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, 2024

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: (425) 939-7410

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	☐	Non-accelerated filer	☒	Smaller reporting company	☒
Accelerated filer	☐			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 $642.7 million based on the closing price reported by NASDAQ on June 28, 2024 (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 all executive officers and directors and their affiliates.

The number of outstanding shares of the registrant's common stock as of March 14, 2025 was 86,950,655.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement on Schedule 14A for the 2025 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, 2024, 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," "ongoing," "plan," "predict," "project," "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 these medicines. We caution you that the foregoing may not encompass all 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 these statements, this 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 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. 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. Information that is based on data, estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and involve a number of assumptions and limitations, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Accordingly, you are cautioned not to give undue weight to such information. While we believe such information is reliable, there can be no assurance as to the accuracy or completeness of the indicated information.

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" in Part I of this Annual Report 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:

- 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 a limited operating history, which may make it difficult to evaluate our drug development capabilities and predict our future performance.
- We have not yet demonstrated successful completion of clinical development, submitted a New Drug Application, or NDA, or Biologics License Application, or BLA, obtained U.S. Food & Drug Administration, or FDA, approval for marketing, or successfully commercialized a product, and we may be unable to do so. Furthermore, varegacestat, which we recently acquired, is currently in Phase 3 clinical development, but such acquisition and prior clinical success is not indicative of our ability to obtain NDA approval or successfully commercialize varegacestat.
- We may be unable to advance any of our product candidates into and through clinical development, obtain regulatory approvals and ultimately commercialize them, or we could experience significant delays in doing so.
- We may not be successful in our efforts to use and expand our ADC platform to build and progress a pipeline.
- We may pursue particular programs or product 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 future strategic transactions.
- As a targeted radioligand therapy, our IM-3050 program may face additional and potentially unpredictable challenges.
- 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 and generally could be impacted by other factors beyond our reasonable control.
- If we encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We may experience delays in completion of our clinical trials based on study design.
- 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 we or others identify undesirable side effects caused by a product candidate undergoing clinical trials, our ability to market and derive revenue from the product candidate could be compromised.

- If third parties on which we rely to conduct our current and future preclinical and clinical studies 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.

- Because we 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.

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

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

- Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan. In addition, prior successes of our personnel may not be indicative of our future success.

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

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

PART I

Item 1. Business

General

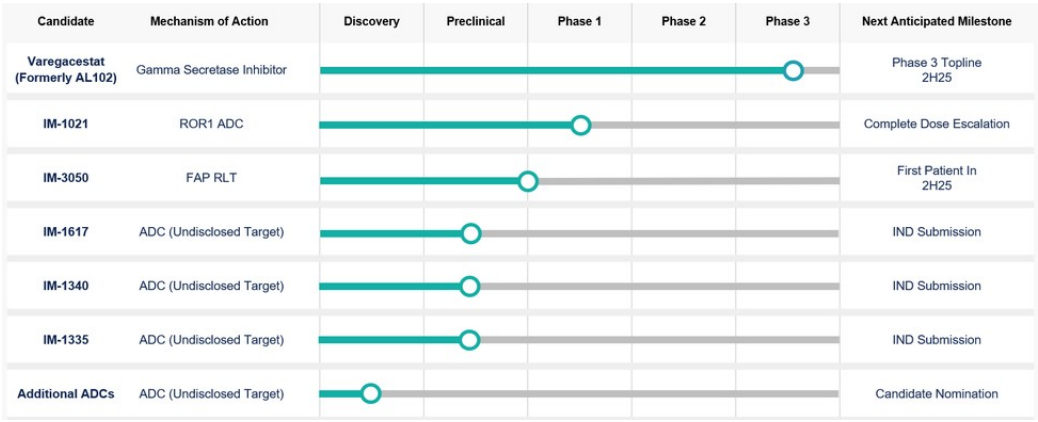
We are a clinical-stage targeted oncology company committed to developing targeted therapies designed to improve outcomes for cancer patients. We are advancing an innovative portfolio of therapeutics, drawing on leadership that previously played key roles in the design, development, and commercialization of cutting-edge targeted cancer therapies, including antibody-drug conjugate therapies, or ADCs. We believe that the pursuit of novel or underexplored targets will be central to the next generation of transformative therapies, and we are dedicated to developing targeted cancer therapies with first-in-class and best-in-class potential. Our goal is to establish a broad pipeline of preclinical and clinical assets and develop these assets into approved products for commercialization.

We are advancing a pipeline comprising two clinical assets and four preclinical assets. Varegacestat, formerly AL102, is an investigational gamma secretase inhibitor, or GSI, currently under evaluation in a Phase 3 clinical trial for the treatment of desmoid tumors. Our investigational new drug application, or IND, for IM-1021, a receptor tyrosine kinase-like orphan receptor 1, or ROR1, antibody-drug conjugate, received FDA clearance in December 2024, and the Phase 1 trial is ongoing with the first patient dosed in February 2025. Our other preclinical assets include IM-3050, a fibroblast activation protein, or FAP, targeted radioligand therapy, or RLT, for which we submitted an IND in March 2025, and three solid tumor ADC drug candidates: IM-1617, IM-1340, and IM-1335, all of which are in IND-enabling activities. We have six additional ADCs currently undergoing lead optimization in advance of future development decisions.

At present, our internal discovery efforts center on designing ADCs against novel or underexplored targets. We believe that pursuing differentiated targets provides a path to significant clinical benefit and meaningful market opportunities. This strategy is supported by HC74, the differentiated, novel topoisomerase 1, or TOP1, inhibitor payload we exclusively licensed from Zentalis Pharmaceuticals, Inc., or Zentalis, in January 2024 and subsequently purchased from Zentalis in October 2024. We have efforts underway to develop additional linkers and payloads and believe that a broad toolbox of linkers and payloads supports our mission to design and develop a diverse pipeline of ADCs.

To expand and advance our innovative portfolio of therapeutics, we draw on leadership that previously played key roles in the design, development, and commercialization of cutting-edge targeted cancer therapies, including the first ADCs commercialized for Hodgkin and T-cell lymphoma, urothelial cancer and cervical cancer.

Immunome Pipeline



Varegacestat (formerly AL102)

Varegacestat is an oral, once daily GSI therapy that is being evaluated for the treatment of desmoid tumors. In the Phase 2 RINGSIDE study Part A, varegacestat demonstrated objective response rates, or ORR, of 75% of evaluable patients and 64% in the intent-to-treat population; median reduction in tumor volume of 88%; and an 85% reduction in T2 imaging, which is suggestive of a reduction in cellularity. The Phase 2 data also show that varegacestat has a safety profile consistent with other GSI therapies. Enrollment in a Phase 3 registrational trial was completed in February 2024, and we expect to report topline data from this trial in the second half of 2025. We acquired varegacestat from Ayala Pharmaceuticals, Inc., or Ayala, in March 2024.

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 5,500-7,500 actively managed patients in the United States. They typically occur in people between the ages of 15 and 60 and are most common in adults, 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 can 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 one and three 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 of these, 85% 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.

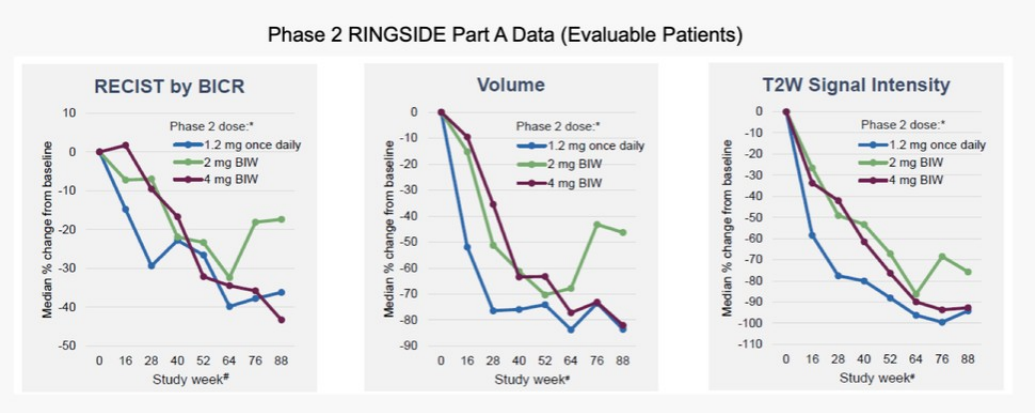
Prior to the November 2023 FDA approval of the GSI OGSIVEO® (nirogacestat) for the treatment of adult patients with progressing desmoid tumors who require systemic treatment, the treatment landscape for desmoid tumors included active surveillance, surgery, radiation therapy, low-dose or conventional chemotherapy, or tyrosine kinase inhibitors. Treatment considerations include tumor progression, symptoms, risk of morbidity, surgical risk, and the need for a fast response. The uptake of OGSIVEO® in the United States in the treatment of desmoid tumors demonstrates the potential for GSIs to address unmet need, and we believe that GSIs may ultimately capture much of the market for desmoid tumor therapy.

Proposed mechanism of action

Varegacestat 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 varegacestat may block this cleavage and inhibits Notch pathway activation.

Clinical development

Prior to the initiation of the Phase 3 clinical trial of varegacestat in desmoid tumors (RINGSIDE Part B), varegacestat 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 varegacestat in patients with progressing desmoid tumors who required therapy. RINGSIDE Part A enrolled 42 patients at three different dosing regimens of varegacestat: 2 mg once a day for two days every week, 4 mg once a day for two days every week and 1.2 mg once a day daily. Overall, the ORR in evaluable patients as measured by RECIST v1.1 by an independent radiologist was 64% for all doses tested. The 1.2 mg daily dosing cohort had an ORR of 75% in the evaluable population. Among patients in the intention-to-treat population, the overall response rate was 55% across all doses tested and the response rate was 64% for patients in the 1.2 mg daily dosing cohort. In this study, more rapid and deeper responses were achieved with 1.2 mg once-daily dosing compared with the other dosing schedules, as evaluated based on RECIST by blinded independent central review, or BICR, tumor volume, and T2W signal intensity. These data were reported in a poster presentation at ESMO in 2024.



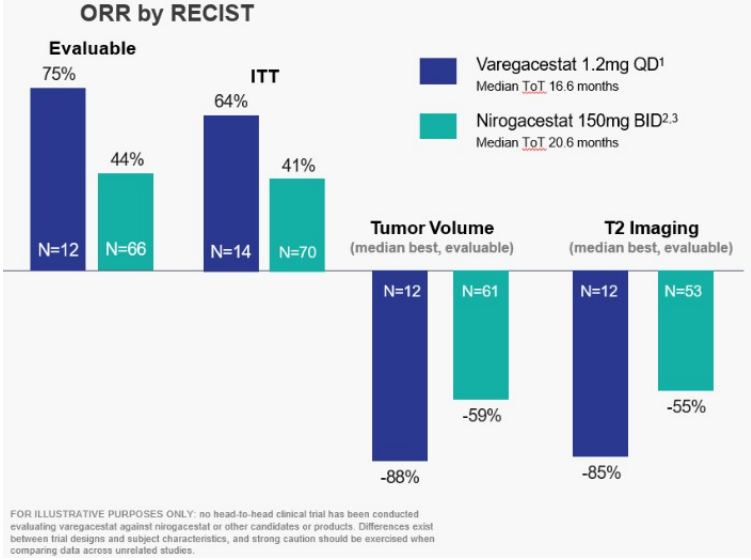
Safety results from the Phase 2 portion of RINGSIDE show that varegacestat was well tolerated and has an overall safety profile consistent with that reported with other GSIs. A lower rate of ovarian dysfunction in premenopausal women was observed for varegacestat (55.6%) compared with published data for an approved GSI (75.0%).

Study Population, n(%)	Varegacestat, 1.2mg QD, (n=14)		Nirogacestat 150mg BID (n=69)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Diarrhoea	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 aminostransferase increased	4 (28.6)	–	11 (16)	–
Months on the study (mean, range), months	16.6 (1-21.6)		20.6 (0.3 – 33.6)	

Ovarian dysfunction in pre-menopausal women: 5/9 (55.6%) with varegacestat in 1.2 mg QD arm versus 27/36 (75.0%) in nirogacestat DeFi Study

FOR ILLUSTRATIVE PURPOSES ONLY: no head-to-head clinical trial has been conducted evaluating varegacestat against nirogacestat or other candidates or products. Differences exist between trial designs and subject characteristics, and strong caution should be exercised when comparing data across unrelated studies.

Additionally, responses observed in the 1.2mg once-daily cohort in the Phase 2 portion of RINGSIDE compared favorably to nirogacestat across all measures assessed.



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, RINGSIDE Part B (NCT04871282) was initiated in November 2022. RINGSIDE Part B is a registrational Phase 3, global, double-blind, randomized, placebo-controlled clinical trial, conducted at clinical sites in North America, Europe, Asia and Australia. It is designed to evaluate the efficacy, safety and tolerability of varegacestat 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. Enrollment was completed in February 2024 and the study is ongoing.

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 1:1 to receive either varegacestat 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 varegacestat 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.

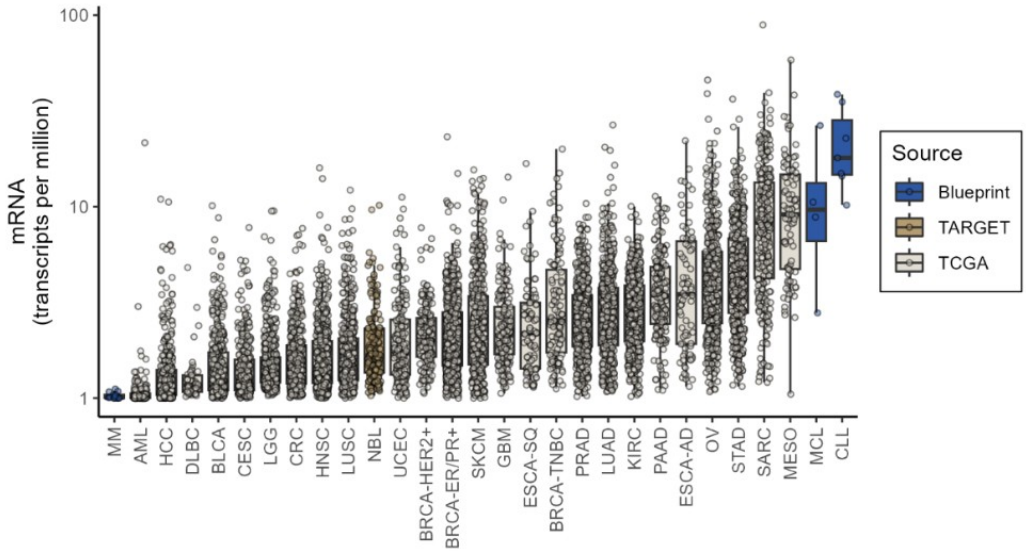
We expect to share topline data for RINGSIDE Part B in the second half of 2025. In parallel, we are completing the manufacturing, toxicology and pharmacology work required to support an NDA submission.

IM-1021 (Solid Tumor and B-Cell Lymphoma ADC)

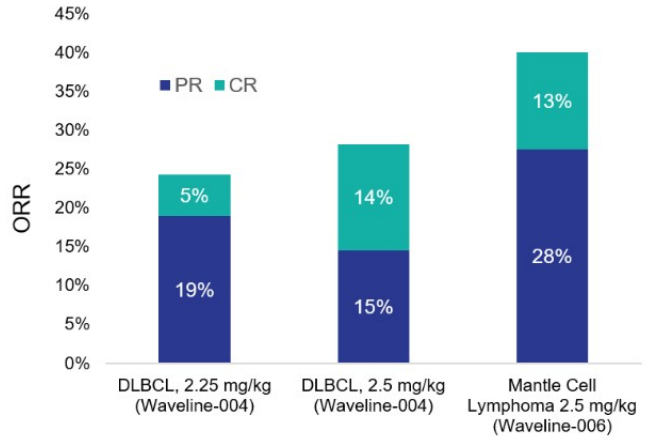
IM-1021 is a ROR1 ADC that incorporates HC74, our proprietary TOP1i payload. ROR1 is expressed in both hematologic malignancies and solid tumors with limited normal tissue expression, and previous ADCs targeting ROR1 have demonstrated clinical activity. In preclinical studies, IM-1021 showed sustained tumor regression in preclinical models, including a mouse model of triple-negative breast cancer, or TNBC, and a mouse model of mantle cell lymphoma, or MCL. We believe that IM-1021 may provide improved therapeutic index as compared to other ROR1-targeted ADCs in development. IM-1021 received IND clearance in December 2024, and the phase 1 clinical trial is ongoing with a starting dose of 2 mg/kg of adjusted ideal body weight. We expect dose escalation to include patients both with solid tumors and with B-cell lymphoma.

