UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number: 001-39655

DAMORA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**37-1957007**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
221 Crescent Street Building 23, Suite 105 Waltham, MA 02453	**02109**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 281-9020

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, par value $0.00001 per share	DMRA	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 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of the registrant's common stock on the Nasdaq Capital Market on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was $4.4 million.

The number of shares of registrant's common stock outstanding as of March 17, 2026 was 60,303,212.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the registrant's 2026 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2025. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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Summary of Material Risks Associated with Our Business

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

- There is no guarantee that our acquisition of Pre-Acquisition Damora in November 2025 will increase stockholder value.
- We are a preclinical stage biotechnology company with a limited operating history on which to assess our business; we have no products that have been administered to humans or approved for commercial sale, which may make it difficult to evaluate our current business and likelihood of success and viability.
- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research programs or future commercialization efforts.

Risks Related to Our Discovery, Development and Commercialization

- We face competition from entities that have developed or may develop product candidates for the diseases addressed by our product candidates.
- Our programs are in the preclinical stages of development and may fail in development or suffer delays that materially and adversely affect our viability. If we or our current or future collaborators are unable to complete development of or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- We are substantially dependent on the success of DMR-001, and our anticipated future clinical trials of such product candidate may not be successful.
- If we do not achieve our projected development objectives in the time frames we announce and expect, the commercialization of our product candidates may be delayed which may harm our reputation and prospects, increase our expenses and cause our stock price to decline.
- Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Risks Related to Our Reliance on Third Parties

- We rely on collaborations and licensing arrangements with third parties, including Paragon. If we are unable to maintain these collaborations or licensing arrangements, or if these collaborations or licensing arrangements are not successful, our business could be negatively impacted.

Risks Related to Our Business and Operations

- In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.
- We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.
- Our internal information technology systems, or those of any of our CROs, manufacturers, other contractors or consultants, third-party service providers, or existing or future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

•We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

Risks Related to Our Intellectual Property

•Our intellectual property portfolio is at an early stage. Therefore, our ability to obtain and protect our patent rights, and protect other proprietary rights, is uncertain, exposing us to the possible loss of competitive advantage.

•If we are unable to obtain or maintain necessary rights to our programs through acquisitions and in-licenses, our business may be materially harmed.

Risks Related to Government Regulation

•The regulatory approval processes of the U.S. Food and Drug Administration (the "FDA") and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

General Risk Factors

•Our business could be adversely affected by economic downturns, inflation, fluctuating interest rates, natural disasters, public health crises, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

•Litigation costs and the outcome of litigation could have a material adverse effect on our business.

Risks Related to the Ownership of Our Common Stock

•The market price of our common stock has been and is expected to continue to be volatile.

•If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

•Conflicts of interest may arise between us and Paragon or us and Fairmount.

The material and other risks summarized above should be read together with the text of the full risk factors below and in the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission (the "SEC"). If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including "Business" in Item 1, "Risk Factors" in Item 1A and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical fact are "forward-looking statements" for purposes of this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "project," "continue," "potential," "ongoing," "goal," or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements regarding:

•our ability to successfully execute on our strategy for the discovery and development of DMR-001, DMR-002 and DMR-003;

- the success, cost and timing of our planned filing of investigational drug applications or their equivalents, planned product development activities, and initiation of clinical trials of our current product candidates, including DMR-001, DMR-002, and DMR-003, and any future product candidates;
- our ability to retain the continued service of our directors, officers, key employees and consultants;
- our ability to continue to grow and manage our growth effectively;
- our ability to obtain regulatory approval for our current or future product candidates that we may identify or develop;
- our ability to ensure adequate supply of our current or future product candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our ability to establish an adequate safety or efficacy profile for our current or future product candidates that we may pursue;
- the implementation and execution of our strategic plans for our business, our current or future product candidates we may develop and our technology;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- the rate and degree of market acceptance and clinical utility for our current or future product candidates we may develop;
- our estimates about the size of our market opportunity;
- our estimates of expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations;
- our financial performance and liquidity;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and consultants and to identify, hire and retain additional qualified professionals;
- our ability to maintain adequate internal controls over financial reporting;
- the effects of global economic uncertainty and financial market volatility caused by economic effects of volatility in inflation and interest rates, tariffs, geopolitical instability, changes in international trade relationships and conflicts; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors."

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Part I, Item 1A – "Risk Factors" below and for the reasons described elsewhere in this Annual Report on Form 10-K. Any forward-looking statement in this Annual Report on Form 10-K reflects our current view with respect to future events and is subject to these and other risks, uncertainties, and assumptions relating to our operations, results of operations, industry, and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections, and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by third parties, industry, medical and general publications, government data, and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Except where the context otherwise requires, in this Annual Report on Form 10-K, "we," "us," "our," "Damora," and the "Company" refer to Damora Therapeutics, Inc. and, where appropriate, its consolidated subsidiaries.

Trademarks

We have applied for various trademarks that we use in connection with the operation of our business. This Annual Report on Form 10-K includes trademarks, service marks, and trade names owned by us or other companies. All trademarks, service marks, and trade names included in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company developing therapies for the treatment of hematologic disorders. In our previously announced Asset Acquisition (as defined below), we bolstered our pipeline with the addition of three product candidates designed to treat myeloproliferative neoplasms ("MPNs"), a group of related, chronic disorders of the bone marrow. Our lead product candidate, DMR-001, targets mutant forms of the calcium binding protein calreticulin ("CALR"), which are collectively known as mutCALR. We have exercised our Option to license exclusive worldwide development and commercialization rights to DMR-001 from Paragon Therapeutics, Inc. ("Paragon"), pursuant to the Antibody Discovery and Option Agreement, dated as of October 7, 2025, by and among Paragon, Paramora Holding LLC ("Paramora") and Pre-Acquisition Damora (as defined below) (the "Paragon Option Agreement"). We intend to develop DMR-001 for the treatment of essential thrombocythemia ("ET"), an MPN associated with the overproduction of platelets, and myelofibrosis ("MF"), an MPN involving the overproliferation of blood cells and deposition of fibrous material in the bone marrow and spleen. Approximately 25% and 35% of cases of ET and MF, respectively, are caused by mutCALR rather than mutations in Janus-associated kinase 2 ("JAK2"). In contrast to marketed therapies for ET and MF, DMR-001 is designed to selectively target cells that express mutCALR while avoiding the adverse effects associated with non-specific cytoreductive drugs. Furthermore, DMR-001 was designed to have increased affinity, potency and a prolonged half-life when compared with other antibodies in development that target mutCALR. We believe that the potential combination of increased clinical activity and improved pharmacokinetics of DMR-001 positions it as a potential best-in-class therapy for ET and MF. We also have the option to license exclusive worldwide development and commercialization rights from Paragon of two other mutCALR-targeting product candidates, DMR-002 and DMR-003, pursuant to the Paragon Option Agreement. We intend to submit an Investigational New Drug Application ("IND") or Clinical Trial Application ("CTA") for DMR-001 and DMR-002 in mid-2026 and the second half of 2026, respectively, and for DMR-003 in 2027. Pursuant to the Paragon Option Agreement, we have engaged Paragon to execute a mutually agreed research plan for DMR-001, DMR-002, and DMR-003 aimed at producing potential product candidates to be licensed for further development, manufacture and commercialization by us. The research plan activities performed by Paragon are overseen by a joint development committee comprised of our employees and employees of Paragon.

MPNs are caused by excessive proliferation of myeloid cells. In some patients, including ET patients, MPNs are considered chronic diseases that lead to significant decreases in quality of life. MPNs also include MF, which is associated with poor prognosis and increased mortality. One feature that makes MPNs attractive indications for drug development is that mutations in just a small number of genes are responsible for a significant percentage of cases, which enables the opportunity to develop targeted therapies. Our ultimate goal is to develop a portfolio of targeted mutation-directed candidates to address the full spectrum of MPN disease.

DMR-001 is a monoclonal antibody that targets mutations in CALR, including the two major forms of CALR mutations referred to as Type 1 and Type 2 mutCALR. CALR mutations are the drivers of about a quarter of all cases of ET, a disease with a prevalence in the United States of about 140,000 patients. ET is characterized by excessive production of platelets, leading to symptoms that range from tingling or burning in the hands and feet to headache, visual problems, weakness, dizziness and increased risk of blood clots, causing heart attacks, strokes and other thromboses. CALR mutations are the drivers of about 35% of all cases of MF, a disease with a prevalence in the United States of about 20,000 patients. MF is characterized by abnormal myeloid cell proliferation leading to inflammation and a fibrotic response in the bone marrow. This results in bone marrow scarring, splenomegaly, elevated cytokine levels, and bone marrow dysfunction. Symptoms include fatigue, easy bruising and bleeding, night sweats and fever. Approximately 17% of ET patients who have CALR mutations progress to MF. We believe there exists at least a $5 billion addressable market in the United States for mutCALR driven ET and MF.

We believe that DMR-001 has the potential to become a best-in-class anti-mutCALR therapy due to two differentiating features compared to marketed therapies and therapies in development, including INCA033989. First, our preclinical studies demonstrated that DMR-001 is a more potent inhibitor of mutCALR-dependent cell proliferation compared to a reference mutCALR targeted monoclonal antibody. This is especially relevant with regard to patients with Type 2 mutCALR, which represent about a third of mutCALR patients. Whereas Type 1 mutations are characterized by a deletion of 52 base pairs in the gene for CALR, Type 2 mutations have an insertion of 5 base pairs. Our preclinical assays demonstrated that DMR-001 has approximately ten-fold higher potency on Type 2 mutCALR than a reference mutCALR antibody with the same mechanism of action as INCA033989. Second, DMR-001 was engineered to have an increased half-life in circulation through the incorporation of sequence modifications that have previously been shown to improve pharmacokinetics in humans. Our preclinical data generated in non-human primates ("NHPs"), confirmed the improved half-life of DMR-001 compared to a reference antibody.

The expected combination of increased clinical activity and longer half-life is predicted to enable the delivery of sufficient amounts of DMR-001 via subcutaneous injection to match and potentially exceed the reported efficacy of INCA033989 that was intravenously administered in Incyte Corporation's ("Incyte") Phase 1 trial. We believe such a subcutaneous formulation is critically important because it provides a more convenient dosing option for ET and MF patients, most of whom have a long life expectancy after diagnosis and thus require long-term treatment. We intend to file an IND or CTA for DMR-001 in mid-2026 and initiate a Phase 1 trial in ET and MF patients with a subcutaneous formulation thereafter, subject to regulatory approval, with two proof-of-concept readouts expected beginning mid-2027.

In addition, we are developing DMR-002 and DMR-003, both anti-mutCALR-based therapies, with the intent to ultimately address the full spectrum of mutCALR MPN patients. We intend to file an IND or CTA for DMR-002 in the second half of 2026 and for DMR-003 in 2027.

We periodically evaluate our product pipeline to assess whether development of certain assets in our portfolio align with our strategic objectives. Following a recent review of our product candidate portfolio, we have determined to focus on our mutCALR portfolio to address the full mutCALR MPN disease spectrum and have deprioritized continued development of GB3226, a small molecule inhibitor of ENL-YEATS and FLT3 for the treatment of acute myeloid leukemia ("AML"). We intend to explore entering into one or more corporate partnerships or collaboration arrangements to advance the development and commercialization of our legacy assets, including GB3226, GB1211 (galectin-3 inhibitor candidate), and GB2064 (LOXL-2 inhibitor candidate).

Our Pipeline

The following table summarizes our product candidates and programs and their current stage of development.

Program	MoA	Stage		
		Discovery	IND-enabling	Clinical
DMR-001	Anti-mutCALR mAb (Fc-null, half-life extended)			Two POC readouts expected mid-2027
DMR-002	mutCALR-targeted MoA (Undisclosed)			IND or CTA expected 2H26
DMR-003	Anti-mutCALR x CD3 bsAb (T-cell engager)			IND or CTA expected 2027

Our Strategy

Our goal is to develop potential best-in-class therapies to treat a range of hematologic disorders, including MPNs such as ET and MF. Our strategy to achieve this is as follows:

- **Initiate clinical development of DMR-001.** Our preclinical results have shown that DMR-001 has improved potency and pharmacokinetics compared to a reference antibody with the same mechanism of action as INCA033989, a molecule for which impressive Phase 1 clinical results in the treatment of ET and MF have been reported. We plan to file an IND or CTA for DMR-001 for the treatment of ET and MF patients in mid-2026 and initiate a Phase 1 trial in ET and MF patients with a subcutaneous formulation thereafter, subject to regulatory approval, with two proof-of-concept readouts expected beginning mid-2027.

- **Invest early in preparation for late-stage development of DMR-001.** Although DMR-001 is not the first anti-mutCALR antibody to enter the clinic, we believe that it has the potential to be best-in-class. We intend to be in a position to execute additional clinical trials for DMR-001 in response to both the results that we generate and to those of our competitors, with the intent of minimizing unnecessary delays.
- **Advance DMR-002 and DMR-003 into clinical development.** We are developing mutCALR targeted therapies that are designed to be even more potent than DMR-001 with the goal of addressing the full spectrum of mutCALR-driven MPNs. We anticipate filing an IND or CTA for DMR-002 in the second half of 2026 and for DMR-003 in 2027.
- **Build focused company infrastructure and foster a positive corporate culture.** We are building the infrastructure of Damora by incorporating our commitments to science-driven drug development and rapidly addressing the needs of patients with hematologic disorders.

MPNs - a spectrum of diseases with high unmet medical need

MPNs are a group of rare blood cancers in which excess red blood cells, white blood cells or platelets are produced in the bone marrow. The three most common MPNs are MF, ET, and polycythemia vera ("PV"). Common symptoms of MPNs include fatigue, itching, weight loss, night sweats, fever, difficulty breathing, abdominal swelling and discomfort due to spleen enlargement, bruising and stroke, all of which can be devastating and debilitating. Patients with ET and PV can progress to MF, and all MPN patients have a risk that their cancer progresses into AML, a hematological malignancy with a five-year survival rate of 33%.

MPNs generally arise from mutations in the blood-forming stem cells of the bone marrow. The most commonly mutated genes observed in MPNs are JAK2, CALR, and myeloproliferative leukemia virus oncogene ("MPL"). These mutations lead to constitutive or always-on activation of signaling pathways that, when over-activated, drive the aberrant production of blood cells.

DMR-001, a product candidate designed to treat mutCALR-driven MPNs

DMR-001 is a monoclonal antibody that targets mutCALR, a mutant protein that is believed to be a critical driver of approximately 25% of ET cases and 35% of MF cases. Third-party Phase 1 clinical data for INCA033989, an anti-mutCALR antibody, demonstrated that direct targeting of mutCALR can lead to rapid and sustained reduction in excess platelets, the key pathology in ET, and reduction in spleen volume and symptom improvement in MF. DMR-001 is designed to improve on the clinical activity and pharmacokinetics of INCA033989, which we believe will provide the opportunity to capture a sizable portion of the mutCALR market. We anticipate filing an IND or CTA for DMR-001 in mid-2026 and initiating a Phase 1 trial in ET and MF patients with a subcutaneous formulation thereafter, subject to regulatory approval, with two proof-of-concept readouts expected beginning mid-2027.

ET background

ET, an MPN characterized by excessive platelet production, is associated with an increased risk of thrombosis and bleeding. The annual incidence of ET in the United States is 1.5/100,000 persons. The prevalence in the United States is approximately 140,000 patients.

Excessive levels of platelets in ET are associated with increased risk of serious conditions such as arterial thrombosis, venous thrombosis and hemorrhagic complications. In addition, patients with ET can experience symptoms that include tingling or burning in the hands and feet, headache, visual problems, weakness and dizziness. These symptoms and others result from excessive numbers of platelets causing blockages in small or large blood vessels in different parts of the body that can reduce patients' quality of life. More serious potential complications include an increased risk of blood clots, causing heart attacks and strokes, as well as an increase in the risk of hemorrhage that rises with the platelet count. The median age at diagnosis of ET is 59 years. A significant fraction of ET patients progress to more aggressive cancers, including 17% who have CALR mutations who develop MF and 3% who develop AML.

Approximately 90% of individuals with ET have genetic variants that upregulate the Janus-associated kinase/signal transducer and activator of transcription ("JAK-STAT") signaling pathway, including JAK2, CALR or MPL, which encodes the thrombopoietin ("TPO") receptor.

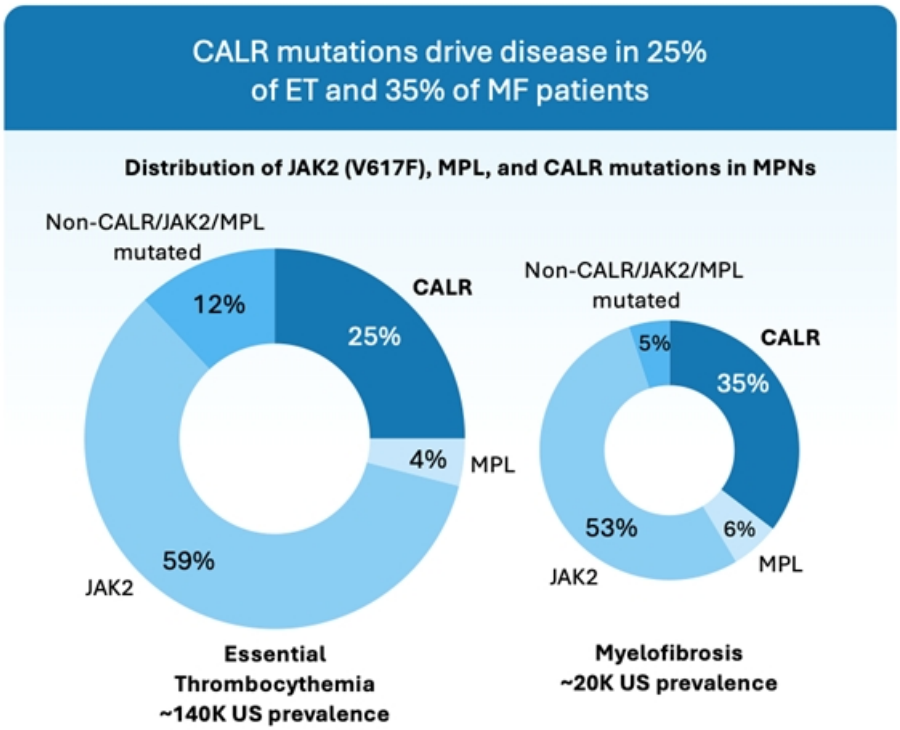


Figure 1. Mutations that drive JAK/STAT signaling, including those in JAK2, CALR and MPL are the primary causes of ET

The main treatment objectives for patients with ET are to lower platelet levels to the normal range, lower the risk of fibrosis and lower the risk of progression to MF. About 30% to 40% of ET patients are classified as lower-risk patients who have elevated platelet counts without a history of clotting events. These patients are often treated with aspirin alone. The remaining ET patients carry a higher risk of clotting and bleeding. These patients are generally treated with hydroxyurea, which is not approved for the treatment of ET in the United States. Hydroxyurea does not alter the underlying disease process and, as a result, disease progression may continue in some patients. Long-term use of hydroxyurea is also associated with the development of mucosal ulcers, actinic keratosis and an increased risk of skin cancer. Anagrelide, an inhibitor of the maturation of megakaryocytes to platelets, is approved to treat ET but is associated with cardiotoxicity. Current treatments, including drugs such as hydroxyurea and anagrelide, are not selective for platelets affected by mutCALR. Although 59% of ET patients have mutations in JAK2, inhibitors of JAK, such as ruxolitinib, are not routinely used. Ruxolitinib is not approved to treat ET, as it failed to improve response rates and is associated with a number of toxicities that are barriers to widespread use. Interferon has also been reported to reduce platelet counts in ET patients in a small number of clinical trials, but it has not been approved for this indication.

