeline of preclinical and clinical assets which we can efficiently develop through successive value inflection points. To support that goal, we pair business development activity with significant investment in our internal discovery programs.

We are advancing a named pipeline comprising one clinical and three preclinical assets. The clinical asset is AL102, an investigational gamma secretase inhibitor, currently under evaluation in a Phase 3 trial for the treatment of desmoid tumors. The preclinical assets are IM-1021, a receptor tyrosine kinase-like orphan receptor 1, or ROR1, antibody-drug conjugate, or ADC; IM-3050, a fibroblast activation protein, or FAP, targeted radioligand therapy, or RLT, candidate; and IM-4320, an anti-IL-38 immunotherapy candidate. We anticipate submitting investigational new drug applications, or INDs, for IM-3050 and IM-1021 in the first quarter of 2025 and for IM-4320 at a later date. We believe that each of these drugs has the potential to improve outcomes for patients across multiple indications.

Recent Events

Collaboration with AbbVie

In January 2023, we entered into a collaboration and option agreement, or the Collaboration Agreement, with AbbVie. As part of the agreement, we will use our discovery platform to discover and validate targets derived from patients with three specified tumor types, and antibodies that bind to such targets, which may be the subject of further development and commercialization by AbbVie. The research term is at least 66 months, subject to extension in certain circumstances by specified extension periods. Under the Collaboration Agreement, AbbVie paid us an upfront payment of $30.0 million in January 2023 and may pay us certain additional platform access payments in the aggregate amount of up to $70.0 million based on our use of our discovery platform in connection with activities under each stage of the research plan, and delivery of VTPs (as defined in the Collaboration Agreement) to AbbVie. AbbVie will also pay an option exercise fee in the low single digit millions for each of the up to 10 VTPs for which it exercises an option. If AbbVie progresses development and commercialization of a Product (as defined in the Collaboration Agreement), AbbVie will pay us development and first commercial sale milestones of up to $120.0 million per target, and sales milestones based on achievement of specified levels of net sales of Products of up to $150.0 million in the aggregate per target, in each case, subject to specified deductions in certain circumstances. On a Product-by-Product basis, AbbVie will pay us tiered royalties on net sales of Products at a percentage in the low single digits, subject to specified reductions and offsets in certain circumstances. We are potentially eligible to receive up to approximately $2.8 billion from AbbVie under the Collaboration Agreement from the sources described above.

Merger

In October 2023, we completed the merger with Morphimmune Inc., or Morphimmune a preclinical biotechnology company focused on developing targeted oncology therapeutics. Under the terms of the Agreement and Plan of Merger and Reorganization dated as of June 28, 2023, or the Merger Agreement, among the Company, Morphimmune and Ibiza Merger Sub, Inc., a wholly owned subsidiary of us, or Merger Sub, Morphimmune merged with and into Merger Sub, with Morphimmune surviving as a wholly-owned subsidiary of us, or the Merger. In connection with the Merger, on October 2, 2023, we issued and sold 21,690,871 shares of our common stock pursuant to the subscription agreements in a Private Investment in Public Equity, or PIPE, transaction which provided us with gross proceeds of $125.0 million.

Atreca, Inc. Asset Purchase Agreement

In December 2023, we entered into an asset purchase agreement, or the Atreca Purchase Agreement, with Atreca, Inc., or Atreca, pursuant to which we will acquire certain antibody-related assets and materials for an upfront payment of $5.5 million and up to $7.0 million in clinical development milestones. The closing of the transaction is subject to customary conditions, including the approval of Atreca's stockholders. We expect the closing to occur in the second quarter of 2024.

Zentalis Pharmaceuticals, Inc License Agreement

In January 2024, we entered into a license agreement with Zentalis Pharmaceuticals, Inc., or the Zentalis Agreement, pursuant to which we received an exclusive, worldwide, royalty-bearing, sublicensable license under certain intellectual property relating to Zentalis' proprietary antibody-drug conjugate, or ADC, platform technology, ROR1 antibodies and ADCs targeting ROR1 to exploit products covered by or incorporating the licensed intellectual property rights. Under the Zentalis Agreement, we are required to use commercially reasonable efforts to develop an ADC targeting ROR1, two additional ADCs, and commercialize any product that has received regulatory approval.

Under the Zentalis Agreement, we paid to Zentalis upfront consideration totaling $15 million in cash and $20 million in shares of our common stock with the shares valued at the trailing 30-day volume-weighted average price. We are obligated to pay Zentalis up to $150 million in development and regulatory milestones for the first product containing an ADC targeting ROR1, or a ROR1 ADC Product, to achieve such milestones and commercial milestones on ROR1 ADC Products. We are also obligated to pay to Zentalis mid-to-high single digit royalties on ROR1 ADC Products. In addition, we are obligated to pay Zentalis $25 million in development and regulatory milestones for the first product from each of the first five additional development programs using the licensed platform technology to generate products, and mid-single digit royalties on products from each such program. Our royalty payment obligation will commence, on a product-by-product and country-by-country basis, on the first commercial sale of such product in such country and will expire on the latest of (a) the ten (10)-year anniversary of such first commercial sale for such product in such country, (b) the expiration of regulatory exclusivity for such product in such country, and (c) the expiration of the last-to-expire valid claim of a licensed patent covering such product in such country.

Ayala Asset Purchase Agreement

In February 2024, we and Ayala Pharmaceuticals, Inc., or Ayala, entered into an Asset Purchase Agreement, or the Ayala Purchase Agreement, pursuant to which we-acquired Ayala's AL101 and AL102 programs and assumed certain of Ayala's liabilities associated with the acquired assets. The Ayala Asset Purchase closed on March 25, 2024, or the Ayala Closing. At the Ayala Closing, we (i) paid Ayala $20.0 million in cash, less certain adjustments, (ii) issued Ayala 2,175,489 shares of our common stock with the shares valued at the trailing 30-day volume-weighted average price and (iii) assumed specified liabilities. Pursuant to the Ayala Purchase Agreement, we are obligated to pay Ayala up to $37.5 million in development and commercial milestones. No legal entities or employees were acquired from Ayala.

Follow-On Public Offering

In February 2024, we raised $230.0 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by us, through a public offering of our common stock, or the 2024 Financing. In connection with the closing of the public offering, we issued and sold 11,500,000 shares of our common stock.

Financial Overview

Since our inception in 2006, we have devoted substantially all our resources to research and development, raising capital, building our management team, building our intellectual property portfolio and entering and executing on collaborations and strategic transactions. To date, we have financed our operations primarily through sales of our equity securities, and strategic partnerships and transactions. In addition, we received $17.6 million in expense reimbursement from the Department of Defense, or the DoD, under the Other Transaction Authority for Prototype Agreement, or the OTA Agreement, from inception through 2022. As of December 31, 2023, our obligations under the OTA agreement with the DoD were completed.

To date, we have not generated any revenue from commercial sales and do not expect to generate revenue from commercial sale of products for the foreseeable future. Since inception, we have incurred significant operating losses. Our net losses were $106.8 million, including non-cash write off of in-process research and development of $80.8 million acquired in the Merger, and $36.9 million for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, we had cash, cash equivalents and marketable securities of $138.1 million. In addition, we raised gross proceeds of $230.0 million in the 2024 Financing. We expect to continue to incur significant expenses and increasing operating losses in connection with ongoing research and development activities related to our portfolio of programs as we continue advancement of our programs and development candidates, including the ongoing and future clinical development of AL102 and preclinical and potential clinical development of IM-1021, IM-3050, IM-4320 and any of our future product candidates, and our business development efforts to pursue and give effect to further strategic transactions and collaborations. We also plan to perform research activities as we seek to discover and develop additional programs and development candidates; carry out maintenance, expansion, enforcement, defense, and protection of our intellectual property portfolio; and hire research and development, clinical and administrative personnel. As a result of these anticipated expenditures and potential unanticipated expenditures, we will need substantial additional financing to support our continuing operations and pursue our growth strategy. Until such time as we generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of any stockholder will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market programs and development candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. If we cannot obtain the necessary funding to support these activities on favorable terms, if at all, we will need to delay, scale back or eliminate some or all of our research and development programs, including our clinical and preclinical development of our product candidates.

In October 2023, we issued and sold 21,690,871 shares of our common stock pursuant to the subscription agreements in the PIPE transaction which provided us with gross proceeds of $125.0 million. In addition, in February 2024, we issued and sold 11,500,000 shares of our common stock in a public offering which provided us with gross proceeds of $230.0 million.

We expect that our existing cash, cash equivalents and marketable securities as of December 31, 2023, in combination with the proceeds from the 2024 Financing, will enable us to fund our current and planned operating expenses and capital expenditures for at least 12 months from the filing date of this Annual Report on Form 10-K. We have based these estimates on assumptions that may prove to be imprecise, and we may exhaust our available capital resources sooner than we currently expect. See "Liquidity and capital resources." Due to the numerous risks and uncertainties associated with the research and development of our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our programs and development candidates.

Components of our results of operations

Collaboration revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for the foreseeable future. To date, we have generated our revenue through the Collaboration Agreement with AbbVie. Our Collaboration revenue to date consists of payments from AbbVie that we recognize over the expected performance period under this agreement. We expect that revenues for the foreseeable future will be derived primarily from this agreement and any additional collaborations into which we may enter. We have not received any royalties under the Collaboration Agreement with AbbVie to date.

In-process research and development expenses, or IPR&D

Intangible assets acquired in an asset acquisition for use in research and development, or R&D, activities which have no alternative future use are expensed as IPR&D on the acquisition date. In-process research and development expenses for the year ended December 31, 2023 relate to the acquisition of Morphimmune's assets.

Research and development expenses

Research and development expenses consist of costs incurred in performing research and development activities, which include:

- personnel-related expenses, including salaries, bonuses, benefits and share-based compensation for employees engaged in research and development functions;
- expenses incurred in connection with the advancement of our programs and development candidates, including under agreements with consultants, contractors, contract research organizations and other third-party vendors and suppliers;
- expenses to conduct clinical trials including regulatory and quality assurance;
- the cost of developing and validating our manufacturing process for use in our preclinical studies and clinical trials;
- laboratory supplies and research materials and other infrastructure-related expenses; and
- facilities, depreciation and amortization and other expenses which include direct and allocated expenses.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the benefits are consumed.

Research and development activities are central to our business model. We expect that our research and development expenses will increase substantially in connection with the continuation of our activities and new agreements.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including share-based compensation for personnel in our executive, business development, and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees for accounting, auditing, tax and consulting services, insurance costs, travel, direct and allocated facility related expenses, Merger costs and other operating costs.