ROR1 is a clinically validated target in B-cell lymphoma

High or moderate expression of ROR1 has been demonstrated in a variety of hematopoietic malignancies, particularly in B-cell lymphomas, and clinical results have validated it as a target in these tumors. Preliminary Phase 1 data from zilovertamab vedotin (also known as MK-2140 or VLS-101), a ROR1-targeted ADC with a vedotin payload, in heavily pre-treated patients (median prior lines of therapy = 4, range 1-9), showed objective tumor responses in participants with mantle cell lymphoma, or MCL, and diffuse large B-cell lymphoma, or DLBCL. Subsequent evaluation in a Phase 2 study by Merck in DLBCL showed that of 103 patients treated at 2.5 mg/kg, 15 participants had complete responses, or CRs, 14 had partial responses, or PRs, and 17 had stable disease, or SDs. Of 37 participants treated at 2.25 mg/kg, there were 7 CRs, 2 PRs, and 7 SDs. Both of these dose levels were associated with a high degree of toxicity. In February 2025, Merck announced the initiation of waveLINE-010 (ClinicalTrials.gov, NCT06717347), a pivotal Phase 3 clinical trial evaluating zilovertamab vedotin in combination with rituximab plus cyclophosphamide, doxorubicin and prednisone, or R-CHP, compared to rituximab plus cyclophosphamide, doxorubicin, vincristine and prednisone, or R-CHOP, alone, for the treatment of patients with previously untreated DLBCL. In addition, CStone Phamaceuticals has shared Phase 1 data demonstrating activity in both Hodgkin and non-Hodgkin lymphoma for CS5001, their ROR1-targeted ADC.



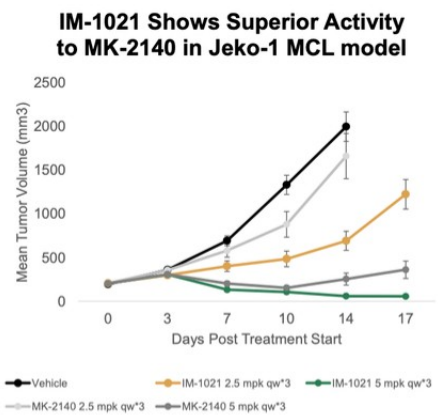
MK-2140 Monotherapy Demonstrates Potential of ROR1 in B-Cell Lymphoma[2]

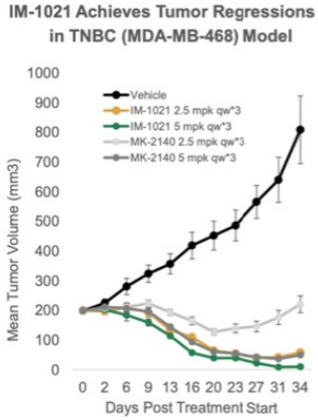


ROR1 is an attractive target for select solid tumors

While ROR1 expression is more variable in solid tumors than in B-cell lymphomas, it is known to be expressed in a variety of malignancies including NSCLC, TNBC, ovarian cancer, mesothelioma, liposarcoma and pancreatic cancer, and responses have been observed in NSCLC and pancreatic cancer with CS5001. We believe that developing a successful ADC for ROR1 in solid tumors requires overcoming challenges like moderate-to-low expression and slow internalization. IM-1021 embodies our approach to overcoming these challenges: it incorporates a ROR1 antibody that is designed to promote internalization; it utilizes a cleavable, undisclosed linker to conjugate the payload to the ROR1 antibody via cysteine conjugation; and it includes a proprietary camptothecin derivative, HC74, a TOP1 inhibitor, that is designed to maximize the potential bystander effect and that supports a drug-antibody ratio, or DAR, of 8. We believe that this combination of attributes could provide IM-1021 with an improved therapeutic index compared with other ROR1-targeted ADCs in development.

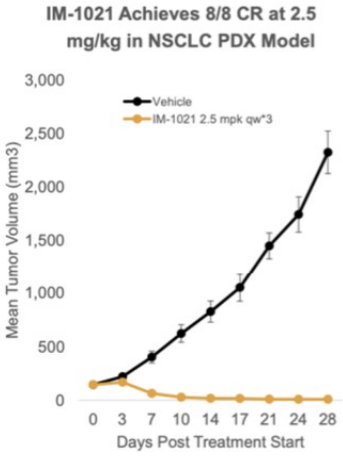
In October 2024, we presented preclinical data demonstrating robust anti-tumor activity for IM-1021 at the 36th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics. IM-1021 showed superior activity compared to zilovertamab vedotin[1] at both dose levels in both the Jeko-1 mantle cell lymphoma model and the MDA-MB-468 TNBC model. In the MDA-MB-468 study, five out of eight animals achieved complete responses after three 5 mg/kg doses.





[1]The head-to-head data is based on our synthesized version of MK-2140, which we believe is structurally equivalent to MK-2140.

In a patient-derived NSCLC xenograft model, eight out of eight animals achieved complete responses after three 2.5 mg/kg doses IM-1021.



We received IND clearance for IM-1021 in December 2024 and began dosing patients in our Phase 1 clinical trial in February 2025 with a starting dose of 2 mg/kg of adjusted ideal body weight. Our clinical strategy is designed to efficiently evaluate dose escalation in patients with solid tumors and lymphoma, followed by potential expansion into specific indications. Dose escalation will evaluate B-cell lymphomas, including diffuse large B-cell lymphoma, mantle cell lymphoma, follicular lymphoma and small lymphocytic lymphoma, as well as solid tumor indications like non-small cell lung cancer triple-negative breast cancer, ovarian cancer, liposarcoma, mesothelioma, and pancreatic cancer. Expansion cohorts may include any of the above-mentioned tumor types. We are also evaluating the need and benefit of developing a potential companion diagnostic(s) 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 early-stage trials, present significant commercial opportunities, and offer a potential accelerated path to approval.

IM-3050 (FAP Radioligand Therapy)

IM-3050 is a FAP-targeted lutetium-177, Lu-177 or 177Lu, RLT product candidate for the treatment of solid tumors. FAP, or fibroblast activation protein, is a cell surface protease that serves as a tumor-specific marker due to its broad expression on cancer associated fibroblasts, the most common tumor stromal cell. FAP is expressed in 75% of solid tumors. IM-3050 is designed to deliver radioactive 177Lu 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. *In vivo* data show single dose antitumor activity and tolerability.

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.

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.

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.

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.

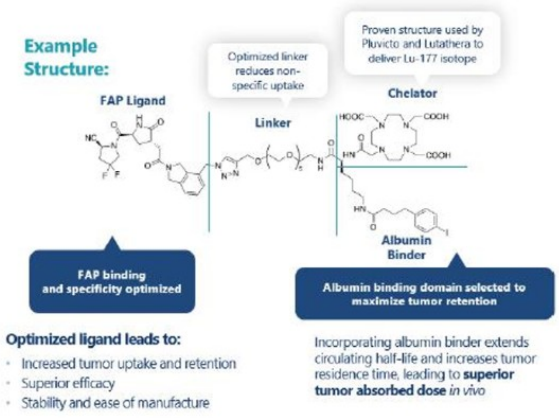
Emerging field of targeted radiotherapies

Two targeted radiotherapies have been approved by the FDA in the past few years: Lutathera® for gastroenteropancreatic neuroendocrine tumors, or GEP-NETs, that express the somatostatin receptor; and Pluvicto® for metastatic castration-resistant prostate cancer, or mCRPC that expresses PSMA. 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; the $1.4 billion dollar acquisition of Point Biopharma Global, Inc. by Eli Lilly and Company; 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 FAP-targeted RLT 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 response, highlighting the need for FAP-targeted therapies with improved activity.

IM-3050 is a FAP-targeted RLT with best-in-class potential

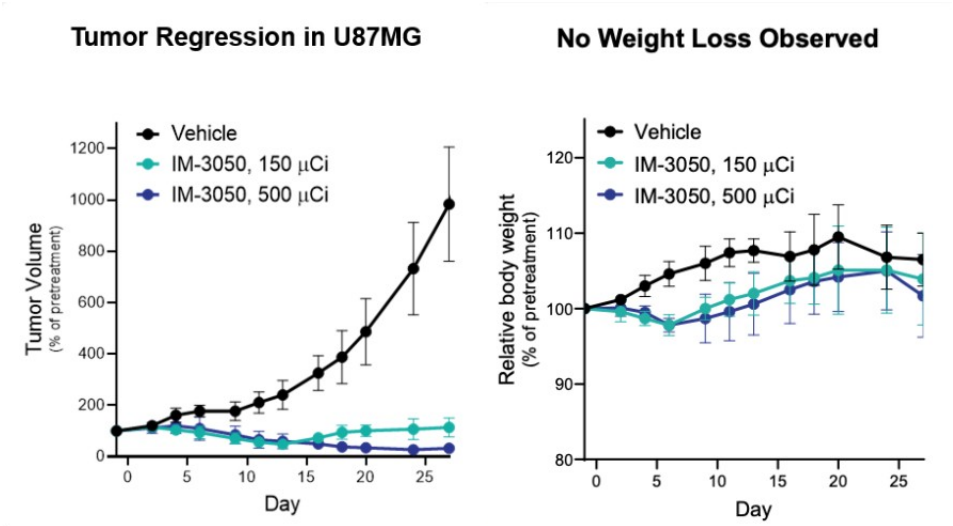
IM-3050, our lead FAP-targeted RLT is an optimized molecule with best-in-class potential. It has four functional domains: a small molecule FAP-specific ligand, a linker tuned to drive tumor-specific uptake, an albumin-binding domain to improve tumor retention, and a chelator to deliver the radionuclide.



Over the last three 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 a 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.

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



We submitted an IND for this program to the FDA in March 2025, and expect to initiate a Phase 1 clinical trial in the second half of 2025.

ADC Strategy

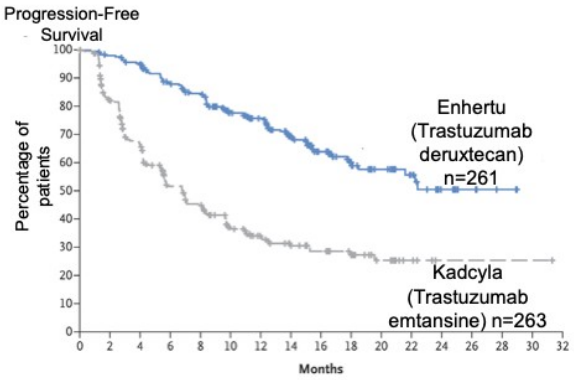
We believe that our team's ADC expertise positions us to develop the next generation of transformative ADCs. This expertise comprises executive leadership with a proven record of success, an ADC-focused discovery team with deep experience in ADC design, and a seasoned development team whose members spearheaded the development of multiple FDA-approved ADCs. We pair our portfolio of antibodies to potential first-in-class ADC targets with rigorous target selection based on a deep understanding of target biology. That target-driven approach is complemented by HC74, our differentiated, proprietary TOP1 inhibitor payload and our optimized, proprietary linkers.

A key challenge to realizing the full potential of ADCs in the treatment of cancer is the disproportionate focus on a small number of targets, with 10 targets accounting for 55% of active clinical ADC programs.

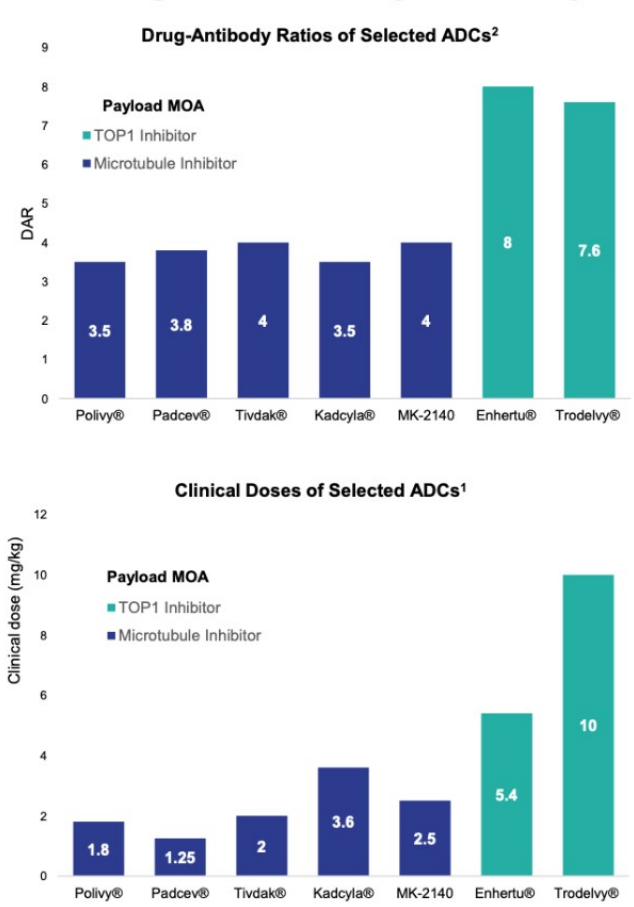


We believe there are several downsides to pursuing these targets. One downside is the potential difficulty in overcoming limitations of existing ADCs against these targets due to considerations like the heterogeneity of target expression on tumor cells and the likelihood that changes in payload or linker technology will yield only incremental gains in efficacy. Another is their challenging development and commercialization pathways. Additionally, with multiple therapies in development against them, these highly prevalent targets provide reduced opportunity to address unmet need — which is an essential component of our mission. Instead, we are focusing on targets with no approved therapeutics.

A critical challenge in the pursuit of novel or underexplored targets is optimizing the design of the molecule to match target biology. HC74, our proprietary camptothecin-derived TOP1 inhibitor payload, is designed to address this challenge by supporting development of ADCs for novel targets. TOP1 inhibitors are DNA-damaging agents and are validated ADC payloads. ADCs with these payloads generally show greater tolerability and achieve higher doses than earlier ADCs. For example, a third-party randomized controlled clinical trial found that a HER2-targeted ADC with a TOP1 inhibitor payload, Enhertu, showed a significant progression-free survival benefit compared with a HER2-targeted ADC with an emtansine payload.

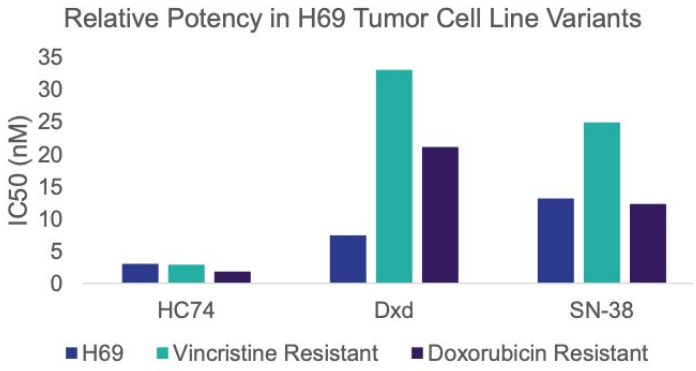


Additionally, ADCs containing TOP1 inhibitors have achieved higher DARs and have the ability to achieve higher clinical doses compared to ADCs with microtubule payloads, allowing for potential increased payload delivery.



These attributes may allow for a higher clinical dose of TOP1 inhibitor-containing ADCs, enabling an increased therapeutic index.

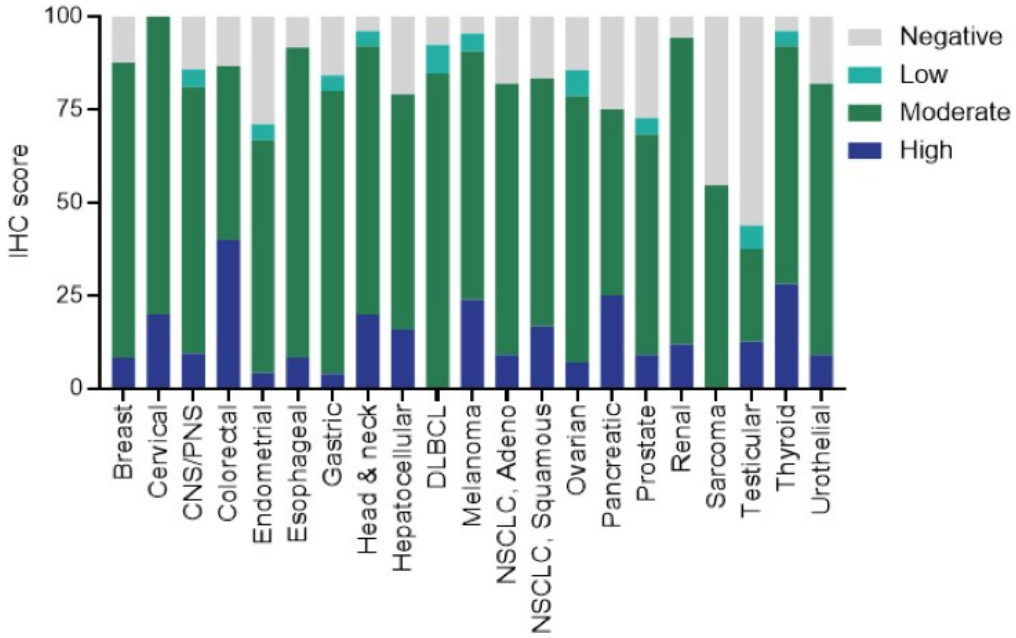
In October 2024, we presented preclinical data at the 36th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics demonstrating that, compared to deruxtecan, or DXd, HC74 demonstrated superior potency measured across 89 cell lines while retaining potency in chemotherapy-resistant cell lines. HC74 also shows increased permeability that may lead to superior bystander effect, reduced efflux that may lead to avoiding certain mechanisms of resistance, and rapid hepatocyte clearance that may improve tolerability.