MF disease overview

MF is a MPN characterized by abnormal myeloid cell proliferation leading to inflammation and a fibrotic response in the bone marrow. This results in bone marrow scarring, splenomegaly, elevated cytokine levels, and marrow dysfunction. Symptoms include fatigue, easy bruising and bleeding, night sweats and fever. At the time of diagnosis, 35% to 54% of patients with MF have anemia. Within a year of diagnosis, 60% of patients develop anemia and 46% of all patients require treatment with red blood transfusions. Anemia is the disease feature most consistently associated with poor prognosis in MF. Up to 20% of MF patients will ultimately develop AML.

Because the median age of MF diagnosis is around 65 years, disease-associated complications are often compounded by concurring medical conditions such as diabetes, hypertension, atherosclerotic or pulmonary disease, and obesity. Patients with intermediate-risk disease have a median overall survival of about five years which decreases to two years in those with high-risk disease. Common fatal complications include transformation into AML, thrombohemorrhagic events, organ failure, and infections. The prevalence of MF in the United States is estimated at 20,000 patients.

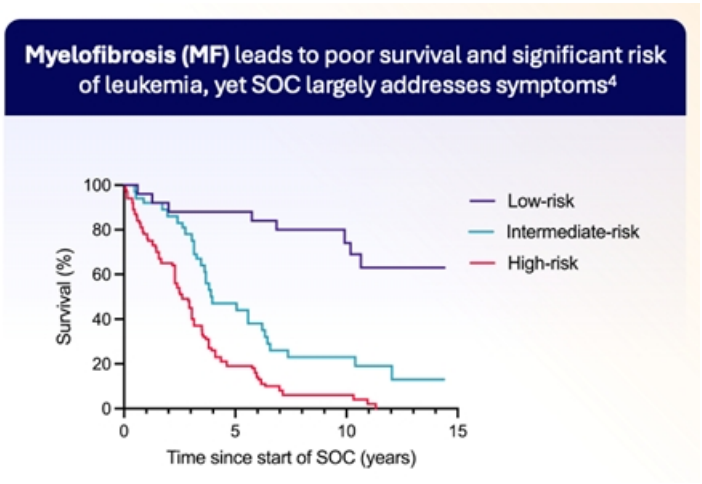


Figure 2. Median overall survival for patients with MF

Current treatments for MF

The only current curative treatment for MF is allogeneic hematopoietic stem cell transplantation ("HSCT"); however, this procedure has both significant morbidity and a high mortality rate. Because many patients diagnosed with MF are elderly and have other comorbidities, only a minority are eligible for this treatment. In other patients, inhibitors of cell proliferation are used such as JAK inhibitors or chemotherapy agents.

These therapies, however, increase the risk of anemia, reduce platelet counts causing increased risk of bleeding and bruising, and reduce white blood cell counts, a condition known as neutropenia, resulting in increased risk of serious infections.

Management of anemia can be one of the most challenging aspects of treating patients with MF. In patients with mild anemia, erythropoiesis stimulating agents, are used to stimulate red blood cell formation. Other patients are treated with steroids, including danazol, which lead to increases in hemoglobin ("Hb"), levels with a mean response time of five months in 30% of patients. Patients with more serious anemia are treated with blood transfusions, but over time, repeated transfusions lead to the development of iron overload, alloantibodies, and other toxicities.

We believe there remains a substantial unmet need for new therapies that can reduce disease symptoms and slow progression for MF patients.

Potential of targeting mutCALR

We believe that mutCALR is a highly desirable target in oncology given its clear role as a disease driver. CALR normally functions as a calcium-binding chaperone that is active in three areas: intracellularly, on the cell surface, and extracellularly. However, in patients who have deleterious mutations, the gene for CALR is mutated so that the DNA transcription machinery does not stick to the normal reading frame. This so-called frameshift occurs in the protein-coding region of the gene and it results in the synthesis of mutCALR proteins that contain an amino acid sequence at the C-terminal end of the protein that is not present in normal CALR. In response to this additional sequence, these mutCALR proteins begin to drive abnormal cell proliferation by gaining the ability to bind to and stimulate signaling through a receptor known as the TPO receptor. TPO activation, in turn, activates the JAK/STAT pathway, a well-known pathway leading to cell proliferation. It is this JAK/STAT pathway activation which, in turn, drives the unhealthy proliferation of myeloid cells.

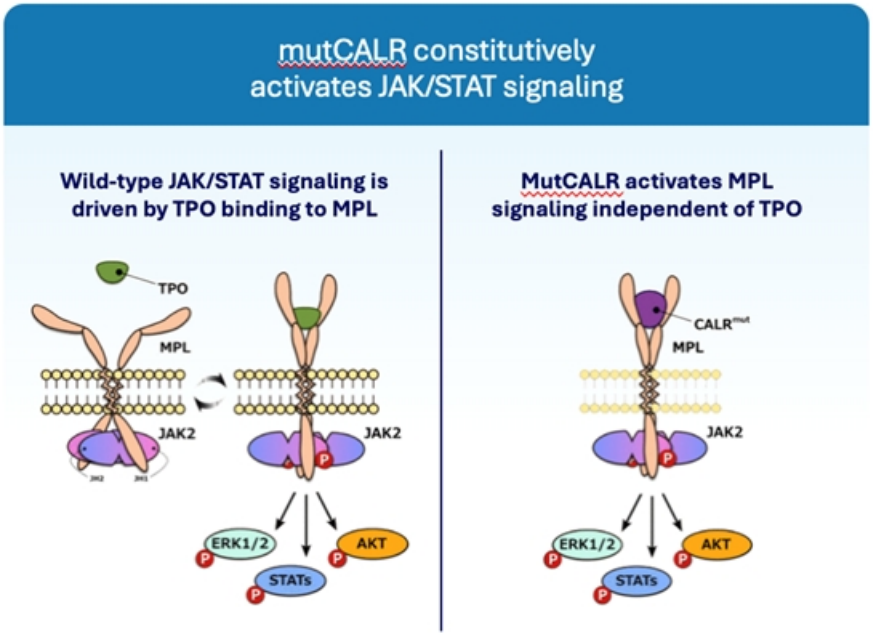


Figure 3. mutCALR leads to TPO-independent activation of JAK/STAT signaling

The majority of CALR mutations associated with ET are classified as Type 1 mutations (52 bp deletion) or Type 2 mutations (5 bp insertion) depending on the size and location of the frameshift causing genetic changes. Both Type 1 and Type 2 mutations result in a novel, shared mutant C-terminal domain.

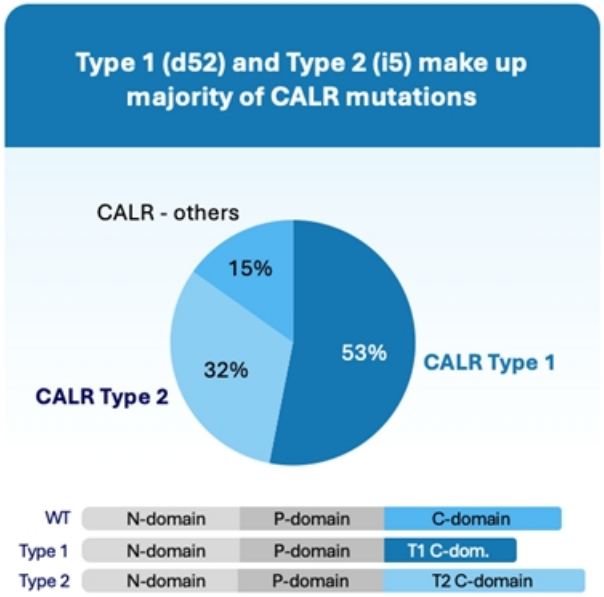


Figure 4. Two types of mutCALR account for 85% of CALR mutations in ET

In addition to the critical role of mutCALR in stimulating cell proliferation, several other factors make mutCALR an especially attractive drug target. First, the frameshift mutations that create mutCALR lead to the expression of a protein domain that is not present in wild-type ("WT") CALR, thereby providing an opportunity to specifically target mutCALR and avoid potential consequences of binding to CALR on healthy cells. Second, due to the deletion of the endoplasmic reticulum-localization signal that occurs when mutated, mutCALR localizes to the cell surface while WT CALR does not. Third, the pathology of mutCALR appears to be limited to its ability to activate the TPO receptor which is primarily expressed on platelets and hematopoietic progenitor cells that give rise to platelets, providing the ability to selectively and specifically target the root cause of the pathological cell proliferation. Fourth, mutations in CALR are mutually exclusive with other driver mutations, providing an opportunity to block oncogenic signaling through selective mutCALR inhibition with less potential for resistance.

A recent third-party advancement in the treatment of ET and MF

In 2025, Incyte announced preliminary data from multiple Phase 1 clinical trials of INCA033989 in ET patients resistant or intolerant to prior cytoreductive therapy and MF patients resistant, intolerant or ineligible for JAK inhibitor treatment. Results from these trials demonstrated:

- **Clinical proof-of-concept for targeting mutCALR**. In ET patients, INCA033989 induced rapid decreases in platelets and a trend toward normalization of healthy hematopoiesis. In MF patients, INCA033989 treatment resulted in rapid and robust spleen and anemia responses, as well as symptom improvements.
- **Evidence of disease modification with anti-mutCALR therapy**. In ET patients, INCA033989 induced dose-dependent reductions in mutCALR variant allele frequency ("VAF").
- **Favorable safety and tolerability with no evidence of on-target toxicity associated with anti-mutCALR therapy**. INCA033989 was well tolerated with no dose-limiting toxicities.

•**Opportunity for improvement with optimized anti-mutCALR therapy**. In the INCA033989 trials, MF patients with non-Type 1 CALR mutations generally had poorer outcomes compared to patients with Type 1 mutations. In addition, the trials required IV doses of INCA033989 of up to 2,500 mg.

We believe the INCA033989 data provide important clinical validation for our therapeutic approach of potent and selective targeting of mutCALR in patients with mutCALR-driven ET and MF. In addition, we believe the data highlight an opportunity to achieve a best-in-class profile with an optimized therapy that potently inhibits both Type 1 and Type 2 CALR mutations with an extended half-life enabling convenient, infrequent and low-volume subcutaneous dosing.

Our solution, DMR-001

DMR-001 is an anti-mutCALR monoclonal antibody designed to improve the ability to treat all patients that have either Type 1 or Type 2 mutCALR. DMR-001 is engineered to have improved potency against both Type 1 and Type 2 mutCALR, which we believe will provide the potential to treat patients with both classes of mutations at lower doses than may be required using INCA033989. Furthermore, DMR-001 contains modifications that are known to increase the half-life of antibodies in circulation. We believe that the increased potency and associated improvements in the half-life of DMR-001 will enable infrequent subcutaneous dosing and result in more convenience for patients compared to treatment with INCA033989, which is currently dosed by intravenous infusion every two weeks.

In our preclinical studies, DMR-001 demonstrated approximately three-fold greater inhibition of cell proliferation of a cell line that is dependent on Type 1 mutCALR than a reference mutCALR antibody with the same mechanism of action as INCA033989. In this *in vitro* assay, the proliferation of Ba/F3 cells was engineered to be dependent on Type 1 mutCALR and the TPO receptor. At 72 hours, DMR-001 led to more potent inhibition of proliferation than the reference antibody.

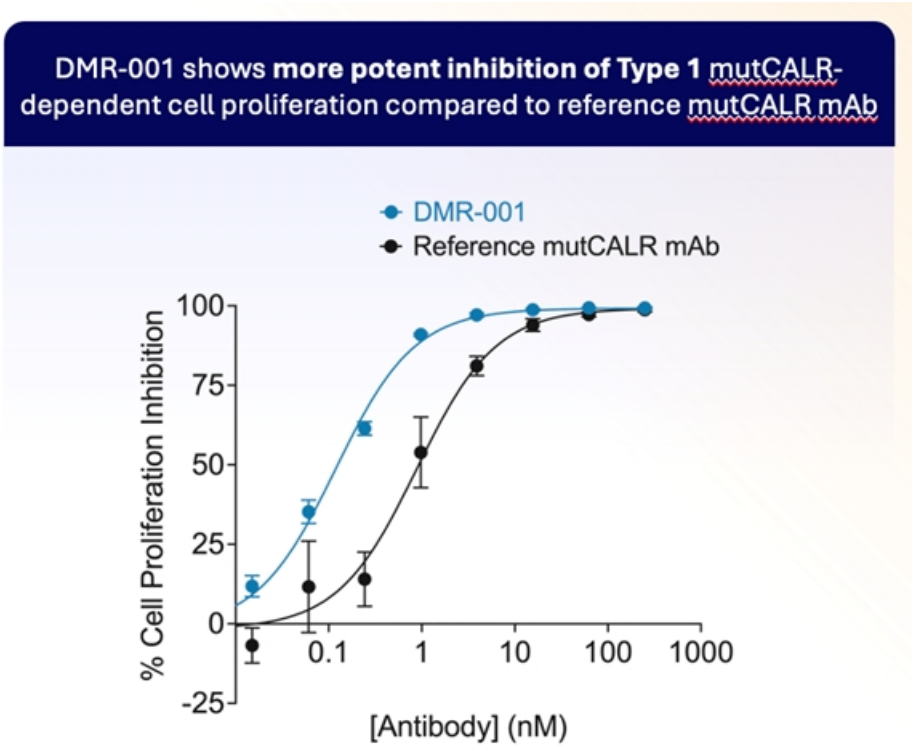


Figure 5. DMR-001 was more potent than a reference mutCALR antibody in a Type 1 mutCALR-dependent cell assay

In a similar assay in which the Ba/F3 cells were engineered to be dependent on a Type 2 mutCALR, DMR-001 had an approximately ten-fold greater inhibition of cell proliferation than the reference antibody.

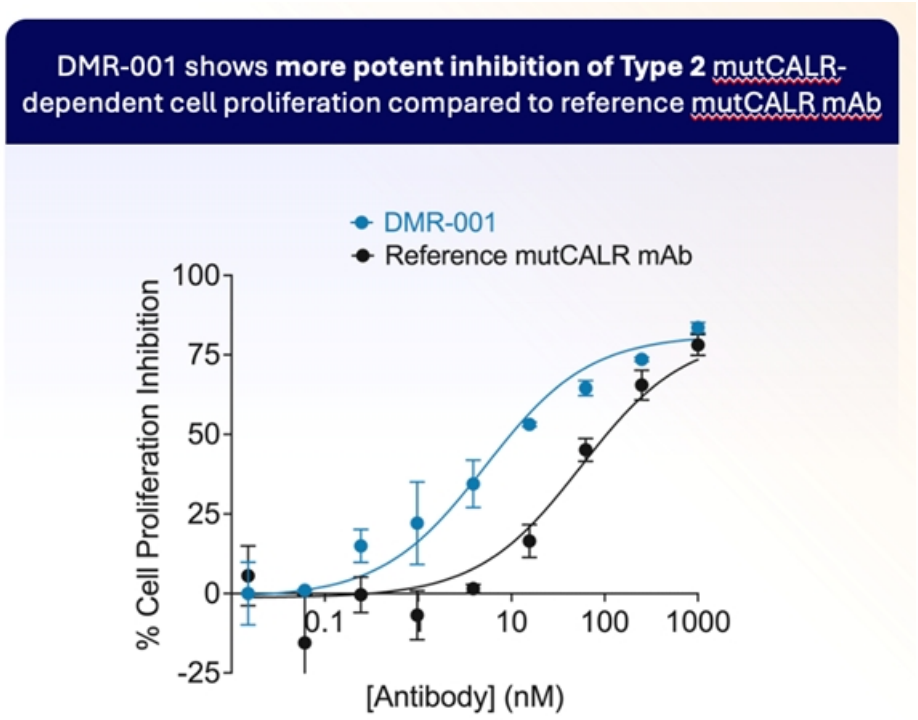


Figure 6. DMR-001 was more potent than a reference mutCALR antibody in a Type 2 mutCALR-dependent cell assay

High-molecular-weight biologics, such as antibodies, are routinely dosed via intravenous or subcutaneous administration. Subcutaneous administration has certain advantages in that patients can be dosed either during a clinic visit or via self-administered dosing at home, e.g., with an auto-injector, instead of receiving an hours-long intravenous administration in a hospital or infusion center. Subcutaneous administration is not only more convenient and desirable to patients, it also reduces the burden on healthcare facilities by lowering the cost of administration and increasing the number of patients who can be treated in a given time. The ability to administer treatment by subcutaneous injection is especially important for the treatment of chronic diseases, such as ET and MF, for which most patients have a long life expectancy after diagnosis and thus require long-term treatment.

DMR-001 has been engineered to have an extended half-life based on specific modifications that have been shown to extend the half-life of antibodies by three- to four-fold in other third-party therapies. In our preclinical studies, DMR-001 had a five-fold longer half-life in NHPs compared to a reference mutCALR antibody that lacked these modifications. We believe that the extended half-life observed in NHPs with DMR-001 has the potential to carry over into clinical development, as the half-life of other antibodies in NHPs, including those engineered to have extended half-lives, has been shown to correlate with that observed in humans.

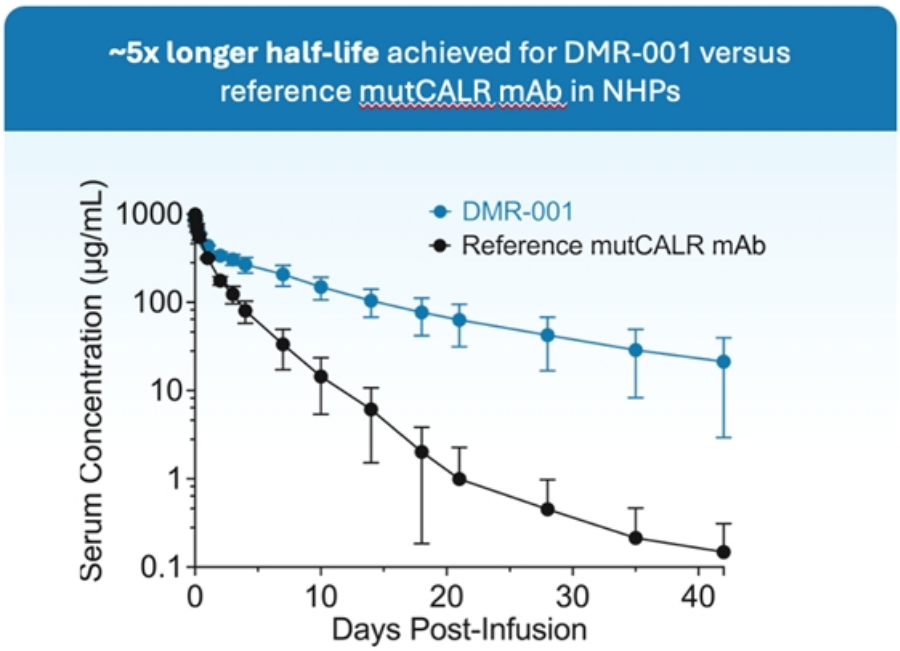


Figure 7. DMR-001 had a five-fold longer half-life in non-human primates than a reference mutCALR antibody

We believe that the potential combination of the increased potency of DMR-001 combined with its longer half-life provides the opportunity to gain a competitive advantage to existing anti-mutCALR antibodies in development. We believe the combination of these enhancements provides the opportunity for low doses of DMR-001 to be administered subcutaneously using an autoinjector and for DMR-001 potentially to be administered less frequently than INCA033989.