We anticipate that our general and administrative expenses will increase in the future to support increased and progressed research and development activities and to operate as a public company.

Interest income

Interest income consists of interest earned on our marketable securities and on our cash and cash equivalent balances held with financial institutions.

Results of operations

Comparison of the years ended December 31, 2023 and 2022:

	Year Ended December 31,		
	2023	2022	Change
		(in thousands)	
Collaboration Revenue	$ 14,018	$ —	14,018
Operating expenses:			
In-process research and development	80,802	—	80,802
Research and development	23,089	23,272	(183)
General and administrative	19,657	13,629	6,028
Total operating expenses	123,548	36,901	86,647
Loss from operations	(109,530)	(36,901)	(72,629)
Interest income	2,724	5	2,719
Net loss	$ (106,806)	$ (36,896)	$ (69,910)

Collaboration revenue

In January 2023, we entered into the Collaboration Agreement with AbbVie and recognized collaboration revenue of $14.0 million for the year ended December 31, 2023. No collaboration revenue was recognized for the year ended December 31, 2022.

In-process research and development expenses

In-process research and development expense for the year ended December 31, 2023 was related to the write-off of in-process research and development assets that were acquired in the Merger and determined to have no alternative future use. There were no similar transactions for the year ended December 31, 2022.

Research and development expenses

Research and development expenses were $23.1 million and $23.3 million for the years ended December 31, 2023 and 2022, respectively.

We record direct research and development expenses, consisting principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, and costs related to manufacturing, to specific product development programs. We do not allocate costs related to purchasing clinical trial materials, employee and contractor-related costs, and costs associated with our facility expenses, including depreciation or other indirect costs, to specific product programs because these costs support multiple product programs. The table below shows our research and development expenses incurred with respect to each active program.

	Year Ended December 31,		
	2023	2022	Change
SARS-CoV-2 (IMM-BCP-01) (1)	$ (16)	$ 5,635	$ (5,651)
IM-4320 (2)	1,881	6,332	(4,451)
AbbVie Collaboration (3)	2,915	-	2,915
Other Research and Development Activities (4)	6,498	3,012	3,486
Indirect Research and Development (5)	11,811	8,293	3,518
Total	$ 23,089	$ 23,272	$ (183)

(1) The decrease in 2023 compared to 2022 for SARS-CoV-2 (IMM-BCP-01) was due primarily to a decrease in clinical trial activity for this program following our decision in 2022 to cease further development of IMM-BCP-01 until we identify a development partner.

(2) The decrease in 2023 compared to 2022 for IM-4320 was due primarily to decreased development and manufacturing activities as we shifted available resources to the AbbVie Collaboration.

(3) The increase in 2023 compared to 2022 was due primarily to outsourced research and materials relating to the AbbVie Collaboration which was initiated in 2023.

(4) The increase in 2023 compared to 2022 was due primarily to the merger with Morphimmune and other research discovery related activities.

(5) The increase in 2023 compared to 2022 was due primarily to increased personnel and personnel-related costs in support of the AbbVie collaboration.

General and administrative expenses

General and administrative expenses were $19.7 million and $13.6 million for the years ended December 31, 2023 and 2022, respectively. The increase of $6.1 million is primarily a result of a $3.0 million increase in personnel-related costs including increases of $1.1 million in salary and benefits costs due to increased headcount associated with the Merger and supporting the AbbVie Collaboration Agreement, $1.1 million in severance costs, and $0.8 million in share-based compensation. In addition, professional fees increased $4.0 million due to merger related costs with Morphimmune, partially offset by a decrease of $1.0 million in D&O insurance and other overhead related costs.

Interest income

Interest income was $2.7 million and an immaterial amount for the years ended December 31, 2023 and 2022, respectively.

Interest income increased by $2.7 million for the year ended December 31, 2023, primarily as a result of interest on marketable securities and also due to increased interest rates on our cash and cash equivalent balances held with a financial institution. Our average marketable securities and cash and cash equivalent balances were higher in 2023 as a result of the proceeds from the AbbVie Collaboration Agreement and PIPE financing.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we continue advancement of our programs and development candidates. Through December 31, 2023, we raised an aggregate of $280.5 million in gross proceeds from strategic partnerships and transactions and the sale of our equity securities. In addition, we received $17.6 million in expense reimbursement from the DoD under the OTA Agreement, from inception through 2022. As of December 31, 2023, our obligation under the OTA agreement with the DoD were completed.

In February 2024, we raised $230.0 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by us, in the 2024 Financing. In connection with the closing of the 2024 Financing we issued and sold 11,500,000 shares of our common stock.

In June 2023, we entered into subscription agreements with certain investors pursuant to which we sold 21,690,871 shares of our common stock, immediately following the completion of the Merger in October 2023, in exchange for gross proceeds of $125.0 million.

We will need to raise additional capital before we exhaust our current cash to continue to fund our research and development, including our plans to continue advancement of our programs and development candidates and new product development, strategic transactions, as well as to fund operations. As and if necessary, we will seek to raise additional funds through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Cash flows

The following table summarizes our sources and uses of cash for the years ended December 31, 2023 and 2022:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Cash used in operating activities	$ (7,568)	$ (28,690)
Cash used in investing activities	(30,484)	(248)
Cash provided by financing activities	116,408	32
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 78,356	$ (28,906)

Operating activities

Net cash used in operating activities for the year ended December 31, 2023 was $7.6 million, consisting primarily of our net loss of $106.8 million, increases in prepaid expenses and other assets of $4.1 million, offset by a noncash charge of $80.8 million for the purchase of in-process research and development assets, a noncash charge of $6.2 million for share-based compensation expense, and a $16.0 million increase in deferred revenue.

Net cash used in operating activities for the year ended December 31, 2022 was $28.7 million, consisting primarily of our net loss of $36.9 million and decreases in accrued expenses and other liabilities, accounts payable, and other long-

term liabilities of $2.8 million, offset by noncash charges of $5.3 million for share-based compensation expense and a $5.1 million decrease in prepaids expenses and other assets.

Investing activities

Net cash used in investing activities for the year ended December 31, 2023 was $30.5 million, consisting primarily of $38.9 million used to purchase marketable securities and $0.8 million to purchase property and equipment, offset by $9.3 million received in connection with the Morphimmune merger.

Net cash used in investing activities for the year ended December 31, 2022 was $0.2 million, consisting primarily of the purchase of property and equipment.

Financing activities

During the year ended December 31, 2023, financing activities provided $116.4 million consisting of gross proceeds of $125.4 million from the PIPE transaction, the exercise of options, and the issuance of common stock under the ATM, partially offset by the payment of $9.0 million for offering costs related to the PIPE transaction.

During the year ended December 31, 2022, financing activities provided $32,000 from exercise of stock options.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing and future activities, particularly as we advance and expand our clinical development of AL102, seek regulatory approval for AL102, continue the preclinical and potential clinical development of IM-1021, IM -4320, IM-3050, and any other future product candidates, and continue to pursue our business development strategy. We expect that our primary uses of capital will be for clinical development services, non-clinical research, strategic transactions, manufacturing, legal and other regulatory compliance expenses, compensation and related expenses, risk management, and general overhead costs.

We expect that our existing cash, cash equivalents and marketable securities as of December 31, 2023, in combination with the proceeds from the 2024 Financing, will enable us to fund our current and planned operating expenses and capital expenditures for at least 12 months from the filing date of this Annual Report on Form 10-K. We will need additional financing to support our continuing operations and pursue our research and development strategy. We have based these estimates on assumptions that may prove to be imprecise, and we may exhaust our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our programs and development candidates.

Our future funding requirements will depend on many factors including:

- the extent to which we acquire or in-license products, intellectual property, and other technologies, and the terms on which we acquire or in-license those assets;
- the scope, progress, results and costs of discovery, preclinical development, manufacturing and clinical trials for programs and development candidates that we currently own and those that we may acquire rights to in the future;
- the costs of continuing to operate and advance our discovery and ADC platforms;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims and the success of our intellectual property portfolio;

- the costs, timing, and outcome of regulatory review of the programs and development candidates we may develop;

- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, distribution, coverage and reimbursement for any programs or development candidates for which we receive regulatory approval;

- the success of our existing and any future license agreements, collaborations and other strategic transactions and the achievement of milestones or occurrence of other developments that trigger payments to or from us under any such agreements and transactions and;

- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. As a result of the war between Russia and Ukraine, conflict in the Middle East, bank failures, inflationary pressures on the economy and monetary policy responses taken by government agencies and other macroeconomic and political factors, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth and uncertainty about economic stability. There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of any purchaser will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market programs and development candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Contingencies

We have no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase order basis. Our expected material cash requirements do not include potential contingent payments upon the achievement by us of development, regulatory or commercial milestones that we may be required to make under the terms of the Ayala Purchase Agreement or Atreca purchase agreement, nor do they include potential contingent payments upon the achievement by us of development, regulatory and commercial milestones or royalty payments that we may be required to make under license agreements we have entered into or may enter into with various entities pursuant to which we have in-licensed certain intellectual property. For further details on the potential contingent payments related to asset acquisitions and license agreements, see Notes 10 and 16 of the notes of our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Critical accounting policies and significant judgments

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known

trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Asset Acquisitions

Acquisitions of assets or a group of assets that do not meet the definition of a business are accounted for as asset acquisitions, with a cost accumulation model used to determine the cost of the acquisition. Common stock issued as consideration in an acquisition of assets is generally measured based on the acquisition date fair value of the equity interests issued. Direct transaction costs are recognized as part of the cost of an acquisition of assets. Intangible assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as IPR&D. Acquired IPR&D that has no alternative future use is expensed immediately in the consolidated statements of operations and comprehensive loss.

Collaboration revenue

In January 2023, we entered into the Collaboration Agreement with AbbVie, which was determined to be within the scope of ASC 606, Revenue from Contracts with Customers, or ASC 606.

We evaluate our collaborative arrangements pursuant to ASC 808, Collaborative Arrangements, or ASC 808, and ASC 606. We consider the nature and contractual terms of collaborative arrangements and assesses whether the arrangement involves a joint operating activity pursuant to which we are an active participant and is exposed to significant risks and rewards with respect to the arrangement. If we are an active participant and are exposed to significant risks and rewards with respect to the arrangement, we account for the arrangement as a collaboration under ASC 808. If we are not exposed to significant risks and rewards and the contract is with a customer, we account for the collaboration under ASC 606.