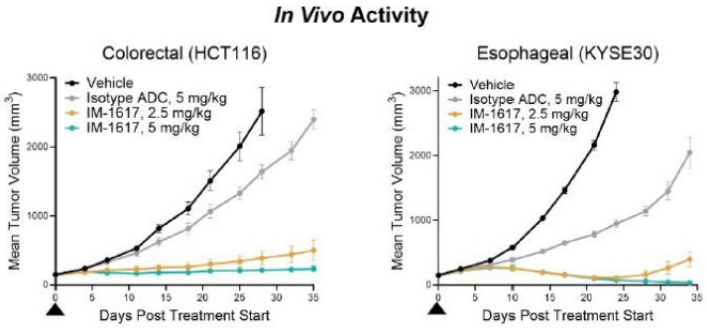
Our unique combination of ADC expertise, novel targets, proprietary payload, and novel linkers enables us to pursue a differentiated ADC development strategy, which is focused on targets that have no approved ADCs and on indications with substantial unmet need. We perform extensive expression analyses to understand where and at what levels these targets are expressed and optimize our antibodies for enhanced internalization and tumor localization. We also prioritize definitive preclinical experiments that enable rapid and financially efficient development. Executing on this strategy, we have screened more than 1,000 targets, and this effort has to-date yielded more than 40 targets evaluated *in vitro* and more than 15 targets evaluated *in vivo*. This has yielded three novel solid tumor ADCs for which IND-enabling studies are ongoing and six additional ADCs currently undergoing lead optimization. Continued execution of this ADC development strategy is anticipated to yield multiple new and highly differentiated ADC candidates each year.

IM-1617 (Solid Tumor ADCs)

IM-1617 is a potential first-in-class ADC that targets an undisclosed receptor that is preferentially expressed in a broad array of solid tumors, including colorectal cancer, or CRC, non-small cell lung cancer, or NSCLC, and breast and ovarian cancers. The target is a receptor tyrosine kinase that promotes tumor cell survival and mediates immune cell exclusion, providing potential for a secondary mechanism of action.



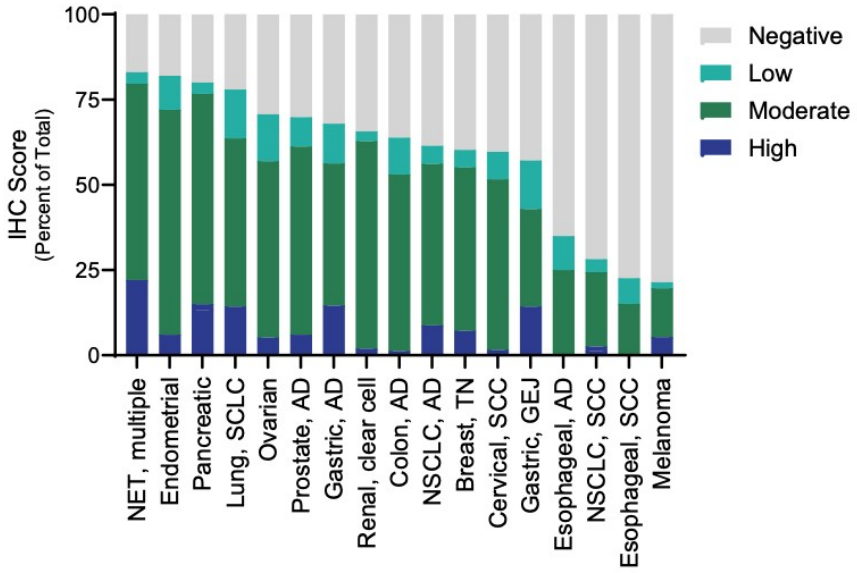
IM-1617 incorporates a proprietary antibody that was selected for attributes that may drive tumor binding while minimizing normal tissue binding; a cleavable, undisclosed linker; and HC74. An initial study in non-human primates, or NHPs, found a highest non-severely toxic dose of 40 mg/kg, indicating a potentially robust therapeutic window. Preclinical *in vivo* efficacy studies have shown tumor regression after a single, clinically relevant dose of IM-1617 in tumor models derived from melanoma, esophageal cancer, CRC, NSCLC, and other carcinomas.



IND-enabling work for IM-1617 was initiated in the fourth quarter of 2024.

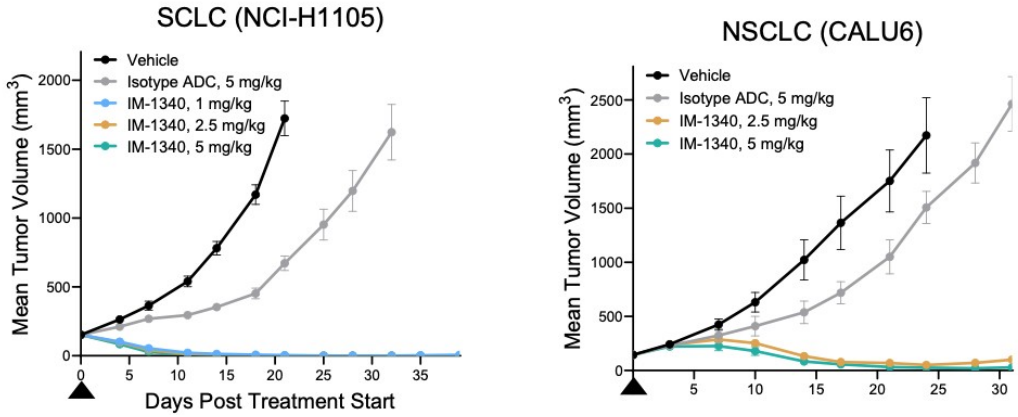
IM-1340 (Solid Tumor ADCs)

IM-1340 is a potential first-in-class ADC for the treatment of multiple solid tumors. The target of IM-1340 is underexplored and non-obvious in cancer and, to our knowledge, there are no ADCs or other therapeutic modalities in development against it. It has a unique expression profile that spans neuroendocrine tumors, or NETs, and other carcinomas, including lung and prostate tumors, with limited expression in normal tissue.



This target is known to promote tumor growth by accelerating proliferation, cell cycle progression, and migration of cancer cells. Additionally, it is a transport receptor for an endolysomal protease, leading to potential favorable ADC internalization dynamics.

IM-1340 incorporates a proprietary antibody selected for attributes that drive tumor binding while minimizing normal tissue binding; a cleavable, undisclosed linker; and HC74. IM-1340 has shown robust preclinical activity, with evidence of regressions following a single 1 mg/kg dose in *in vivo* tumor models representing NETs and carcinomas including NSCLC, SCLC, pancreatic cancer, and prostate cancer. An initial study in NHPs found a highest non-severely toxic dose of 40 mg/kg, indicating potential for a robust therapeutic window.



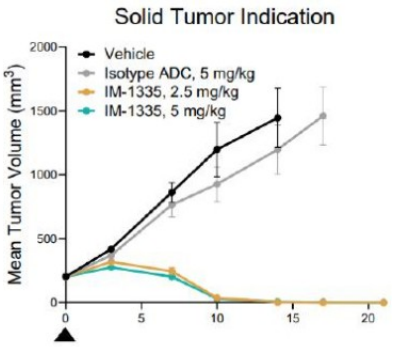
IND-enabling work for IM-1340 was initiated in the fourth quarter of 2024.

IM-1335 (Solid Tumor ADCs)

IM-1335 is being developed for the treatment of solid tumor indications. It shares a target with a competitor's now-discontinued investigational ADC that showed clinical activity prior to discontinuation. Our goal in designing IM-1335 was to optimize the safety and efficacy through a deep understanding of target biology and ADC optimization. We identified limitations that we expect contributed to the failure of the prior ADC against this target, and we believe that IM-1335 overcomes these limitations. Toward this end, the antibody portion of IM-1335 has been designed for improved pharmacokinetic and tumor biodistribution profiles. IM-1335 also incorporates a linker designed to enhance stability for on-target activity as well as our proprietary HC74 to match drug sensitivity in top indications.

As shown below, IM-1335 shows in vivo preclinical efficacy in a solid tumor indication.

***In Vivo* Preclinical Efficacy**



IND-enabling work for IM-1335 was initiated in the fourth quarter of 2024.

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 merger with Morphimmune, a preclinical biotechnology company led by Dr. Siegall, in October 2023.

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. Jack Higgins, Ph.D., is our Chief Scientific Officer. Most recently, he was Chief Scientific Officer at Morphimmune. Previously, he was 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. Phil Tsai, Ph.D., serves as our Chief Technical Officer. Prior to joining Immunome, Dr. Tsai spent 21 years at Seagen and then Pfizer (following the acquisition of Seagen in December 2023) in positions of increasing responsibility. Most recently, he was the SVP of Technical Development, responsible for end-to-end development of biologics and drug-linker manufacturing processes, analytics, and drug products.

Max Rosett, our Chief Financial Officer, most recently served as Acting Chief Operating Officer at Morphimmune and joined Immunome as Senior Vice President, Operations. Mr. Rosett previously served as a Principal at Research Bridge Partners, where he led Research Bridge Partners' investment in Morphimmune's Series A financing. 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. Roee Shahar is our Executive Vice President, Commercial. Mr. Shahar served as Vice President and Franchise Lead for Pfizer, where he managed the combined hematology portfolio resulting from the December 2023 acquisition of Seagen. Before the acquisition, he served as Vice President and Franchise Lead for Seagen overseeing all commercial activities for hematology.

Strategic Transactions

Acquisition of Assets from Ayala Pharmaceuticals, Inc.

In March 2024, we completed an asset purchase, or the Ayala Closing, pursuant to an asset purchase agreement, or the Ayala Purchase Agreement, initially entered into with Ayala in February 2024, pursuant to which we acquired Ayala's AL101 and varegacestat programs and assumed certain liabilities associated with the acquired assets. Under the Ayala Purchase Agreement, we paid Ayala approximately $20.0 million in cash and issued 2,175,489 shares of our common stock with an aggregate fair value of $50.6 million on the date of issuance. We are also obligated to pay Ayala up to $37.5 million in the aggregate upon the achievement of certain development, regulatory and commercial milestones.

Acquisition of Assets from Zentalis Pharmaceuticals, Inc.

In January 2024, we entered into a license agreement with Zentalis, or the Zentalis License Agreement, 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, or, collectively, the Zentalis Licensed Assets. Under the Zentalis License Agreement, we paid Zentalis $15.0 million in cash and issued Zentalis 2,298,586 shares of our common stock with an aggregate fair value of $23.4 million on the date of issuance.

In October 2024, we completed an asset purchase agreement with Zentalis, or the Zentalis Purchase Agreement, pursuant to which we purchased the Zentalis Licensed Assets and the Zentalis License Agreement was terminated. Under the Zentalis Purchase Agreement, we issued Zentalis 1,805,502 shares of our common stock with an aggregate fair value of $21.0 million on the date of issuance. We are also obligated to pay Zentalis a one-time payment of $5.0 million in cash upon the achievement of a developmental milestone that was previously a milestone under the Zentalis License Agreement. The $5.0 million developmental milestone was achieved in the fourth quarter of 2024 and paid in the first quarter of 2025.

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.

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. Following the closing of the Ayala Purchase Agreement on August 7, 2024, we entered into Amendment No. 2 to the BMS License Agreement, or the BMS License Agreement Amendment. As consideration to BMS for entering into the BMS License Agreement Amendment, we issued BMS 230,415 unregistered shares of our common stock at an aggregate fair value of $2.7 million on the date of issuance.

Under the BMS License, BMS 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 varegacestat, or the BMS Licensed Compounds, and products containing AL101 or varegacestat, 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 BMS 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.

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, we 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, we will pay PRF the milestone payments as specified in the Purdue License Agreement, which may be up to $3.75 million in the aggregate. We are 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. We 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 we fail to cure a payment default or other material breach of the Purdue License Agreement after written notice from PRF, or if we become 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 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 six named programs. We do not have 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. We expect our future contractual manufacturing organizations to 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 developing ADCs, including, but not limited to, ADC Therapeutics SA, Ipsen SA, Exelexis, Inc., and Zymeworks Inc. and competitors based overseas, including, but not limited to, Hansoh Pharmaceutical Group, Ltd., Jiangsu Hengrui Pharmaceuticals Company Ltd. and LaNova Medicines. We also expect to compete with companies pursuing targeted radiotherapies, including, but not limited to, RayzeBio, (acquired by BMS), Fusion Pharmaceuticals (acquired by AstraZeneca), Point Biopharma (acquired by Eli Lilly and Company), 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; Daiichi Sankyo; 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 varegacestat, 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 desmoid tumors who require systemic treatment. Desmoid tumors treatments also include surgery, hormonal therapy, targeted therapy and chemotherapy.

We believe that IM-1021, our preclinical ROR1 ADC program, has the potential to address hematologic and solid tumor indications. There are several other companies developing antibodies, ADCs, and 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 3 clinical trial for B-cell lymphoma. CStone Pharmaceuticals, Inc. has an ADC program in a Phase I trial. CSPC Pharmaceutical Group Limited and Radiance Biopharma have received clearance from Chinese regulatory authority clearance to initiate clinical trials for SYS6005, a ROR1 ADC.

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 2. 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.

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 important to the advancement of our pipeline and growth of our business by seeking, maintaining, and defending patent rights, whether developed internally, or 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 coverage areas such as 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 December 31, 2024, we own or exclusively in-license 141 issued or granted patents and 117 pending applications on a world-wide basis (including major commercial and manufacturing jurisdictions of the United States, Europe, Japan and China) covering our varegacestat, IM-1021, IM-3050, IM-1617, IM-1340 and IM-1335 product candidates. The US composition of matter patent covering varegacestat will expire in 2038, which includes 5 years of expected patent term extension. Patent applications covering varegacestat and various derivatives, if issued, are expected to expire between 2033-2045, absent any patent term extensions or adjustments and without accounting for terminal disclaimers. Patent or Patent applications covering IM-1021, if issued, are expected to expire in 2045, 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. Patent applications covering IM-1617, IM-1340 and IM-1335 will expire in 2045 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 ability to obtain and maintain patent protection and/or 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 the subject matter 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.

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. When available to expand market exclusivity, we may also obtain, or license additional patented intellectual property related to current or future technology and/or programs.

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.

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 product 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 NDAs 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 product 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 nonclinical 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 product candidate, the sponsor must submit an IND to the FDA. 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.

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. Failure to timely register an applicable clinical trial 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 as well as prevent publication of the results in a scholarly journal.

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 and NDA 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. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug (or safety, purity and potency of the investigational biologic product) to the satisfaction of the FDA.

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. 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 cGCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

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.

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 and/or clinical trial sites where appropriate, 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. 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

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 disease 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 product no longer meets the qualifying criteria of fast track designation.

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 trial(s) 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 product 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 and substantially completed 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, certain NDAs or BLAs or supplements thereto must contain data to assess the safety and efficacy of the drug candidate (or safety, purity and potency of the biologic candidate) 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.

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 product candidate may receive an orphan drug designation for the same indication. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan 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 product candidate or if our program or product 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 product 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 products 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.

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.

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. 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 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 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.

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 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 require pharmaceutical and biotechnology companies to: establish the pedigree of product in the chain of distribution, including new technology capable of tracking and tracing product; 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, Further, certain states prohibit certain pharmacies and other health care entities from sharing certain physician prescribing data for use in sales and marketing, and other sales and marketing practices by pharmaceutical and biotechnology companies. 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 product 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. 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 product candidate that we successfully develop.

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 product 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 product 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 product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell programs and product candidates for which marketing approval is obtained.

For example, the ACA was enacted in March 2010 and has had a significant impact on the health care industry in the United States.

There have been judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or the IRA, was signed 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.

For example, 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 and biologics that have been on the market for at least 7 years for drugs and 11 years for biologics without generic or biosimilar competition. On August 15, 2024, the agreed-upon prices for the first ten drugs that were subject to price negotiations was published, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, CMS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare drug price negotiation program If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. Additionally, 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.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may, for example, include directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation ("CMMI") to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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, particularly in light of the recent U.S. Presidential and Congressional elections. 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, 2024, we had 118 full-time employees, including 71 who hold advanced degrees. Of these 118 employees, 87 were engaged in research and development activities and 31 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 incentives, 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.

Corporate and Other Information

We were incorporated in the Commonwealth 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, Washington 98011, and our telephone number is (425) 939 7410. 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. We intend to announce material information to the public through filings with the SEC, the investor relations page on our website, press releases, public conference calls and public webcasts. 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 a reference to 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, 2024, we had an accumulated deficit of $515.8 million. Our net loss was $293.0 million and $106.8 million for the years ended December 31, 2024 and 2023, respectively. 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 programs and product 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 programs and product 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 product candidates, or if sales revenue from any program or product 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 varegacestat, a product candidate in late-stage clinical trials, and initiation of the Phase 1 clinical trial for IM-1021 in February 2025, we have not undertaken 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 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, 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 or NDA, or Biologics License Application, or BLA, obtained FDA approval for marketing, or successfully commercialized a product, and we may be unable to do so. Furthermore, varegacestat, which we recently acquired, is currently in Phase 3 clinical development, but such acquisition and prior clinical success is not indicative of our ability to obtain NDA approval or successfully commercialize varegacestat.

As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals for marketing, 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 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. We have not previously completed any clinical trials for any of our current product candidates. We also have limited experience as a company in preparing and submitting marketing applications and have not previously submitted an NDA, a BLA, 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 product 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 product candidates. Notably, varegacestat's prior development was not conducted by us. As a result, our assumptions about varegacestat'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. Further, even if we believe the nonclinical or clinical data for our product candidates 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 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 our current and future product candidates.