To estimate the potential impact of the increased potency and the improved half-life of DMR-001, we modeled the pharmacokinetics of DMR-001 and compared that to the maximum dose of 2500 mg INCA033989 that was tested and led to clinical responses in Incyte's Phase 1 trials. We believe that it is feasible for subcutaneous doses administered approximately every four weeks or less frequently to deliver sufficient DMR-001 to match what is known as the C_{trough}, the lowest concentration of drug substance before administration of the subsequent dose, of 2500 mg of INCA033989 when INCA033989 is delivered intravenously biweekly. We note that this analysis is based on an improvement in activity against Type 2 mutCALR for DMR-001 of only two-fold, which is substantially lower than the ten-fold improvement that we observed in our *in vitro* experiments.

We believe that the increased potency and improved pharmacokinetics of DMR-001 as well as the anticipated subcutaneous doses have the potential for DMR-001 to match doses of INCA033989 that have demonstrated meaningful clinical results in third-party clinical trials. We believe that the improved properties of DMR-001 may provide the opportunity to not only simplify dosing, but also to increase the response rates in patients with Type 2 mutCALR mutations.

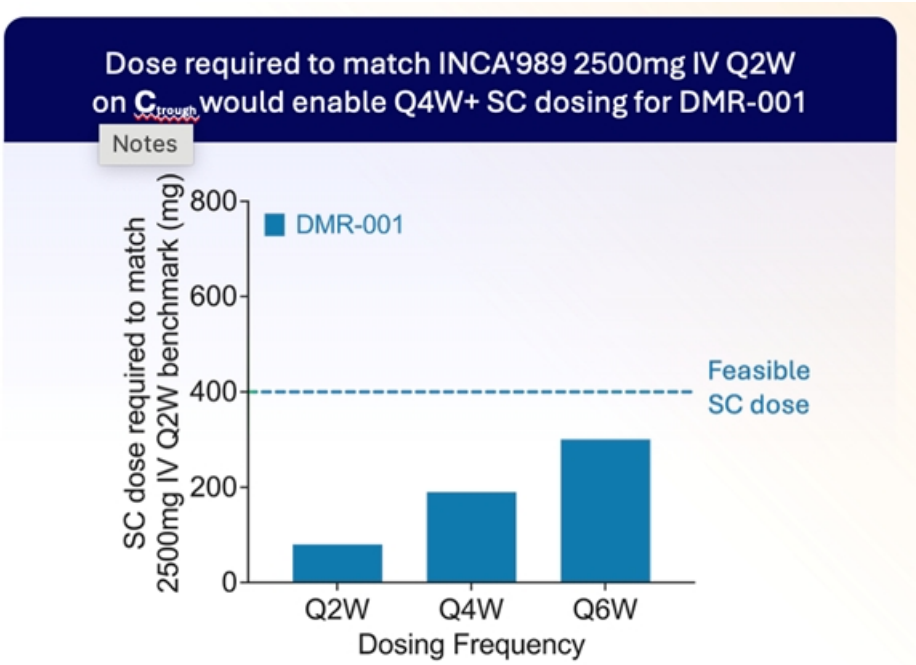


Figure 8. Pharmacologic modeling suggests that subcutaneous doses of DMR-001 can match the clinical activity of the highest dose of INCA033989 tested in the clinic

We anticipate filing an IND or CTA in mid-2026 and initiating a Phase 1 trial of a subcutaneous formulation in ET and MF patients thereafter, subject to regulatory approval.

DMR-002 and DMR-003

Although ET is a chronic disease that typically requires lifelong management, about 17% of patients with mutCALR ET progress to MF, a life-threatening condition. In addition, primary MF can occur, where patients are newly diagnosed with MF without any contributing progression from ET. Primary MF has an incidence in the United States of 3,700 to 3,900 new patients per year. Third-party clinical data of INCA033989 demonstrated promising activity as a monotherapy and as a combination therapy in reducing anemia and spleen volume, as well as improving symptoms in mutCALR MF patients.

In addition, pursuant to the Paragon Option Agreement, we have the option to develop two additional anti-mutCALR product candidates: DMR-002, an undisclosed mechanism of action, and DMR-003, a bispecific CD3 x anti-mutCALR T cell engager. We plan to disclose specifics about both of these product candidates as they advance into formal clinical development. We anticipate filing an IND or CTA for DMR-002 in the second half of 2026 and for DMR-003 in 2027.

Our Team and Investors

On November 10, 2025, we announced the completion of the Asset Acquisition with the focus on advancing a pipeline of next-generation antibodies targeting mutCALR with respect to which we have the option to acquire intellectual property license rights pursuant to the Paragon Option Agreement. The antibodies subject to the Paragon Option Agreement were discovered and developed by Paragon, a biotechnology company applying cutting-edge science and technology to shape the next generation of novel best-in-class complex biologics for major medical needs. Paragon's scientific founders' discoveries have also led to the creation of six other successful, publicly traded biotechnology companies.

Concurrent with the closing of the Asset Acquisition, we completed a $285 million private placement with a syndicate of healthcare investors led by Fairmount Funds Management LLC, with participation from Viking Global Investors, Venrock

Healthcare Capital Partners, Commodore Capital, Janus Henderson Investors, Wellington Management, RA Capital Management, TCGX, Forbion, BB Biotech, Blackstone Multi-Asset Investing, Perceptive Advisors, Vestal Point Capital, Balyasny Asset Management, Andreessen Horowitz (a16z Bio + Health), and a leading life sciences investment firm.

We have a strong management team, board of directors and group of employees with diverse backgrounds and significant experience in developing novel treatments for patients at biopharmaceutical companies such as CRISPR Therapeutics, Cogent Biosciences, Jade Biosciences, Oruka Therapeutics, Apogee Therapeutics, Spyre Therapeutics, Ultragenyx, Roche/Genentech, Arena Pharmaceuticals, Blueprint Medicines Corporation, IO Biotech, Inc., Anthos Therapeutics, and Xilio Therapeutics, Inc. Together, our team has a proven track record in the discovery, development, and commercialization of numerous approved therapeutics.

Recent Developments

Acquisition of Damora Therapeutics, Inc.

On November 10, 2025, we effected the Asset Acquisition to acquire Damora Therapeutics, Inc., a private Delaware corporation ("Pre-Acquisition Damora"), in accordance with the terms of the Agreement and Plan of Merger (the "Acquisition Agreement"), by and among the Company, Daylight Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("First Merger Sub"), Daylight Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Second Merger Sub"), and Pre-Acquisition Damora. Pursuant to the Acquisition Agreement, First Merger Sub merged with and into Pre-Acquisition Damora, pursuant to which Pre-Acquisition Damora was the surviving corporation and became a wholly owned subsidiary of the Company (the "First Merger"). Immediately following the First Merger, Pre-Acquisition Damora merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity.

The Asset Acquisition was structured as a stock-for-stock transaction pursuant to which all of Pre-Acquisition Damora's outstanding equity interests were exchanged based on a fixed exchange ratio of 1-for-1.6366, for consideration of a combination of 265,309 shares of common stock, 16,366 shares of Series B non-voting convertible preferred stock, par value $0.00001 per share (the "Series B Preferred Stock") (or 16,366,000 shares on an as-converted-to-common stock basis), and 4,241 shares of Series C non-voting convertible preferred stock, par value $0.00001 per share (the "Series C Preferred Stock") (or 4,241,000 shares on an as-converted-to-common stock basis), in addition to the assumption of outstanding and unexercised stock options to purchase 434,508 shares of common stock from the Damora Therapeutics, Inc. 2025 Equity Incentive Plan.

With respect to the Asset Acquisition, we determined that we were the acquiror for accounting purposes under ASC 805-10-25-4 and ASC 805-10-55-11. The primary factors considered were (a) the relative voting rights in the combined entity not resulting in a change of control, (b) legacy members of our board of directors maintained control of the board, and (c) the composition of senior management remained the same at the closing of the Transactions (as defined below). Next, we considered whether the Asset Acquisition should be defined as a business under ASC 805. ASC 805-10-55-5A through 55-5C describe a screen test to determine whether an acquired set of assets and activities is not a business. We determined that substantially all (greater than 90%) of the fair value of the assets acquired were concentrated in a single asset, Pre-Acquisition Damora's Option to license intellectual property rights related to DMR-001, DMR-002, and DMR-003 pursuant to the Paragon Option Agreement. Accordingly, we treated the Asset Acquisition as an asset acquisition for accounting purposes. Even if the transaction would have failed the screen test, Pre-Acquisition Damora lacked the financial resources to have inputs, processes, and outputs to constitute a business under ASC 805. Following the Asset Acquisition, we will need to invest in infrastructure and the continuing research and development being conducted under the Paragon Option Agreement to be able to have any measurable outputs.

Concurrently with the Asset Acquisition, we entered into a securities purchase agreement (the "Securities Purchase Agreement") for a private investment with existing and new investors (the "Investors") to raise $285 million in which the Investors were issued 39,641 shares of Series C Preferred Stock (or 39,641,000 shares on an as-converted-to-common stock basis) at a price of $7,186.90 per share (or $7.1869 per share on an as-converted-to-common stock basis) (the "PIPE," and together with the Asset Acquisition, the "Transactions"). The PIPE transaction closed on November 12, 2025.

The Transactions were approved by our board of directors and the board of directors and stockholders of Pre-Acquisition Damora. The closings of the Transactions were not subject to the approval of our stockholders. Subject to certain beneficial ownership limitations set by each holder, each share of Series B Preferred Stock and Series C Preferred stock will be convertible at the option of the holder into 1,000 shares of common stock. Except as otherwise required by law (e.g. voting on a change to the authorized shares of Series B Preferred Stock or the rights of such shares as required by Delaware General Corporation Law (the "DGCL")) and the Certificate of Designation of Series B Non-Voting Convertible Preferred Stock (the "Series B Certificate of

Designation"), the Series B Preferred Stock does not have voting rights. Except as otherwise required by law (e.g. voting on a change to the authorized shares of Series C Preferred Stock or the rights of such shares as required by DGCL) and the Certificate of Designation of Series C Non-Voting Convertible Preferred Stock (the "Series C Certificate of Designation"), the Series C Preferred Stock does not have voting rights. On February 9, 2026, we held a special meeting of stockholders of the company and received stockholder approval of, among other proposals, (i) the issuance of shares of common stock upon conversion of the Series B Preferred Stock and Series C Preferred Stock and (ii) an amendment to our amended and restated certificate of incorporation (the "Share Increase Amendment") to increase the number of authorized shares of common stock from 300,000,000 to 500,000,000. Following the special meeting of stockholders of the company, on February 9, 2026, 42,005 shares of Series C Preferred Stock were automatically converted into 42,005,000 shares of common stock. On February 9, 2026, we filed with the Secretary of State of the State of Delaware the Share Increase of Amendment to increase the number of authorized shares of common stock from 300,000,000 to 500,000,000.

Concurrently and in connection with the execution of the Acquisition Agreement, certain Pre-Acquisition Damora stockholders as of immediately prior to the Asset Acquisition, and certain of our directors and officers as of immediately prior to the Asset Acquisition entered into lock-up agreements with us and Pre-Acquisition Damora, pursuant to which each such stockholder will be subject to a 180-day lockup on the sale or transfer of shares of common stock held by each such stockholder at the closing of the Asset Acquisition, including those shares received by such Pre-Acquisition Damora stockholders in the Asset Acquisition.

Shelf Registration Statement, ATM Offering Program and February 2026 Public Offering

On February 10, 2026, we filed an automatically effective shelf registration statement (the "Registration Statement") with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units.

On February 10, 2026, we entered into a sales agreement (the "ATM Agreement"), pursuant to which we may sell, from time-to-time, shares of our common stock under an at-the-market ("ATM") offering program for up to $150.0 million. As of the date of this filing, we have not made any sales under the ATM offering program and have $150.0 million in remaining capacity under the ATM offering program.

On February 10, 2026, we also entered into an underwriting agreement with certain underwriters to issue and sell 14,473,685 shares of our common stock, including the full exercise by the underwriters of their option to purchase an additional 2,171,052 shares, at a public offering price of $19.00 per share. The net proceeds from this offering were approximately $297.3 million, after deducting underwriting discounts and commissions and expenses of the offering. The underwritten offering closed on February 12, 2026.

We intend to use the net proceeds from this offering to advance our preclinical studies, clinical trials, and manufacturing in support of our antibody programs, as well as for additional research and development activities, working capital, and general corporate purposes. We may also use a portion of the proceeds to license, acquire or invest in new product candidates or for drug development activities related to such product candidates, complementary businesses, technology or assets.

The underwritten offering was made pursuant to the Registration Statement. A final prospectus supplement dated February 10, 2026 relating to and describing the terms of the underwritten offering was filed with the SEC on February 11, 2026.

Name Change

On March 6, 2026, we filed with the Secretary of State of the State of Delaware an amendment to our amended and restated certificate of incorporation to change the name of the Company from "Galecto, Inc." to "Damora Therapeutics, Inc." (the "Name Change Amendment"). The Name Change Amendment became effective at 12:01 a.m. Eastern Time on March 10, 2026.

Our Relationship with Fairmount, Paragon and Paramora

In connection with the Asset Acquisition, we assumed the rights and obligations of Pre-Acquisition Damora under the Paragon Option Agreement. Fairmount beneficially owns more than 5% of Paragon, appointed Paragon's board of directors, and has the contractual right to approve the appointment of any executive officers of Paragon. Paramora is an entity formed by Paragon as a vehicle to hold equity in Pre-Acquisition Damora (and as a result of the Asset Acquisition, us) in order to share profits with certain employees of Paragon and will not perform any substantive role under the Paragon Option Agreement other than to receive warrants expected to be granted to Paramora under the Paragon Option Agreement. Three of our directors are affiliated with Fairmount (Peter Harwin, Christopher Cain, Ph.D., and Julianne Bruno) and were appointed in accordance with the Acquisition

Agreement. We consider Paragon, Paramora, and Fairmount to be related parties. See the section titled "Paragon Option Agreement" below for more information on the Paragon Option Agreement.

Paragon Option Agreement

On October 7, 2025, Pre-Acquisition Damora entered into the Paragon Option Agreement with Paragon and Paramora. In connection with the Asset Acquisition, we assumed the rights and obligations of Pre-Acquisition Damora under the Paragon Option Agreement. Under the terms of the Paragon Option Agreement, Paragon agreed to perform certain research activities to discover, generate, identify, and characterize one or more antibody candidates directed to certain mutually agreed therapeutic targets of interest (each, a "Research Program"). The Paragon Option Agreement includes mutCALR as the selected target for DMR-001 and DMR-002, and mutCALR and CD3 as the selected targets for DMR-003. From time to time, we may choose to add additional targets to the Paragon Option Agreement by mutual agreement with Paragon and Paramora.

The Paragon Option Agreement requires us, Paragon, and Paramora to develop a research plan for each target that includes design, modeling, synthesis, evaluation, and other mutually agreed activities (each, a "Research Plan"). Paragon will perform the activities set forth in each Research Plan on the timelines set forth in such Research Plan and in compliance with a mutually agreed budget. Each Research Program will be overseen and coordinated by a joint development committee consisting of two of our employees and two employees from Paragon, with us and Paragon each having one vote with respect to decisions of the committee. When Paragon and Paramora have produced an antibody against a selected target, and upon the completion of each Research Program, Paragon and Paramora will deliver to us a data package that includes sequence information for all then-existing antibodies and information directed to such target. We, Paragon, and Paramora have developed a Research Plan for each of DMR-001, DMR-002, and DMR-003 consistent with the foregoing, and Paragon and Paramora have delivered an antibody against mutCALR with respect to DMR-001 in accordance with the applicable Research Plan.

Under the Paragon Option Agreement, we have an option (an "Option"), on a Research Program-by-Research Program basis, to enter into a separate agreement with Paragon consistent with a set of pre-negotiated terms (a "License Agreement"). Each License Agreement will include (a) an exclusive, worldwide license to all of Paragon's right, title, and interest in and to certain product-specific intellectual property resulting from the applicable Research Program to develop, manufacture, and commercialize the antibodies and products directed to the selected target(s), and (b), for DMR-001 and DMR-002, a non-exclusive, worldwide license to all of Paragon's right, title, and interest in and to the intellectual property resulting from the applicable monospecific Research Program to develop, manufacture, and commercialize multispecific antibodies and products directed to the selected target(s). Additionally, each License Agreement under the Paragon Option Agreement will include a non-exclusive, worldwide license to certain patents controlled by Paragon or its affiliates that (i) include a claim that expressly recites the sequence of the monospecific or bispecific antibody, as applicable, or the derived antibodies applicable to the Research Program, and (ii) are necessary to develop, manufacture or commercialize the monospecific or bispecific antibody, as applicable, or the derived antibodies applicable to the Research Program, but exclude any patents owned or otherwise controlled by Paragon or its affiliates that cover (x) that antigen-binding portion of any antibody or moiety that is directed to a target other than the target(s) of the Research Program (e.g., a second binder in a multispecific antibody), (y) any portion of any multispecific antibody other than an antibody directed to the target(s) of the Research Program, and (z) the composition of matter of, or any method of specifically making or using, a multispecific antibody directed to targets other than the target(s) of the Research Program that is developed, manufactured, commercialized or otherwise exploited by Paragon or its affiliate or sublicensee (other than us and our affiliates and sublicensees). The Option with respect to each Research Program is exercisable at our sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following the delivery of the data package from Paragon related to the results of the Research Program (an "Option Period"). There is no payment due upon exercise of an Option pursuant to the Paragon Option Agreement. Activities under a Research Plan may continue past the exercise of an Option or entry into a License Agreement. We have exercised our Option with respect to DMR-001 and are negotiating the related License Agreement, but our Options with respect to DMR-002 and DMR-003 currently remain unexercised.