Payments pursuant to collaborative arrangements may include non-refundable upfront payments, research option and license option payments, milestone payments upon the achievement of significant regulatory and development events, commercial sales milestones, and royalties on product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under a collaboration arrangement, we apply the five-step model of ASC 606: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract, including whether they are capable of being distinct; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

We apply significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, and assessing the recognition of variable consideration. When consideration is received prior to us completing our performance obligation under the terms of a contract, a contract liability is recorded as deferred revenue. Deferred revenue expected to be recognized as revenue within the twelve months following the balance sheet date is classified as a current liability.

Share-based compensation

We recognize the grant-date fair value of share-based awards issued as compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The fair value of stock options

is estimated at the time of grant using the Black-Scholes option pricing model, which requires the use of inputs and assumptions such as the fair value of the underlying common stock, exercise price of the option, expected term, risk-free interest rate, expected volatility and dividend yield.

The inputs and assumptions used to estimate the fair value of share-based payment awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different inputs and assumptions, our share-based compensation expense could be materially different for future awards.

Expected volatility is a subjective assumption based on the historical stock volatility of several of our comparable publicly traded companies over a period of time equal to the expected term.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders and communicating with personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us on a pre-determined schedule or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is set forth on pages 119 through 145 hereto.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15I and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on such evaluation, our Chief Executive Officer and Interim Chief Financial Officer have concluded that, as of the end of December 31, 2023, our disclosure controls and procedures were effective as of December 31, 2023 to ensure the timely disclosure of required information in our SEC filings.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. The Company's internal control over financial reporting is a process designed, as defined in Rule 13a-15(f) under the Exchange Act, 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. The Company's internal control over financial reporting is supported by written 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 Company's assets;

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 the Company's management and directors; 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.

In connection with the preparation of the Company's annual consolidated financial statements, management of the Company has undertaken an assessment of the effectiveness of the Company's internal control over financial reporting based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of the Company's internal control over financial reporting. Based on this assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2023.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. 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.

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting occurred during our fourth quarter ended December 31, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

We will file a definitive proxy statement for our 2024 Annual Meeting of Stockholders, or the Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this Item 10 will be set forth in the sections headed "Election of Directors," "Information Regarding the Board and Corporate Governance," "Executive Officers" and "Delinquent Section 16(a) Reports," if any, in the Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Governance section of our website at investors.immunome.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation

The information required by this Item 11 will be set forth in the sections headed "Executive Compensation" and "Non-Employee Director Compensation" in the Proxy Statement and is incorporated herein by reference.

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

The information required by this Item 12 will be set forth in the sections headed "Security Ownership of Certain Beneficial Owners and Management," and "Executive Compensation," in the Proxy Statement and is incorporated herein by reference.

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

The information required by this Item 13 will be set forth in the sections headed "Certain Related-Person Transaction," and "Information Regarding the Board and Corporate Governance," contained in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be set forth in the section headed "Ratification of Selection of Independent Registered Accounting Firm," in the Proxy Statement and is incorporated herein by reference.

Part IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K

(1) Financial Statements

Our consolidated financial statements listed in the "Index to the Consolidated Financial Statements" and Report of Independent Registered Public Accounting Firm are included after this Part IV, Item 15, "Exhibits and Financial Statement Schedules" of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

None.

(3) Exhibits

The documents listed in the Exhibit Index of this Annual Report on Form 10-K are incorporated by reference or are filed with this Annual Report on Form 10-K, in each case as indicated therein.

Immunome, Inc.

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Immunome, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2022.

Philadelphia, Pennsylvania

March 28, 2024

Immunome, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 98,679	$ 20,323
Marketable securities	39,463	-
Prepaid expenses and other current assets	6,561	2,326
Total current assets	144,703	22,649
Property and equipment, net	2,073	681
Operating right-of-use asset, net	1,564	284
Restricted cash	100	100
Deferred offering costs	-	332
Other long-term assets	100	-
Total assets	$ 148,540	$ 24,046
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,311	$ 2,400
Accrued expenses and other current liabilities	8,025	4,931
Deferred revenue, current	10,493	-
Total current liabilities	21,829	7,331
Deferred revenue, non-current	5,489	-
Other long-term liabilities	1,340	62
Total liabilities	28,658	7,393
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 43,251,778 shares issued and outstanding at December 31, 2023 and 12,128,843 shares issued and outstanding at December 31, 2022	4	1
Additional paid-in capital	342,663	132,653
Accumulated other comprehensive income	22	-
Accumulated deficit	(222,807)	(116,001)
Total stockholders' equity	119,882	16,653
Total liabilities and stockholders' equity	$ 148,540	$ 24,046

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

Immunome, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year ended December 31,	
	2023	2022
Collaboration revenue	$ 14,018	$ —
Operating expenses:		
In-process research and development	80,802	—
Research and development	23,089	23,272
General and administrative	19,657	13,629
Total operating expenses	123,548	36,901
Loss from operations	(109,530)	(36,901)
Interest income	2,724	5
Net loss	$ (106,806)	$ (36,896)
Deemed dividend arising from warrant modification	—	(622)
Net loss attributable to common stockholders	$ (106,806)	$ (37,518)
Per share information:		
Net loss per common share, basic and diluted	$ (5.38)	$ (3.09)
Weighted-average common shares outstanding, basic and diluted	19,843,651	12,126,573
Comprehensive loss		
Net loss	$ (106,806)	$ (37,518)
Unrealized gain on marketable securities	22	—
Comprehensive loss	$ (106,784)	$ (37,518)

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

Immunome Inc.
Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except share amounts)

	Stockholders' equity					
	Common stock					
	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total
Balance at January 1, 2022	12,110,373	$ 1	$ 127,289	$ —	$ (79,105)	$ 48,185
Share-based compensation expense	—	—	5,332	—	—	5,332
Exercise of stock options	18,470	—	32	—	—	32
Net loss	—	—	—	—	(36,896)	(36,896)
Balance at December 31, 2022	12,128,843	1	132,653	—	(116,001)	16,653
Unrealized gain on marketable securities	—	—	—	22	—	22
Share-based compensation expense	—	—	6,153	—	—	6,153
Issuance of common stock under ATM, net of $1 of issuance costs	5,925	—	34	—	—	34
Issuance of common stock	55,250	—	221	—	—	221
Vesting of restricted stock awards	12,498	—	70	—	—	70
Exercise of stock options	522,681	—	371	—	—	371
Issuance of common stock for PIPE funding, net of $9.0 million of issuance costs	21,690,871	2	116,001	—	—	116,003
Issuance of common stock and stock-based equity awards for Morphimmune merger	8,835,710	1	87,160	—	—	87,161
Net loss	—	—	—	—	(106,806)	(106,806)
Balance at December 31, 2023	43,251,778	$ 4	$ 342,663	$ 22	$ (222,807)	$ 119,882

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

Immunome Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (106,806)	$ (36,896)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	457	422
Amortization of right-of-use asset	271	209
Accretion of discount related to marketable securities	(512)	—
Share-based compensation	6,223	5,332
Charge for purchase of in-process research and development assets	80,802	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,144)	5,071
Accounts payable	(608)	(677)
Accrued expenses and other current liabilities	614	(1,922)
Deferred revenue	15,982	—
Other long-term liabilities	153	(229)
Net cash used in operating activities	(7,568)	(28,690)
Cash flows from investing activities:		
Purchases of marketable securities	(38,929)	—
Cash acquired in connection with Morphimmune merger, net of transaction costs	9,276	—
Purchases of property and equipment	(831)	(248)
Net cash used in investing activities	(30,484)	(248)
Cash flows from financing activities:		
Payment of offering costs	(8,997)	—
Proceeds from PIPE transaction	125,000	—
Proceeds from exercise of stock options	371	32
Proceeds from issuance of common stock under ATM, net	34	—
Net cash provided by financing activities	116,408	32
Net increase (decrease) in cash and cash equivalents and restricted cash	78,356	(28,906)
Cash and cash equivalents and restricted cash at beginning of year	20,423	49,329
Cash and cash equivalents and restricted cash at end of year	$ 98,779	$ 20,423
Supplemental disclosures of non-cash investing and financing activities:		
Operating lease right-of-use asset and lease liability recorded upon adoption of ASC 842	$ —	$ 492
Issuance of common stock and stock-based equity awards for the Morphimmune merger	87,161	—
Remeasurement of operating right-of-use asset and lease liability due to lease extension	226	—
Right-of-use asset and lease liability recognized for new operating lease liabilities	1,325	—
Issuance of common stock to certain board of directors in lieu of accrued compensation	221	—
Property and equipment included in accounts payable	372	—

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

Immunome, Inc.
Notes to the consolidated financial statements

1. Nature of the business

Organization

Immunome, Inc., or the Company, is a biopharmaceutical company focused on the development of targeted oncology therapies. The Company believes that the pursuit of novel or underexplored targets will be central to the next generation of transformative therapies. For that reason, Immunome pursues therapeutics that it believes have best-in-class or first-in-class potential. The Company's goal is to establish a broad pipeline of preclinical and clinical assets which it can efficiently develop through successive value inflection points. To support that goal, the Company pairs business development activity with significant investment in its internal discovery programs.

Immunome is advancing a named pipeline comprising one clinical and three preclinical assets. The clinical asset is AL102, an investigational gamma secretase inhibitor, currently under evaluation in a Phase 3 trial for the treatment of desmoid tumors that was acquired from Ayala Pharmaceuticals, Inc. on March 25, 2024. The preclinical assets are IM-1021, a receptor tyrosine kinase-like orphan receptor 1, or ROR1, antibody-drug conjugates, or ADC; IM-3050, a fibroblast activation protein, or FAP, targeted radioligand therapy, or RLT, candidate; and IM-4320, an anti-IL-38 immunotherapy candidate.

The Company was incorporated as a Pennsylvania corporation on March 2, 2006, and was converted to a Delaware corporation on December 2, 2015. Since its inception, the Company has devoted substantially all its resources to research and development, raising capital, building its management team, extending its intellectual property portfolio, and executing strategic partnerships and transactions. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, risks associated with research, development, and manufacturing activities, uncertain results of preclinical and clinical testing, development of new technological innovations and products by competitors, dependence on key personnel, partners and third-party vendors, protection of proprietary technology, compliance with government regulations, regulatory approval of products and the ability to secure additional capital to fund operations.

On October 2, 2023, the Company completed its merger with Morphimmune Inc., or Morphimmune, a preclinical biotechnology company focused on developing targeted oncology therapies. Under the terms of the Agreement and Plan of Merger and Reorganization dated as of June 28, 2023, or the Merger Agreement, among the Company, Morphimmune and Ibiza Merger Sub, Inc., a wholly owned subsidiary of the Company, or Merger Sub, Morphimmune merged with and into Merger Sub, with Morphimmune surviving as a wholly-owned subsidiary of Immunome, or the Merger.