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

The research and development of biotechnology products is capital-intensive. If our product 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 product candidates and will require significant funds to continue to advance our ADC platform 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 as of December 31, 2024, together with the proceeds of our January 2025 financing, will be sufficient 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 programs or product candidates. Additional funding may not be available on acceptable terms, or at all. 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, including tariffs and the prospects of trade wars, and other macroeconomic and political factors, 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, 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, achieve targets or milestones for existing or future collaborations, 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 costs related to the integration of assets, businesses, 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 product 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, including pursuant to the 2024 ATM Agreement, 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 product 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 further 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, including pursuant to the 2024 ATM Agreement, or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of certain 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 Programs and Product Candidates

We may be unable to advance any of our product 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 product 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 varegacestat, 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, and we only recently initiated our Phase 1 clinical study for IM-1021, which received IND clearance in the fourth quarter of 2024. 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 product 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 product 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 product candidates. Most of our product candidates are in the early stages of development, other than varegacestat, which is a Phase 3 clinical asset, and IM-1021, which is a Phase 1 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.

Reports of adverse events or safety concerns involving our product candidates could result in the limitation, denial or withdrawal of regulatory approval by the FDA or other regulatory authorities for any or all indications, the need to conduct additional trials, implementation of a REMS or the inclusion of unfavorable information in our product labeling and, in turn, could delay or prevent us from commercializing the applicable product or product candidate.

Any failures or setbacks in our ADC platform or with respect to any of our additional proprietary technologies, including adverse effects resulting from the use of this technology in human clinical trials and/or the imposition of clinical holds on our trials of our product candidates, could have a detrimental impact on our current and future pipeline, as well as our ability to enter into and/or maintain collaborations related to our ADC technology, which could negatively affect our business and financial position.

Additionally, we may not have the financial resources to continue development of, or to enter into new collaborations for, our product 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 product 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, including the occurrence of adverse events, 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 product 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 not be successful in our efforts to use and expand our ADC platform to build and progress a pipeline.

A key element of our strategy is to use and expand our ADC platform 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 ADC platform 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 ADC platform are not proven to be superior to competing technologies. Even if we are successful in building our pipeline, the product 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 product candidates, we will not be able to generate product revenue.

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

In the natural course of progressing our product 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 product candidates of interest, including IM-1021, IM-3050 and varegacestat, 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 product 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 future strategic transactions.

The success of our business strategy to pursue acquisitions and in-licenses 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 and deliver on a timely basis sufficient supply of raw materials, isotopes and clinical trial materials for our preclinical needs and potential future clinical and commercial needs;
- we may not be able to find and retain 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.

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 varegacestat and implementing its Phase 3 clinical trial. Additionally, because our other product 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 product 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 and generally could be impacted by other factors beyond our control.

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.

Furthermore, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program and the approvability or commercialization of the particular product candidate. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate.

Moreover, if preliminary or topline results that we report differ from later, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached by us or other actions taken by us with respect to any clinical trial, our ability to obtain approval for, and commercialize, the applicable product candidate or any of our other product candidates could be harmed, which could have an adverse impact on our business, financial condition, results of operations and prospects.

Additionally, we have in the past and may in the future create synthetic molecules for comparative purposes. For example, we have created a synthetic version of zilovertamab vedotin for use in preclinical efficacy studies. We believe the results of these tests help us understand how the therapeutic index of our programs and product candidates compared to competitors' product candidates. However, we cannot be certain that any synthetic molecule that we create is the same as the molecule we are attempting to recreate, and the results of the tests comparing any such synthetic molecule to any other program or product candidate may be different than the actual results of a head-to-head test of any such other program or product candidate against a competitor molecule. Additional preclinical and clinical testing will be needed to evaluate the therapeutic index of our programs or product candidates, and to understand their therapeutic potential relative to other programs and product candidates in development. Without head-to-head comparative data, we will not be able to make comparative claims to other products in our promotional materials, if our programs and product candidates are approved.

It is impossible to predict when or if any of our programs or product 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 product candidates may not be predictive of the results of later-stage clinical trials. In addition, product 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, varegacestat's prior development was not conducted by us, and we did not conduct many of the preclinical studies for IM-1021, which we initially in-licensed from Zentalis and subsequently acquired in October 2024. 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 or otherwise adversely affected due to a variety of reasons, including:

- 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 product 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 or other vendors supporting a trial not performing as planned;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements, or applicable regulatory guidelines in other countries;
- patients who enroll in clinical trials may later drop out due to adverse events, a perception they are not benefiting from participating in the study, fatigue with the clinical study process or personal issues;

- 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, materials, diagnostics 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 or circumstances that could affect their 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, lack of adequate funding to continue the clinical trial and other factors beyond our control. 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, if any, 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 product 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 product 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 or lymphomas, the patients are typically in the late stages of the disease and may experience disease progression or adverse events independent from our product 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 may experience delays in completion of our clinical trials based on study design.

The clinical trial for AL102, RINGSIDE Part B is an event-driven study, which means that ending the study is tied to the occurrence of a certain number of events. It is not possible to predict accurately when the requisite events will occur, if at all. Given this inherent uncertainty, there can be no assurance that timing for completion of the study and reporting of data will be achieved as and when anticipated by the Company. Any delays in our clinical programs could significantly harm our business, financial condition and prospects.

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 small molecules, ADCs, targeted radiotherapies, antibodies, and other therapeutic modalities. This may include large, multinational pharmaceutical companies 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 varegacestat, we expect to compete with companies advancing treatments for desmoid tumors, including SpringWorks Therapeutics,Inc. In November2023, 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, cryotherapy, 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.) Perspective Therapeutics lead pre-clinical candidate is a FAP- targeted radiopharmaceutical (RPT), PSV 359, with a Phase I expected in 2025. Additionally, our IM-3050 program faces competition from competitors who may have superior access to a consistent supply of radioactive isotopes.

IM-1021 is a ROR1 ADC program with the potential to address hematologic and solid tumor indications. There are several other companies developing therapeutics, including ADCs, 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 3 clinical trial for B-cell lymphoma. CStone Pharmaceuticals, Inc. has an ADC program in a Phase I 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 product 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 product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any program or product 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 product 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 product 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 product 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 product candidates undergoing clinical trials, our ability to market and derive revenue from the product candidate could be compromised.

Undesirable side effects caused by any product 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 product 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 product candidate may only be uncovered when a significantly larger number of participants are exposed to the product candidate or when participants are exposed for a longer period of time.

If any of our product 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 product 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 product 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 varegacestat 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 varegacestat 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, 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 varegacestat 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 product 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 product candidate, and we cannot predict success in these jurisdictions. If we obtain approval of any of our programs or product candidates and ultimately commercialize any such program or product 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.

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 programs could be adversely affected.

With respect to certain of our product 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.

Risks Related to Government Regulation

We and the third parties with whom we work 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 (or the third parties with whom we work) 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 the third parties with whom we work, including 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 apply to our operations or the operations of the third parties with whom we work. For example, HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. We 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 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.

Numerous U.S. states 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 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. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations in certain U.S. state privacy laws, these laws increase compliance costs and potential liability with respect to other personal information we maintain. 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.

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, (GDPR) impose strict requirements for processing personal information. For example, under the GDPR, companies subject to these laws and in the event of non-compliance may experience 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 requires us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impacts our ability to operate in certain jurisdictions.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and certain other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws.

Although there are currently various mechanisms that can be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these mechanisms to lawfully transfer personal data to the United States.

If there were no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Regulators in the United States are also increasingly scrutinizing certain personal data transfers and have and may further impose personal data localization requirements or restrictions on cross-border personal data transfers.

Our employees and personnel 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 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 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, some clinical trial sites who share data about clinical trial participants contractually limit our ability to use and disclose personal information.

We publish privacy policies, marketing materials, whitepapers, and other statements, such as statements related to compliance with certain certifications or self-regulatory principles, regarding data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, 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 are 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, and has in the past and may in the future necessitate changes to our services, information technologies, systems, and practices and to those of any third parties with whom we work.

Failure or the perceived failure to address or comply with applicable data privacy and security obligations, 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 or the third parties with whom we work 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: 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 and amendments to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or the IRA, was signed 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. Additional federal and state legislative and regulatory developments are likely, particularly in light of the change in Presidential administrations, 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 product 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 product candidates.

Further, among other things, the IRA has multiple provisions that may impact the prices of 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 product's price increases faster than the rate of inflation. This calculation is made on a product by product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will begin to reimburse negotiated drug prices annually for a select number of single source Part D drugs and biologics that have been on the market for at least 7 years for drugs and 11 years for biologics without generic or biosimilar competition. On August 15, 2024, CMS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, CMS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare drug price negotiation program If a product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. 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 product 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 product 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 product 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 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 product candidates and have already undertaken efforts in this regard. 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 product 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 product candidate ahead of our competitors, our programs or product candidates may face competition from biosimilar or generic products. In the United States, our antibody-based programs and product candidates are expected to be regulated by the FDA as biological products, and we intend to seek approval for these programs and product 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.

We believe that any of our product 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 product 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 product 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 product 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 product candidates may have received approval.

If the FDA, the European Medicines Agency, or EMA, the European Commission, 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 product 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 product 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 product 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 product candidate. The FDA may also require a REMS program as a condition of approval of our product 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 product 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 product candidates. For example, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. 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 product candidate, the program and product 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 product 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 varegacestat 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 product 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 product 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 product 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 Strategic Transactions, Manufacturing, Commercialization and Reliance on Third Parties

We have, and may in the future choose, to engage in and 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 engaged in, and may continue to consider and engage in, strategic transactions, 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 product candidates and our ADC platform. Such collaborations, or other strategic transactions, have required, and may in the future require, us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges and/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 have and may in the future 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 existing or future transactions of the nature described above, any transactions that we have or may in the future 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 product candidates and have a negative impact on the competitiveness of any program or product 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 product 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 product 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 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 currently rely, and intend to continue 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 for the Phase 3 clinical trial of varegacestat and the Phase 1 clinical trial of IM-1021. Since we 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 are not 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 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 currently rely, and intend to continue to rely, on third-party contract manufacturers for our preclinical and clinical trial product materials and commercial supplies, including for our Phase 3 clinical trial of varegacestat and our Phase 1 clinical trial of IM-1021. 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 product 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.

Certain Chinese biotechnology companies, CROs and contract development and manufacturing organizations may become subject to trade restrictions, tariffs, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could potentially impact services available for our research and development or our ability to secure the materials we need for our product candidates. For example, the House of Representatives of the prior Congress (the 118th Congress) passed the BIOSECURE Act, which proposed targeting U.S. government contracts, grants, and loans for entities that use biotechnology equipment or services from certain named Chinese biotechnology companies, and potentially additional Chinese biotechnology companies designated in the future. The language of the proposed BIOSECURE Act would, among other things, prohibit U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern." The version of the bill passed by the prior House of Representatives included a grandfathering provision allowing biotechnology equipment and services provided or produced by named biotechnology companies of concern under a contract or agreement entered into before the effective date until January 1, 2032. The BIOSECURE Act did not become law in the 118th Congress. It is unclear whether the current Congress (the 119th Congress) will introduce the BIOSECURE Act or similar legislation in this congressional session and, if so, how the scope, prohibitions, or designated biotechnology companies of concern may differ from the version of the BIOSECURE Act passed by the House in the prior 118th Congress.

Since we engage third party vendors located outside the United States, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or applicable foreign government, political unrest or unstable economic conditions. Any additional U.S. executive action, legislative action, or potential sanctions with China or any other country could materially impact our business and activities. Furthermore, U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. Additionally, a trade war could lead to tariffs on supplies and materials we use that are manufactured internationally, including in China. Any of these matters could materially and adversely affect our business and results of operations.

If we are unable to obtain or maintain third-party manufacturing for any program or product candidate, or to do so on commercially reasonable terms, or if our relationship with third-party vendors on whom we rely is otherwise adversely impacted by changing United States or applicable foreign government policies, 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 product candidates, we will need to manufacture large quantities. If any programs or product 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 product 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 product 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 ADC platform and/or current or future product 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 product 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 data, or those of the third parties with whom we work, could cause adverse consequences, including 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, our collaborators, our vendors, and other third parties with whom we work may 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 with whom we work. 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 with whom we work are 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. For example, we have clinical trial activities in regions experiencing geopolitical or other conflicts, including in Israel, where businesses have experienced an increase in cyberattacks in relation to the Israel/Hamas conflict.

We and the third parties with whom we work are subject to a variety of evolving threats, including social-engineering attacks (including through deep fakes, which are 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 attacks, 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.

It may be difficult and costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Remote work 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 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 with whom we work experience a material security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work 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 third-parties' with whom we work supply chains have not been compromised.

While we have implemented security measures designed to protect against and recover from 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 with whom we work), 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. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats have in the past and may in the future 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 or otherwise impact our ability (and that of third parties upon whom we rely) to conduct our business. We have in the past and may in the future 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 require us to implement and maintain specific security measures or industry-standard or reasonable security measures in an effort to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such requirements could lead to material adverse consequences. Security incidents or perceived security incidents may result in material 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, some of our contracts do 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.

Although we have insurance coverage, including cybersecurity insurance, in place, 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 by third parties or losses that we directly incur.

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 the use of generative AI technologies by our employees, our personnel, or third parties with whom we work.

Our current laboratory operations are concentrated in one location, and we and the third parties upon whom we depend 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 area. 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 area, 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 ADC platform and/or 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. For a patent filed before March 16, 2013, a petition for *inter partes* review can be filed immediately following the issuance of the patent. 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 efforts, 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 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 or other technologies in the future, we might become dependent on proprietary rights from third parties with respect to those licensed assets. 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 or dependent upon 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, defense 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 technologies from third parties that are or may become important or necessary to our ADC platform and/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, certain of our license agreements 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. Termination of any of our license agreements could result in a material adverse effect on our ability to use our ADC platform and/or targeted therapeutics and our ability to develop, manufacture, and sell products that are discovered using or are otherwise covered by technology licensed under those agreements, 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 certain of our license agreements, 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 product 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 us to litigation and have a significant adverse effect on our 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 and consultants 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 platform and programs, we may be subject to claims that we or these employees or consultants have misappropriated the intellectual property of a third party or breached other obligations to. 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

Any inability to attract and retain qualified key management, technical personnel and employees would impair our ability to implement our business plan. In addition, prior successes of our personnel may not be indicative of our future success.

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.

In addition, although our leadership team and other key personnel previously played key roles in the design, development, and commercialization of cutting-edge targeted cancer therapies, no assurance can be given that their prior successes will be indicative of our future success.

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, product 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, 2024, we had 118 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 ADC platform, develop our programs or product candidates or run our operations or to accomplish our objectives.

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

As our product candidates enter and advance through preclinical studies and any clinical trials, including our Phase 1 clinical trial of IM-1021 and our Phase 3 clinical trial of varegacestat, 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 product candidates using our ADC platform 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 product candidates, and delays or failures to obtain such approvals;
- failure of any of our product 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 product candidates;
- any inability to obtain adequate supply of our product 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 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, including pursuant to the 2024 ATM Agreement, 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 healthcare 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 product 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, preferred 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, 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. Additionally, in February 2024, we filed an automatic shelf registration statement on Form S-3, pursuant to which we have, and may in the future issue from time-to-time securities in one or more offerings at prices and terms to be determined at the time of sale. For example, in February 2024 and January 2025, we raised $230.0 million and $172.5 million, respectively, before deducting underwriting discounts and commissions and estimated offering expenses payable by us, through the public offering of our common stock. In connection with the closing of the public offerings, we issued and sold 11,500,000 shares of our common stock in February 2024 and 22,258,064 shares of our common stock in January 2025. In May 2024, we also entered into the 2024 ATM Agreement with TD Cowen, pursuant to which we may offer and sell, from time to time through TD Cowen, at our option, shares of our common stock. As of the filing of this Annual Report, we have sold 2,030,431 shares of our common stock for gross proceeds of approximately $20.0 million pursuant to the 2024 ATM Agreement and approximately $180.0 million remains available for future sales. If we sell shares of common stock, preferred stock, convertible securities or other equity securities, including pursuant to sales under the 2024 ATM Agreement, investors may be materially diluted. 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.

We issued 2,298,586 shares to Zentalis in connection with the Zentalis License Agreement, 2,175,489 shares to Ayala in connection with the Ayala Asset Purchase Agreement, 230,415 shares to BMS in connection with the BMS License Agreement Amendment and 1,805,502 shares to Zentalis in connection with the Zentalis Asset Purchase, all of which are registered for resale on Forms S-3 filed with the SEC in April 2024, October 2024 and November 2024, respectively. The shares issued to Zentalis in October 2024 are subject a to a six-month lock-up with respect to half of the shares. The shares issued to Ayala in April 2024 and Zentalis in October 2024 are subject to an orderly market disposition for one year from the date of issuance. Notwithstanding these contractual protections, any sales of these shares may cause our stock price to fall.

Pursuant to our 2020 Equity Incentive Plan, or 2020 Plan, our board of directors or committee thereof or, in accordance with applicable law, designated members of management are authorized to grant stock options to our employees, directors and consultants. In addition, pursuant to our 2024 Inducement Plan, our board of directors, or a committee thereof, is authorized to grant inducement awards to new hires as a material inducement to their employment with us. The aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2020 Plan as of December 31, 2024 shall not exceed 8,243,627 shares, and the aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2024 Inducement Plan shall not exceed 2,000,000 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 as of December 31, 2024 may not exceed 2,822,308 shares. Although we did not initially anticipate issuing awards under the Morphimmune Plan, depending on our needs, we may in the future issue awards under the Morphimmune Plan. Additionally, on June 28, 2023, Clay Siegall was granted options to purchase shares of the Company's common stock pursuant to an Inducement Grant. The aggregate number of stock awards that may be issued under the Inducement Grant may not exceed 2,137,080 shares.