Upon exercise of an Option with respect to a Research Program, the parties are obligated to use reasonable efforts to finalize and execute a License Agreement within 90 days. Under the terms of a License Agreement, we expect that we will have sole authority over and control of the development, regulatory approval, manufacturing and commercialization of such in-licensed product worldwide. In addition, we expect to have sole authority over and control of the application for and issuance of all regulatory approvals related to such in-licensed product. Prior to entry into a License Agreement, Paragon is responsible for the prosecution, defense, maintenance and enforcement of patents related to the Research Program. Following entry into a License Agreement, we expect to control prosecution, defense, maintenance and enforcement of patents exclusively in-licensed under such License Agreement. However, there is no assurance that we will successfully negotiate future License Agreements with Paragon or that the terms will not differ from those described in this prospectus.

Unless terminated earlier, the Paragon Option Agreement shall continue in force on a Research Program-by-Research Program basis until the earlier of: (i) the end of the Option Period for such Research Program, as applicable, if such Option is not exercised by us; (ii) if we exercise our Option with respect to a Research Program, but the parties are unable to finalize and execute a License Agreement within 90 days, the expiration of such 90-day period (subject to any mutually agreed extension of such period); and (iii) the expiration of the applicable Research Term (as defined under the Paragon Option Agreement). We may terminate the Paragon Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon; provided, that we must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Paragon may terminate the Paragon Option Agreement or any Research Program immediately upon written notice to us if, as a result of any action or failure to act by us or our affiliates, such Research Program or all material activities under the applicable Research Plan are suspended, discontinued or otherwise delayed for a period of four consecutive months. Each party has the right to terminate the Paragon Option Agreement or any Research Program upon (i) 30 days' prior written notice of the other party's material breach that remains uncured for the 30-day period and (ii) the other party's bankruptcy.

Upon signing of the Paragon Option Agreement, Pre-Acquisition Damora became obligated to reimburse Paragon $10.6 million for research and development costs related to DMR-001, DMR-002, and DMR-003, other general and administrative costs incurred by Paragon though September 30, 2025, and certain additional development costs incurred between October 1, 2025 and October 7, 2025 (the "Pre-Development Costs"). The Pre-Development Costs reflect the actual historical costs incurred by Paragon, including a 20% mark-up on certain direct costs to approximate the indirect costs incurred by Paragon from inception of the programs to the entry into the Paragon Option Agreement. Such direct costs incurred by Paragon were related to development activities. Paragon's cash flows related to DMR-001, DMR-002, and DMR-003 are operating cash flows.

We are also required to pay Paragon for certain development fees and costs on a Research Program-by-Research Program basis. Under the Paragon Option Agreement, we are required to pay Paragon a one-time, non-refundable research initiation fee within 30 days following finalization of a Research Plan in the amount of $1.25 million for each of DMR-001, DMR-002, and DMR-003. The Research Plans for each of DMR-001, DMR-002, and DMR-003 were completed in December 2025, and we paid the related fees in January 2026. Under the Paragon Option Agreement, on a Research Program-by-Research Program and product-by-product basis, we are required to make one-time non-refundable milestone payments to Paragon of up to a total of $22.0 million, upon the achievement of certain clinical development and regulatory milestones. We recognized research and development expense of $1.5 million related to the milestone payment due to Paragon in connection with the achievement of a development candidate for DMR-001 in December 2025, and we paid the related amount in January 2026.

Upon exercise of the Option with respect to a Research Program, the parties are obligated to use reasonable efforts to finalize and execute a License Agreement within 90 days. Any License Agreement entered into with respect to a given Research Program shall contain the same milestone payment obligations as the Paragon Option Agreement, provided that any milestone set in the Paragon Option Agreement that has not yet been achieved and is duplicated in such License Agreement shall no longer be achievable and payable under the terms of the Paragon Option Agreement and shall only be achievable under the terms of the License Agreement. For the avoidance of doubt, if a milestone is achieved and paid by us pursuant to the Paragon Option Agreement for a certain product, then there shall be no milestone payment due for the achievement of such milestone for such product under a subsequently executed License Agreement for the applicable Research Program. Further, under a License Agreement, we would also be required to make royalty payments to Paragon in the low to mid-single-digit percentage range based on net sales of products, subject to certain reductions. The royalty term will terminate on a product-by-product and country-by-country basis upon the later of the expiration of the last-to-expire valid claim within the relevant patent rights or the twelfth anniversary of the first commercial sale of such product in such country.

Additionally, as part of the Paragon Option Agreement, on each of December 31, 2025 and December 31, 2026, we are required to grant Paramora warrants to purchase a number of shares equal to 1.00% of our outstanding capital stock as of the date of the grant on a fully-diluted basis, with an exercise price equal to the fair market value of the underlying shares of our common stock on each respective grant date. If the Research Term with respect to all Research Programs ends prior to the end of a calendar year, the warrant grant for such calendar year shall be pro-rated. On December 31, 2025, in accordance with the Paragon Option Agreement, we issued to Paramora a warrant (the "Paramora Warrant") to purchase an aggregate of up to 628,302 shares of common stock, with a per share exercise price equal to $23.01.

As of the closing of the Asset Acquisition, Pre-Acquisition Damora had incurred total expenses of $15.2 million under the Paragon Option Agreement since its inception, along with $3.8M of expense related to the Paramora Warrant. No payments were made by Pre-Acquisition Damora to Paragon prior to the closing of the Asset Acquisition. From the Asset Acquisition through December 31, 2025, we have recognized $12.7 million of total expense pursuant to the Paragon Option Agreement, along with $9.4M of expense related to the Paramora Warrant. The $12.7 million of total expense pursuant to the Paragon Option Agreement, includes $12.6 million related to research and development expense and $0.1 million related to general and administrative expense.

Of the research and development expense, $8.1 million related to DMR-001, $2.2 million related to DMR-002, $1.6 million related to DMR-003, and $0.7 million was for shared program costs supporting all three programs. As of the date of this 10-K filing, there are no outstanding payments to Paragon related to expenses under the Paragon Option Agreement.

Intellectual Property

Overview

We strive to protect the proprietary programs and technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our programs, our methods of use and manufacture, and other inventions.

Paragon has filed provisional patent applications directed to antibodies that bind to mutCALR, including applications covering composition of matter, pharmaceutical formulations, and methods of using such antibodies. These applications disclose planned products for our DMR-001 and DMR-002 programs. A provisional patent application is an application filed in the United States Patent and Trademark Office ("USPTO") for the purpose of securing an early date of priority for the applicant's invention. The provisional application must include a written description of what the inventor has discovered, along with a drawing of the invention, but need not include patent claims, statements concerning or disclosing the prior art, or certain other formalities. A provisional patent application allows for an effective filing date to be established with regard to an invention, but once a provisional patent application is filed, either a corresponding non-provisional patent application or a petition to convert the provisional patent application into a non-provisional patent application must be filed within 12 months or such effective filing date will be lost.

The maximum term of a U.S. patent, excluding extensions and adjustments, begins on the effective filing date of the first non-provisional application claiming the patented invention and ending 20 years from that date. In essence, a provisional patent application provides a patent applicant two principal advantages over filing a non-provisional application. First, it allows the applicant to secure an earlier priority date for its invention than that of an equivalent non-provisional application-up to one year earlier than the filing date of a related non-provisional application. Second, since the term of a patent runs from the effective filing date of the first non-provisional application but does not begin upon filing a provisional application, filing a provisional application provides the applicant an additional year's time to refine that invention before filing a related non-provisional application without surrendering the earlier priority date. Securing an earlier priority date both ensures that later inventors cannot obtain a patent to the same invention and provides protection against certain arguments that developments in the field arising after the priority date should prevent or invalidate the applicant's invention.

If the non-provisional patent applications filed for DMR-001 result in issued patents, such patents are expected to expire in 2046, without taking potential patent term adjustment or patent term extension into consideration. If we or Paragon timely file non-provisional patent applications in the United States and in countries outside of the United States with regard to Paragon's DMR-002-related provisional patent applications and these non-provisional patent applications result in issued patents, such patents are expected to expire in 2046, without taking potential patent term adjustment or patent term extension into consideration.

Other IP Rights

In addition to patents, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part by executing confidentiality agreements with our collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, that such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, please see the section titled "*Risk Factors-Risks Related to Our Intellectual Property*" in this prospectus.

Commercial

Should any of our product candidates be approved for commercialization, we intend to develop a plan to commercialize them in the United States and other key markets, through internal infrastructure and/or external partnerships in a manner that will

enable us to realize the full commercial value of our programs. Given our stage of development, we have not yet established a commercial organization or distribution capabilities.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. All of our preclinical and clinical drug supply development, manufacturing, storage, distribution and testing are outsourced to third-party manufacturers and facilities. Our manufacturing strategy enables us to more efficiently direct financial resources to the research, development and commercialization of programs rather than diverting resources to internally develop and maintain manufacturing facilities. As our programs advance through development, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure our supply needs.

Competition

We expect to face competition from other biopharmaceutical companies that are developing agents for the treatment of mutCALR-driven MPNs, including ET and MF. If approved for the treatment of patients with mutCALR-driven MPNs, our portfolio of products would compete with hydroxyurea, which is not approved for the treatment of ET in the United States, anagrelide, ruxolitinib, and interferon, which has not been approved for ET, and well as ruxolitinib, momelotinib, pacritinib and fedratinib in MF.

We are aware of several companies with product candidates in development for the treatment of patients with mutCALR-driven MPNs, including Incyte's INCA033989 and INCA035784, Janssen Pharmaceuticals, Inc.'s JNJ-88549968, Meiji Seika Pharma's mutCALR TCE, Prelude Therapeutics, LLC's mCALR CDK9d DAC, Alethio Therapeutics' AT-02, PharmaEssentia Corporation's ropeginterferon alfa-2b, Merck & Co., Inc's bomedemstat, Novartis AG's pelabresib, Geron Corporation's imetelstat, and Kartos Therapeutics, Inc.'s navtemadlin.

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 biologics such as those we are developing. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory authorities of the countries in which we conduct studies or seek approval or licensure of our product candidates. Generally, before a new therapeutic product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity and potency, must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. For biological product candidates, potency is similar to efficacy and is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

U.S. Biologics Regulation

In the United States, biological products (or "biologics") are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA") and other federal, state, local, and foreign 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 at any time during the product development process, approval process or following approval may subject an applicant to administrative action and judicial sanctions. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with current good manufacturing practices ("cGMPs");

- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice ("GCP") requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application ("BLA"), after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning any clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on partial or full clinical hold and the IND sponsor, and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, 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 IRB representing 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 trial 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, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical trial results to public registries.

For purposes of 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 patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution 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 identify possible adverse side effects and safety risks. 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 to provide an adequate basis for product approval.

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 BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, 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 product 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 product candidate does not undergo unacceptable deterioration over its shelf life.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain FDA regulatory requirements in order to use the trial as support for an IND or application for marketing approval or licensure, including that the trial was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the trial through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within 10 months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a 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 are in compliance with cGMP requirements and adequate to ensure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to ensure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if

applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a risk evaluation and mitigation strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling 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 studies 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.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency or effectiveness of biologics. 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. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state authorities, and are subject to periodic unannounced inspections by the FDA and certain state authorities for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

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

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. 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 governmental regulatory authorities 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. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. 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 ("BPCIA") created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

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, is generally shown through analytical studies, animal studies, and a clinical trial or trials. 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. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA. The FDA has issued two guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars. On December 20, 2020, Congress amended the PHSA as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the

BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

As discussed below, the Inflation Reduction Act of 2022 ("IRA") is a significant law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

Patent Term Extension

In the United States, after a BLA is approved, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between (1) the later of (a) the effective date of an IND and (b) issue date of the patent for which extension is sought, and (2) the submission date of a BLA, plus the time between BLA submission date and the BLA approval date, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue licensure with due diligence. The total patent term after the extension may not exceed 14 years from the date of product licensure. Only one patent applicable to a licensed biological product is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the United States.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may restrict certain general business and marketing practices. Such laws include, without limitation: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. 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. In 2025, the Department of Justice continued to apply the Supreme Court's 2023 scienter framework in United States ex rel. Schutte v. SuperValu Inc. for FCA matters, focusing on a defendant's subjective understanding and beliefs at the time of claim submission, thus expanding the use of the FCA against recipients of federal funds that allegedly misrepresented compliance with federal civil rights laws.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that caused the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services ("CMS") information related to payments or other transfers of value to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act. In 2025, CMS continued incremental Open Payments program updates, published updates to data publication timelines, and expanded taxonomy lists for covered recipients, which may increase reporting and validation burdens for manufacturers and expand public transparency regarding transfers of value.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Data Privacy and Security

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH"), and their respective implementing regulations imposes privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable protected health information for or on behalf of such covered entities. These requirements imposed by HIPAA and the HITECH Act on covered entities and business associates include entering into agreements that require business associates protect protected health information ("PHI") provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present, or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators.

Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with the U.S. Department of Health and Human Services ("HHS") to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied. In addition, state health information privacy laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, govern the privacy and security of health-related information, specifically, may apply even when HIPAA does not and impose additional requirements.

Even when HIPAA and state health information privacy laws do not apply, according to the Federal Trade Commission and state Attorneys General, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal

information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act and state consumer protection laws.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CCPA"), govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA in various ways. Numerous other states have passed similar laws, but many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices and affords rights to California residents in relation to their personal information. Health information falls under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked, directly or indirectly, with a particular consumer or household unless it is subject to HIPAA and is included under a new category of personal information, "sensitive personal information," which is offered greater protection.

The numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels also exempt some data processed in the context of clinical trials; but others exempt covered entities and business associations subject to HIPAA altogether, further complicating compliance efforts, and increasing legal risk and compliance costs for us and the third parties upon whom we rely.

There are also an increasing number of, and continuous change within, foreign laws regulating data privacy and security, such as Canada's Personal Information Protection and Electronic Documents Act, Australia's Privacy Act 1988, New Zealand's Privacy Act 2020 and South Korea's Personal Information Protection Act. In particular, when we conduct clinical trials, including in New Zealand, we need to comply with the applicable country data privacy and security laws with respect to the processing of clinical data, which impose obligations similar to those described below in the section titled "- *Other Government Regulation Outside of the United States - Regulation in the European Union - European Data Laws*" of this prospectus. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burden on us.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. 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 product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic

products. The IRA provides CMS with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. On August 15, 2024, CMS announced the agreed-upon reimbursement prices of the first 10 drugs that were subject to price negotiations. In January 2025, CMS announced a list of 15 additional drugs Medicare Part D drugs that will be subject to price negotiations. The IRA also provides a new "inflation rebate" covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar's market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. Notwithstanding these provisions, the IRA's impact on commercialization and competition remains largely uncertain.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

For example, the ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the IRA, 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.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of on average 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional action is taken by Congress. In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Moreover, there has recently 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 measures designed to, among other things, reduce the cost of prescription drugs, 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, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS 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. Further, 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.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. We expect regulators to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

European Data Laws

The collection and use of personal health data and other personal data in the European Union ("EU")is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 (GDPR), which came into force in May 2018, and related data protection laws in individual member states of the EU ("EU Member States"). The GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EU and in Iceland, Norway and Liechtenstein (together the European Economic Area ("EEA")) that are not considered by the European Commission ("EC") to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on SCCs, data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer with regard to the transfer of data from the EEA to the United States, on July 10, 2023, the EC adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework. With regard to the transfer of data from EU to the United Kingdom ("UK"), personal data may freely flow from the EEA to the UK since the UK is deemed to have an adequate data

protection level. However, the adequacy decisions include a "sunset clause" which entails that the decisions will automatically expire four years after their entry into force, unless renewed.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including public disclosure obligations provided in the EU Clinical Trial Regulation No. 536/2014 ("CTR"), European Medicines Agency ("EMA") disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results.

On February 11, 2025, the European Union adopted Regulation (EU) 2025/327 establishing the European Health Data Space, which imposes new obligations and liabilities on companies that handle electronic health data in the EU, including mandatory interoperability, logging, security and cross-border exchange requirements for electronic health record systems, expanded individual rights of access and control, and conditions and prohibitions on secondary uses of health data (e.g., for research or regulatory purposes), with staged implementation beginning in late 2025 and 2026. Compliance may require significant investments in technology, processes and governance, as well as engagement with national health data access bodies, and could limit companies' ability to collect, process, transfer, or commercialize health data or delay product development and post-market activities. Failure to comply-or differing national implementations, enforcement actions or evolving guidance-could result in audits, restrictions, fines, litigation, reputational harm, interruption of operations and increased costs.

Additionally, following the UK's withdrawal from the EU and the EEA, companies also have to comply with the UK's data protection laws (including the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (the "DPA 2018")), the DPA 2018, and related data protection laws in the UK). Separate from the fines that can be imposed by the GDPR, the UK regime has the ability to fine up to the greater of £17.5 million or 4% of global turnover.

Companies are subject to specific transfer rules under the UK regime which broadly mirror the GDPR rules. On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the EC's standard contractual clauses for international data transfers (the "IDTA Addendum") and a document setting out transitional provisions. The IDTA and IDTA Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime.

With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the United States (the "UK-US Data Bridge"), which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension to the EU-US Data Privacy Framework.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization ("MA") for human medicines in the EU/EEA must have been carried out in accordance with EU regulations. This means that clinical trials conducted in the EU/EEA have to comply with EU clinical trial legislation but also that clinical trials conducted outside the EU/EEA have to comply with ethical principles equivalent to those set out in the EEA, including adhering to international good clinical practice and the Declaration of Helsinki. The conduct of clinical trials in the EU is governed by the CTR, which entered into force on January 31, 2022. The CTR replaced the Clinical Trials Directive 2001/20/EC ("Clinical Trials Directive") and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

Under the former regime, which will expire after a transition period of three years, as outlined below in more detail, before a clinical trial can be initiated it must be approved in each EU member state where there is a site at which the clinical trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority ("NCA") and one or more ethics committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent ethics committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU member state before the commencement of the trial. Any substantial changes to the trial protocol or other information

submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and ethics committees. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and to the ethics committees of the EU member state where they occur.

A more unified procedure will apply under the new CTR. A sponsor will be able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the "CTIS"). One national regulatory authority (the reporting EU member state proposed by the applicant) will take the lead in validating and evaluating the application and consult and coordinate with the other concerned EU Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned EU Member States. However, a concerned EU member state may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such member state. The CTR also aims to streamline and simplify the rules on safety reporting and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database. The CTR foresees a three-year transition period. EU Member States will work in CTIS immediately after the system has gone live. Since January 31, 2023, submission of initial clinical trial applications via CTIS is mandatory, and CTIS serves as the single entry point for submission of clinical trial-related information and data. By January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will need to comply with the CTR and have to be transitioned to CTIS. On July 19, 2023, the EC published guidance concerning the steps to be taken in this transition. This guidance provides, among other things, that (i) documentation which was previously assessed will not be reassessed, (ii) templates that were developed and endorsed by the EU Clinical Trials Expert Group to provide compliance with the CTR do not need to be updated and (iii) there is no need to retrospectively create a site suitability form, which are only necessary for new trial sites.