Liquidity

The Company has incurred net losses since inception, including net losses of $106.8 million and $36.9 million for the years ended December 31, 2023 and 2022, respectively, and it expects to generate losses from operations for the foreseeable future primarily due to research and development costs for its programs and development candidates. As of December 31, 2023, the Company had an accumulated deficit of $222.8 million. The Company expects to generate operating losses for the foreseeable future.

Through December 31, 2023, the Company has funded its operations primarily through sales of equity securities and strategic partnerships and transactions as well as expense reimbursements from the Department of Defense, or DoD, under the Other Transaction Authority for Prototype Agreement, or the OTA Agreement.

In February 2024, the Company raised $230.0 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, from a public offering of 11,500,000 shares of the Company's common stock, or the 2024 Financing.

In June 2023, the Company entered into subscription agreements with certain investors pursuant to which the Company sold 21,690,871 shares of its common stock, immediately following the completion of the Merger in October 2023, in exchange for gross proceeds of $125.0 million.

The Company expects that its existing cash, cash equivalents and marketable securities at December 31, 2023, in combination with the proceeds from the 2024 Financing, will enable the Company to fund its current and planned operating expenses and capital expenditures for at least 12 months from the filing date of this Annual Report on Form 10-K. Beyond that date, more funding will be necessary to fund additional research and development activities and operations in order to pursue the Company's growth strategy.

If the Company cannot obtain the necessary funding, it will need to delay or scale back some of its research and development programs, enter into collaborations with third parties relative to potential programs, products or technologies that it might otherwise seek to progress independently (or enter into these collaborations sooner than it might otherwise have intended to), or reduce operations. Additionally, volatility in the capital markets generally and the biotechnology sector specifically, as well as general economic conditions in the United States may be a significant obstacle to raising the required funds on satisfactory terms, if at all.

Operations of the Company are subject to certain risks and uncertainties including various internal and external factors that will affect whether and when the Company's programs and development candidates become approved drugs and how significant their market share will be, many of which are outside of the Company's control. The length of time and cost of developing and commercializing these programs and development candidates and/or failure of them at any stage of the drug approval process will materially affect the Company's financial condition and future operations.

2. Summary of significant accounting policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted, or GAAP, in the United States. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASU, promulgated by the Financial Accounting Standards Board, or FASB.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the expected volatility used to estimate fair value of stock options, accrued research and development expenses, the fair value of acquired in-process research and development assets, and the estimated costs which drive the revenue recognition for the Collaboration Agreement with AbbVie. Estimates and assumptions are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from these estimates.

Segment and geographic information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or CODM, or decision-making group, in deciding how to allocate resources and in assessing performance. The CODM is the Company's Chief Executive Officer. The Company views its operations as and manages its business in one operating segment operating exclusively in the United States.

Cash and cash equivalents

Cash and cash equivalents consist of standard checking accounts, a money market account and three-month treasury bills. The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents.

Restricted cash

Restricted cash represents collateral provided for a letter of credit issued as a security deposit in connection with the Company's lease of its corporate facilities. Cash will be released from restriction upon termination of the lease. Restricted cash was $100,000 at both December 31, 2023 and 2022, respectively. The following table provides a reconciliation of the components of cash and cash equivalents and restricted cash presented in the consolidated statements of cash flows:

(in thousands)	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 98,679	$ 20,323
Restricted cash	100	100
	$ 98,779	$ 20,423

Marketable Securities

The Company's marketable securities consist of investments in U.S. Treasury debt securities. Debt securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses, net of tax, included in accumulated other comprehensive income, a component of stockholders' equity. These debt securities have an original maturity period greater than 90 days, but less than one year. The Company classifies marketable securities that are available for use in current operations as current assets on the consolidated balance sheets. Unrealized losses are evaluated for impairment under ASC 326*, Financial Instruments - Credit Losses, or* ASC 326, to determine if the impairment is credit-related or non-credit-related. Credit-related impairment is recognized as an allowance on the consolidated balance sheet with a corresponding adjustment to earnings, and non-credit-related impairment is recognized in accumulated other comprehensive loss.

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company maintains deposits in a financial institution in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at a financial institution that management believes to be of high credit quality, and the Company has not experienced any losses on these deposits. Management also believes that the Company is not exposed to significant credit risk as it relates to marketable securities because the Company only invests in U.S government securities.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

Asset category	Estimates useful life
Lab equipment	5 years
Leasehold improvements	Lesser of lease term or 5 years
Computer equipment	3 years
Office equipment	5 years
Furniture and fixtures	5 years

Expenditures for repairs and maintenance of assets are charged to expense as incurred, while major betterments are capitalized. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations and comprehensive loss.

Asset Acquisitions

Acquisitions of assets or a group of assets that do not meet the definition of a business are accounted for as asset acquisitions, with a cost accumulation model used to determine the cost of the acquisition. Common stock issued as consideration in an acquisition of assets is generally measured based on the acquisition date fair value of the equity interests issued. Direct transaction costs are recognized as part of the cost of an acquisition of assets. Intangible assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in-process research and development, or IPR&D. Acquired IPR&D that has no alternative future use is expensed immediately in the consolidated statements of operations and comprehensive loss. For further disclosures related to asset acquisitions see Note 3 to the consolidated financial statements.

Impairment of long-lived assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment losses recognized during the years ended December 31, 2023 and 2022.

Equity issuance costs

The Company capitalizes costs directly associated with equity financings as deferred offering costs on its consolidated balance sheet. These costs remain capitalized until such financings are consummated, at which time such costs are recorded against the gross proceeds from the applicable financing. If a financing is abandoned, deferred offering costs are expensed.

As of December 31, 2022, there were $0.3 million of deferred offering costs related to the Open Market Sale Agreement, or the ATM Agreement, and shelf registration that were expensed in 2023 as a result of the termination of the ATM Agreement. There were no deferred offering costs as of December 31, 2023.

Government assistance programs

The Company accounts for amounts received under its DoD expense reimbursement contract as contra-research and development expenses in the consolidated statements of operations and comprehensive loss.

Collaboration revenue

The Company evaluates its collaborative arrangements pursuant to ASC 808, *Collaborative Arrangements*, or ASC 808, and ASC 606, *Revenue from Contracts with Customers*, or ASC 606. The Company considers the nature and contractual terms of collaborative arrangements and assesses whether the arrangement involves a joint operating activity pursuant to which the Company is an active participant and is exposed to significant risks and rewards with respect to the arrangement. If the Company is an active participant and is exposed to significant risks and rewards with respect to the arrangement, the Company accounts for the arrangement as a collaboration under ASC 808. If it is not exposed to significant risks and rewards and the contract is with a customer, the Company accounts for the collaboration under ASC 606.

Payments pursuant to collaborative arrangements may include non-refundable upfront payments, research option and license option payments, milestone payments upon the achievement of significant regulatory and development events, commercial sales milestones, and royalties on product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under a collaboration arrangement, the Company applies the five-step model of ASC 606: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract, including whether they are capable of being distinct; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, and assessing the recognition of variable consideration. When consideration is received prior to the Company completing its performance obligation under the terms of a contract, a contract liability is recorded as deferred revenue. Deferred revenue expected to be recognized as revenue within the twelve months following the balance sheet date is classified as a current liability.

In January 2023, the Company entered into the Collaboration Agreement with AbbVie, which was determined to be within the scope of ASC 606. Please see Note 4 for further information related to the accounting for the Collaboration Agreement.

Research and development expenses

Research and development costs are charged to expense as incurred. Research and development costs consist of costs incurred in performing research and development activities, including salaries and bonuses, share-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation and amortization, preclinical and clinical development expenses, including manufacture and testing of clinical supplies, consulting and other contracted services. Additionally, under the terms of the license agreements described in Note 10, the Company is obligated to make future payments should certain development, regulatory, and sales milestones be achieved. Costs for certain research and development activities are recognized based on the terms of the individual arrangements, which may differ from the timing of receipt of invoices and payment of invoices and are reflected in the financial statements as a prepaid or accrued expense.

Share-based compensation

The Company's share-based compensation program allows for grants of stock options and restricted stock awards. Grants are awarded to employees and non-employees, including directors.

The Company accounts for its share-based compensation awards granted to employees and non-employees based on the estimated fair value on the date of grant and recognized compensation expense of those awards over the requisite service period, which is the vesting period of the respective award. The Company accounts for forfeitures as they occur. For share-based awards with service-based vesting conditions, the Company recognized compensation expense on a

straight-line basis over the service period. The Company classified share-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of Company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and biopharmaceutical industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method to calculate the expected term for options granted to employees and non-employees whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The exercise price is the fair value of the common stock as of the measurement date.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Leases

The Company accounts for leases in accordance with ASC 842, *Leases*. At the inception of an arrangement, the Company determines whether an arrangement contains a lease based on facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Typically, lessees are required to recognize leases with a term greater than one year on the consolidated balance sheets as an operating or finance lease liability and right-of-use asset. Right-of-use assets represent the Company's right to use an underlying asset during the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. The Company has elected the practical expedient to not recognize leases with a term of 12 months or less. The Company does not have any financing leases as of December 31, 2023.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the remaining lease term. Options to extend the lease term are included in the Company's assessment of the lease term only if there is a reasonable assessment that the Company will renew. Lease payments are discounted to their present value using either the interest rate implicit in the lease or the Company's incremental borrowing rate, which reflects the fixed rate in which the Company could borrow on a collateralized basis the amount of lease payments in the same currency, for a similar term, in a similar economic environment.

Income taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that

meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

Fair value of financial instruments

ASC Topic 820, *Fair Value Measurement* (ASC 820), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the assets or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered value hierarchy that distinguishes between the following:

- Level 1: Quoted market prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.
- Level 3: Unobservable inputs for the asset or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

In accordance with the fair value hierarchy described above, the following tables set forth the Company's assets and liabilities measured at fair value on a recurring basis:

	Level 1	Level 2	Level 3	Total Fair Value
December 31, 2023				
Assets:				
Cash equivalents – money market funds	$ 73,988	$ —	$ —	$ 73,988
Cash equivalents – short-term U.S. Treasury securities	—	22,993	—	22,993
Marketable securities – U.S. Treasury securities	—	39,463	—	39,463
Total	$ 73,988	$ 62,456	$ —	$ 136,444
December 31, 2022				
Assets:				
Cash equivalents – money market funds	$ 20,013	$ —	$ —	$ 20,013

The Company's marketable securities consist of U.S. Treasury debt securities with a contractual maturity date of 6 months. The following is a summary of available-for-sale marketable securities which provides a reconciliation of historical cost basis to fair value as of December 31, 2023, including cumulative unrealized gains and losses.