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 in a taxable year is limited to 80% of taxable income in such year. 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. In addition, there may be other limitations under state law on our ability to utilize NOLs, including temporary suspensions or other limitations on the use of NOLs to offset taxable income. 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 inflation, higher interest rates and potential recession. Furthermore, uncertainties associated with a severe or prolonged economic downturn, recessions or depressions, or political disruption such as potential trade wars, tariffs or the war between Ukraine and Russia and the conflicts in the Middle East, and other macroeconomic developments could result in a variety of risks to our business, including weakened demand for our product 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, if approved. 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 vendors or collaborators 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 Trump 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 are 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 Head of Information Technology, who leads our information technology department and reports to Mr. Rosett, our Chief Financial Officer, 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 Chief Financial Officer, and our Head of Information Technology. Mr. Rosett has over 10 years of experience in the biotech and technology industry, including serving as a software engineer at Google. Our Head of Information Technology has over 30 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 Head of Information Technology 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 Mr. Rosett. Mr. Rosett and our Head of Information Technology 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 39,000 square feet of office and laboratory space in Bothell, Washington under a lease that expires on March 31, 2033. 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 14, 2025, there were approximately 63 record holders of our common stock. A substantially greater number of holders are beneficial owners whose shares are held of record by banks, brokers and other nominees.

Dividends

We have not declared or paid any dividends since our inception, nor do we expect to pay dividends in the foreseeable future.

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 clinical-stage targeted oncology company committed to developing targeted therapies designed to improve outcomes for cancer patients. We are advancing an innovative portfolio of therapeutics, drawing on leadership that previously played key roles in the design, development, and commercialization of cutting-edge targeted cancer therapies, including antibody-drug conjugate therapies, or ADCs. We believe that the pursuit of novel or underexplored targets will be central to the next generation of transformative therapies, and we are dedicated to developing targeted cancer therapies with first-in-class and best-in-class potential. Our goal is to establish a broad pipeline of preclinical and clinical assets and develop these assets into approved products for commercialization.

We are advancing a pipeline comprising two clinical assets and four preclinical assets. Varegacestat, formerly AL102, is an investigational gamma secretase inhibitor, or GSI, currently under evaluation in a Phase 3 clinical trial for the treatment of desmoid tumors. Our investigational new drug application, or IND, for IM-1021, a receptor tyrosine kinase-like orphan receptor 1, or ROR1, antibody-drug conjugate, received FDA clearance in December 2024, and the Phase 1 trial is ongoing with the first patient dosed in February 2025. Our other preclinical assets include IM-3050, a fibroblast activation protein, or FAP, targeted radioligand therapy, or RLT, for which we submitted an IND in March 2025, and three solid tumor ADC drug candidates: IM-1617, IM-1340, and IM-1335, all of which are in IND-enabling activities. We have six additional ADCs currently undergoing lead optimization in advance of future development decisions.

At present, our internal discovery efforts center on designing ADCs against novel or underexplored targets. We believe that pursuing differentiated targets provides a path to significant clinical benefit and meaningful market opportunities. This strategy is supported by HC74, the differentiated, novel topoisomerase 1, or TOP1, inhibitor payload we exclusively licensed from Zentalis Pharmaceuticals, Inc., or Zentalis, in January 2024 and subsequently purchased from Zentalis in October 2024. We have efforts underway to develop additional linkers and payloads and believe that a broad toolbox of linkers and payloads supports our mission to design and develop a diverse pipeline of ADCs.

To expand and advance our innovative portfolio of therapeutics, we draw on leadership that previously played key roles in the design, development, and commercialization of cutting-edge targeted cancer therapies, including the first ADCs commercialized for Hodgkin and T-cell lymphoma, urothelial cancer and cervical cancer.

Our current programs

Varegacestat (formerly AL102)

Our lead clinical asset is varegacestat, an oral, once daily GSI therapy that is being evaluated for the treatment of desmoid tumors. In the Phase 2 RINGSIDE study Part A, varegacestat demonstrated objective response rates, or ORR, of 75% of evaluable patients and 64% in the intent-to-treat population; median reduction in tumor volume of 88%; and an 85% reduction in T2 imaging, which is suggestive of a reduction in cellularity. The Phase 2 data also show that varegacestat has a safety profile consistent with other GSI therapies. Enrollment in a Phase 3 registrational trial was completed in February 2024, and we expect to report topline data from this trial in the second half of 2025. We acquired varegacestat from Ayala Pharmaceuticals, Inc., or Ayala, in March 2024.

IM-1021 (Solid Tumor and B-Cell Lymphoma ADC)

IM-1021 is a ROR1 ADC that incorporates HC74, our proprietary TOP1i payload. ROR1 is expressed in both hematologic malignancies and solid tumors with limited normal tissue expression, and previous ADCs targeting ROR1 have demonstrated clinical activity. In preclinical studies, IM-1021 showed sustained tumor regression in preclinical models, including a mouse model of triple-negative breast cancer, or TNBC, and a mouse model of mantle cell lymphoma, or MCL We believe that IM-1021 may provide improved therapeutic index as compared to other ROR1-targeted ADCs in development. IM-1021 received IND clearance in December 2024, and the phase 1 clinical trial is ongoing with a starting dose of 2 mg/kg of adjusted ideal body weight. We expect dose escalation to include patients both with solid tumors and with B-cell lymphoma.

IM-3050 (FAP Radioligand Therapy)

IM-3050 is a FAP-targeted lutetium-177, Lu-177 or 177Lu, RLT product candidate for the treatment of solid tumors. FAP, or fibroblast activation protein, is a cell surface protease that serves as a tumor-specific marker due to its broad expression on cancer associated fibroblasts, the most common tumor stromal cell. FAP is expressed in 75% of solid tumors. IM-3050 is designed to deliver radioactive 177Lu 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. *In vivo* data show single dose antitumor activity and tolerability. We submitted an IND for this program to the FDA in March 2025, and expect to initiate a Phase 1 clinical trial in the second half of 2025.

IM-1617 (Solid Tumor ADC)

IM-1617 is a potential first-in-class ADC that targets an undisclosed receptor that is preferentially expressed in a broad array of solid tumors, including colorectal cancer, or CRC, non-small cell lung cancer, or NSCLC, and breast and ovarian cancers. The target is a receptor tyrosine kinase that promotes tumor cell survival and mediates immune cell exclusion, providing potential for a secondary mechanism of action. IND-enabling work for IM-1617 was initiated in the fourth quarter of 2024.

IM-1340 (Solid Tumor ADC)

IM-1340 is a potential first-in-class ADC for the treatment of multiple solid tumors. The target of IM-1340 is underexplored and non-obvious in cancer and, to our knowledge, there are no ADCs or other therapeutic modalities in development against it. It has a unique expression profile that spans neuroendocrine tumors, or NETs, and other carcinomas, including lung and prostate tumors, with limited expression in normal tissue. IND-enabling work for IM-1335 was initiated in the fourth quarter of 2024.

IM-1335 (Solid Tumor ADC)

IM-1335 is being developed for the treatment of solid tumor indications. It shares a target with a competitor's now-discontinued investigational ADC that showed clinical activity prior to discontinuation. Our goal in designing IM-1335 was to optimize the safety and efficacy through a deep understanding of target biology and ADC optimization. We identified limitations that we expect contributed to the failure of the prior ADC against this target, and we believe that IM-1335 overcomes these limitations. IND-enabling work for IM-1335 was initiated in the fourth quarter of 2024.

Other Programs and Platforms

In addition to the already described current programs, we expect to continue to invest in discovery efforts intended to expand our pipeline. Additional ADC programs are the primary focus of these efforts. We believe that our team's ADC expertise positions us to develop the next generation of transformative ADCs. This expertise comprises executive leadership with a proven record of success, an ADC-focused discovery team with deep experience in ADC design, and a seasoned development team whose members spearheaded the development of multiple FDA-approved ADCs. We pair our portfolio of antibodies to potential first-in-class ADC targets with rigorous target selection based on a deep understanding of target biology. That target-driven approach is complemented by HC74, our differentiated, proprietary TOP1 inhibitor payload and our optimized, proprietary linkers.

Recent Events

Ayala Purchase Agreement

In March 2024, we completed an asset purchase pursuant to an asset purchase agreement, or the Ayala Purchase Agreement, initially entered into with Ayala Pharmaceuticals, Inc., or Ayala, in February 2024, pursuant to which we acquired Ayala's AL101 and varegacestat (then known as AL102) programs and assumed certain liabilities associated with the acquired assets. Under the Ayala Purchase Agreement, we paid Ayala approximately $20.0 million in cash and issued 2,175,489 shares of our common stock with an aggregate fair value of $50.6 million on the date of issuance. We are also obligated to pay Ayala up to $37.5 million in the aggregate upon the achievement of certain development, regulatory and commercial milestones.

Zentalis Pharmaceuticals License and Purchase Agreements

In January 2024, we entered into a license agreement with Zentalis, or the Zentalis License Agreement, 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 or, collectively, the Zentalis Licensed Assets. Under the Zentalis License Agreement, we paid Zentalis $15.0 million in cash and issued Zentalis 2,298,586 shares of our common stock with an aggregate fair value of $23.4 million on the date of issuance.

In October 2024, we completed an asset purchase agreement with Zentalis, or the Zentalis Purchase Agreement, pursuant to which we purchased the Zentalis Licensed Assets previously licensed to us under the then-existing Zentalis License Agreement. Upon closing of the Zentalis Purchase Agreement, the Zentalis License Agreement was terminated. Under the Zentalis Purchase Agreement, we issued Zentalis 1,805,502 shares of our common stock with an aggregate fair value of $21.0 million on the date of issuance. We are also obligated to pay Zentalis a one-time payment of $5.0 million in cash upon the achievement of a developmental milestone that was previously a milestone under the Zentalis License Agreement. The $5.0 million developmental milestone was achieved in the fourth quarter of 2024 and paid in the first quarter of 2025.

Bristol-Myers Squibb

In connection with the closing of the Ayala Purchase Agreement in March 2024, we assumed a license agreement, the BMS License Agreement, with Bristol-Myers Squibb Company, or BMS, pursuant to which we obtained a worldwide, non-transferable, royalty-bearing, exclusive, sublicensable, license under certain patent rights and know-how of BMS to research, discover, develop, make, have made, use, sell, offer to sell, export, import and commercialize AL101 and varegacestat, or the BMS Licensed Compounds, and products containing AL101 or varegacestat, or the BMS Licensed Products, for all uses including the prevention, treatment or control of any human or animal disease, disorder or condition.

In August 2024, we amended the BMS License Agreement and issued BMS 230,415 shares of our common stock with an aggregate fair value of $2.7 million on the date of issuance. Under the as amended BMS License Agreement, we are obligated to pay BMS up to approximately $142.0 million in the aggregate upon the achievement of certain clinical development or regulatory milestones for AL101 and varegacestat across multiple indications. In addition, we are obligated to pay BMS up to $50.0 million in the aggregate upon the achievement of certain commercial milestones for each BMS Licensed Product.

2025 Public Offering

In January 2025, we issued 22,258,064 shares of our common stock in a public offering for aggregate proceeds of $172.5 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by us, or the 2025 Financing.

2024 Public Offering

In February 2024, we issued 11,500,000 shares of our common stock in a public offering for net proceeds of $215.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us, or the 2024 Financing.

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 a Collaboration and Option Agreement, or the Collaboration Agreement, with AbbVie Global Enterprises Ltd., or 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

Intangible assets acquired in an asset acquisition for use in research and development activities which have no alternative future use are expensed as in-process research and development, or IPR&D, expense on the acquisition date. IPR&D expense for the year ended December 31, 2024 primarily relates to the acquisition of certain assets and licenses from Ayala, Zentalis, and others. IPR&D expense for the year ended December 31, 2023 primarily relates to the acquisition of certain assets and licenses in connection with the Morphimmune merger.

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 product candidates, including under agreements with consultants, contractors, contract research organizations, or CROs, and other third-party vendors and suppliers;
- expenses to conduct clinical trials including regulatory and quality assurance;

- the cost of process development, validation, and the manufacturing of drug supplies 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 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, 2024 and 2023:

The following table summarizes our results of operations for the periods presented (in thousands):

	Year Ended December 31,		
	2024	2023	Change
Collaboration revenue	$ 9,041	$ 14,018	$ (4,977)
Operating expenses:			
In-process research and development	152,344	80,802	71,542
Research and development[(1)]	129,542	23,089	106,453
General and administrative[(1)]	32,955	19,657	13,298
Total operating expenses	314,841	123,548	191,293
Loss from operations	(305,800)	(109,530)	(196,270)
Interest income	12,837	2,724	10,113
Net loss	$ (292,963)	$ (106,806)	$ (186,157)

(1) Amounts include non-cash share-based compensation expense as follows (in thousands):

	Year Ended December 31,		
	2024	2023	Change
Research and development	$ 5,146	$ 1,981	$ 3,165
General and administrative	10,602	4,242	6,360
Total share-based compensation expense	$ 15,748	$ 6,223	$ 9,525

Collaboration revenue

Collaboration revenue decreased by $5.0 million, from $14.0 million for the year ended December 31, 2023 to $9.0 million for the year ended December 31, 2024. The decrease was primarily due to a decrease in certain research and development activities allocated to AbbVie during the year ended December 31, 2024 compared to the year ended December 31, 2023.

In-process research and development expenses

IPR&D expense for the year ended December 31, 2024 primarily related to the write-off of acquired IPR&D assets that were determined to have no alternative future use. IPR&D expense for the year ended December 31, 2023 related to the write-off of IPR&D assets acquired in connection with the Morphimmune merger that were determined to have no alternative future use.

Research and development expenses

Research and development expenses increased by $106.5 million, from $23.1 million for the year ended December 31, 2023 to $129.5 million for the year ended December 31, 2024.

We record direct research and development expenses which consist primarily of external costs related to manufacturing, outsourced research, product development, and clinical trial costs, including fees paid to investigators, consultants, central laboratories and CROs, to specific product candidates. Indirect research and development expenses have not been allocated directly to a program as they benefit multiple product programs, and primarily consist of personnel salary, benefit and stock-based compensation costs, depreciation, laboratory materials and services, and costs to maintain our facilities.

The table below shows our research and development expenses incurred with respect to each active program (in thousands):

	Year Ended December 31,		
	2024	2023	Change
Varegacestat [1]	$ 27,954	$ —	$ 27,954
IM-1021 [2]	24,130	—	24,130
IM-3050 [3]	13,359	—	13,359
Other product candidates [4]	35,335	11,278	24,057
Indirect research and development [5]	28,764	11,811	16,953
Total	$ 129,542	$ 23,089	$ 106,453

(1) The increase for the year ended December 31, 2024 compared to the year ended December 31, 2023 was due primarily to manufacturing and clinical trial activities related to varegacestat, which we acquired from Ayala in March 2024.

(2) The increase for the year ended December 31, 2024 compared to the year ended December 31, 2023 was due primarily to increased outsourced research, manufacturing and IND-enabling activities pertaining to IM-1021, which we licensed from Zentalis in January 2024 and subsequently acquired from Zentalis in October 2024.

(3) The increase for the year ended December 31, 2024 compared to the year ended December 31, 2023 was due primarily to increased outsourced research, manufacturing and IND-enabling activities for IM-3050.

(4) The increase for the year ended December 31, 2024 compared to the year ended December 31, 2023 was due primarily to increased ADC discovery activities.

(5) The increase for the year ended December 31, 2024 compared to the year ended December 31, 2023 was due primarily to an increase in personnel and personnel-related costs in support of varegacestat, IM-1021, IM-3050 and other development and discovery programs.

General and administrative expenses

General and administrative expenses increased by $13.3 million, from $19.7 million for the year ended December 31, 2023 to $33.0 million for the year ended December 31, 2024. The increase was primarily a result of a $10.1 million increase in personnel-related costs from an increase in headcount, including a $6.4 million increase in share-based compensation.

Interest income

Interest income increased by $10.1 million from $2.7 million for the year ended December 31, 2023 to $12.8 million for the year ended December 31, 2024. The increase was primarily a result of higher cash and cash equivalent and marketable security balances.

Liquidity and capital resources

Sources of liquidity

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, collaboration arrangements, strategic partnerships and transactions and to a lesser extent, through expense reimbursements received from a governmental contract that ended in 2022.

To date, we have not generated any revenue from commercial sale of products and do not expect to generate revenue from commercial sales for the foreseeable future. Since inception, we have incurred significant operating losses and negative cash flows from operations. Our net losses were $293.0 million and $106.8 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had cash, cash equivalents and marketable securities of $217.3 million and an accumulated deficit of $515.8 million.

In February 2024, we completed our 2024 Financing and issued 11,500,000 shares of our common stock at $20.00 per share for net proceeds of $215.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

In May 2024, we entered into an "at the market" sales agreement, or the 2024 ATM Agreement, with TD Securities (USA) LLC, or TD Cowen, as sales agent, pursuant to which we may offer and sell from time to time shares of our common stock having an aggregate offering price of up to $200.0 million, or the ATM Shares . We have agreed to pay TD Cowen a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold through the 2024 ATM Agreement. In November 2024, we sold 2,030,431 shares of common stock under the 2024 ATM Agreement, resulting in net proceeds of approximately $19.6 million.