Under both the former regime and the new CTR, national laws, regulations, and the applicable GCP and GLP standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on GCP and the ethical principles that have their origin in the Declaration of Helsinki.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application ("MAA") of the product concerned.

Drug Marketing Authorization

In the EEA, after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a MA. To obtain an MA of a drug under European Union regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure.

To be used or sold in the UK, a drug must have an effective MA obtained by a centralized application through EMA or a national application. National applications are governed by the Human Medicines Regulations (SI 2012/1916). Applications are made electronically through the Medicines and Healthcare products Regulatory Agency ("MHRA") Submissions Portal. The process from application to authorizations generally takes up to 210 days, excluding time taken to provide any additional information or data required by the MHRA.

On August 30, 2023, the MHRA published detailed guidance on its new International Reliance Procedure ("IRP") for MAAs. The IRP applies since January 1, 2024 and replaces existing EU reliance procedures to apply for authorizations from seven international regulators (e.g., Health Canada, Swiss Medic, FDA, EMA, among others). The IRP allows medicinal products approved in other jurisdictions that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK. Applicants can submit initial MAAs to the IRP, but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single MA that is issued by the EC following the scientific assessment of the application by the EMA that is valid for all EU Member States as well as in the three additional EEA member states (Norway, Iceland and Liechtenstein). The centralized procedure is compulsory for certain types of medicinal products, including

for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy, or tissue engineered medicines) and medicinal products with a new active substance indicated for the treatment of certain diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a MA through the centralized procedure.

Under the centralized procedure, the CHMP established at the EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. This opinion is then transmitted to the EC, which has the ultimate authority for granting MA within 67 days after receipt of the CHMP opinion.

Decentralized Authorization Procedure

Medicines that fall outside the mandatory scope of the centralized procedure have three routes to authorization: (i) they can be authorized under the centralized procedure if they concern a significant therapeutic, scientific or technical innovation, or if their authorization would be in the interest of public health; (ii) they can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one EU member state; or (iii) they can be authorized in an EU member state in accordance with that state's national procedures and then be authorized in other EU countries by a procedure whereby the countries concerned agree to recognize the validity of the original, national MA (mutual recognition procedure).

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various EU Member States simultaneously if such medicinal product has not received marketing approval in any EU Member State before. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU Member State, the reference member state, is appointed to review the application and provide an assessment report. The competent authorities of the other EU Member States, the concerned member states, are subsequently required to grant a MA for their territories on the basis of this assessment. The only exception to this is where the competent authority of an EU Member State considers that there are concerns of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU Member States.

Risk Management Plan

All new MAAs must include a risk management plan ("RMP") describing the risk management system that a company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. An updated RMP must be submitted: (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. Since October 20, 2023, all RMPs for centrally authorized products are published by the EMA, subject only to limited redactions.

MA Validity Period

MAs have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

For the UK, the period of three years during which the drug has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain MA. Conversion refers to the procedure by which, as of January 1, 2021, MAs granted on the basis of a centralized procedure in the EU are only valid in Northern Ireland but not in Great Britain, whereas, prior EU authorizations have all been automatically converted into UK MAs effective in Great Britain only.

On the other hand, for the EU, in the case the drug has been marketed in the UK, the placing on the UK market before the end of the period starting when the UK left the EU on January 31, 2020 and ending on December 31, 2020 (the "Brexit Transition Period") will be taken into account. If, after the end of the Brexit Transition Period, the drug is not placed on any other market of the remaining EU Member States, the three-year period will start running from the last date the drug was placed on the UK market before the end of the Brexit Transition Period.

Advanced Therapy Medicinal Products

In the EU, medicinal products, including advanced therapy medicinal products ("ATMP") are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are genes, cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to cure, diagnose or prevent diseases or regenerate, repair or replace a human tissue. Pursuant to Regulation (EC) No 1394/2007, the Committee for Advanced Therapies ("CAT") is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CHMP and CAT are also responsible for providing guidelines on ATMPs. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs. Although such guidelines are not legally binding, compliance with them is often necessary to gain and maintain approval for product candidates.

In addition to the mandatory RMP, the holder of a MA for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution where the product is used.

Exceptional Circumstances/Conditional Approval

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU in exceptional circumstances. A conditional MA can be granted for medicinal products where, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, a number of criteria are fulfilled: (i) the benefit/risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical needs will be fulfilled by the grant of the MA and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. Once a conditional MA has been granted, the MA holder must fulfil specific obligations within defined timelines. A conditional MA must be renewed annually, but it can be converted into a standard MA once the MA holder fulfils the obligations imposed and the complete data confirm that the medicine's benefits continue to outweigh its risks.

Data and Market Exclusivity

As in the United States, it may be possible to obtain a period of market and / or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor's generic, hybrid or biosimilar product (even if the pharmaceutical product has already received a MA) and prohibiting another applicant from relying on the MA holder's pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market. New Chemical Entities ("NCEs") approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product's first MA in the EU. After eight years, a generic product application may be submitted and generic companies may rely on the MA holder's data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU of the innovator product), or three years later (or a total of 11 years after the first MA in the EU of the innovator product) if the MA holder obtains MA for a new indication with significant clinical benefit within the eight-year data exclusivity period. Additionally, another noncumulative one-year period of data

exclusivity can be added to the eight years of data exclusivity where an application is made for a new indication for a well-established substance, provided that significant preclinical or clinical studies were carried out in relation to the new indication. Another year of data exclusivity may be added to the eight years, where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials (when examining an application by another applicant for or holder of market authorization for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorized).

Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the European Union's regulatory authorities to include an NCE. Even if a compound is considered to be a NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product if such company can complete a full MAA with their own complete database of pharmaceutical tests, preclinical studies and clinical trials and obtain MA of its product.

On April 26, 2023, the EC submitted a proposal for the reform of the European pharmaceutical legislation. The current draft envisages, e.g., a shortening of the periods of data exclusivity; however, there is currently neither a final version of this draft nor a date for its entry into force. While the European Parliament adopted its approving position on the reform on April 10, 2024, no further required legislative steps have been taken since.

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a pediatric improvement plan ("PIP") together with a request for agreement to the EMA. The EMA issues a decision on the PIP based on an opinion of the EMA's Pediatric Committee. Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g., until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g., because the relevant disease or condition occurs only in adults) has been granted by the EMA. The MAA for the medicinal product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless a waiver or a deferral has been granted, in which case the pediatric clinical trials may be completed at a later date. Medicinal products that are granted an MA on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when a MA holder wants to add a new indication, medicinal form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

In the UK, the MHRA has published guidance on the procedures for UK PIPs which, where possible, mirror the submission format and requirements of the EU system. EU PIPs remain applicable for Northern Ireland and EU PIPs agreed by the EMA prior to January 1, 2021 have been adopted as UK PIPs.

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small-and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact point and rapporteur from the CHMP or from CAT are appointed facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts to provide guidance on the overall development plan and regulatory strategy. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU Member States. This oversight

applies both before and after grant of manufacturing licenses and marketing authorizations. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of MA, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of MA for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of Periodic Safety Update Reports ("PSURs") in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase 4 safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the European Union is highly regulated, and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC (repealed by Directive 2017/1572 on January 31, 2022), Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union. Amendments or replacements of at least Directive 2001/83/EC and Regulation (EC) No 726/2004 are part of the reform proposal for European pharmaceutical legislation. Similarly, the distribution of pharmaceutical products into and within the European Union is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with cGMPs, before releasing the product for commercial distribution in the European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with cGMPs.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's summary of product characteristics ("SmPC") as approved by the competent regulatory authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the

product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the European Union could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with healthcare professionals.

EU regulation with regards to dispensing, sale and purchase of medicines has generally been preserved in the UK following Brexit, through the Human Medicines Regulations 2012. However, organizations wishing to sell medicines online need to register with the MHRA. Following Brexit, the requirements to display the common logo no longer apply to UK-based online sellers, except for those established in Northern Ireland.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In the UK, the pharmaceutical sector is recognized as being particularly vulnerable to corrupt practices, some of which fall within the scope of the Bribery Act 2010. Due to the Bribery Act 2010's far-reaching territorial application, the potential penalized act does not have to occur in the UK to come within its scope. If the act or omission does not take place in the UK, but the person's act or omission would constitute an offense if carried out there and the person has a close connection with the UK, an offense will still have been committed. The Bribery Act 2010 is comprised of four offenses that cover (i) individuals, companies and partnerships that give, promise or offer bribes, (ii) individuals, companies and partnerships that request, agree to receive or accept bribes, (iii) individuals, companies and partnerships that bribe foreign public officials, and (iv) companies and partnerships that fail to prevent persons acting on their behalf from paying bribes. The penalties imposed under the Bribery Act 2010 depend on the offence committed, harm and culpability and penalties range from unlimited fines to imprisonment for a maximum term of 10 years and in some cases both.

Regulations in the UK and Other Markets

The UK formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland and as amended by the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. The EU and the UK agreed on a trade and cooperation agreement, which includes provisions affecting the life sciences sector (including on customs and tariffs) specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and issued GMP documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 ("MMDA") to enable the existing regulatory frameworks to be updated following the UK's departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

The MMDA supplements the UK Medical Devices Regulations 2002 (the "UK Regulations"), which are based on the EU Medical Devices Directive as amended to reflect the UK's post-Brexit regulatory regime. Notably, the UK Regulations do not include any of the revisions that have been made by the EU Medical Devices Regulation (EU) 2017/745, which has gained full application in all EU Member States since May 26, 2021, but is not applicable in the UK as "retained law". Additionally, the MHRA launched a comprehensive consultation in 2021 with proposals to amend the regulatory framework for medical devices in the UK. The stated objectives of the proposals include expansion of the scope of the UK Regulations (for example, by expanding the in vitro diagnostic medical device definition to include software and other products, including products without an intended

medical purpose but with similar functioning and risk profiles) and potentially through use of internationally recognized definitions (for example, by excluding products that contain viable biological substances and excluding food), remove trade barriers, further the availability of medical devices and improve the favorability of the UK market. The consultation period closed on November 25, 2021 and on June 26, 2022, the MHRA published a response to its consultation, which sets out the proposed new UK regulatory framework for medical devices and in vitro diagnostic medical devices. The proposals are intended to improve patient safety and public health through appropriate regulatory oversight, improve the traceability of medical devices, improve the regulation of the rules governing software and AI as medical devices and introduce alternative routes to market to ensure the UK aligns with any superior international best practices. Core aspects of the new framework are expected to apply from July 1, 2025 with appropriate transitional measures and the introduction of secondary legislation.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Regulation of Medical Products in New Zealand

Clinical trials in New Zealand are regulated under the Medicines Act 1981 ("Medicines Act") and Medicines Regulations 1984.

Clinical trial requirements

The New Zealand Medicines and Medical Devices Safety Authority ("Medsafe") is the regulatory authority that administers the application and approval process for medicines and clinical trials in New Zealand (under delegation from the Director-General of Health). Approval from Medsafe is required in the following two circumstances:

- before a medicine can be distributed in New Zealand - see "Approval for distribution" below; however, there is an exemption from this approval requirement for medicines that are imported or manufactured for the sole purpose of use in a clinical trial (including pharmacokinetic, bioequivalence and first-in-human studies); and
- for all clinical trials involving unapproved medicines carried out in New Zealand; however, if a medicine is already approved by Medsafe for distribution in New Zealand, then there is no separate requirement to obtain approval for clinical trials with that medicine (including if the medicine is being tested for a use not provided for under its existing authorization).

Medsafe also expects all clinical trials to be carried out in accordance with internationally accepted standards for good clinical practice as published by the EMA in its Guideline for Good Clinical Practice, to the extent that these standards are compatible with the Medicines Act.

Clinical trial approval process

The clinical trial approval process requires submission of an online application to Medsafe. The application must include information about the nature of the medicine, the purpose of the trial, details of the investigators conducting the trial, written consent to nomination from each investigator, copies of information supplied to the investigators, a protocol of the trial, and details of the sites and facilities used. The application must be made by the actual or intended importer, manufacturer, packer, or supplier of the medicine in New Zealand. Once approved, the applicant becomes the "sponsor" and assumes responsibility and legal liability for the trial in New Zealand.

Once an application is received, Medsafe provides it to the Health Research Council of New Zealand ("HRC"). One of two HRC standing committees will consider the application and make a recommendation to Medsafe as to whether the clinical trial should be approved (with or without conditions) or declined.

The Standing Committee on Therapeutic Trials considers pharmaceutical medicine trial applications, while the Gene Technology Advisory Committee considers applications for trials involving gene and other biotechnology therapies. Both standing committees undertake a similar scientific assessment process, and consider factors such as trial protocol and design, data collection, and general compliance with the Guideline for Good Practice before making a recommendation to Medsafe.

Ethical requirements

Medsafe expects all clinical trials to be approved by the Health and Disability Ethics Committee ("HDEC"), regardless of whether Medicines Act approval is required. HDEC reviews and approves applications and provides ongoing oversight of clinical trials to ensure alignment with good ethical practice. HDEC approval can be sought before, during, or after Medicines Act approval is sought from Medsafe.

Registration

A clinical trial's sponsor may register a trial with the Australian New Zealand Clinical Trials Registry ("ANZCTR"), an online public registry of clinical trials undertaken in New Zealand, Australia, and elsewhere. While not mandatory, the ANZCTR is a recognized part of the World Health Organisation Registry Network and registration is encouraged by the World Health Organisation.

Approval for distribution

If a sponsor decides to distribute the new medicine product in New Zealand after the clinical trial, the sponsor must apply for distribution approval. This is separate to the approval process for clinical trials and involves submitting an application to Medsafe for consideration. Medsafe assesses the safety, efficacy, quality and risk profile of the medicine, and makes a recommendation to the Minister of Health as to whether the medicine should be approved for distribution (in practice, the Minister follows Medsafe's recommendation).

Human Capital

As of December 31, 2025, we had seven full-time employees, including one who holds a Ph.D. and M.D. degree. In January 2026, we expanded our leadership team to include Dr. Becker Hewes as our Chief Medical Officer and Sherwin Sattarzadeh as our Chief Operating Officer. Most of our employees work remotely. None of our employees are represented by labor unions or covered by collective bargaining agreements.

We consistently assess the current business environment and labor market to refine our compensation and benefits programs and other resources available to our employees. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We believe that a compensation program with both short-term and long-term awards provides fair and competitive compensation and aligns employee and stockholder interests, including incentivizing business performance and integrating compensation with our overall business plans and strategy.

Corporation Information

We were founded as Galecto Biotech AB, a Swedish company, in 2011 and incorporated in Delaware as Galecto, Inc. in October 2019. On November 10, 2025, we completed the Asset Acquisition, pursuant to which we assumed the rights and obligations of Pre-Acquisition Damora under the Paragon Option Agreement, and all of Pre-Acquisition Damora's outstanding equity interests were exchanged based on a fixed exchange ratio of 1 to 1.6366 for consideration from us of 265,309 shares of common stock, 16,366 shares of Series B Preferred Stock (or 16,366,000 shares on an as-converted-to-common stock basis), and 4,241 shares of Series C Preferred Stock (or 4,241,000 shares on an as-converted-to-common stock basis), in addition to the assumption of outstanding and unexercised stock options to purchase 434,508 shares of common stock from the Damora Therapeutics, Inc. 2025 Equity Incentive Plan. In connection with the Asset Acquisition, we also issued 39,641 shares of Series C Preferred Stock (or 39,641,000 shares on an as-converted-to-common stock basis) to new and existing investors in the PIPE. On March 6, 2026, we filed with the Secretary of State of the State of Delaware an amendment to our amended and restated certificate of incorporation to change the name of the Company from "Galecto, Inc." to "Damora Therapeutics, Inc.", which became effective on March 10, 2026. Our principal executive offices are located at 221 Crescent Street, Building 23, Suite 105, Waltham, MA 02453, and our telephone number is (781) 281-9020.

Available Information

Our Internet address is www.damoratx.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy, and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Exchange Act are available through the "Investors" portion of our

website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at www.sec.gov.

Information contained on, or that can be accessible through, our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Our code of business conduct and ethics, corporate governance guidelines and the charters of our audit committee, compensation committee and nominating and corporate governance committee are available through our Internet website at www.damoratx.com.

Item 1A. Risk Factors.

You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K and in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations". The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

There is no guarantee that our acquisition of Pre-Acquisition Damora will increase stockholder value.

In November 2025, we acquired Pre-Acquisition Damora. We cannot guarantee that implementing the Asset Acquisition and related transactions will not impair stockholder value or otherwise adversely affect our business. The Asset Acquisition poses significant integration challenges between our businesses which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Asset Acquisition to our stockholders.

We are a preclinical stage biotechnology company with a limited operating history on which to assess our business; we have no products that have been administered to humans or approved for commercial sale, which may make it difficult to evaluate our current business and likelihood of success and viability.

We are a preclinical stage biotechnology company with limited operating history. Since our inception, we have incurred operating losses with no corresponding revenue and have utilized substantially all of our resources to identify, license and develop our product candidates, organize and staff our company and provide other general and administrative support for our operations. We have limited experience as a company in initiating, conducting and completing preclinical studies and clinical trials. In part because of this lack of experience, we cannot be certain that our preclinical studies or clinical trials will begin or be completed on time, if at all. In addition, we have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with an early research and development focus to a company capable of supporting larger scale clinical trials and eventually commercial activities. We may not be successful in such a transition.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research programs or future commercialization efforts.

Developing biotechnology products is a long, time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct preclinical studies and clinical trials of, and seek regulatory approval for our product candidates, advance discovery efforts with respect to our research and research programs, and advance any future programs and product candidates that we may develop or license. Even if one or more of the programs that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to or more expansive than those that we currently anticipate. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any program we develop. Our future capital requirements depend on many factors, including but not limited to:

- the scope, design, progress, results and costs of discovery, preclinical and clinical development for our product candidates;
- the cost and timing of completion of clinical and commercial-scale manufacturing activities;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, defending and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims, including claims of infringement, misappropriation or other violations of third-party intellectual property;

- the costs, timing and outcome of the regulatory review of our product candidates and obtaining the requisite regulatory approvals;
- the costs of our future commercialization activities, either on our own or in collaboration with others, including product sales, marketing, manufacturing, and distribution for any product candidate for which we receive regulatory approval;
- the revenue, if any, received from commercial sales of product candidates for which we receive regulatory approval;
- the success of our current or future collaborations, including our collaboration with Paragon pursuant to the Paragon Option Agreement and any future license agreements we enter into with Paragon;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license products, intellectual property and technologies;
- the costs of operational, financial and management information systems and associated personnel; and
- the costs of operating as a public company.

As a result, we will require substantial additional funding to continue our operations. As of December 31, 2025, we had $257.6 million of cash and cash equivalents. We expect that our existing cash and cash equivalents will be sufficient to fund our operations into Phase 3 development of DMR-001. We will still need to raise additional capital to continue to fund our operations in the future. If we are unable to raise additional capital when needed, that could raise substantial doubt about our ability to continue as a going concern.