	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
December 31, 2023				
U.S. Treasury securities	$ 39,441	$ 22	$ —	$ 39,463

Net loss per share

Basic net loss per share of common stock is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss per share of common stock is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share of common stock is computed by dividing the diluted net loss by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The following potentially dilutive securities outstanding as of December 31, 2023 and 2022 have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	Year ended December 31,	
	2023	2022
Stock options[(1)]	7,978,291	2,519,405
Common stock warrants[(1)]	500,000	1,303,112
	8,478,291	3,822,517

(1) Represents common stock equivalents

In periods in which the Company reports a net loss per share of common stock, diluted net loss per share of common stock is the same as basic net loss per share of common stock since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss per share of common stock for the years ended December 31, 2023 and 2022.

Recently adopted accounting standards

ASU 2016-13, Credit Losses

On January 1, 2023, we adopted ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments*. This standard amended the guidance on the recognition of impairment losses of certain financial instruments. The ASU established the current expected credit loss model, which is based on expected losses rather than incurred losses. Adoption of this standard had no impact on our consolidated financial statements.

Recent accounting standards not yet adopted

ASU 2023-09, Income Tax Disclosures

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which updates income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This update also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in this update are effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is still in the process of determining the effect this ASU will have on the consolidated financial statements.

3. Merger

On October 2, 2023 the Company closed the Merger transaction contemplated by the Merger Agreement. As a result of the Merger, the Company acquired 100% of the outstanding equity interests of Morphimmune through the issuance of 8,835,710 shares of the Company's common stock to Morphimmune stockholders, based upon an exchange ratio of 0.3042 shares of the Company's common stock for each outstanding share of Morphimmune capital stock.

Upon completion of the Merger, 8,128,096 options to purchase shares of Morphimmune capital stock pursuant to the Morphimmune 2020 Equity Incentive Plan, or Morphimmune Plan, were converted into 2,472,563 options to purchase shares of the Company's common stock with a weighted average exercise price of $1.29 per share. The Company assumed the Morphimmune Plan and all other terms and conditions associated with these options, including vesting and exercisability, are governed by the original terms and conditions of the Morphimmune's Plan.

The Company accounted for the acquisition of Morphimmune as an asset acquisition as substantially all of the fair value of the gross assets acquired of Morphimmune was concentrated within two programs that are considered a group of similar assets. These programs are deemed to be similar IPR&D assets being acquired based on the similarity of: (i) their current preclinical stage of development, (ii) solid tumor therapeutic indications, (iii) risks for development, (iv) regulatory pathway, and (v) economics of commercialization.

The consideration paid for an acquisition of assets is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis.

The fair value of the consideration transferred for the acquisition of Morphimmune was calculated based on the closing stock price of Immunome's common stock on October 2, 2023, which was $8.20 per share, and based upon the vested and unvested balances of Morphimmune share-based awards as of the same date. Direct transaction costs for an asset acquisition are typically deferred and recognized as part of the consideration paid; however, the Company expensed $2.7 million of transaction costs for the Merger as incurred because substantially all of the fair value acquired relates to Morphimmune IPR&D assets that have no alternative future use and were immediately expensed following the closing of the Merger. Transaction costs capitalized as part of consideration paid were costs that were contingent on the closing of the Merger.

The consideration paid and the relative fair values of assets acquired and liabilities assumed were as follows:

Common stock issued to Morphimmune shareholders	$	72,453
Share-based equity awards allocated to consideration paid		14,708
Transaction costs		792
Consideration paid	$	87,953
Assets acquired:		
Cash and cash equivalents	$	10,068
Prepaid expenses and other current assets		191
Property and equipment		646
In-process research and development		80,802
Total assets acquired	$	91,707
Liabilities assumed:		
Accounts payable	$	1,147
Accrued expenses		2,607
Total liabilities assumed	$	3,754
Net assets acquired	$	87,953

Under the asset acquisition model, an entity that acquires IPR&D assets follows the guidance in ASC 730, *Research and Development*, which requires that both tangible and intangible identifiable research and development assets with no alternative future use be initially allocated a portion of the consideration transferred and then charged to expense at the acquisition date. As the Morphimmune IPR&D assets acquired have no alternative future use to the Company, the Company charged $80.8 million to expense within its consolidated statement of operations and comprehensive loss for the year ended December 31, 2023.

4. Collaboration Agreement with AbbVie

In January 2023, the Company entered into the Collaboration Agreement with AbbVie, pursuant to which the Company will use its discovery platform to discover and validate targets derived from patients with three specified tumor types, and antibodies that bind to such targets, which may be the subject of further development and commercialization by AbbVie. Pursuant to the terms of the Collaboration Agreement, the Company granted to AbbVie an exclusive option to purchase all rights to each novel target-antibody pair, or a Validated Target Pair or VTP, that the Company generates that meets certain mutually agreed criteria, up to a maximum of 10 in total, for all human and non-human diagnostic, prophylactic and therapeutic uses throughout the world, including the development and commercialization of certain products, or Products, derived from the assigned VTP.

AbbVie paid the Company a nonrefundable upfront payment of $30.0 million in January 2023 and will pay certain additional platform access payments in the aggregate amount of up to $70.0 million based on the Company's use of its discovery platform in connection with activities under each stage of the research plan, and delivery of VTPs to AbbVie. AbbVie will also pay an option exercise fee in the low single digit millions for each of up to 10 VTPs for which it exercises an option. If AbbVie progresses development and commercialization of a Product, AbbVie will pay the Company development and commercial sale milestones of up to $120.0 million per target, and sales milestones based on achievement of specified levels of net sales of Products of up to $150.0 million in the aggregate per Product, subject to specified deductions in certain circumstances. On a Product-by-Product basis, AbbVie will pay the Company tiered royalties on net sales of Products at a percentage in the low single digits, subject to specified reductions and offsets in certain circumstances. AbbVie's royalty payment obligation will commence, on a Product-by-Product and country-by-country basis, on the first commercial sale of such Product in such country and will expire on the earlier of (a) the later of (i) the ten-year anniversary of the first commercial sale for such Product in such country, or (ii) solely with respect to a Product that incorporates an antibody comprising a VTP (or certain other antibodies derived from such delivered antibody), the expiration of all valid claims of patent rights covering the composition of matter of any such antibody and (b) the expiration of regulatory exclusivity for such Product in such country.

The Collaboration Agreement will expire upon the expiration of the last to expire royalty payment obligation with respect to all Products in all countries, subject to earlier expiration if all option exercise periods for all VTPs expire without AbbVie exercising any option, if AbbVie does not elect to make certain platform access payments at specified points during the research term, or upon the uncured material breach or any insolvency event of either party. AbbVie may also terminate the Collaboration Agreement for convenience upon a specified period prior written notice, or upon the Company's breach of representations and warranties with respect to debarment or compliance with anti-bribery and anti-corruption laws.

The Company assessed the Collaboration Agreement under ASC 808 and ASC 606 and concluded that it represents a contract with a customer. The Company applied the relevant guidance of ASC 606 to evaluate the accounting under the Collaboration Agreement and identified one performance obligation under the arrangement: a promise to provide research and development services to AbbVie, or R&D Services. The Company evaluated the options to continue the R&D services and options to purchase licenses to each VTP and concluded that these options did not represent material rights.

The Company determined the initial transaction price of the single performance obligation to be $30.0 million, as the variable consideration for additional R&D services, option exercise payments, and development milestone payments are all subject to constraint at contract inception. At each reporting period, the Company will reevaluate the variable consideration subject to constraint and, if necessary, will adjust its estimate of the overall transaction price. For the sales-based royalties, the Company will recognize revenue when the related sales occur.

Collaboration revenue from the single performance obligation will be recognized over the estimated performance of the R&D services using the cost-to-cost input method which the Company believes best depicts the transfer of control to the customer. Under the cost-to-cost input method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the performance obligation. The Company recognized $14.0 million of collaboration revenue for the year ended December 31, 2023.

The following table summarizes the change in deferred revenue (in thousands):

	Year Ended December 31, 2023
Balance at the beginning of the period	$ —
Deferral of revenue	30,000
Recognition of unearned revenue	(14,018)
Balance at the end of the period	$ 15,982

As of December 31, 2023, the Company expects to recognize the deferred revenue associated with the non-refundable upfront fee over the estimated remaining research and development period of approximately 1.5 years.

5. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
(in thousands)	2023	2022
Short-term deposits	$ 4,009	$ —
Prepaid subscriptions and prepaid service contracts	718	876
Tax credit receivable	—	847
Research and development advance payments	336	445
Prepaid insurance	950	158
Interest income receivable	289	—
Other	259	—
	$ 6,561	$ 2,326

6. Property and equipment, net

Property and equipment consisted of the following:

	December 31,	
(in thousands)	2023	2022
Lab equipment	$ 5,386	$ 3,681
Leasehold improvements	233	194
Computer equipment	326	235
Office equipment and furniture and fixtures	36	22
	5,981	4,132
Less accumulated depreciation and amortization	(3,908)	(3,451)
Property and equipment, net	$ 2,073	$ 681

Depreciation and amortization expense was $0.5 million and $0.4 million for the years ended December 31, 2023 and 2022, respectively.

7. Government assistance programs

DoD expense reimbursement contract

In July 2020, the Company entered into the OTA Agreement with the U.S. Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, or JPEO-CBRND, in collaboration with the Defense Health Agency, to fund the Company's efforts in developing an antibody cocktail therapeutic to treat COVID-19. The amount of funding originally made available to the Company under the OTA Agreement was $13.3 million. In May 2021, the Company and the DoD amended the OTA Agreement, pursuant to which the DoD award was increased from $13.3 million to $17.6 million. In January 2023, the Company and the DoD modified the OTA Agreement to extend the termination date of the agreement to July 2023, at no additional cost to the government. The Company's obligations under the OTA agreement with the DoD were completed.

Under the OTA Agreement, the DoD is required to pay the Company, upon submission of invoices for approved budgeted supplies delivered and services rendered in carrying out the prototype project, within 30 calendar days of receipt of request for payment. The Company received the maximum $17.6 million in expense reimbursement from the DoD under the OTA Agreement from inception through 2022.

The Company recorded contra-research and development expense of $0.6 million for the year ended December 31, 2022, in the consolidated statements of operations and comprehensive loss. No contra-research and development expense related to the OTA Agreement was recorded during the year ended December 31, 2023.