In January 2025, we completed our 2025 Financing and issued 22,258,064 shares of our common stock at $7.75 per share for gross proceeds of $172.5 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Cash flows

The following table summarizes our sources and uses of cash for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	**2023**
Cash used in operating activities	$ (110,794)	$ (7,568)
Cash used in investing activities	(85,063)	(30,484)
Cash provided by financing activities	240,529	116,408
Net increase in cash and cash equivalents and restricted cash	$ 44,672	$ 78,356

Operating activities

Net cash used in operating activities for the year ended December 31, 2024 was $110.8 million, consisting primarily of our net loss of $293.0 million, partially offset by noncash charges of $167.3 million and a net change in operating assets and liabilities of $14.9 million. The noncash charges primarily consisted of $152.3 million of IPR&D assets acquired without alternative future use and $15.7 million of share-based compensation. The change in operating assets and liabilities primarily consisted of an increase in accrued expenses and other current liabilities of $13.6 million, an increase in accounts payable of $9.5 million and a decrease in prepaid expenses and other assets of $0.9 million, partially offset by a decrease in deferred revenue of $9.0 million.

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, partially offset by noncash charges of $87.2 million and a net change in operating assets and liabilities of $12.0 million. The noncash charges primarily consisted of $80.8 million of IPR&D assets acquired without alternative future use and $6.2 million of share-based compensation. The change in operating assets and liabilities primarily consisted of an increase in deferred revenue of $16.0 million, partially offset by an increase in prepaid expenses and other assets of $4.1 million.

Investing activities

Net cash used in investing activities for the year ended December 31, 2024 was $85.1 million, consisting primarily of $186.6 million of purchases of marketable securities, $46.3 million of purchases of IPR&D assets and $7.2 million of purchases of property and equipment, partially offset by $155.0 million from maturities of marketable securities

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

Financing activities

Net cash provided by financing activities for the year ended December 31, 2024 was $240.5 million, consisting of gross proceeds of $230.0 million from the 2024 Financing, gross proceeds of $20.0 million from the issuance of common stock under the 2024 ATM Agreement and $5.8 million from the exercise of options and common stock warrants, partially offset by offering costs of $15.2 million from our 2024 Financing and 2024 ATM Agreement.

Net cash provided by financing activities for the year ended December 31, 2023 was $116.4 million, consisting of gross proceeds of $125.4 million from the private investment in public equity, or PIPE, transaction held concurrently with the closing of the Morphimmune merger in October 2023, the exercise of options, and the issuance of common stock under our prior ATM sales agreement that we terminated in November 2023, partially offset by the payment of $9.0 million for offering costs related to the PIPE transaction.

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 varegacestat, seek regulatory approval for varegacestat, advance the clinical development of IM-1021, continue the development of IM-3050 and any other current and 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, 2024, together with the proceeds from the 2025 Financing, will be sufficient 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 product 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 product candidates that we currently own and those that we may discover or acquire rights to in the future;
- 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 product candidates we may develop;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, distribution, coverage and reimbursement for any programs or product 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, including pursuant to the 2024 ATM Agreement, debt financings, collaborations, strategic alliances and licensing arrangements. As a result of the war between Russia and Ukraine, conflicts in the Middle East, trade wars, 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, including pursuant to the 2024 ATM Agreement, 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 product candidates that we would otherwise prefer to develop and market ourselves. If we cannot obtain the necessary funding to support these activities on favorable terms, or 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.

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. Except for the $5.8 million in developmental milestones accrued as of December 31, 2024, as further described in Note 7 to our audited consolidated financial statements, our expected material cash requirements do not include potential contingent payments that we may be required to pay upon the achievement of development, regulatory or commercial milestones pursuant to asset acquisitions and license agreements to which we are a party, nor do they include potential contingent payments upon the achievement 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 Note 7 to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Critical accounting policies and estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

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 accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas that involve management's judgement and estimates and are reasonably likely to have a material impact on our financial condition or results of operations.

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 a research discovery collaboration arrangement, which was determined to be within the scope of Accounting Standards Codification, or 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 12 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 subjective assumptions such as the expected volatility, expected term, risk-free interest rate, and dividend yield.

Due to the lack of company-specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to us, 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. We use 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 our 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 we have never paid dividends and have no current plans to pay any dividends on our common stock.

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.

Research and development expenses and accruals

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, and preclinical and clinical development expenses, including process development, validation, and the manufacture of drug supplies, costs to conduct clinical trials, and amounts incurred under license agreements, consulting agreements and other contracted services. Research and development costs are expensed as incurred.

As part of preparing our financial statements, we are required to estimate and accrue expenses. We estimate preclinical, clinical trial and other research and development expenses based on the services performed pursuant to contracts with research institutions, contract manufacturing organizations, or CMOs, and third-party service providers that conduct and manage preclinical studies and clinical trials and perform research services on our behalf. We record these costs of research and development activities based upon the estimated services provided but not yet invoiced and include these costs in accrued expenses and other current liabilities in our consolidated balance sheets and in research and development expense in our consolidated statements of operations. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. 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 may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from external third-party service providers. Amounts ultimately incurred in relation to amounts accrued for these services at a reporting date may be substantially higher or lower than our estimates.

We execute all our clinical trials with support from contract research organizations, or CROs, and other vendors and we accrue costs for clinical trial activities performed by these third parties based upon the estimated amount of work completed on each trial. The significant factors used in estimating accruals include the number of patients enrolled, the activities to be performed for each patient, the number of active clinical sites, and the duration for which the patients will be enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms. We base our estimates on the best information available at the time. However, additional information may become available to us, which may allow us to make a more accurate estimate in future periods. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

JOBS Act

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of our initial public offering (i.e., December 31, 2025) or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.235 billion in annual revenue during our most recently completed fiscal year, we have more than $700.0 million in market value of our stock held by non-affiliates as of the last business day of our most recently completed second fiscal quarter, or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

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 126 to 153 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 Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) 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 Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2024 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. Our 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. Our 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 our 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 our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

In connection with the preparation of our annual consolidated financial statements, management has undertaken an assessment of the effectiveness of our 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 our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2024.

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, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the quarter ended June 30, 2024, entities in which one of our directors has an indirect pecuniary interest that is reportable under Section 16 of the Exchange Act, adopted a Rule 10b5-1 trading plan, which is set forth in the table below.

Name and Position	Action	Adoption/Termination Date	Rule 10b5-1[1]	Non-Rule 10b5-1[2]	Total Shares of Common Stock to be Sold	Expiration Date
Isaac Barchas, Director [3]	Adoption	May 23, 2024	X		2,410,553	May 21, 2027

[1] Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

[2] "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.

[3] The Rule 10b5-1 trading plan was adopted by Arsenal Bridge Venture II, LLC, or ABV II, and Arsenal Bridge Venture II-B LLC, or ABV II-B. Mr. Barchas is a co-founder and holder of a power of attorney with the ability to exercise voting and investment power over the shares held by ABV II and ABV II-B. Mr. Barchas disclaims beneficial ownership of the shares covered by the Rule 10b5-1 trading plan, except to the extent of his pecuniary interest, if any.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

We will file a definitive proxy statement for our 2025 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 Relationships and Related-Person Transactions," 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

The financial statements filed as part of this Annual Report on Form 10-K are listed in the "Index to the Consolidated Financial Statements" found on page 126.

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

(3) Exhibits

The following 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.

EXHIBIT INDEX

Exhibit Number	Description
1.1	Sales Agreement, by and between the Company and TD Securities (USA) LLC, dated May 14, 2024 (incorporated by reference to Exhibit 1.1 to our Quarterly Report on Form 10-Q filed on May 14, 2024).
2.1†+	Agreement and Plan of Merger and Reorganization, by and among the Company, Ibiza Merger Sub, Inc. and Morphimmune Inc., dated 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 Immunome, Inc. 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).
2.3†+	Asset Purchase Agreement, by and among Immunome, Inc., Zentalis Pharmaceuticals, Inc. and Zeno Management, Inc., dated October 25, 2024 (incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed October 29, 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 to the Amended and Restated Certificate of Incorporation of Immunome, Inc., dated October 2, 2023, to implement Officer Exculpation (incorporated by reference to Exhibit 3.3 to our Current Report on Form 8-K filed October 4, 2023).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Immunome, Inc., dated October 2, 2023, to implement Authorized Share Increase (incorporated by reference to Exhibit 3.4 to our Current Report on Form 8-K filed October 4, 2023).
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	Description of Securities (incorporated by reference to Exhibit 4.6 to our Annual Report on Form 10-K filed on March 16, 2023).
4.3	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).
4.4	Stock Issuance Agreement, dated January 5, 2024, by and between Immunome, Inc. and Zentalis Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.3 to our Registration Statement on Form S-3 filed with the SEC on February 13, 2024).
4.5	Stock Issuance Agreement, dated August 7, 2024, by and between Immunome, Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 4.7 to our Registration Statement on Form S-3 filed with the SEC on October 8, 2024).
4.6	Stock Issuance Agreement, by and between the Company and Zentalis Pharmaceuticals, Inc., dated October 25, 2024 (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on October 29, 2024).

10.1#	Form of Indemnification Agreement between the Company 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 Executive and Non-Executive Stock Option Grant Notice, Option Agreement and Notice of Exercise for the 2020 Equity Incentive Plan.
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 Company'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 Company's Registration Statement on Form S-4/A (File No. 333-273792) filed with the SEC on August 28, 2023).
10.11#*	Immunome, Inc. 2024 Inducement Plan and Forms of Executive and Non-Executive Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder.
10.12#	Inducement Non-Qualified Stock Option Agreement, dated June 28, 2023, by and between the Company and Clay B. Siegall, Ph.D. (Filed as Exhibit 99.4 to the Company's Registration Statement on Form S-8 filed on February 2, 2024 and incorporated herein by reference).
10.13#	Executive Employment Agreement dated June 28, 2023, by and between the Company and Clay B. Siegall, Ph.D. (Filed as Exhibit 10.5 to the Company's Current Report on Form 8-K filed on June 29, 2023 and incorporated herein by reference).
10.14#	Amendment No. 1 to Executive Employment Agreement dated December 1, 2023, by and between the Company and Clay B. Siegall, Ph.D (incorporated by reference to Exhibit 10.16 to our Annual Report on Form 10-K filed on March 28, 2024).
10.15#	Amended and Restated Employment Offer Terms dated November 30, 2023, by and between the Company and Sandra G. Stoneman (incorporated by reference to Exhibit 10.17 to our Annual Report on Form 10-K filed on March 28, 2024).

10.16#	Amended and Restated Employment Offer Terms dated November 30, 2023, by and between the Company and Max Rosett (incorporated by reference to Exhibit 10.19 to our Annual Report on Form 10-K filed on March 28, 2024).
10.17#	Amended and Restated Employment Offer Terms dated November 30, 2023, by and between the Company and Jack Higgins, Ph.D (incorporated by reference to Exhibit 10.20 to our Annual Report on Form 10-K filed on March 28, 2024).
10.18#	Amended and Restated Employment Offer Terms dated November 30, 2023, by and between the Company and Robert Lechleider, M.D (incorporated by reference to Exhibit 10.21 to our Annual Report on Form 10-K filed on March 28, 2024).
10.19#	Employment Offer Letter dated February 7, 2024, by and between the Company and Kinney Horn (incorporated by reference to Exhibit 10.23 to our Annual Report on Form 10-K filed on March 28, 2024).
10.20#	Employment Offer Letter dated June 17, 2024, by and between Immunome, Inc. and Phil Tsai (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on August 12, 2024).
10.21#	Relocation Offer Letter dated January 20, 2025, by and between the Company and Max Rosett (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 3, 2025).
10.22#	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).
10.23†+	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).
10.24*	Amendment #1 to Master License Agreement, by and between Morphimmune, Inc. and Purdue Research Foundation, dated October 16, 2024.
10.25†+	License Agreement dated November 29, 2017, by and between the Company (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).
10.26†	Amendment No. 2 to License Agreement, dated August 7, 2024, by and between the Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on November 13, 2024).
10.27†+*	Lease dated October 5, 2023, by and between the Company and Nitrogen Propco 2020, L.P., as amended by the First Amendment to Lease dated May 13, 2024, and as amended by the Second Amendment to Lease dated December 16, 2024.
10.28†+*	Lease dated December 16, 2024, by and between the Company and Nitrogen Propco 2020, L.P.
19.1*	Amended and Restated Insider Trading Policy
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 of our Annual Report on Form 10-K filed March 28, 2024).

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 (incorporated by reference to Exhibit 97 of our Annual Report on Form 10-K filed March 28, 2024).
101*	The following financial information from the Annual Report on Form 10 K of IMMUNOME, INC. for the year ended December 31, 2024, formatted in Inline XBRL (eXtensible Business Reporting Language): (1) Balance Sheets as of December 31, 2024 and 2023; (2) Statements of Operations and Comprehensive Loss for the years ended December 31, 2024 and 2023; (3) Statements of Changes in Stockholders' Equity for the years ended December 31, 2024 and 2023; (4) Statements of Cash Flows for the years ended December 31, 2024 and 2023; 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 is the type of information the Company treats as private or confidential.

+ Schedules and exhibits to the agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

†† 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 Company 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.

IMMUNOME, INC.

Date: March 19, 2025

By: /s/ Clay B. Siegall Ph.D.
Name: Clay B. Siegall, Ph.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS 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 or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her 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 Clay B. Siegall Ph.D.	President, Chief Executive Officer and Director (*Principal Executive Officer*)	March 19, 2025
/s/ Max Rosett Max Rosett	Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 19, 2025
/s/ Isaac Barchas Isaac Barchas, J.D	Director	March 19, 2025
/s/ Jean-Jacques Bienaime Jean-Jacques Bienaime	Director	March 19, 2025
/s/ James Boylan James Boylan	Director	March 19, 2025
/s/ Carol Schafer Carol Schafer	Director	March 19, 2025
/s/ Sandra Swain Sandra Swain, M.D.	Director	March 19, 2025
/s/ Philip Wagenheim Philip Wagenheim	Director	March 19, 2025

IMMUNOME, INC.

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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, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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 19, 2025

IMMUNOME, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 143,351	$ 98,679
Marketable securities	73,952	39,463
Prepaid expenses and other current assets	4,036	6,561
Total current assets	221,339	144,703
Property and equipment, net	10,113	2,073
Operating right-of-use assets	4,278	1,564
Restricted cash	100	100
Other long-term assets	4,411	100
Total assets	$ 240,241	$ 148,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 14,189	$ 3,311
Accrued expenses and other current liabilities	33,177	8,025
Deferred revenue, current	6,941	10,493
Total current liabilities	54,307	21,829
Deferred revenue, non-current	—	5,489
Operating lease liabilities, net of current portion	4,769	1,340
Total liabilities	59,076	28,658
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at December 31, 2024 and 2023; 64,460,829 and 43,251,778 shares issued and outstanding at December 31, 2024 and 2023, respectively	6	4
Additional paid-in capital	696,872	342,663
Accumulated other comprehensive income	57	22
Accumulated deficit	(515,770)	(222,807)
Total stockholders' equity	181,165	119,882
Total liabilities and stockholders' equity	$ 240,241	$ 148,540

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,	
	2024	2023
Collaboration revenue	$ 9,041	$ 14,018
Operating expenses:		
In-process research and development	152,344	80,802
Research and development	129,542	23,089
General and administrative	32,955	19,657
Total operating expenses	314,841	123,548
Loss from operations	(305,800)	(109,530)
Interest income	12,837	2,724
Net loss	$ (292,963)	$ (106,806)
Net loss per share, basic and diluted	$ (5.00)	$ (5.38)
Weighted-average shares outstanding, basic and diluted	58,639,441	19,843,651
Comprehensive loss:		
Net loss	$ (292,963)	$ (106,806)
Unrealized gain on marketable securities	35	22
Comprehensive loss	$ (292,928)	$ (106,784)

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)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance at December 31, 2022	12,128,843	$ 1	$ 132,653	$ —	$ (116,001)	$ 16,653
Share-based compensation expense	—	—	6,153	—	—	6,153
Issuance of common stock under prior ATM, net of $1 of issuance costs	5,925	—	34	—	—	34
Issuance of common stock	55,250	—	221	—	—	221
Issuance of common stock for PIPE transaction, net of $9,000 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
Vesting of restricted stock awards	12,498	—	70	—	—	70
Exercise of stock options	522,681	—	371	—	—	371
Unrealized gain on marketable securities	—	—	—	22	—	22
Net loss	—	—	—	—	(106,806)	(106,806)
Balance at December 31, 2023	43,251,778	4	342,663	22	(222,807)	119,882
Share-based compensation expense	—	—	15,748	—	—	15,748
Issuance of common stock under Zentalis License Agreement	2,298,586	—	23,388	—	—	23,388
Issuance of common stock under the Ayala Asset Purchase Agreement	2,175,489	—	50,645	—	—	50,645
Issuance of common stock in connection with BMS License Agreement Amendment	230,415	—	2,699	—	—	2,699
Issuance of common stock under Zentalis Purchase Agreement	1,805,502	—	20,990	—	—	20,990
Issuance of common stock for public offering, net of commissions and offering costs of $14,592	11,500,000	2	215,408	—	—	215,410
Issuance of common stock under ATM, net of $424 issuance costs	2,030,431	—	19,576	—	—	19,576
Exercise of stock options	795,571	—	2,024	—	—	2,024
Exercise of common stock warrants	373,057	—	3,731	—	—	3,731
Unrealized gain on marketable securities	—	—	—	35	—	35
Net loss	—	—	—	—	(292,963)	(292,963)
Balance at December 31, 2024	64,460,829	$ 6	$ 696,872	$ 57	$ (515,770)	$ 181,165