We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, and adequate additional financing may not be available to us on acceptable terms, or at all. Such financing may dilute our stockholders or the failure to obtain such financing may restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our business. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect the rights of our stockholders. Debt financing may result in the imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to current or future collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by global macroeconomic conditions and volatility in the credit and financial markets in the United States and worldwide. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our product candidates, clinical trials or future commercialization efforts or cease our operations.

We expect to continue to incur losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products approved for sale, have not generated any revenue from our product candidates and may never generate revenue or become profitable.

Investment in biotechnology product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risks that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products that have been dosed in humans or approved for commercial sale, have not generated any revenue from product sales to date, and continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until we successfully complete preclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we are unable to raise sufficient additional capital to advance a product candidate to commercialization or generate sufficient revenue through the sale of any approved products, we may be unable to continue operations without additional funding.

We have incurred significant net losses in each period since our inception in 2011. For the years ended December 31, 2025 and 2024, we had net losses of $209.8 million and $21.4 million, respectively. As of December 31, 2025, we had an accumulated deficit of $487.4 million. We expect to continue to incur losses for the foreseeable future. Our operating expenses and net losses

may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance our existing and future product candidates through preclinical and clinical development;
- seek to identify additional product candidates;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- seek, obtain and maintain regulatory and regulatory approvals for our product candidates;
- seek to identify, establish and maintain additional collaborations and license agreements;
- make milestone payments to Paragon under the Paragon Option Agreement and under any additional future collaboration or license agreements that we enter into;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drug products for which we may obtain regulatory approval, either on our own or in collaboration with others;
- generate revenue from commercial sales of product candidates for which we receive regulatory approval, if any;
- hire additional personnel including research and development, clinical and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development;
- acquire or in-license products, intellectual property and technologies;
- establish clinical and commercial-scale cGMPs capabilities through a third-party or our own manufacturing facility; and
- continue to integrate Pre-Acquisition Damora into our operations.

In addition, our expenses will increase if, among other things, we are required by the FDA or other regulatory authorities to perform clinical trials or studies in addition to, or different than, those that we currently anticipate, there are any delays in completing our clinical trials or the development of any of our product candidates, or there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain regulatory approval for, and are successful in commercializing, one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates and/or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Our failure to become profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business and/or continue our operations. A decline in the value of our stock could also cause stockholders to lose all or part of their investment.

Risks Related to Our Discovery, Development and Commercialization

We face competition from entities that have developed or may develop product candidates for the diseases addressed by our product candidates.

The development and commercialization of drugs is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies. If approved for the treatment of patients with mutCALR-driven MPNs, our portfolio of products would compete with hydroxyurea, which is not approved for the treatment of ET in the United States, anagrelide, ruxolitinib, and interferon, which has not been approved for ET, as well as ruxolitinib, momelotinib, pacritinib and fedratinib in MF. In addition, we are aware of several companies with product candidates in development for the treatment of patients with mutCALR-driven MPNs, including Incyte's INCA033989 and INCA035784, Janssen Pharmaceuticals, Inc.'s JNJ-88549968, Meiji Seika Pharma's mutCALR TCE, Prelude Therapeutics, LLC's mCALR CDK9d DAC, Alethio Therapeutics' AT-02, PharmaEssentia Corporation's ropeginterferon alfa-2b, Merck & Co., Inc's bomedemstat, Novartis AG's pelabresib, Geron Corporation's imetelstat, and Kartos Therapeutics, Inc.'s navtemadlin. We also compete with academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development,

manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and regulatory approved products than we do, and are further along in the clinical development and/or commercialization process. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, raising capital, patient registration for clinical trials, establishing and defending rights to intellectual property, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

Our competitors have developed or are developing, and may in the future develop, product candidates or products competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any potential new treatments, including those currently under clinical development. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if our competitors develop competing products or biosimilars that enter the market more quickly than we do and are able to gain market acceptance. Conversely, the lack of commercial success of other competing therapies may raise concerns about the financial viability of our product candidates.

In addition, because of the competitive landscape for MPNs, we may also face competition for establishing trial sites and clinical trial enrollment. Patient enrollment will depend on many factors, including if potential clinical trial patients choose to undergo treatment with approved products or enroll in competitors' ongoing clinical trials for product candidates that are under development for the same indications as our product candidates. An increase in the number of approved products for the indications we are targeting with our product candidates will likely further exacerbate this competition. Our inability to enroll a sufficient number of patients could, among other impacts, delay our development timeline, which may further harm our competitive position.

Our programs are in the preclinical stages of development and may fail in development or suffer delays that materially and adversely affect our viability. If we or our current or future collaborators are unable to complete development of or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have no commercially approved products. Our programs are in the preclinical stages of development, and we have not begun or completed any clinical trials for these product candidates. As a result, we expect it will be many years before we commercialize any product candidate, if ever. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Before obtaining regulatory approval for the commercial distribution of any product candidate, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of the product candidate.

We or our collaborators may experience delays in initiating or completing preclinical studies or clinical trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, any future preclinical studies or clinical trials that we could conduct that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators, such as the FDA, institutional review boards ("IRBs") or comparable foreign regulatory authorities may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from the trial protocol, fail to conduct trials in a compliant manner or drop out of a trial, which may require that we add new clinical trial sites or investigators or otherwise negatively impact the timing or integrity of our clinical trial(s);
- clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon a product research program;

- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, and enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or suffer other quality or performance issues that negatively impact the timing or integrity of our clinical trial(s);
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or successfully complete a given clinical trial;
- we may be unable to manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- we may fail to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidates as well as data emerging from other therapies in the same class as our product candidates; and
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA. Commencing clinical trials in jurisdictions outside of the United States is similarly subject to acceptance by the applicable regulatory authority of clinical trial documentation following discussions with such authority. In the event that the FDA or other applicable regulatory authority requires us to complete additional preclinical studies or we are required to satisfy other FDA or foreign regulatory authority requests, respectively, prior to commencing clinical trials, the start of our first clinical trial for a product candidate may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree as to whether we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we currently expect. There are analogous processes and risks applicable to clinical trial applications in other countries, including but not limited to Canada, New Zealand, Australia, countries in the EU and countries in Asia.

We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates. We or our current or future collaborators' inability to complete development of, or commercialize our product candidates, or significant delays in doing so, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are substantially dependent on the success of DMR-001, and our anticipated future clinical trials of such product candidate may not be successful.

Our future success is substantially dependent on our ability to timely obtain regulatory approval for, and then successfully commercialize, DMR-001. We are initially investing a majority of our efforts and financial resources into the research and development of this program. We intend to file an IND or CTA for DMR-001 in mid-2026 and initiate a Phase 1 trial in ET and MF patients with a subcutaneous formulation thereafter, subject to regulatory approval. The success of DMR-001 is dependent on observing rapid and sustained reduction in excess platelets, the key pathology in ET, compared to other anti-mutCALR antibody product candidates in clinical development. This is based in part on the assumption that the increased *in vitro* potency and improved pharmacokinetics observed in NHPs will translate into inhibition of Type 1 and Type 2 mutCALR-dependent cell proliferation and improved pharmacokinetic properties of DMR-001 in humans, resulting in a more convenient dosing regimen. To the extent we do not observe this inhibition of Type 1 and Type 2 mutCALR-dependent cell proliferation or improved pharmacokinetic properties in our Phase 1 clinical trial of DMR-001 or in additional clinical trials, it would significantly and adversely affect the clinical and commercial potential of DMR-001.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote these product candidates, or any other product

candidates, before we receive regulatory approval from the FDA and comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

The success of our product candidates will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights, potential threats from the intellectual property rights of third parties and the manufacturing, marketing, distribution and sales efforts of any current or future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these product candidates, even if approved. If we are not successful in obtaining regulatory approval and commercializing DMR-001, DMR-002, DMR-003 or future product candidates, or are significantly delayed in doing so, our business will be materially harmed.

If we do not achieve our projected development objectives in the time frames we announce and expect, the commercialization of our product candidates may be delayed which may harm our reputation and prospects, increase our expenses and cause our stock price to decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, such as the expected timing for the initiation of our Phase 1 clinical trials of DMR-001, DMR-002 and DMR-003, the timing for receipt of clinical data, and the timing for the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in many cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our prospects and reputation may be adversely affected and our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

The target patient population for the treatment of MPNs is small and has not been definitively determined, and if estimates of the number of treatable patients is lower than expected, our potential revenues from sales of our product candidates, if approved, and our ability to achieve profitability would be compromised.

The estimates of both the number of patients who have MPNs, as well as the subset of patients with the disease in a position to receive treatment from DMR-001 (i.e., those with mutCALR proteins > 42,000 patients in the United States), if approved, may prove to be incorrect. These estimates have been derived from a variety of sources, including scientific literature, input from physicians that treat patients with the diseases we are targeting, patient foundations and secondary market research databases. For example, estimates of the prevalence of MPNs in certain geographies are based in part on the published prevalence of MPNs among patient populations in the United States split across ethnicities, and our own analyses of prevalence in Europe, and on published disease incidence rates for certain geographies and estimated for the populations of such geographies. Further, new studies may change the estimated incidence or prevalence of MPNs, and any regulatory approvals that patient population. Similar considerations would apply to estimates of patient population for target indications we select for DMR-002, DMR-003 and any future product candidates. Accordingly, our target patient populations may turn out to be lower than expected, in which case the potential revenues from sales of our product candidates, if approved, would be lower than expected.

Our approach to the discovery and development of DMR-001, DMR-002 and DMR-003 is unproven, and we may not be successful in our efforts to build a pipeline of product candidates with commercial value.

Our approach to the discovery and development of our product candidates leverages well-established mechanisms of action and incorporates advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies, including increased binding affinity. Our product candidates are purposefully designed to improve upon existing product candidates and products while maintaining the same, well-established mechanisms of action. However, the scientific research that forms the basis of our efforts to develop DMR-001, DMR-002 and DMR-003 using half-life extension technologies and to enhance efficacy through improved binding affinity, including monoclonal antibodies, is ongoing and may not result in viable product candidates. We have limited clinical data on product candidates utilizing monoclonal antibody half-life extension technologies, especially in autoimmune indications, demonstrating whether they are safe or effective for long-term treatment in humans. We also have no clinical data to indicate whether our modifications to enhance binding affinity translate into improved efficacy in humans. The long-term safety and efficacy of DMR-001, DMR-002 and DMR-003 compared to currently approved products is unknown.

We may ultimately discover that utilizing half-life extension technologies for our specific targets and indications and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. We currently have

only preclinical data regarding the increased half-life properties of DMR-001, DMR-002 and DMR-003, and the same results may not be seen in humans. In addition, product candidates using half-life extension technologies may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. This technology and any product candidates resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. Many product candidates that appeared highly promising in preclinical studies or in early-stage clinical trials have failed when advanced into, or further in, clinical development.

In addition, other companies are developing drug products that utilize half-life extension technology in other targets and indications. The failure of those companies to demonstrate the safety and efficacy of their product candidates may be harmful to our business, financial condition, results of operations and prospects.

In addition, we may in the future seek to discover and develop product candidates that are based on novel targets and technologies that are unproven. If our discovery or business development activities fail to identify novel targets or technologies for drug development, or such targets or technologies prove to be unsuitable for treating human disease, we may not be able to develop viable additional product candidates. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the products resulting from our product candidates prove to be ineffective, unsafe or commercially unviable, our product candidates and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. For example, we depend on the availability of NHPs to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development. There is currently a global shortage of NHPs available for drug development. While we currently do not anticipate that this shortage will materially impact our costs or timelines, a continuing or future shortage could cause the cost of obtaining NHPs for our future preclinical studies to increase significantly or result in delays to our development timelines.

Moreover, enrolling patients in clinical trials for cancer therapies is challenging, as cancer patients will first receive the applicable standard of care. Many patients who respond positively to the standard of care therapy (and thus do not enroll in clinical trials) are believed to have tumor types that may have responded well to our product candidates. This may limit the number of eligible patients able to enroll in our clinical trials and could extend development timelines or increase costs for these programs. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these patients may have either compromised immune function from prior administration of chemotherapy or an enhanced immune response from the prior administration of checkpoint inhibitors. Either of these prior treatment regimens may render our therapies less effective in clinical trials. We have sought and may continue to seek to mitigate these effects in the future through modification of enrollment eligibility criteria. Additionally, patients who have failed approved therapies will typically have more advanced cancer and a poorer long-term prognosis. If we are unable to initiate or adequately enroll our clinical trial sites, our clinical trials may be delayed.

Furthermore, a failure of one or more clinical trials can occur at any clinical trial phase. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. In addition, we expect to rely on patients to provide feedback on measures such as measures of disease and quality of life, which are subjective and inherently difficult to evaluate. These measures can be influenced by factors outside of our control and can vary widely from day to day for a particular patient, and from patient to patient and from site to site within a clinical trial.

We cannot be sure that the FDA or comparable foreign regulatory authorities will agree with our clinical development plans, and there is no guarantee that data from our Phase 1 trial will support additional trials. If the FDA or comparable foreign

regulatory authorities require us to conduct additional trials or enroll additional patients, our development timelines may be delayed. We cannot be sure that submission of an IND or similar foreign application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in 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; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval or positive ethics committee opinions at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's GCP requirements or regulatory guidelines; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements, guidance or clinical trial plans that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to new or larger-scale facilities and delays or failure by our contract manufacturing organizations ("CMOs") or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations would be adversely affected.

We may find it difficult to enroll patients in our clinical trials, particularly given the relatively small patient population. If we encounter difficulties enrolling patients in our future clinical trial of DMR-001 or our other programs, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our current or future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until our conclusion.

In addition, cancer therapies are sometimes characterized by line of therapy (first, second, third, fourth, etc.), and the FDA often initially approves new therapies only for use in a particular line or lines of therapy. For example, we may initially seek approval of our product candidates as a third-line therapy for patients who have failed other approved treatments. We may subsequently seek approval as a second- and first-line therapy. There is no guarantee that our product candidates, even if initially approved, would be subsequently approved as a second or first line therapy, which may further reduce the number of patients available to us.

Currently, most ET patients are often treated with aspirin alone. However, the remaining ET patients carry a higher risk of clotting and bleeding and are generally treated with hydroxyurea, which is not approved for the treatment of ET in the United States, anagrelide or interferon.

The enrollment of patients in future trials for any of our product candidates will depend on many factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility and exclusion criteria for the trial in question;

- patients' and clinicians' perceived risks and benefits of the product candidate under study;
- if patients choose to enroll in clinical trials, rather than using approved products, or if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients instead enroll in such clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

Additionally, the number of patients required for clinical trials of our product candidates may be larger than we anticipate. Even if we are able to enroll a sufficient number of patients for our future clinical trials, we may have difficulty maintaining patients in our clinical trials. Our inability to enroll or maintain a sufficient number of patients would result in significant delays in completing clinical trials or receipt of regulatory approvals and increased development costs or may require us to abandon one or more clinical trials altogether, which could cause our value to decline, limit our ability to obtain additional financing and otherwise harm our prospects.

Preliminary, "topline" or interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data. The results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures.

Any preliminary or topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory authorities, 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 product candidate, the approvability or commercialization of the particular product candidate and of us as a company. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. As a result, you or others may have reached different conclusions based on such extensive information in comparison to our publicly disclosed conclusion regarding a particular preclinical study or clinical trial. If the preliminary, topline or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our future clinical trials or those of our current or future collaborators may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of any of our product candidates.

Results of our clinical trials could reveal a high or unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. For example, although anti-mutCALR monoclonal antibodies have been generally well tolerated in clinical trials to date, four discontinuations out of 55 patients, one of which was due to a treatment-emergent adverse event ("TEAE"), were reported by Incyte in its Phase 1 trial investigating INCA033989 in ET patients resistant or intolerant to prior cytoreductive therapy. The most frequent grade ≥ 3 TEAEs were neutropenia, amylase increase, anemia and lipase increase. Because DMR-001 will have a similar mechanism of action, it is possible that patients in our future clinical trials could exhibit similar grade TEAEs as well. We, the FDA or other applicable regulatory authorities, or an IRB or ethics committee, may suspend any clinical trials of any product candidate at any time for various reasons, including a belief

that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies and trials have later been found to cause side effects that prevented their further development. Other potential products have shown side effects in preclinical studies, which side effects do not present themselves in clinical trials in humans. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance of the approved product due to our tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. TEAEs could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with our product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidates may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations and prospects significantly.

In addition, even if we successfully advance our product candidates or any future product candidate through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of the foregoing events occur or if one or more of our product candidates prove to be unsafe, our entire pipeline could be affected, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may expend our resources to pursue a particular program and fail to capitalize on programs that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected programs. For example, we are currently focused primarily on DMR-001. As a result, we may forgo or delay pursuit of opportunities with other programs that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development of product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we select product candidates amongst a variety of potential product candidates from Paragon, and the product candidates we select may fail to be viable commercial products or the product candidates we do not select may have a greater likelihood of success.

Any approved products resulting from our current programs or any future program may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products.

Even if regulatory approval is obtained for a product candidate resulting from one of our current or future programs, we may not gain market acceptance among physicians, healthcare professionals, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. Market acceptance will depend on many factors, including factors that are not within our control. There are two recently approved products and additional product candidates in later stages of development for the treatment of MPNs, including momelotinib (approved in 2023) and pacritinib (approved in 2022) as well as late-stage ropeginterferon alfa-2b, imetelstat, pelabresib, bomedemstat, and navtemadlin. However, DMR-001 is designed to have improved potency against both Type 1 and Type 2 mutCALR and contain modifications that are known to increase the half-life of antibodies in circulation; to date, no such disease-modifying therapy that reduces platelet counts in ET patients with high risk of clotting and bleeding has been approved by the FDA for the treatment of MPNs, though several such agents are in advanced clinical development and close to approval. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic that incorporates anti-mutCALR antibodies and half-life extension for our targeted indication, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any programs developed by us or our existing or future collaborators. Market acceptance of our product candidates may be negatively impacted by potential poor performance of our competitors, including the occurrence of serious adverse events in such competitors' clinical trials or failure by such competitors to obtain and maintain regulatory approval for their product candidates. Additionally, although we believe that the improved dosing and convenience we expect our product candidates to provide will improve market acceptance of such product candidates and that

our candidates will have a competitive efficacy profile, our predictions may not be accurate and other competitive products may instead gain and hold the applicable market. Sales of medical products also depend on the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective, cost effective or less burdensome as compared with competing treatments. If any current or future product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Certain of our programs may compete with our other programs, which could negatively impact our business and reduce our future revenue.

We are developing DMR-001 for the treatment of ET and MF and intend to develop DMR-002 and DMR-003 for other MPNs, and we may in the future develop programs for additional MPNs. However, developing multiple product candidates for MPNs may negatively impact our business if the product candidates compete with each other. For example, if multiple product candidates are conducting clinical trials at the same time, they could compete for the enrollment of patients. In addition, if multiple product candidates are approved for the same indication, they may compete for market share, which could limit our future revenue.