8. Accrued expenses and other liabilities

Accrued expenses and other liabilities consisted of the following:

	December 31,	
(in thousands)	2023	2022
Research and development	$ 1,680	$ 2,261
Compensation and related benefits	2,734	1,874
Severance accruals	1,436	—
Professional fees	1,670	481
Short-term operating lease liability	310	229
Other	195	86
	$ 8,025	$ 4,931

9. Commitments and contingencies

Employment agreements

The Company entered into employment agreements, or the Employment Agreements, with certain key personnel providing for compensation and severance in certain circumstances, as defined in the respective Employment Agreements. The Employment Agreements may be terminated by either the Company or the employees in accordance with the respective Employment Agreements (subject to the payment of severance upon certain terminations) and provide for annual pay adjustments and bonuses at the discretion of the Board of Directors.

Employee benefit plan

The Company maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code, or the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company assumes all administrative costs of the 401(k) Plan and makes matching contributions as defined in the 401(k) Plan document. The Company made matching contributions of $0.2 million to the 401(k) Plan for the years ended December 31, 2023 and 2022, respectively.

10. Licensing arrangements

License Agreement with Purdue Research Foundation

Upon closing of the merger with Morphimmune, the Company assumed certain license agreements that Morphimmune had entered into prior to the Merger. In January 2022, Morphimmune entered into a Master License Agreement, or the Purdue License Agreement, with Purdue Research Foundation, or PRF. Under the Purdue License Agreement, PRF granted Morphimmune a royalty-bearing, transferable, worldwide, exclusive license, sublicensable through multiple tiers, under certain intellectual property owned by PRF to research, develop, manufacture, and commercialize the licensed products in all fields of use with limited exceptions.

Under the Purdue License Agreement, Morphimmune paid PRF a one-time upfront payment of $0.2 million upon execution and $0.1 million on each of the first and second anniversary of the effective date of the Purdue License Agreement. During the period commencing on the date of first commercial sale of a licensed product and ending upon the date of expiration of the last valid claim of the licensed patents covering such licensed product in a country, referred to as the royalty term, the Company will pay PRF an earned unit royalty of a low single-digit percentage on gross receipts from sale of the licensed product, and beginning with the first sale of a licensed product, a tiered minimum annual royalty from the low to mid six-digit figure range less the unit royalties due for the annual period. Upon the achievement of specified development and commercialization milestones, Morphimmune will pay PRF the milestone payments as specified in the Purdue License Agreement, which may be up to $3.8 million in the aggregate. The Company is also required to pay PRF an annual maintenance fee ranging from a low five-digit figure to a low six-digit figure prior to first sale of a licensed product and a low double-digit percentage of sublicense income received for sublicenses of licensed intellectual property, the percentage depending upon the timing of execution of the sublicense.

The Purdue License Agreement expires on a licensed product-by-licensed product and country-by-country basis, upon expiration of the royalty term for such licensed product for the applicable country. The Company may terminate the Purdue License Agreement upon at least one month's prior written notice to PRF. PRF may terminate the Purdue License Agreement and the licenses granted thereunder if the Company fails to cure a payment default or other material breach of the Purdue License Agreement after written notice from PRF, or if Morphimmune becomes insolvent.

2023 Amendment to Exclusive License Agreement

In June 2019, the Company entered into an exclusive license agreement, or the Arrayjet Agreement, with Arrayjet Limited, or Arrayjet, amended on July 10, 2020, December 30, 2022 and December 24, 2023. Immunome and Arrayjet terminated the Arrayjet Agreement pursuant to the December 2023 amendment.

2021 Patent License Agreement

In June 2021, the Company entered into an exclusive worldwide patent license agreement with several Philadelphia based universities and hospitals, or the Licensors, to further discover, develop and commercialize human antibodies, identified using Immunome's human hybridoma technology, for the treatment of diseases associated with the formation of bacterial biofilms. The Licensors are eligible to receive up to $2.2 million in the aggregate for certain regulatory, developmental, and commercial milestone payments. In addition, the Licensors are eligible to receive low single digit royalty rates for net product sales, which are subject to adjustment in the event the Company sublicenses the approved technology.

The Company recorded $0.1 million and $0.1 million in initiation and minimum annual payments related to this agreement for the years ended December 31, 2023 and 2022, respectively, in research and development expenses in the statement of operations and comprehensive loss.

Effective December 12, 2023, the Patent License Agreement was terminated, and the Company has no remaining obligations under this agreement.

Other License Agreements

The Company has entered into various other license agreements to further discover, develop and commercialize certain technologies and treatments. As of December 31, 2023, the Company may need to pay developmental and regulatory milestone payments of up to approximately $2.9 million. In addition, the Company may need to pay royalty rates on net product sales, a portion of certain sublicense and collaboration payments, and certain commercial milestone payments of up to approximately $2.8 million, if any.

The Company recorded $0.1 million in development and regulatory milestone payments during the year ended December 31, 2022 in research and development expenses in the consolidated statements of operations and comprehensive loss. There was no similar expense for the year ended December 31, 2023.

Whitehead Letter Agreement

On November 17, 2022, the Company entered into a Letter Agreement, or the Letter Agreement, with the Whitehead Institute of Biomedical Research, or Whitehead, which became effective on January 4, 2023 upon the satisfaction of the conditions described therein. The Letter Agreement supplements the Exclusive Patent License Agreement entered into between the Company and Whitehead on June 25, 2009 (as amended on December 17, 2009, March 21, 2013, August 21, 2017 and July 21, 2020, the License Agreement), which has since expired. Pursuant to the Letter Agreement, Whitehead and the Company agreed that certain payments received by the Company from the Collaborator (as defined in the Letter Agreement) (i.e., a corporate partner, as defined in the License Agreement) would be excluded from the Company's payment obligations to Whitehead. The Company and Whitehead further agreed, among other things, that the Company will make certain payments to Whitehead (i) as Net Sales (as defined in the License Agreement) as long as the Company receives those payments from the Collaborator on a specified number of products purchased by the Collaborator and (ii) upon the achievement of certain milestones whether by the Company or the Collaborator.

11. Leases

The Company currently leases approximately 11,000 square feet of office and laboratory space in Exton, Pennsylvania under a lease that expires on March 31, 2025. The Company currently leases approximately 14,000 square feet of office and laboratory space in Bothell, Washington, under a lease that expires on October 31, 2028. Supplemental balance sheet information related to leases as of December 31, 2023 and 2022 are as follows (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Operating leases:		
Operating lease right-of-use assets	$ 1,564	$ 284
Operating lease liability, current portion	$ 310	$ 229
Operating lease liability, net of current portion	1,340	62
Total operating lease liability	$ 1,650	$ 291

Operating lease liability and operating lease liability, net of current portion is included in accrued expenses and other current liabilities and other long-term liabilities, respectively, in the accompanying consolidated balance sheets.

Operating lease expense recorded as research and development and general and administrative expenses in the consolidated statements of operations and comprehensive loss is as follows (in thousands):

Operating lease cost (in thousands)	Year Ended December 31, 2023	Year Ended December 31, 2022
General and administrative	$ 161	$ 78
Research and development	164	163
Total lease expense	$ 325	$ 241

Short term lease expense recorded as research and development expense in the consolidated statements of operations and comprehensive loss was $0.2 million and $0.1 million for years ended December 31, 2023 and 2022, respectively.

Other information related to the operating leases where the Company is the lessee was as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Weighted-average remaining lease term (in years)	4.81	1.25
Weighted-average discount rate	8.3%	9.0%

Supplemental cash flow information related to the operating leases was as follows (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash paid for operating lease liability	$ 246	$ 234

As of December 31, 2023, minimum rental commitments under the operating leases were as follows (in thousands):

Years ending December 31,	Amount
2024	$ 451
2025	464
2026	412
2027	422
2028	433
Total lease payments	2,182
Less imputed interest	(532)
Present value of lease liability	$ 1,650

12. Common stock

Common stock

The holders of common stock are entitled to one vote for each share of common stock. Subject to the approval of the majority of shareholders, the holders of common stock shall be entitled to receive dividends out of funds legally available. In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, the holders of common stock shall be entitled to share ratably in the remaining assets of the Company available for distribution.

In June 2023, in connection with the Merger Agreement, the Company entered into subscription agreements with certain investors pursuant to which the Company sold 21,690,871 shares of its common stock, immediately following the completion of the Merger, in exchange for gross proceeds of $125.0 million. The Company also incurred $9.0 million of offering costs which were netted against the proceeds in the consolidated balance sheet.

On January 15, 2023, the Company issued 55,250 shares of common stock in the aggregate to certain non-employee board of directors pursuant to the 2020 Equity Incentive Plan in lieu of the non-employee director board and committee cash retainers owed for service on the board of directors in 2022.

On October 1, 2021, the Company entered into the ATM Agreement with Jefferies Group LLC, which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, the Company may elect, from time to time, to offer and sell shares of common stock under the registration statement having an aggregate offering price of up to $75.0 million through Jefferies Group LLC acting as sales agent. The Company filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 14, 2021, pursuant to which the Company may issue from time-to-time securities with an aggregate value of up to $200.0 million. In January 2023, the Company sold 5,925 shares of common stock under the ATM Agreement resulting in net proceeds of approximately $34,000. In November 2023, the Company terminated the ATM Agreement.

Warrants to acquire shares of common stock

On September 2, 2022, the Company notified holders of the Company's Series B Warrants, or the Holders, of the Company's agreement to permit Holders to exercise the Series B Warrants at an exercise price of $10.00 per share (reduced from the previous exercise price of $45.00 per share) at any time prior to the expiration date of the Series B Warrants. The Company recognized a deemed dividend of $0.6 million, which represents the incremental fair value of the outstanding warrants as a result of the modification. This deemed dividend is recorded in the Company's consolidated statement of operations and comprehensive loss as an increase to the net loss attributable to common stockholders for purposes of computing net loss per share, basic and diluted. The net impact to the consolidated statements of changes in stockholders' equity was zero because the warrants were equity classified before and after the modification.

At December 31, 2023 common stock warrants outstanding were as follows:

Warrants	Warrants Outstanding	Exercise Price per Share	Expiration Date
Series B	500,000	$ 10.00	April 28, 2024

For the years ended December 31, 2023 and 2022, no warrants were exercised.

13. Share-based compensation

On September 18, 2020, the Company adopted the 2020 Equity Incentive Plan, or the 2020 Plan, which supersedes all prior equity incentive plans. Under the 2020 Plan, the number of shares of common stock reserved for issuance under the 2020 Plan will automatically increase on January 1 of each year, beginning on January 1, 2021 and continuing through and including January 1, 2030, by 4% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's Board of Directors. On January 1, 2023, the number of shares available for future issuance under the 2020 Plan increased by 485,153 shares. Through a board resolution related to the Merger, the number of shares available for future issuance under the 2020 Plan increased by 2,955,280 shares on September 29, 2023. As of December 31, 2023, there were 3,320,601 shares available for future issuance under the 2020 Plan. On January 1, 2024, the number of shares available for future issuance under the 2020 Plan increased by 1,730,071.