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (292,963)	$ (106,806)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,567	457
Amortization of right-of-use asset	535	271
Accretion of discounts on marketable securities	(2,899)	(512)
Share-based compensation expense	15,748	6,223
Charge for purchase of in-process research and development assets	152,344	80,802
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	906	(4,144)
Accounts payable	9,526	(608)
Accrued expenses and other current liabilities	13,550	614
Deferred revenue	(9,041)	15,982
Operating lease liabilities	(67)	153
Net cash used in operating activities	(110,794)	(7,568)
Cash flows from investing activities:		
Purchases of in-process research and development assets	(46,335)	—
Purchases of marketable securities	(186,555)	(38,929)
Cash acquired in connection with Morphimmune merger, net of transaction costs	—	9,276
Maturities of marketable securities	155,000	—
Purchases of property and equipment	(7,173)	(831)
Net cash used in investing activities	(85,063)	(30,484)
Cash flows from financing activities:		
Proceeds from public offering	230,002	—
Payment of offering costs	(15,228)	(8,997)
Proceeds from PIPE transaction	—	125,000
Proceeds from exercise of stock options	2,024	371
Proceeds from exercise of common stock warrants	3,731	—
Proceeds from issuance of common stock under ATM	20,000	34
Net cash provided by financing activities	240,529	116,408
Net increase in cash and cash equivalents and restricted cash	44,672	78,356
Cash and cash equivalents and restricted cash at beginning of period	98,779	20,423
Cash and cash equivalents and restricted cash at end of period	$ 143,451	$ 98,779
Reconciliation of cash and cash equivalents and restricted cash:		
Cash and cash equivalents	$ 143,351	$ 98,679
Restricted cash	100	100
Total cash, cash equivalents, and restricted cash	$ 143,451	$ 98,779

IMMUNOME, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2024	2023
Supplemental disclosures of non-cash investing and financing activities:		
Issuance of common stock and stock-based equity awards for the Morphimmune merger	$ —	$ 87,161
Issuance of common stock in exchange for in-process research and development assets	$ 97,722	$ —
Net liabilities assumed from purchases of in-process research and development assets	$ 2,041	$ —
Purchase of in-process research and development assets in accounts payable and accrued expenses	$ 6,246	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ 1,189	$ 1,325
Remeasurement of operating right-of-use asset and lease liability due to lease modifications	$ 2,035	$ 226
Issuance of common stock to certain board of directors in lieu of accrued compensation	$ —	$ 221
Purchases of property and equipment in accounts payable and accrued expenses and other current liabilities	$ 2,806	$ 372

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

IMMUNOME, INC.
Notes to Consolidated Financial Statements

1. Nature of the business

Organization

Immunome, Inc., or the Company or Immunome, a clinical-stage targeted oncology company committed to developing targeted therapies designed to improve outcomes for cancer patients. 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, and Morphimmune became a wholly owned subsidiary of Immunome.

Liquidity

The Company has incurred significant operating losses since inception and expects to continue to incur losses from operations for the foreseeable future as it pursues development of its therapeutic candidates and other programs. As of December 31, 2024, the Company had an accumulated deficit of $515.8 million, cash and cash equivalents of $143.4 million and marketable securities of $74.0 million. The Company has not generated any product revenue to date and does not expect to generate product revenue until it successfully completes development and obtains regulatory approval for at least one of its product candidates.

Through December 31, 2024, the Company has funded its operations primarily through sales of equity securities and strategic partnerships and transactions as well as expense reimbursements from a government contract that ended in 2022. The Company expects that its existing cash, cash equivalents and marketable securities at December 31, 2024, together with the proceeds received from the 2025 Financing (see Note 13), will be sufficient 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, the Company may need to raise additional capital through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements to achieve its longer-term business objectives.

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 subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the audited consolidated financial statements and the accompanying notes. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates. The Company's significant accounting estimates include, but are not necessarily limited to, revenue recognition, the estimated fair value of share-based awards, accrued research and development expenses and the fair value of acquired in-process research and development assets.

Segment and geographic information

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

Cash and cash equivalents

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. Cash and cash equivalents consist of cash held in banks, money market funds and U.S. treasury securities.

Restricted cash

Restricted cash represents collateral provided for a letter of credit issued as a security deposit in connection with one of the Company's leased facilities. Cash will be released from restriction upon termination of the lease. Restricted cash was $0.1 million at both December 31, 2024 and 2023.

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.

The Company periodically reviews its marketable securities for declines in fair value below the amortized cost basis to determine whether the impairment, if any, is due to credit-related or other factors. This review includes the credit worthiness of the security issuers, the severity of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not the Company will be required to sell the securities before the recovery of the amortized cost basis. Unrealized gains and losses on available-for-sale securities are reported in other comprehensive loss, and as a component of stockholders' equity until their disposition, with the exception of unrealized losses believed to be related to credit losses which are recognized as an allowance for credit losses on the consolidated balance sheet with the corresponding charge in other income in the period the impairment occurs. Impairment assessments are made at the individual security level each reporting period. The Company elected to exclude accrued interest receivable from the amortized cost basis of its available-for-sale debt securities and to not measure an allowance for credit losses for accrued interest receivable. To date, there have been no credit-related declines in value or other impairments of the Company's investments in marketable securities. Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method.

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	Estimated useful life
Lab equipment	5 years
Leasehold improvements	Shorter of useful life or remaining lease term
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 as a component of in-process research and development expense in the consolidated statements of operations and comprehensive loss.

In addition to upfront consideration, acquisitions of assets may also include contingent consideration payments to be made for future milestone events or royalties on net sales of future products. The Company assesses whether such contingent consideration is subject to liability classification and fair value measurement or meets the definition of a derivative. Contingent consideration payments in an acquisition of assets not required to be accounted for as a liability at fair value are recognized when the contingency is resolved and the consideration is paid or becomes payable. Contingent consideration payments made prior to regulatory approval are expensed as incurred.

Impairment of long-lived assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment and operating right-of-use assets, 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, 2024 and 2023.

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 on a pro rata basis against the gross proceeds from the applicable financing. If a financing is abandoned, deferred offering costs are expensed.

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 a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

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 12 months following the balance sheet date is classified as a current liability.

Research and development expenses

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, and preclinical and clinical development expenses, including process development, validation, and the manufacture of drug supplies, costs to conduct clinical trials, and amounts incurred under license agreements, consulting agreements and other contracted services. Research and development costs are expensed as incurred. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed. Such payments are evaluated for current or long-term classification based on when such services are expected to be received.

The Company estimates preclinical, clinical trial, and other research and development expenses based on the services performed pursuant to contracts with research institutions, contract manufacturing organizations, and third-party service providers that conduct and manage preclinical studies and clinical trials and perform research services on its behalf. The Company records these costs of research and development activities based on the estimated services provided but not yet invoiced and includes these costs in accrued expenses and other current liabilities in the consolidated balance sheets and in research and development expense in the consolidated statements of operations.

The Company accrues these costs based on factors such as estimates of the work completed in accordance with agreements established with its third-party service providers, actual levels of patient enrollment and reported activities at clinical trial sites. The Company makes judgments and estimates in determining the accrued expenses balance. As actual costs become known, the Company adjusts its accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from the Company's estimates, resulting in adjustments to expenses in future periods. Changes in these estimates that result in material changes to the Company's accrued expenses could materially affect the Company's results of operations.

Share-based compensation

The Company's share-based compensation program allows for grants of stock options and restricted stock awards 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 recognizes 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 recognizes compensation expense on a straight-line basis over the service period.

The Company estimates the fair value of stock option awards on the grant date using the Black-Scholes option pricing model. 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.

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 right-of-use assets for leases with a term of 12 months or less. The Company does not have any finance leases as of December 31, 2024 or 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 reasonable assurance that the Company will renew. As the rate implicit on the Company's leases is not readily determinable, the Company uses its secured incremental borrowing rate to determine the present value of lease payments. The incremental borrowing rate is the rate of interest that 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.

In addition, the Company's leases may require payment of additional costs, such as utilities, maintenance, and other operating costs, which are generally referred to as non-lease components and vary based on future outcomes. The Company has elected not to separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of an operating right-of-use asset and lease liability. Any variable expenses are recognized in operating expenses as incurred. Rent expense for an operating lease liability is recognized on a straight-line basis over the lease term and is included in operating expenses in the consolidated statements of operations and comprehensive loss.

Income taxes

The Company accounts for income taxes using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some or all of the net deferred tax assets may not be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies, and recent results of operations, primarily over the most recent three-year period. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained upon an audit. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being recognized. Change in recognition or measurement are reflected in the period in which the change in judgement occurs.

Net loss per share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, including the effect of dilutive securities.

As the Company was in a net loss position for the years ended December 31, 2024 and 2023, diluted net loss per share is the same as basic net loss per share because the effects of potentially dilutive securities are antidilutive.

The following potentially dilutive securities have been excluded from the computation of diluted net loss per share for the periods presented because including them would have been anti-dilutive (on an as-converted basis):

	December 31,	
	2024	2023
Stock options outstanding	11,990,781	7,978,291
Common stock warrants	—	500,000
	11,990,781	8,478,291

Recently adopted accounting standards

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures*. ASU 2023-07 requires disclosure of incremental segment information on an interim and annual basis and provides new segment disclosure requirements for entities with a single reportable segment. ASU 2023-07 is effective for all public companies for fiscal years beginning after December 15, 2023, and interim periods within fiscal periods beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. The Company adopted annual requirements under ASU 2023-07 on January 1, 2024 and adopted interim requirements under ASU 2023-07 on January 1, 2025. There was no impact on the Company's reportable segments identified and additional required disclosures have been included in Note 11.

Recent accounting standards not yet adopted

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 believes that the adoption of this ASU will not have a material impact on the consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* ASU 2024-03 requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. This guidance is effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

3. Fair value measurement

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables summarize the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2024				
	Level	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Cash equivalents:					
Money market funds	1	$ 46,987	$ —	$ —	$ 46,987
U.S. treasury securities	2	94,379	40	—	94,419
Marketable securities:					
U.S. treasury securities	2	73,935	17	—	73,952
Total financial assets		$ 215,301	$ 57	$ —	$ 215,358

	December 31, 2023				
	Level	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Cash equivalents:					
Money market funds	1	$ 73,988	$ —	$ —	$ 73,988
U.S. treasury securities	2	22,993	—	—	22,993
Marketable securities:					
U.S. treasury securities	2	39,441	22	—	39,463
Total financial assets		$ 136,422	$ 22	$ —	$ 136,444

The Company's marketable securities consist of U.S. treasury debt securities with a contractual maturity date of up to 6 months.

4. Collaboration agreement with AbbVie

In January 2023, the Company entered into a Collaboration and Option Agreement, or the Collaboration Agreement, with AbbVie Global Enterprises Ltd., or AbbVie, pursuant to which the Company is using 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 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 be required to pay certain additional platform access payments of up to $70.0 million in aggregate 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. If AbbVie exercises its option to purchase a VTP, then AbbVie will be required to pay an option exercise fee in the low single-digit millions for each of up to 10 VTPs for which it exercises an option. For each Product, the Company is eligible to receive development and commercial based milestones of up to $120.0 million in the aggregate and sales milestones of up to $150.0 million in the aggregate for the achievement of specified levels of annual net sales. The Company is also eligible to receive tiered royalties at percentage rates in the low single digits on annual net sales of any Products that are commercialized by AbbVie.

AbbVie's obligation to pay royalties will terminate, on a Product-by-Product and country-by-country basis, upon the earlier of (a) the later of (i) 10 years following the first commercial sale for such Product in such country, or (ii) expiration of all valid claims of patent rights covering the Product in such country, and (b) the expiration of all applicable regulatory exclusivities for such Product in such country. AbbVie may terminate the Collaboration Agreement at any time for convenience upon a specified period of prior written notice.

The Company determined that the Collaboration Agreement represents a contract with a customer and consists of one performance obligation to provide research and development services, or R&D services, to AbbVie. 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.

Revenue from the Collaboration Agreement 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 collaboration revenue of $9.0 million and $14.0 million for the years ended December 31, 2024 and 2023, respectively.

The following table summarizes the change in deferred revenue (in thousands):

	Year Ended December 31,	
	2024	2023
Beginning balance	$ 15,982	$ —
Deferral of revenue	—	30,000
Recognition of revenue	(9,041)	(14,018)
Balance at the end of the period	$ 6,941	$ 15,982

As of December 31, 2024, 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 0.5 years.

5. Balance sheet components

Property and equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2024	2023
Lab equipment	$ 9,501	$ 5,386
Construction in progress	3,297	—
Leasehold improvements	1,636	233
Computer equipment	270	326
Office equipment and furniture and fixtures	158	36
Property and equipment at cost	14,862	5,981
Less accumulated depreciation and amortization	(4,749)	(3,908)
Property and equipment, net	$ 10,113	$ 2,073

Depreciation and amortization expense was $1.6 million and $0.5 million for the years ended December 31, 2024 and 2023, respectively.

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2024	2023
Research and development	$ 24,185	$ 1,794
Compensation and related benefits	5,222	2,734
Severance accruals	639	1,436
Professional services and consulting	933	1,019
Operating lease liabilities, current portion	63	310
Other	2,135	732
Total accrued expenses and other current liabilities	$ 33,177	$ 8,025

6. 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 $0.6 million and $0.2 million to the 401(k) Plan for the years ended December 31, 2024 and 2023, respectively.

7. Strategic transactions and agreements

Ayala Pharmaceuticals

On March 25, 2024, the Company and Ayala Pharmaceuticals, Inc., or Ayala, completed an Asset Purchase Agreement, or the Ayala Purchase Agreement, that was entered into in February 2024, pursuant to which the Company acquired Ayala's AL101 and varegacestat (then known as AL102) programs and assumed certain liabilities associated with the acquired assets. The upfront consideration included (i) payment of approximately $20.0 million in cash, and (ii) the issuance of 2,175,489 unregistered shares of the Company's common stock at an aggregate fair value of $50.6 million on the acquisition date. The fair value of the shares issued to Ayala was based on the closing stock price of the Company's common stock on March 25, 2024 of $ 24.00 per share less a discount of 3.0% related to unregistered share restrictions.

The Company accounted for the transaction as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in two programs that were grouped as a single identifiable IPR&D asset. The assets acquired in the transaction were measured based on the estimated fair value of the consideration paid of $71.3 million, which included direct transaction costs of $0.7 million.

The consideration paid and the relative fair values of the assets acquired and liabilities assumed were as follows (in thousands):

	Amount	
Common stock issued to Ayala	$	50,645
Upfront consideration paid to Ayala		20,039
Transaction costs		657
Consideration paid	$	71,341
Assets acquired:		
In-process research and development	$	73,382
Other long-term assets		2,480
Total assets acquired	$	75,862
Liabilities assumed:		
Accrued expenses	$	4,521
Total liabilities assumed	$	4,521
Net assets acquired	$	71,341

The cost attributable to the IPR&D was expensed in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2024 since the acquired IPR&D had no alternative future use.

Under the Ayala Purchase Agreement, the Company will be required to pay Ayala up to $37.5 million in the aggregate upon the achievement of certain development, regulatory and commercial milestone events. Any potential future milestone payment amounts will be accrued when the related contingency is resolved and the milestone consideration becomes payable.

Zentalis Pharmaceuticals

On January 5, 2024, the Company entered into a license agreement with Zentalis Pharmaceuticals, Inc., or the Zentalis License Agreement, pursuant to which the Company 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, or, collectively, the Zentalis Licensed Assets.

As upfront consideration for the license, the Company paid to Zentalis $15.0 million in cash and issued to Zentalis 2,298,586 unregistered shares of its common stock at an aggregate fair value of $23.4 million. The fair value of the common stock issued to Zentalis was based on the closing stock price of the Company's common stock on January 5, 2024 of $11.12 per share less a discount of 8.5% related to unregistered share restrictions. The Company accounted for the transaction as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable IPR&D asset. The consideration paid to acquire the license and intellectual property rights, which included transaction costs of $0.2 million, was immediately recognized as IPR&D expense in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2024 since the acquired IPR&D had no alternative future use.

On October 25, 2024, the Company and Zentalis entered into an asset purchase agreement, or the Zentalis Purchase Agreement, pursuant to which the Company purchased the Zentalis Licensed Assets that were licensed to the Company under the then-existing Zentalis License Agreement dated January 5, 2024, together with all the customary rights and obligations of a sole owner, or the Zentalis Asset Purchase. Upon the closing of the Zentalis Asset Purchase, the Zentalis License Agreement was terminated in its entirety, including the termination of all of the Company's contingent milestone and royalty payment obligations. Certain accrued rights and obligations of the parties survive the closing of the Zentalis Asset Purchase.

As consideration for the Zentalis Asset Purchase, the Company issued to Zentalis 1,805,502 unregistered shares of its common stock at an aggregate fair value of $21.0 million. The fair value of the common stock issued to Zentalis was based on the closing stock price of the Company's common stock on October 25, 2024 of $12.11 per share less a discount of 4.0% related to unregistered share restrictions. The consideration paid to Zentalis for the Zentalis Asset Purchase was immediately recognized as IPR&D expense in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2024. The Company is also obligated to pay Zentalis a one-time payment of $5.0 million in cash upon the achievement of a developmental milestone that was previously a milestone under the Zentalis License Agreement.