We plan to conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We are planning to conduct our Phase 1 clinical trial of DMR-001 in several geographies, including the United States and Australia, and we may choose to conduct one or more of our future clinical trials outside the United States in whole or in part. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on our determination that the trials also complied with all applicable U.S. laws and regulations. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the relevant jurisdiction, as applicable. If the FDA or any comparable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates or delay or prevent regulatory approval for commercialization in the applicable jurisdiction. Even if the FDA or any comparable foreign regulatory authority accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or the relevant jurisdiction, as applicable, or to continue such trials once initiated.

Further, conducting international clinical trials presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs that could restrict or limit our ability to conduct our clinical trials, the administrative burdens of conducting clinical trials under multiple sets of foreign regulations, foreign exchange fluctuations, diminished protection of intellectual property in some countries, as well as political and economic risks relevant to foreign countries.

Risks Related to Our Reliance on Third Parties

We rely on collaborations and licensing arrangements with third parties, including Paragon. If we are unable to maintain these collaborations or licensing arrangements, or if these collaborations or licensing arrangements are not successful, our business could be negatively impacted.

We rely on our collaboration with a third party, Paragon, for a substantial portion of our discovery capabilities and for the rights necessary to develop and commercialize our product candidates. In the future, we could also rely on additional licensing arrangements with third parties. For example, we have entered into the Paragon Option Agreement. However, Paragon could terminate the Paragon Option Agreement under certain circumstances, including our failure to make any payments owed to Paragon under the agreement or any uncured material breach of the agreement by us, in which event we may lose intellectual property rights and may not be able to develop or commercialize the product candidates covered by that agreement, including DMR-001, DMR-002 or DMR-003, as applicable.

Collaborations or licensing arrangements that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of our collaborators or licensors experiences delays in performance of, or fails to perform, our obligations under our agreement with us, disagrees with our interpretation of the terms of such agreement or terminates their agreement with us, our pipeline and product candidates and development timeline could be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Our collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, leading to the potential invalidation of our intellectual property, or they may even infringe upon our intellectual property rights, any of which could subject us to litigation or arbitration, which would be time-consuming and expensive and could harm our ability to commercialize our product candidates. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

As part of our strategy, we plan to evaluate additional opportunities to enhance our capabilities and expand our development pipeline or add development or commercialization capabilities. We may not realize the benefits of such collaborations, alliances or licensing arrangements. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

We may face significant competition in attracting appropriate collaborators, and more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies may be unwilling to assign or license rights to us, whether they perceive us to be a competitor or for other reasons. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If we fail to enter into collaborations and does not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

Risks associated with the in-licensing or acquisition of product candidates could cause substantial delays in the preclinical and clinical development of our product candidates.

We have relied and continue to rely on Paragon, and expect to rely on our future licensing partners, to (i) conduct research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, (ii) accurately report the results of all preclinical trials conducted prior to our licensing or acquisition of the relevant product candidates and (iii) correctly collect and interpret the data from these trials. If the research and development processes or the results of the research programs prior to our licensing or acquisition of our product candidates prove to be unreliable, this could result in increased costs and delays in the development of our product candidates, which could adversely affect any future revenue from such product candidates, if approved.

We may also acquire or in-license additional product candidates for preclinical or clinical development in the future as we continue to build our pipeline. The risks associated with acquiring or in-licensing product candidates could result in delays in the commencement or completion of our preclinical studies and clinical trials, if they are ever commenced or completed, and our ability to generate revenues from our product candidates may be delayed. Please see the section titled "*Risk Factors-Risks Related to Our Intellectual Property-If we are unable to obtain or maintain necessary rights to our programs through acquisitions and in-licenses, our business may be materially harmed*" below for additional information regarding such risks.

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract testing labs and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing

and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP. In addition, our clinical trials must be conducted with products manufactured in accordance with cGMPs. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, and foreign equivalents.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our programs. These third parties may encounter challenges hiring and retaining sufficient qualified personnel or they may be involved in mergers, acquisitions or similar transactions and may have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our current or future product candidates. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates.

In addition, we plan to rely on foreign CROs and CMOs, including WuXi Biologics (Hong Kong) Limited ("WuXi Biologics (Hong Kong)"), for formulation and manufacturing of our Phase 1 clinical trial materials, and will likely continue to rely on foreign CROs and CMOs in the future. WuXi Biologics (Hong Kong) is a subsidiary or affiliate of WuXi Biologics, which was previously identified in the U.S. legislation proposed in 2024 known as the BIOSECURE Act as a biotechnology "company of concern." The BIOSECURE Act as it was enacted into law on December 18, 2025, will prohibit U.S. federal agencies from entering into, extending or renewing procurement contracts with, as well as providing grants and loans to, an entity that uses biotechnology equipment or services from a "biotechnology company of concern," and includes 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 of revisions to the Federal Acquisition Regulation designating an entity a biotechnology company of concern until five years from such effective date. The timing for implementation of the BIOSECURE Act is uncertain. Depending on how the BIOSECURE Act is implemented by U.S. federal agencies, we could be potentially restricted from pursuing U.S. federal government business or grants in the future if we continue to use WuXi Biologics (Hong Kong) and if WuXi Biologics (Hong Kong) or other parties we contract with are identified as "biotechnology companies of concern" beyond the grandfathering period. Foreign CMOs may be the target of U.S. legislation, including the BIOSECURE Act, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, restrict or even prohibit our ability to work with such CMOs, or have an adverse effect on our ability to secure significant commitments from governments to purchase potential therapies.

The biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. In addition, the United States government has imposed significant tariffs on imports from China and other countries and may impose more restrictions on goods, including biologically derived substances, manufactured in or imported from China or other countries or impose other restrictions on companies' ability to work with Chinese or other foreign counterparties. Evolving changes in China's public health, economic, political, and social conditions and uncertainty around China's relationship with other governments, such as the United States and the UK, could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical research programs. Furthermore, if one or more of our collaborators or vendors in China, including WuXi Biologics (Hong Kong), is named a biotechnology company of concern, our operations and financial condition may be negatively impacted as a result of any delays or increased costs arising from the trade restrictions and other foreign regulatory requirements affecting such collaborators. In addition, while we have established relationships with CROs

and CMOs outside of China, moving to those suppliers in the event of a geopolitical instability affecting our collaborators in China could introduce delays into the research program.

We rely on the use of third-party CMOs to manufacture our product candidates, and we expect to continue to rely on third-party CMOs to produce our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must rely on CMOs to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We currently have a single source for our supply of our product candidates and recently entered into an agreement with a second supplier. If there should be any disruption in such supply arrangement, including any adverse events affecting our sole supplier, or if we experience delays or difficulties in transferring, or are unable to successfully transfer, our manufacturing processes, it could have a negative effect on the clinical development of our product candidates and other operations while we work to identify and qualify an alternate supply source. We have limited control over the manufacturing process of, and may be dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or another applicable regulatory authority does not approve these facilities for the manufacture of our product candidates or withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and delays and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. We, or our future contract manufacturers, any current or future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, competent authorities of the EU Member States or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMPs. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or products, if approved, and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, intellectual property disputes or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a commercially reasonable cost, our business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA or comparable foreign regulatory authorities, result in higher costs or adversely impact commercialization of our product candidates.

Risks Related to Our Business and Operations

In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our managerial, scientific and medical personnel. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time. If we do not succeed in attracting and retaining qualified personnel, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates, if approved, in foreign markets for which we may rely on collaboration with third parties. Recent and ongoing changes in the United States trade policy with foreign countries, including the continued uncertainty surrounding U.S. tariffs and potential retaliatory measures by foreign governments, may disrupt the global supply chain for biopharmaceutical products. For example, in September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of active pharmaceutical ingredients and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. Any direct tariffs, if imposed on pharmaceutical products, may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical CMOs, and a delay in our development timelines.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we 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 our product candidates, if approved, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare 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. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties 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 comply with these laws or regulations.

Our internal information technology systems, or those of any of our CROs, manufacturers, other contractors or consultants, third-party service providers, or existing or future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "Process") proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, "Sensitive Information").

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials), third-party service providers and supply chain companies, and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, 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.

To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

Our remote workforce may create additional risks for our information technology systems and data because our employees work remotely and utilize network connections, computers, and devices working at home, while in transit and in public locations. Additionally, 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.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to Process Sensitive Information in a variety of contexts. 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 our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on Processing Sensitive Information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our platform, deter new customers from products, and negatively impact our ability to grow and operate our business.

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

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We, and third parties we work with, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. In addition, we are and may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules governing U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service ("IRS") and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted.

For example, the United States enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and JOBS Act eliminated the previously available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over fifteen years for research activities conducted outside the United States. July 4, 2025, the U.S. Congress enacted the One Big Beautiful Bill Act, which includes a provision restoring the immediate deductibility of domestic research and development expenditures. The impact of this newly enacted law on our tax position will depend on how the provision is implemented and interpreted by the IRS and other regulatory authorities. In addition, we have no assurance as to whether, when and how this provision may be subject to further amendment or repeal. Such changes, among others, may adversely affect our effective tax rate, results of operation and financial condition.

We may acquire businesses, product candidates or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new product candidates or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank in March 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

Risks Related to Our Intellectual Property

Our intellectual property portfolio is at an early stage. Therefore, our ability to obtain and protect our patent rights, and protect other proprietary rights, is uncertain, exposing us to the possible loss of competitive advantage.

We will rely upon a combination of patents, trademarks, trade secret protection, copyrights and confidentiality agreements, licenses and the Paragon Option Agreement to protect the intellectual property related to our programs and technologies and to prevent third parties from competing unfairly with us. Our success depends in large part on our ability to obtain and maintain patent protection for our product candidates and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. We do not currently own or license any patents with respect to DMR-001, DMR-002, DMR-003. Paragon has filed patent applications directed to anti-mutCALR monoclonal antibodies, including applications covering composition of matter, pharmaceutical formulations, and methods of using such antibodies, including DMR-001, which we have the option to license pursuant to the Paragon Option Agreement. In the future, we expect to prosecute underlying intellectual property for DMR-001, DMR-002, DMR-003, and some or all of the in-licensed or owned product candidates that we develop.

We may not be able to obtain or protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of at least certain patents, trade secrets or other intellectual property. Filing,

prosecuting, maintaining and defending patents on product candidates and other related inventions worldwide would be expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States; the reverse may also occur. As such, we may not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we or our licensor files patent applications to obtain such rights. Our competitors may operate in countries where we do not have patent protection and may be able to freely use our technologies and discoveries in such countries, at least to the extent not forbidden by law.

Our intellectual property portfolio is at an early stage. Except as described above, we do not currently own or license any issued patents or pending patent applications. Our future optioned, in-licensed or owned patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that we may license or own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO. If we do not obtain patent coverage for the work we are conducting, or if we obtain such rights but they are invalidated or rendered unenforceable, we may be unable to exclude competitors from pursuing and marketing the same or similar product candidates. Other risks we face if we are not able to obtain and maintain patent coverage for our product candidates are the reduction in valuation of our product candidates, and ultimately of us as a company, by potential investors, and our inability to assert claims for infringement against third parties or counterclaim against such third parties or negotiate more advantageous settlement parameters. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection would be reduced. Thus, the patents that we may own or license may not afford us any meaningful exclusivity period or competitive advantage.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or state actors and those affiliated with or controlled by state actors. In addition, while we undertake reasonable efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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

If we are unable to obtain or maintain necessary rights to our programs through acquisitions and in-licenses, our business may be materially harmed.

Because our research programs currently do and may in the future require the use of proprietary rights held by third parties, the growth of our business will depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our programs. 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 or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain intellectual property rights we obtain in the future, we may have to abandon development of the relevant program, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we have the right to control prosecution, defense, maintenance and enforcement of patents in-licensed under the Paragon License Agreements once the trigger for transfer of prosecution control is met, there may be times when rights for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. For example, Paragon currently has the right to file patent applications and control prosecution with respect to any other inventions that may fall within the Paragon Option Agreement, including those that may apply to DMR-001, DMR-002 and DMR-003. If we, Paragon or any of our future licensors or collaboration partners fail to prosecute, defend, maintain and enforce such patents and patent applications in a manner consistent with our best interests, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even if we have the right to control prosecution of patents and patent applications we have licensed to and from third parties, including under future license agreements with Paragon following the point at which such control is assumed, we may still be adversely affected or prejudiced by actions or inactions of Paragon, additional licensees, or licensors and their counsel prior to the date upon which we assume control over patent prosecution. For example, Paragon is responsible for the prosecution, defense, maintenance and enforcement of patents related to DMR-001, DMR-002 and DMR-003. Subsequent to entering into such license agreements, we expect to control patent prosecution over DMR-001, DMR-002 and DMR-003 following the trigger for transfer of prosecution control for the applicable program to us.

Our future licensors may not be the sole and exclusive owners of all rights in the patents we may in-license. If other third parties have rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates, manufacturing methods or future products or methods resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including (but not limited to): the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and the priority of invention of patented technology. If we or our future licensors breach the terms of our license agreements, such breach may have a material adverse effect on our business and the commercialization efforts for our programs.

We may be subject to intellectual property lawsuits or may need to file lawsuits to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that we can operate without infringing on or violating third-party rights. If certain of our product candidates are ultimately granted regulatory approval, patent rights held by third parties could be alleged to render one or more of our product candidates infringing. If a third party successfully brings a claim against us, and our rights are not held invalid or unenforceable, we may be required to pay substantial damages, be forced to abandon any affected product candidate and/or seek a license from the patent holder. In addition, any intellectual property claims (e.g., patent infringement or trade secret misappropriation) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that future patents, if filed and issued, owned or licensed by us will not be challenged by others, whether in the course of litigation or in agencies like the USPTO. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds.

Competitors may infringe or otherwise violate our future patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any

such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our future patents, if filed and issued, through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees or customers and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees or other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Our success will depend in part on our and our current and future licensors' ability to obtain, maintain and enforce patent protection for our licensed intellectual property.

Our success will depend in part on our and our current and future licensors' (including Paragon's) ability to obtain, maintain and enforce patent protection for our licensed intellectual property. Currently, Paragon controls the prosecution, maintenance, enforcement and defense of DMR-001, DMR-002 and DMR-003. After entry into license agreements with Paragon for DMR-001, DMR-002 and DMR-003, and once the trigger for transfer of prosecution control is met, we expect to hold such rights. We, Paragon and our future licensors may not successfully prosecute the patent applications that cover our product candidates. Even if patents are issued in respect of these patent applications, we and our future licensors (including Paragon) may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for any in-licensed intellectual property, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the biotechnology industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to

pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act") could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation increased the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. For example, the United States Supreme Court in *Amgen, Inc. v. Sanofi* ("*Amgen*") recently held that Amgen's patent claims to a class of antibodies functionally defined by their ability to bind a particular antigen were invalid for lack of enablement where the patent specification provided 26 exemplary antibodies, but the claimed class of antibodies covered a "vast number" of additional antibodies not disclosed in the specification. The Court stated that if patent claims are directed to an entire class of compositions of matter, then the patent specification must enable a person skilled in the art to make and use the entire class of compositions. This decision makes it unlikely that we will be granted U.S. patents with composition of matter claims as broad as Amgen's directed to antibodies functionally defined by their ability to bind a particular antigen. Even if we are granted claims directed to functionally defined antibodies, it is possible that a third party may challenge our patents, when issued, relying on the reasoning in *Amgen* or other precedential court decisions. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. 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. Geopolitical instability in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. In addition, the Unified Patent Court ("UPC") entered into force on June 1, 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for EU Member States. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated.

Although we do not currently own any European patents or applications, if we obtain or license such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce or defend the validity of any European patents we may

obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain any future patents and patent applications, if filed and issued, covering our product candidates, our competitive position would be adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent, the patent's prosecution history and in some cases certain extrinsic evidence of the meaning of terms in a claim. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our future issued patents or our pending applications, if filed, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our future patent applications or patents, if filed and issued, which could require us to obtain rights to issued patents covering such technologies.

We may become subject to claims challenging the inventorship or ownership of our patents, if issued, and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our future patents, if filed and issued, or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being invalid or unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our programs or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position of our product candidates for an adequate amount of time.

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 our earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our technology licensed from various third parties may be subject to retained rights.

Our future licensors may retain certain rights under the relevant agreements with us, including the right to use or license the licensed technology outside of the scope of our license, use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. In addition, while there are certain restrictions on Paragon's ability to develop products that could be competitive with ours, these restrictions may not prevent the possible future license or development by Paragon of certain technology that could lead to product candidates competitive with ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including DMR-001, DMR-002 and DMR-003, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective, may prove to have undesirable or unintended side effects, toxicities or other characteristics, or may fail to improve on the applicable standard of care, any of which may preclude our obtaining regulatory approval. The FDA and comparable foreign regulatory authorities have discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for our proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh our safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or

elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our product candidates; the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or applicable foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, 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. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, this could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects. In addition, the FDA and foreign regulatory authorities may undergo leadership changes, change their policies, issue additional regulations or revise existing regulations, or take other actions, which may impact our clinical development plans or prevent or delay approval of our product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals and increase the costs of compliance. It is difficult to predict how executive actions that may be taken under the current administration may affect the FDA's ability to exercise its regulatory authority. If any actions impose constraints on the FDA's ability to engage in routine oversight and product review activities in the normal course, our business may be negatively impacted. Additionally, federal government could adopt legislation, regulations or policies that adversely affect our business or create a more challenging and costly environment to pursue the development, approval and commercialization of our product candidates.

We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our drug products safely and in accordance with regulatory requirements. This includes manufacturing the active ingredient, developing an acceptable formulation, manufacturing the drug product, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that our drug products meet stability requirements. Meeting these chemistry, manufacturing and control requirements is a complex task that requires specialized expertise. If we are not able to meet the chemistry, manufacturing and control requirements, we may not be successful in getting our products approved.

Our product candidates for which we intend to seek approval as biologics may face competition from biosimilars sooner than anticipated.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved as biologics under a BLA should qualify for the 12-year period of exclusivity. 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 products for competing products, potentially creating the opportunity for competition sooner than anticipated.

Even if we receive regulatory approval of our product candidates, we will be subject to extensive 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 or experience unanticipated problems with our product candidates.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable foreign regulatory authorities may impose similar requirements. In addition, if the FDA or comparable foreign regulatory authorities approve our product candidates, our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs. If we or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, delays or restrictions on our ability to conduct clinical trials or delays or refusal to grant a marketing authorization, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, suspension, withdrawal or variation of any marketing authorization that has been granted, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. Similar penalties may apply in case of failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors, to comply with FDA and EU laws and the related national laws of individual EU Member States and other applicable regulatory authorities governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of a marketing authorization, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements, including administrative, civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

Disruptions at the FDA, the SEC and other government agencies and regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review regulatory filings and our ability to commence human clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the 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 or comparable foreign regulatory authorities may also slow the time necessary for the review and approval of applications for clinical trial or marketing authorization, which would adversely affect our business. For example, in recent years, including for 43 days beginning on October 1, 2025, the U.S. government shut down and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Actions to limit federal agency budgets or personnel may result in reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. If a prolonged government shutdown occurs, 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, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may face difficulties from healthcare and regulatory legislative reform measures.