The Company also adopted the 2020 Employee Stock Purchase Plan, or the ESPP, on September 18, 2020 which provides for the grant of purchase rights to purchase shares of the Company's common stock to eligible employees, as defined by the ESPP. The maximum number of shares of common stock that may be issued under the ESPP will not exceed 125,000 shares of common stock, plus the number of shares of common stock that are automatically added on January 1 of each calendar year for a period of up to ten years, commencing on the first January 1 following the year in which an IPO occurs and ending on, and including, January 1, 2030, in an amount equal to the lesser of (i) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, and (ii) 1,000,000 shares of common stock. On January 1, 2023, the number of shares available for future issuance under the ESPP

increased by 121,288 shares. As of December 31, 2023, there were 473,733 shares available under the ESPP. No shares of common stock have been issued under the ESPP as of December 31, 2023. On January 1, 2024, the number of shares available for future issuance under the ESPP increased by 432,518.

The 2020 Plan and the ESPP are administered by the Board of Directors subject to the Board's right to delegate to a committee. The exercise prices, vesting and other restrictions are determined at the discretion of the Board of Directors. Stock options awarded under the 2020 Plan generally expire 10 years after the grant date unless the Board of Directors sets a shorter term. Vesting periods for awards under the 2020 Plan are determined at the discretion of the Board of Directors. Stock options granted to employees, officers, members of the Board of Directors and consultants of the Company typically vest over one to four years. Certain options provide for accelerated vesting if there is a change in control, as defined in the 2020 Plan.

On October 2, 2023, the Morphimmune Plan was assumed by the Company in conjunction with the Merger (Note 3). There were 929,702 shares available for issuance under the Morphimmune Plan as of December 31, 2023.

Stock Options Granted for New Chief Executive Officer

On June 28, 2023 and contingent upon completion of the Merger, the Company entered into an employment agreement with Dr. Clay Siegall, the President and CEO of Morphimmune whereby Dr. Siegall was granted 2,137,080 options to purchase shares of the Company's common stock at an initial exercise price of $5.91 per share, or the inducement grant. The options vest over time during Dr. Siegall's continued employment, which commenced on October 2, 2023 in connection with the closing of the Merger, to which 25% of the options granted will vest after one year of employment with the Company and the remaining 75% of the options granted will vest monthly over the remaining 36 months following the one year anniversary. Dr. Siegall's stock option is subject to acceleration if he resigns for "good reason" or the Company terminates his employment without "cause" within a "change of control period" (each as defined in Dr. Siegall's employment agreement). The estimated grant date fair value of Dr. Siegall's award was $14.2 million or $6.65 per share. The inducement grant, 2020 Morphimmune Plan, and the 2020 Plan are collectively known as the "Plans".

Share-based compensation expense recorded as research and development and general and administrative expenses in the consolidated statements of operations and comprehensive loss is as follows (in thousands):

	Year Ended December 31,	
In thousands)	2023	2022
General and administrative	$ 4,242	$ 3,471
Research and development	1,981	1,861
	$ 6,223	$ 5,332

Unrecognized compensation cost related to unvested options was $22.8 million as of December 31, 2023 and will be recognized over an estimated weighted average period of 1.9 years.

Stock options

The weighted average assumptions used in the Black-Scholes option-pricing model for stock options granted were:

	Year ended December 31,	
	2023	2022
Expected volatility	92.1 %	85.6 %
Risk-free interest rate	4.6 %	2.7 %
Expected term (in years)	5.6	6.0
Expected dividend yield	—	—
Fair value of common stock	$ 7.92	$ 3.63

A summary of option activity under the Plans during the year ended December 31, 2023 is as follows:

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)
Outstanding at January 1, 2023	2,519,405	9.60	
Replacement options issued at asset acquisition	2,472,563	1.29	
Granted	4,007,552	6.42	
Forfeited	(314,319)	6.67	
Expired	(55,670)	16.59	
Exercised	(651,240)	1.57	
Outstanding at December 31, 2023	7,978,291	6.15	8.62
Exercisable at December 31, 2023	3,151,799	5.86	7.54

The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2023 and 2022 was $6.09 and $2.65, respectively. The weighted-average grant date fair value per share of the replacement awards issued to Morphimmune stockholders on October 2, 2023 was $7.55. The aggregate intrinsic value for options exercised during the years ended December 31, 2023 and December 31, 2022 was $5.9 million and $0.2 million, respectively. The aggregate intrinsic value for options exercisable at December 31, 2023 was $21.9 million. The aggregate intrinsic value of stock options outstanding at December 31, 2023 was $45.4 million.

Accelerated Vesting Due to Termination

Effective October 2, 2023, in accordance with the Merger, the former CEO's employment with the Company was terminated. Based on the terms of his severance agreement, any options that were scheduled to vest through October 2, 2025 were accelerated to vest at termination with an exercise window of 3-months after termination. The Company accounted for the change in vesting terms as an improbable-to-probable modification of his stock options and recognized $0.7 million of expense in relation to this modification.

14. Income taxes

A reconciliation of the federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31,	
	2023	2022
Federal tax benefit at statutory rate	21.0 %	21.0 %
State tax, net of federal benefit	(1.3)	4.3
Effects of state tax legislation, net of federal benefit	—	(7.1)
Research and development credits	0.7	1.9
Permanent differences	(0.9)	(0.2)
Write-off of IPR&D	(15.9)	—
Change in valuation allowance	(3.6)	(19.9)
	— %	— %

The components of the Company's deferred taxes are as follows (in thousands):

	December 31,	
(in thousands)	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 22,784	$ 20,523
Research and development intangibles	10,135	4,839
Research and development credits	3,782	2,878
Share-based compensation	2,533	2,016
Accrued bonus	546	383
Lease liability	350	—
Other	75	1
Gross deferred tax assets	40,205	30,640
Less: valuation allowance	(39,827)	(30,609)
Net deferred tax asset	378	31
Deferred tax liability		
Depreciation	(46)	(31)
Right-of-use asset	(332)	—
Total deferred tax liabilities	(378)	(31)
Net deferred taxes	$ —	$ —

The Company had no income tax expense due to the operating losses utilization for the year ended December 31, 2023 and 2022. Management has evaluated the positive and negative evidence bearing upon the realizability of the Company's net deferred tax assets and has determined that it is more likely than not that the Company will not recognize the benefits of the net deferred tax assets. As a result, the Company has recorded a full valuation allowance at December 31, 2023 and 2022. The valuation allowance increased by $9.2 million and $7.4 million in 2023 and 2022, respectively, due to the acquisition of Morphimmune, increase in net operating loss carryforwards and research and development tax credits, and deductible accrued expenses.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss and other attributes including research and development credit carry forwards which could be used annually to offset future taxable income. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership

changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. Based upon a preliminary evaluation of ownership changes through December 31, 2023, the Company believes that an ownership change likely occurred as a result of the Morphimmune transaction on October 2, 2023 that could limit the Company's ability to utilize its net operating loss or research and development credit carryforwards. The evaluation has not been finalized as of the date of these consolidated financial statements.

As of December 31, 2023, the Company had $92.6 million of federal and $84.3 million of state net operating loss carryforwards. If not utilized, the federal and state net operating loss carryforwards expire starting in 2027. Included in the federal net operating loss carryforwards are $75.6 million of net operating losses generated from 2018 to 2023 that will not expire and are limited to offset 80% of the Company's taxable income for years beginning after December 31, 2020. Certain federal and state net operating loss carryforwards expire at various dates through 2042. As of December 31, 2023, the Company had cumulative $3.5 million of federal and $0.2 million of state R&D tax credits. These tax credit carryforwards will expire at various dates through 2042.

As of December 31, 2023 and 2022, the Company has $37,000 of uncertain tax positions on the research and development credits from Morphimmune. The Company recognizes both interest and penalties associated with unrecognized tax benefits as a component of income tax expense. The Company has not recorded any interest or penalties for unrecognized tax benefits since its inception.

The Company filed income tax returns in the United States and Pennsylvania in all tax years since inception. The tax years 2006 and beyond remain open to examination by these jurisdictions. Carryforward attributes generated in all years since inception remain subject to adjustment. The Company is not currently under examination by the Internal Revenue Service or any other jurisdiction for these years.

15. Subsequent events

Zentalis Pharmaceuticals, Inc. License Agreement

On January 5, 2024, the Company entered into a license agreement with Zentalis Pharmaceuticals, Inc., or the Zentalis License, pursuant to which the Company received an exclusive, worldwide, royalty-bearing, sublicensable license under certain intellectual property relating to Zentalis' proprietary antibody-drug conjugate, or ADC, platform technology, ROR1 antibodies and ADCs targeting ROR1 to exploit products covered by or incorporating the licensed intellectual property rights. Under the Zentalis License, the Company is required to use commercially reasonable efforts to develop an ADC targeting ROR1, two additional ADCs, and commercialize any product that has received regulatory approval.

Under the Zentalis Agreement, the Company paid to Zentalis upfront consideration totaling $15 million in cash and $20 million in shares of Company common stock, with the shares valued at the trailing 30-day volume-weighted average price. The Company is obligated to pay Zentalis up to $150 million in development and regulatory milestones for the first product containing an ADC targeting ROR1, or a ROR1 ADC Product, to achieve such milestones and commercial milestones on ROR1 ADC Products. The Company is also obligated to pay to Zentalis mid-to-high single digit royalties on ROR1 ADC Products. In addition, the Company is obligated to pay Zentalis $25 million in development and regulatory milestones for the first product from each of the first five additional development programs using the licensed platform technology to generate products, and mid-single digit royalties on products from each such program. The Company's royalty payment obligation will commence, on a product-by-product and country-by-country basis, on the first commercial sale of such product in such country and will expire on the latest of (a) the ten (10)-year anniversary of such first commercial sale for such product in such country, (b) the expiration of regulatory exclusivity for such product in such country, and (c) the expiration of the last-to-expire valid claim of a licensed patent covering such product in such country.

The Zentalis License will continue until the expiration of all royalty payment obligations. The Zentalis License may be terminated early by (a) either party in its entirety upon (i) the other party's uncured material breach, subject to a notice and cure period, (ii) any insolvency event of the other party or (iii) prolonged force majeure, (b) the Company, either in its entirety or in part, for convenience upon a specified period prior written notice, or (c) Zentalis (i) in its entirety if the Company challenges one of the licensed patents or (ii) fails to meet certain development activity benchmarks within specified time periods.