As of December 31, 2024, the Company has achieved the developmental milestone and has accrued $5.0 million within accrued expenses and other current liabilities on the consolidated balance sheet since the related contingency is resolved and the milestone consideration is payable.

Morphimmune

On October 2, 2023, the Company completed its merger with Morphimmune, or the Merger, and acquired all of the outstanding equity interests of Morphimmune in exchange for 8,835,710 shares of the Company's common stock, based upon an exchange ratio of 0.3042 shares of the Company's common stock for each outstanding share of Morphimmune capital stock. Under the terms of the Agreement and Plan of Merger and Reorganization dated as of June 28, 2023, the Company assumed Morphimmune's 2020 Equity Incentive Plan and all outstanding options to purchase shares of Morphimmune capital stock 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. All other terms and conditions associated with these options, including vesting and exercisability, are governed by the original terms and conditions of the Morphimmune 2020 Equity Incentive 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 was concentrated in two programs that were grouped as a single identifiable IPR&D asset. The assets acquired in the transaction were measured based on the estimated fair value of the consideration paid of $88.0 million, which included direct transaction costs of $0.8 million. The consideration paid consisted of $72.5 million of the Company's common stock based on the closing stock price on October 2, 2023 of $8.20 per share and $14.7 million related to the value of Morphimmune's share-based awards assumed by Immunome as of the same date. The cost of the acquisition allocated to the acquired IPR&D of $80.8 million was expensed in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2023 since the acquired IPR&D had no alternative future use.

The consideration paid and the relative fair values of assets acquired and liabilities assumed were as follows (in thousands):

	Amount
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

Bristol-Myers Squibb

In connection with the closing of the Ayala Purchase Agreement in March 2024, the Company assumed a license agreement, the BMS License Agreement, with Bristol-Myers Squibb Company, or BMS, pursuant to which the Company obtained a worldwide, non-transferable, royalty-bearing, exclusive, sublicensable, license under certain patent rights and know-how of BMS to research, discover, develop, make, have made, use, sell, offer to sell, export, import and commercialize AL101 and varegacestat, or the BMS Licensed Compounds, and products containing AL101 or varegacestat, 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 Agreement, the Company is obligated to use commercially reasonable efforts to develop at least one BMS Licensed Product. The Company is 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.

The Company is required to pay BMS up to approximately $142.0 million in the aggregate upon the achievement of certain clinical development or regulatory milestones for AL101 and varegacestat across multiple indications. In addition, the Company is required to pay BMS up to $50.0 million in the aggregate upon the achievement of certain commercial milestones for each BMS Licensed Product. Any potential future milestone payment amounts will be accrued when the related contingency is resolved and the milestone consideration becomes payable. BMS is also eligible to receive tiered royalties ranging from a high single-digit to a low teen percentage on annual worldwide net sales of any BMS Licensed Products. Royalty payments will be expensed in the period in which the underlying revenues are earned.

BMS has the right to terminate the BMS License Agreement in its entirety if the Company fails to fulfill its development and commercialization obligations within a defined period of time following written notice by BMS. The Company has the right to terminate the BMS License Agreement for convenience upon prior written notice to BMS. Upon termination of the BMS License Agreement by the Company for convenience or by BMS, the Company will grant an exclusive, non-transferable, sublicensable, worldwide license to BMS for certain patent rights that are necessary to develop, manufacture or commercialize the BMS Licensed Compounds or BMS Licensed Products. In exchange for such license, BMS will be obligated to pay the Company 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.

Following the closing of the Ayala Purchase Agreement, on August 7, 2024, the Company and BMS entered into Amendment No. 2 to the BMS License Agreement, or the BMS License Agreement Amendment. As consideration to BMS for entering into the BMS License Agreement Amendment, the Company issued BMS 230,415 unregistered shares of its common stock at an aggregate fair value of $2.7 million. The fair value of the common stock issued to BMS was based on the closing stock price of the Company's common stock on August 7, 2024 of $12.46 per share less a discount of 6.0% related to unregistered share restrictions. The consideration paid to BMS to amend the BMS License Agreement was immediately recognized as IPR&D expense in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2024.

Other asset acquisitions and license agreements

The Company has entered into various other asset purchase and license agreements to further acquire, discover, develop and commercialize certain technologies and treatments. During the year ended December 31, 2024, the Company paid total consideration of $10.8 million under these other agreements, including upfront fees and transaction costs, which was recognized as IPR&D expense in the Company's consolidated statement of operations and comprehensive loss since the acquired IPR&D had no alternative future use. There was no IPR&D expense under these agreements for the year ended December 31, 2023.

Under the terms of these agreements, the Company may need to pay certain development, regulatory, and commercial milestones payments and royalties on product sales, if any. Any potential future milestone payment amounts will be accrued when the related contingency is resolved and the milestone consideration becomes payable. Royalty payments will be expensed in the period in which the underlying revenues are earned.

As of December 31, 2024, the Company has achieved certain milestones under these agreements and has accrued $0.8 million within accrued expenses and other current liabilities on the consolidated balance sheet since the related contingency is resolved and the milestone consideration is payable.

8. Leases

The Company currently leases approximately 39,000 square feet of office and laboratory space in Bothell, Washington, including 15,000 square feet of space that was added in May 2024 and 10,000 square feet of space that was added in December 2024 under amended lease agreements. In December 2024, the Company was granted a one-time tenant improvement allowance of $3.5 million which was considered payable by the lessor at the commencement date. The Bothell lease also includes an expansion option to lease approximately 13,000 additional square feet of office and laboratory space with a $4.7 million tenant improvement allowance. The Bothell lease expires on March 31, 2033, and includes two five-year renewal options that are not included in the lease term as it is not reasonably certain that they will be exercised.

The Company also leases approximately 11,000 square feet of office and laboratory space in Exton, Pennsylvania. The Exton lease expires on March 31, 2025.

Supplemental balance sheet information related to leases was as follows (in thousands):

	December 31,	
	2024	2023
Operating leases:		
Operating lease right-of-use assets	$ 4,278	$ 1,564
Operating lease liabilities, current portion	$ 63	$ 310
Operating lease liabilities, net of current portion	4,769	1,340
Total operating lease liabilities	$ 4,832	$ 1,650

Operating lease liabilities, current portion is included in accrued expenses and other current liabilities in the accompanying consolidated balance sheets.

The Company recorded operating lease expense of $0.8 million and $0.3 million for the years ended December 31, 2024 and 2023, respectively. Under the terms of the lease agreements, the Company is also responsible for certain variable lease payments that are not included in the measurement of the lease liability. The Company did not incur significant variable lease costs for the years ended December 31, 2024 and 2023.

Other information related to the Company's operating leases was as follows:

	December 31,	
	2024	2023
Weighted-average remaining lease term (in years)	8.15	4.81
Weighted-average discount rate	9.5%	8.3%

Supplemental cash flow information related to the Company's operating leases was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Cash paid for operating lease liabilities	$ 337	$ 246

The Company's future minimum lease payments were as follows as of December 31, 2024 (in thousands):

Years ending December 31,	Amount
2025	$ 929
2026	1,304
2027	1,577
2028	1,616
2029 and thereafter	7,333
Total lease payments	12,759
Less: imputed interest	(4,202)
Less: tenant improvement allowance not yet received	(3,725)
Present value of operating lease liabilities	$ 4,832

9. Common stock

Common stock

The holders of common stock are entitled to one vote for each share of common stock. The holders of common stock are entitled to receive dividends out of funds legally available if and when declared by the Company's board of directors. In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, the holders of common stock are entitled to share ratably in the remaining assets of the Company available for distribution.

The Company has reserved the following shares of common stock for issuance, on an as-converted basis, as follows:

	December 31,	
	2024	2023
Stock options issued and outstanding under the Plans	11,990,781	7,978,291
Common stock warrants outstanding	—	500,000
Remaining shares available for issuance under the Plans	2,631,369	4,250,303
Remaining shares available for issuance under the ESPP	906,251	473,733
Total reserved common stock	15,528,401	13,202,327

2024 Public Offering

In February 2024, the Company completed a public offering and issued 11,500,000 shares of its common stock at $20.00 per share, for net proceeds of $215.4 million, after deducting underwriting discounts and commissions and offering expenses.

2024 ATM Agreement

On May 14, 2024, the Company entered into an "at the market" sales agreement, or the 2024 ATM Agreement, with TD Securities (USA) LLC, or TD Cowen, as sales agent, pursuant to which the Company may offer and sell from time to time shares of its common stock having an aggregate offering price of up to $200.0 million, or the ATM Shares. The Company has agreed to pay TD Cowen a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold through the 2024 ATM Agreement. In November 2024, the Company sold 2,030,431 shares of common stock under the 2024 ATM Agreement resulting in net proceeds of approximately $19.6 million.

Warrants to acquire shares of common stock

The Company had 500,000 issued and outstanding common stock warrants as of December 31, 2023 with an exercise price of $10.00 per share and an expiration date of April 28, 2024. During the year ended December 31, 2024, warrants to purchase 373,057 shares of common stock were exercised for proceeds of $3.7 million and the remaining 126,943 common stock warrants expired unexercised. No warrants were exercised during the year ended December 31, 2023. No warrants were issued and outstanding as of December 31, 2024.

10. Share-based compensation

2020 Equity Incentive Plan

In September 2020, the Company adopted the 2020 Equity Incentive Plan, or the 2020 Plan, which supersedes all prior equity incentive plans. 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. As of December 31, 2024, there were 1,698,331 shares available for issuance under the 2020 Plan. On January 1, 2025, the number of shares available for future issuance under the 2020 Plan increased by 2,578,433 shares.

Stock options under the 2020 Plan typically last ten years unless the board of directors decides otherwise. Vesting periods vary, typically ranging from one to four years for employees, officers, directors, and consultants. Some options may vest faster in case of a change in control, as defined in the 2020 Plan.

On October 2, 2023, the Morphimmune 2020 Equity Incentive Plan, or the Morphimmune Plan, was assumed by the Company in conjunction with the Merger (Note 7). There were 373,738 shares available for issuance under the Morphimmune Plan as of December 31, 2024.

2024 Inducement Plan

In October 2024, the Company adopted the 2024 Inducement Plan, or the 2024 Plan, to reserve 2,000,000 shares of the Company's common stock to be used exclusively for grants of equity awards to individuals that were not previously employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company. The terms and conditions of the 2024 Plan are substantially similar to the Company's 2020 Plan. As of December 31, 2024, there were 559,300 shares available for issuance under the 2024 Plan.

Stock options granted to Chief Executive Officer

On June 28, 2023, Clay 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. 25% of the options granted vest after one year of employment with the Company, and the remaining 75% vest monthly over the 36 months immediately following the one-year anniversary. The Inducement Grant, the Morphimmune Plan, the 2024 Plan and the 2020 Plan are collectively referred to as the Plans.

2020 Employee Stock Purchase Plan

The Company also adopted the 2020 Employee Stock Purchase Plan, or the ESPP, in September 2020. Under the ESPP, employees meeting certain specific employment qualifications are eligible to participate and can purchase shares of common stock through payroll deductions. The purchase price is 85% of the lower of the fair market value of the stock at the commencement or end of the offering period. The ESPP permits eligible employees to purchase shares of common stock through payroll deductions for up to 15% of qualified compensation.

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 initial public offering, or 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. As of December 31, 2024, there were 906,251 shares available under the ESPP. No shares of common stock have been issued under the ESPP as of December 31, 2024. On January 1, 2025, the number of shares available for future issuance under the ESPP increased by 644,608 shares.

Stock options

A summary of option activity under the Plans during the year ended December 31, 2024 is as follows:

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	7,978,291	$ 6.15	8.62	$ 45,360
Granted	6,616,169	14.66		
Exercised	(769,382)	2.93		
Forfeited	(1,443,809)	10.67		
Expired	(390,488)	20.93		
Outstanding at December 31, 2024	11,990,781	$ 10.02	8.69	$ 34,209
Exercisable at December 31, 2024	3,381,263	$ 5.11	7.26	$ 22,083

Aggregate intrinsic value in the above table is calculated as the difference between the exercise price of the options and the Company's fair value of its common stock as of period end.

The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2024 and 2023 was $10.86 and $6.09, respectively. The aggregate intrinsic value for options exercised during the years ended December 31, 2024 and 2023 was $10.3 million and $5.9 million, respectively.

The weighted average assumptions used in the Black-Scholes option-pricing model for stock options granted were:

	Year Ended December 31,	
	2024	2023
Expected volatility	88.4 %	92.1 %
Risk-free interest rate	4.0 %	4.6 %
Expected term (in years)	5.85	5.60
Expected dividend yield	— %	— %

Share-based compensation expense recorded in the consolidated statements of operations and comprehensive loss is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development	$ 5,146	$ 1,981
General and administrative	10,602	4,242
Total share-based compensation expense	$ 15,748	$ 6,223

Unrecognized compensation cost related to unvested options was $75.2 million as of December 31, 2024 and will be recognized over an estimated weighted-average period of 3.4 years.

11. Segment information

The Company has one operating and reportable segment related to the development of targeted oncology therapies. The segment derives its current revenues from research and development collaborations.

The CODM assesses performance for the segment based on net loss, which is reported on the consolidated statement of operations and comprehensive loss as net loss. The measure of segment assets is reported on the consolidated balance sheet as total assets. When evaluating the Company's financial performance, the CODM regularly reviews total revenues, total expenses and research and development expenses by program.

The table below is a summary of the segment net loss, including significant segment expense categories (in thousands):

	Year Ended December 31,	
	2024	2023
Collaboration revenue	$ 9,041	$ 14,018
Less:		
In-process research and development	(152,344)	(80,802)
Direct research and development expenses[1]		
Varegacestat	(27,954)	—
IM-1021	(24,130)	—
IM-3050	(13,359)	—
Other	(35,335)	(11,278)
Indirect research and development[2]	(28,764)	(11,811)
General and administrative[3]	(32,955)	(19,657)
Total operating expenses	(314,841)	(123,548)
Loss from operations	(305,800)	(109,530)
Interest income	12,837	2,724
Net loss	$ (292,963)	$ (106,806)

(1) Direct research and development expenses include external costs, such as costs related to manufacturing, outsourced research, product development, and clinical trial costs, including fees paid to investigators, consultants, central laboratories and CROs to specific product candidates.

(2) Indirect research and development expenses include personnel salary, benefit and share-based compensation costs, depreciation and amortization, laboratory materials and services, and certain overhead expenses.

(3) General and administrative expenses include personnel salary, benefit and share-based compensation costs, legal fees, professional fees for accounting, auditing, tax and consulting services, insurance costs, travel, depreciation and amortization, and certain overhead expenses.

12. Income taxes

A reconciliation of the federal income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2024	2023
Federal tax benefit at statutory rate	21.0 %	21.0 %
State tax, net of federal benefit	0.5	(1.3)
Research and development credits	2.1	0.7
Share-based compensation	(0.7)	(0.9)
Write-off of IPR&D	—	(15.9)
Change in valuation allowance	(22.8)	(3.6)
Other	(0.1)	—
	— %	— %

The components of the Company's deferred taxes are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 29,346	$ 22,784
Research and development intangibles	62,188	10,135
Research and development credits	10,021	3,782
Share-based compensation	2,385	2,533
Deferred revenue	1,474	—
Accruals and reserves	1,236	546
Lease liability	1,026	350
Other	77	75
Gross deferred tax assets	107,753	40,205
Less: valuation allowance	(106,720)	(39,827)
Net deferred tax asset	1,033	378
Deferred tax liability		
Depreciation	(125)	(46)
Right-of-use asset	(908)	(332)
Total deferred tax liabilities	(1,033)	(378)
Net deferred taxes	$ —	$ —

The Company had no income tax expense due to the operating losses utilization for the years ended December 31, 2024 and 2023. 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, 2024 and 2023. The valuation allowance increased by $66.9 million and $9.2 million in 2024 and 2023, respectively, due to capitalized IPR&D expense, 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 the evaluation of ownership changes through December 31, 2024, 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 Company has not generated taxable income or a current tax liability and has not utilized its net operating loss or research and development credit carryforwards as of December 31, 2024.

As of December 31, 2024, the Company had $119.9 million of federal and $95.6 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 $102.8 million of net operating losses generated from 2018 to 2024 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 2043. As of December 31, 2024, the Company had cumulative $9.9 million of federal and $0.2 million of state R&D tax credits. These tax credit carryforwards will expire at various dates through 2044.

A reconciliation of the beginning and ending amount of unrecognized tax benefits were as follows (in thousands):

	December 31,	
	2024	2023
Beginning balance	$ 37	$ 37
Additions for tax positions taken in prior years	19	—
Ending balance	$ 56	$ 37

If the unrecognized tax benefits for uncertain tax positions as of December 31, 2024 are recognized, there will be no impact to the effective tax rate due to the valuation allowance. The Company recognizes interest and penalties related to the unrecognized tax benefits as a component of income tax expense. As of December 31, 2024, there were no material interest and penalties on uncertain tax benefits. The Company does not anticipate any significant changes to its unrecognized tax benefits in the next 12 months.

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.

13. Subsequent events

On January 31, 2025, the Company completed a public offering of 22,258,064 shares of its common stock at a price of $7.75 per share. The gross proceeds to the Company from the offering were $172.5 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.