Asset Purchase Agreement

On February 5, 2024, the Company and Ayala Pharmaceuticals, Inc., or Ayala, entered into an Asset Purchase Agreement, or the Ayala Purchase Agreement, pursuant to which the Company will acquire Ayala's AL101 and AL102 programs and assume certain of Ayala's liabilities associated with the acquired assets, or the Ayala Asset Purchase. On March 25, 2024, the Company consummated the Ayala Asset Purchase, or the Ayala Closing. At the Ayala Closing, the Company (i) paid Ayala $20.0 million, less certain adjustments, (ii) issued Ayala 2,175,489 shares of Company common stock, or the Ayala Shares, with the shares valued at the trailing 30-day volume-weighted average price and (iii) assumed specified liabilities. The Company is obligated to pay Ayala up to $37.5 million in development and commercial milestones.

Follow-On Public Offering

On February 16, 2024, the Company completed a public offering of 11,500,000 shares of the Company's common stock at a price of $20.00 per share. The gross proceeds to the Company from the offering were $230.0 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

Atreca

On December 22, 2023, the Company announced that it had reached agreement with Atreca, Inc., or Atreca, on the terms of a cash acquisition pursuant to which the Company would acquire certain antibody-related assets and materials for an upfront payment of $5.5 million and up to $7.0 million in clinical development milestones. The closing of the transaction is subject to customary conditions, including the approval of Atreca's stockholders.

EXHIBIT INDEX

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, by and among the registrant, Ibiza Merger Sub, Inc. and Morphimmune Inc., dated as of June 29, 2023 (Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on June 29, 2023).
2.2	Asset Purchase Agreement, by and between the registrant and Ayala Pharmaceuticals, Inc., dated February 5, 2024 (incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on February 6, 2024).
3.1	Amended and Restated Certificate of Incorporation of Immunome, Inc. (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed October 6, 2020).
3.2	Certificate of Amendment, dated October 2, 2023, to the Amended and Restated Certificate of Incorporation of Immunome, Inc. to implement Officer Exculpation (Filed as Exhibit 3.3 to the Registrant's Current Report on Form 8-K filed with the SEC on October 4, 2023 and incorporated herein by reference).
3.3	Certificate of Amendment, dated October 2, 2023, to the Amended and Restated Certificate of Incorporation of Immunome, Inc. to implement the Authorized Share Increase (Filed as Exhibit 3.4 to the registrant's Current Report on Form 8-K filed with the SEC on October 4, 2023 and incorporated herein by reference).
3.4	Amended and Restated Bylaws of Immunome, Inc. (incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed October 6, 2020).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020).
4.2	Form of Series B Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on April 26, 2021).
4.3	Description of Securities (incorporated by reference to Exhibit 4.6 to our Annual Report on Form 10-K filed on March 16, 2023).
4.4	Stock Issuance Agreement, dated January 5, 2024, by and between the Registrant and Zentalis Pharmaceuticals, Inc. (Filed as Exhibit 4.3 to the Registrant's Registration Statement on Form S-3 filed with the SEC on February 13, 2024 and incorporated herein by reference).
4.5	Form of Subscription Agreement, dated June 29, 2023 (Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on June 29, 2023).
10.1	Form of Indemnification Agreement between the registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.2#	Amended and Restated 2008 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.3#	Form of Incentive Stock Option and Option Agreement for the Amended and Restated 2008 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 to our Registration Statement on Form S-1 filed on September 9, 2020).

10.4#	Amended and Restated 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.4 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.5#	Form of Incentive Stock Option and Option Agreement for the Amended and Restated 2018 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.5 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.6#	2020 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on November 9, 2023)
10.7#	Forms of Stock Option Grant Notice, Option Agreement, RSU Award Grant Notice and Notice of Exercise for the 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020).
10.8#	2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to our Registration Statement on Form S-1/A filed on September 24, 2020).
10.9#	Morphimmune Inc. 2020 Equity Incentive Plan (incorporated by reference from Exhibit 10.44 to the Registrant's Registration Statement on Form S-4/A (File No. 333-273792) filed with the SEC on August 28, 2023).
10.10#	Forms of Restricted Stock Purchase Agreement, Stock Option Agreement and Early Exercise Stock Purchase Agreement under the Morphimmune Inc. 2020 Equity Incentive Plan (incorporated by reference from Exhibit 10.45 to the Registrant's Registration Statement on Form S-4/A (File No. 333-273792) filed with the SEC on August 28, 2023).
10.11†	Exclusive Patent License Agreement by and between the registrant and the Massachusetts Institute of Technology as licensing agent for Whitehead Institute for Biomedical Research, dated June 25, 2009, as amended by the First Amendment to the Exclusive Patent License Agreement dated December 17, 2009, by the Second Amendment to the Exclusive Patent License Agreement Dated March 21, 2013, by the Third Amendment to the Exclusive Patent License Agreement dated August 21, 2017 and by the Fourth Amendment to the Exclusive Patent License Agreement dated July 21, 2020 (incorporated by reference to Exhibit 10.15 to our Registration Statement on Form S-1 filed on September 9, 2020).
10.12†	Letter Agreement by and between the registrant and the Whitehead Institute for Biomedical Research, dated November 17, 2022. (incorporated by reference to Exhibit 10.12 to our Annual Report on Form 10-K filed on March 16, 2023).
10.13#	Inducement Non-Qualified Stock Option Agreement, dated June 28, 2023, by and between the Registrant and Clay B. Siegall, Ph.D. (Filed as Exhibit 99.4 to the Registrant's Registration Statement on Form S-8 filed on February 2, 2024 and incorporated herein by reference).
10.15#	Executive Employment Agreement dated June 28, 2023, by and between the Registrant and Clay B. Siegall, Ph.D. (Filed as Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on June 29, 2023 and incorporated herein by reference).
10.16#*	Amendment No. 1 to Executive Employment Agreement dated December 1, 2023, by and between the Registrant and Clay B. Siegall, Ph.D.
10.17#*	Amended and Restated Employment Offer Terms dated November 30, 2023, by and between the Registrant and Sandra G. Stoneman.

10.18#*	Amended and Restated Employment Offer Terms dated December 21, 2023, by and between the Registrant and Bruce Turner, M.D., Ph.D.
10.19#*	Amended and Restated Employment Offer Terms dated November 30, 2023, by and between the Registrant and Max Rosett.
10.20#*	Amended and Restated Employment Offer Terms dated November 30, 2023, by and between the Registrant and Jack Higgins, Ph.D.
10.21#*	Amended and Restated Employment Offer Terms dated November 30, 2023, by and between the Registrant and Robert Lechleider, M.D.
10.22#*	Employment Offer dated November 30, 2023, by and between the Registrant and Philip Roberts.
10.23#*	Employment Offer Letter dated February 7, 2024, by and between the Registrant and Kinney Horn.
10.24	Securities Purchase Agreement by and among the Registrant and the Purchasers signatory thereto, dated April 26, 2021 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 26, 2021).
10.26#	Third Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed November 9, 2023) .
10.27	Letter to Holders of Series B Warrants to Purchase Shares of Common Stock (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 2, 2022).
10.28†	Collaboration and Option Agreement by and between the registrant and AbbVie Global Enterprises Ltd., dated January 4, 2023 (incorporated by reference to Exhibit 10.29 to our Annual Report on Form 10-K filed on March 16, 2023).
10.30*†	License Agreement, by and between the registrant and Zentalis Pharmaceuticals, Inc., dated January 5, 2024.
10.31†	Master License Agreement, by and between Morphimmune Inc. and Purdue Research Foundation, dated as of January 19, 2021, as modified pursuant to that certain email by Max Rosett to representatives of Purdue University dated March 15, 2023 (incorporated by reference to Exhibit 10.43 to our Registration Statement on Form S-4 filed on August 8, 2023).
10.32*	Separation Agreement effective October 2, 2023, by and between the Registrant and Dennis Giesing.
10.33*	Consulting Agreement dated October 2, 2023, by and between the Registrant and Dennis Giesing.
10.34*	Separation Agreement effective October 3, 2023, by and between the Registrant and Purnanand D. Sarma, Ph.D.
10.35	Separation Agreement dated December 21, 2023, by and between the Registrant and Corleen Roche (Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 29, 2023)
10.36	Consulting Agreement effective January 2, 2024, by and between the Registrant and Corleen Roche (Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 29, 2023).
10.37*	Asset Purchase Agreement dated December 22, 2023, by and between the Registrant and Atreca, Inc.
10.38#*	Employment Offer dated April 26, 2021, by and between the Registrant and Bob Lapetina.

10.39* †	License Agreement dated November 29, 2017, by and between the Registrant (as assignee) and Bristol-Myers Squibb Company, as amended. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on March 26, 2024).
21.1*	List of Subsidiaries.
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*+	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97	Incentive Compensation Recoupment Policy.
101*	The following financial information from the Annual Report on Form 10 K of IMMUNOME, INC. for the year ended December 31, 2023, formatted in Inline XBRL (eXtensible Business Reporting Language): (1) Balance Sheets as of December 31, 2023 and 2022; (2) Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022; (3) Statements of Changes in Stockholders' Equity for the years ended December 31, 2023 and 2022; (4) Statements of Cash Flows for the years ended December 31, 2023 and 2022; and (5) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

* Filed or furnished herewith.

\# Management contracts or compensatory plans or arrangements

† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to Immunome, Inc. if publicly disclosed.

\+ The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 28, 2024.

IMMUNOME, INC.

By: /s/ Clay B. Siegall Ph.D.
Name: Clay B. Siegall, Ph.D.
Title: President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Clay B. Siegall, Ph.D. and Max Rosett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him in his name, place and stead, in any and all capacities, to sign this report, and file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Clay B. Siegall Ph.D. Clay B. Siegall Ph.D.	President, Chief Executive Officer and Director (*Principal Executive Officer*)	March 28, 2024
/s/ Max Rosett Max Rosett	EVP, Operations and Interim Chief Financial Officer (*Principal Financial Officer*)	March 28, 2024
/S/ Bob Lapetina Bob Lapetina	VP, Finance and Corporate Controller (*Principal Accounting Officer*)	March 28, 2024
/s/ Isaac Barchas, J.D Isaac Barchas, J.D	Director	March 28, 2024
/s/ Jean-Jacques Bienaime Jean-Jacques Bienaime	Director	March 28, 2024
/s/ James Boylan James Boylan.	Director	March 28, 2024
/s/ Carol Schafer Carol Schafer	Director	March 28, 2024
/s/ Philip Wagenheim Philip Wagenheim	Director	March 28, 2024

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