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Even if we are able to commercialize any product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such product candidates at competitive prices, which would seriously harm our business.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any product candidates that we may develop will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. These entities may create preferential access policies for a competitor's product, including a branded or generic/biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Governmental regulation of the import or export of our drug candidates, or our failure to obtain any required import or export authorization for our candidates, when applicable, could harm international operations. Furthermore, export control laws and economic sanctions prohibit the provision of certain items, technology, and services to countries, governments, and persons targeted by sanctions programs. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing,

promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly EU Member States, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected.

If we seek and are unable to obtain accelerated approval, the amount, size and duration of our clinical trials could be greater than planned, which could increase the expense, reduce the likelihood, and/or delay the timing of obtaining necessary regulatory approvals. Even if we receive accelerated approval, if confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-approval requirements, such authorities may withdraw accelerated approval.

We may seek accelerated approval, or other expedited development, review or approval status, for our product candidates. Even if granted, there is no guarantee that receiving an expedited development, review or approval status from the FDA will lead to a faster development or regulatory review or approval process, and such status does not increase the likelihood that our product candidates will ultimately receive marketing approval. The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic advantage over available therapies and demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. If we choose to pursue accelerated approval, there can be no assurance that the FDA will agree that our proposed primary endpoint is an appropriate surrogate endpoint. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue accelerated approval or any other form of expedited development, review, or approval, even if we initially decide to do so. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. Accelerated approval may be contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's predicted effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. The FDA may require that any such confirmatory study be initiated or substantially underway prior to the submission of an application for accelerated approval. Even if we receive accelerated approval from the FDA, we will be subject to rigorous post-approval requirements, including submission to the FDA of all promotional materials prior to their dissemination. The FDA could withdraw accelerated approval for multiple reasons, including our failure to conduct any required post-approval study with due diligence, or the inability of such study to confirm the drug's predicted clinical benefit relative to its risks. A failure to obtain accelerated approval or any other form of expedited review or approval for a product candidate could result in a longer time period prior to commercializing such product candidate, increase the cost of development of such product candidate, and harm our competitive position in the marketplace. Comparable considerations apply outside of the United States.

General Risk Factors

We may become exposed to costly and damaging liability claims, when testing a product candidate in the clinical stage or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. While we currently have no products that have been dosed in humans or approved for commercial sale, the future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product or product candidate, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our products or any prospects for commercialization of our products. Although we intend to obtain product liability insurance for our future clinical trials, it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time, we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal information, contractual relations with collaborators and licensors and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

Our business could be adversely affected by economic downturns, inflation, fluctuating interest rates, natural disasters, public health crises, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, fluctuating interest rates, and uncertainty about economic stability. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs imposed by the U.S. government and potential retaliatory measures by foreign governments and other barriers to trade, especially in light of recent comments and executive orders made by the Trump administration, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), government shutdowns, tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, we and our business partners and suppliers. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. In addition, the U.S. has imposed and taken action to pause, resume or adjust tariffs on imports from a number of countries. Since February 2025, the United States government has imposed various tariffs on imports from most countries, including tariffs on imports from China and South Korea. In September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of active pharmaceutical ingredients and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. There still remains substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified or suspended. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Uncertainty and political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. The Federal Reserve has raised interest rates multiple times in recent years in response to concerns about inflation and it may raise them again. High interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine and in the Middle East and rising tensions with China have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to

obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Risks Related to the Ownership of Our Common Stock

The market price of our common stock has been and is expected to continue to be volatile.

The market price of our common stock has been and is expected to continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if we do not achieve the perceived benefits of our recent merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- 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 adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products and services; 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 addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value 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 such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of

our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results, financial condition and cash flows.

We are governed by Delaware law and our amended and restated certificate of incorporation, as amended (the "Certificate of Incorporation") and amended and restated By-laws, as amended (the "By-laws"), provisions of which have anti-takeover implications.

Provisions that are included in our Certificate of Incorporation and By-laws may discourage, delay or prevent a merger, acquisition or other change in control of the Company that our stockholders may consider favorable, including transactions in which holders of common stock might otherwise receive a premium price for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because the board of directors is responsible for appointing our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for our stockholders to replace members of the board of directors. Among other things, these provisions will:

- continue the use of a classified board of directors such that not all members of our board of directors are elected at one time;
- allow the authorized number of directors to be changed only by resolution of the board of directors;
- limit the manner in which our stockholders can remove directors from the board of directors;
- provide for advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize the board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the board of directors;
- require the approval of the holders of at least 66 2/3% of the voting rights to amend or repeal certain provisions of the Certificate of Incorporation or By-laws; and
- require the affirmative vote of not less than 66 2/3% of the outstanding shares of capital stock entitled to vote on the matter to amend or repeal the By-laws if the board of directors does not recommend the same.

Moreover, we and our organizational documents are governed by Delaware law. Section 203 of the DGCL contains provisions that may enable our board of directors to discourage, delay or prevent a change in our ownership or in our management. The business combinations with interested stockholders provisions of the DGCL, subject to certain exceptions, restrict our ability to engage in any business combination with an interested stockholder for a three year period following the time that this stockholder becomes an interested stockholder, unless (i) before the stockholder became an interested stockholder, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or (iii) at or after the time the stockholder became an interested stockholder, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder. For purposes of the foregoing provisions, "interested stockholder", with certain exceptions is any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person at any time in the last three-year period.

Additionally, the Series B Certificate of Designation may delay or prevent a change in control of the Company. At any time while at least 30% of the originally issued Series B Preferred Stock remains issued and outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock, (i) consummate (x) any Fundamental Transaction (as defined in the Series B Certificate of Designation) or (y) any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which our stockholders immediately before such transaction do not hold at least a majority of our capital stock of immediately after such transaction, (ii) increase the

size of the board of directors, (iii) adopt, amend or repeal any written delegation of authority policy, corporate authority matrix or similar document, framework or schedule unless such adoption, amendment or repeal has been approved by the unanimous vote of the board of directors, or (iv) retain or replace our registered independent public accounting firm, independent compensation consultant or corporate counsel.

Because our Certificate of Incorporation and By-laws limit the court in which you may bring an action against us, you may have difficulty obtaining a more favorable judicial forum or you may incur more expense enforcing any rights which you may claim as compared to another forum.

Our Certificate of Incorporation and our By-laws provide that, to the extent permitted by law, any person who acquires equity in our company shall be deemed to have notice and consented to the forum selection provision of our By-laws, which require actions to be brought only in the Court of Chancery of the State of Delaware, which may inhibit or deter stockholders' actions (i) brought in the name of our company or on our behalf; (ii) asserting a claim for breach of any fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders; (iii) arising or asserting a claim arising pursuant to any provision of the DGCL or any provision of our Certificate of Incorporation or By-laws; (iv) to interpret, apply, enforce or determine the validity of any provision of our Certificate of Incorporation or By-laws; or (v) asserting a claim governed by the internal affairs doctrine. This exclusive forum provision may limit our stockholders' ability to obtain what they believe to be a favorable judicial forum for disputes with us and our officers and directors. This provision does not apply to claims brought under the Securities Act or the Exchange Act.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our By-laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations.

We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will incur significant legal, accounting and other expenses as a public company, including costs associated with public company reporting obligations under the Exchange Act. Our executive officers and other personnel need to devote substantial time to comply with public company reporting requirements and additional applicable laws and obligations. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows.

We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, we may take advantage of exemptions from disclosure requirements and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, as a smaller reporting company with less than $100.0 million in annual revenue, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. Once we are no longer a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for our stockholders for the foreseeable future.

Future sales of shares by existing stockholders could cause our stock price to decline.

If existing securityholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale in connection with our recent merger lapse, the trading price of our common stock could decline. In addition, shares of common stock that are subject to outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own a significant portion of our outstanding shares of common stock (on a fully-diluted basis), subject to beneficial ownership limitations. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

Conflicts of interest may arise between us and Paragon or us and Fairmount.

In connection with the Asset Acquisition, we assumed the rights and obligations of Pre-Acquisition Damora under the Paragon Option Agreement. See the section titled "*Paragon Option Agreement*" for more information on the Paragon Option Agreement. Fairmount beneficially owns more than 5% of Paragon, appointed Paragon's board of directors, and has the contractual right to approve the appointment of any executive officers of Paragon. Paramora is an entity formed by Paragon as a vehicle to hold equity in Pre-Acquisition Damora (and as a result of the Asset Acquisition, us) in order to share profits with certain employees of Paragon. Fairmount beneficially owns 19.99% of our common stock assuming conversion of the Series B Preferred Stock and Series C Preferred Stock into common stock (in each case, subject to beneficial ownership limitations). Three of our directors are affiliated with Fairmount (Peter Harwin, Christopher Cain, Ph.D., and Julianne Bruno) and were appointed in accordance with the Acquisition Agreement. The remaining three members of the board of directors are not affiliated with Fairmount or Paragon.

Our relationship with Paragon, Paramora, Fairmount and our non-employee directors may create, or may create the appearance of, conflicts of interest when we are faced with decisions that could have different implications for Paragon or Paramora than the decisions have for us. For example, such conflicts may arise in connection with the selection of additional targets, the exercise of options under the Paragon Option Agreement, the negotiation of the terms of any future license agreements, the allocation of resources and expenses, the enforcement or defense of intellectual property rights, the pursuit of strategic partnerships or transactions, or the resolution of any disputes that may arise between us and Paragon or Paramora. We expect that the decision to amend the Paragon Option Agreement or enter into any similar agreements or license agreements with Paragon will be subject to the approval of the board of directors. All directors owe fiduciary duties pursuant to Delaware law, and directors are expected to comply with their respective fiduciary duties under Delaware law relevant to related party transactions. We have previously adopted a related party transaction approval policy and our audit committee will be responsible for the review, consideration and approval or ratification of related party transactions.

Furthermore, because Paragon and Fairmount have interests in other biotechnology companies that may compete with us or pursue similar or complementary product candidates or technologies, they may have an incentive to favor or support such other companies over us. These potential conflicts of interest may make it more difficult for us to favorably advance our business interests and may adversely affect our competitive position, business, financial condition, results of operations and prospects.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, then our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In addition, we do not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Our ability to use net operating loss ("NOL") carryforwards and other tax attributes may be limited, including as a result of our recent merger.

We do not expect to become profitable in the near future and may never achieve profitability. As of December 31, 2025, we had federal and state NOL carryforwards and federal and state research and development credits that may be used to offset future taxable income. Under current law, our U.S. federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Internal Revenue Code (the "Code"), U.S. 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 net operating loss carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including, as discussed above, in connection with our recent merger or other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

The class structure of our capital stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The class structure of our capital stock may limit your ability to influence corporate matters. Holders of common stock are entitled to one vote per share, while holders of the Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock are not entitled to any votes. Nonetheless, each share of Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock, may be converted at any time into 1,000 shares of common stock at the option of the holder by providing written notice to us, subject to beneficial ownership limitations and the limitations provided for in our Certificate of Incorporation and the related certificates of designation. Consequently, if holders of the Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of the Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock, respectively, and

correspondingly decreasing the voting power of the holders of common stock, which may limit your ability to influence corporate matters.

Although Series B Preferred Stock does not have voting rights on proposals presented to our holders of common stock, at any time while at least 30% of the originally issued Series B Preferred Stock remains issued and outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock, (i) consummate (x) any Fundamental Transaction (as defined in the Series B Certificate of Designation) or (y) any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which our stockholders immediately before such transaction do not hold at least a majority of our capital stock immediately after such transaction, (ii) increase the size of the board of directors, (iii) adopt, amend or repeal any written delegation of authority policy, corporate authority matrix or similar document, framework or schedule unless such adoption, amendment or repeal has been approved by the unanimous vote of the board of directors, or (iv) retain or replace our registered independent public accounting firm, independent compensation consultant or corporate counsel.

Additionally, stockholders who hold, in the aggregate, more than 10% of common stock, Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock outstanding, but beneficially own 10% or less of common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in the Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We understand the critical importance of maintaining the trust and confidence of universities, medical institutions, clinical investigators, CROs, strategic collaborators, business partners, employees, and others, and take steps to protect the confidentiality, integrity and availability of our business operations and systems. Our board of directors is involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity policies, standards, processes and practices are informed, in part, by recognized frameworks established by applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy

We face risks related to cybersecurity such as unauthorized access to information or information technology systems, cybersecurity attacks, and other cybersecurity incidents. Our processes to identify, assess, and manage material cybersecurity risks are informed, in part, by industry cybersecurity standards, including components of the National Institute of Standards and Technology Cybersecurity Framework, ISO 27001 standard, and HIPAA security regulations. Our processes include assessments designed to identify key risk areas and inform our overall cybersecurity strategy and cybersecurity assessments in connection with our review of key information technology systems. Our processes also include technical security controls, such as network monitoring tools and multi-factor authentication, where appropriate.

We conduct due diligence on our significant third-party vendors and service providers that store or process sensitive company information. Our processes include a security review and implementation of procedures to receive and review security updates and alerts from such third parties.

We have established an incident response process designed to identify, assess, and respond to cybersecurity incidents. This process includes established roles, responsibilities and procedures to guide incident response operations, and reporting procedures for notifying members of management and the audit committee, where appropriate. We also maintain back-ups and disaster recovery plans designed to restore information in the event of a cybersecurity incident. We have not experienced any cybersecurity incidents, and are not aware of any threats, that have materially affected us or are reasonably likely to materially affect us, since the beginning of the last fiscal year. However, like other companies in our industry, we and our third-party vendors may from time to time experience cybersecurity threats and incidents that could affect our information or systems. Additional information on cybersecurity risks we face is discussed in “Item 1A, Risk Factors.”

Governance Related to Cybersecurity Risks

Our board of directors is involved in risk oversight as part of our overall business strategy and has delegated oversight of risk assessment and management to the audit committee. The audit committee administers its risk oversight function by receiving periodic reports from members of senior management. Our audit committee discusses cybersecurity threats and our risk management processes at least annually, receives updates on relevant cybersecurity developments, and considers steps that our management has taken to monitor and manage cybersecurity risk. The full board of directors also discusses with management identified material cybersecurity risks, their potential impact on us, and the steps we plan to take to manage them. Our audit committee and board of directors also receive prompt and timely information regarding any cybersecurity incident that meets establishing reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Our Information Technology Administrator, with support from third-party service providers, including our outsourced Data Protection Officer, implements and administers our information security program. Such individuals have collectively over 40 years of prior work experience in various roles involving managing information security, developing cybersecurity strategy, and implementing effective information and cybersecurity programs. These individuals are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response processes. Additionally, our Information Technology Administrator, in conjunction with our outsourced Data Protection Officer, provides regular reports to our Chief Financial Officer and our General Counsel on cybersecurity risks and the implementation of risk management processes. Such management team members report information on such cybersecurity risks and incidents to our audit committee and board of directors as discussed above.

Item 2. Properties.

As of December 31, 2025, the facilities that we lease are the following:

Location	Primary Use	Approximate Square Footage	Lease Expiration Date	Renewal Option
Ole Maaloes Vej 3, DK-2200 Copenhagen N, Denmark	Office space	350	November 30, 2029	None

We believe that our current facilities are sufficient to meet our current and near-term needs and that, should it be needed, suitable additional space will be available.

Item 3. Legal Proceedings.

We are not party to any material legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources 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.

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades on the Nasdaq Capital Market under the symbol "DMRA".

Holders of Our Common Stock

As of March 17, 2026, we had 60,303,212 outstanding shares of common stock, 158.361 outstanding shares of Series A Preferred Stock, 16,366 outstanding shares of Series B Preferred Stock and 1,722 outstanding shares of Series C Preferred Stock. At March 17, 2026, there were 36 holders of record of our common stock, one holder of record of our Series A Preferred Stock, one holder of record of our Series B Preferred Stock and two holders of record of our Series C Preferred Stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial holders represented by these record holders.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved.

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

The following information should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2025 included in this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth herein and in other SEC filings.

Overview

We are a biopharmaceutical company developing therapies for the treatment of hematologic disorders. In our previously announced Asset Acquisition, we bolstered our pipeline with the addition of three product candidates designed to treat MPNs, a group of related, chronic disorders of the bone marrow. Our lead product candidate, DMR-001, targets mutant forms of the calcium binding protein CALR, which are collectively known as mutCALR. We have exercised our Option to license exclusive worldwide development and commercialization rights to DMR-001 from Paragon pursuant to the Paragon Option Agreement. We intend to develop DMR-001 for the treatment of ET, an MPN associated with the overproduction of platelets, and MF, an MPN involving the overproliferation of blood cells and deposition of fibrous material in the bone marrow and spleen. Approximately 25% and 35% of cases of ET and MF, respectively, are caused by mutCALR rather than mutations in JAK2. In contrast to marketed therapies for ET and MF, DMR-001 is designed to selectively target cells that express mutCALR while avoiding the adverse effects associated with non-specific cytoreductive drugs. Furthermore, DMR-001 was designed to have increased affinity, potency and a prolonged half-life when compared with other antibodies in development that target mutCALR. We believe that the potential combination of increased clinical activity and improved pharmacokinetics of DMR-001 positions it as a potential best-in-class therapy for ET and MF. We also have the option to license exclusive worldwide development and commercialization rights from Paragon of two other mutCALR-targeting product candidates, DMR-002 and DMR-003, pursuant to the Paragon Option Agreement. We intend to submit an IND or CTA for DMR-001 and DMR-002 in mid-2026 and the second half of 2026, respectively, and for DMR-003 in 2027. Pursuant to the Paragon Option Agreement, we have engaged Paragon to execute a mutually agreed research plan for DMR-001, DMR-002, and DMR-003 aimed at producing potential product candidates to be licensed for further development, manufacture and commercialization by us. The research plan activities performed by Paragon are overseen by a joint development committee comprised of our employees and employees of Paragon.

MPNs are caused by excessive proliferation of myeloid cells. In some patients, including ET patients, MPNs are considered chronic diseases that lead to significant decreases in quality of life. MPNs also include MF, which is associated with poor prognosis and increased mortality. One feature that makes MPNs attractive indications for drug development is that mutations in just a small number of genes are responsible for a significant percentage of cases, which enables the opportunity to develop targeted therapies. Our ultimate goal is to develop a portfolio of targeted mutation-directed candidates to address the full spectrum of MPN disease.

DMR-001 is a monoclonal antibody that targets mutations in CALR, including the two major forms of CALR mutations referred to as Type 1 and Type 2 mutCALR. CALR mutations are the drivers of about a quarter of all cases of ET, a disease with a prevalence in the United States of about 140,000 patients. ET is characterized by excessive production of platelets, leading to symptoms that range from tingling or burning in the hands and feet to headache, visual problems, weakness, dizziness and increased risk of blood clots, causing heart attacks, strokes and other thromboses. CALR mutations are the drivers of about 35% of all cases of MF, a disease with a prevalence in the United States of about 20,000 patients. MF is characterized by abnormal myeloid cell proliferation leading to inflammation and a fibrotic response in the bone marrow. This results in bone marrow scarring, splenomegaly, elevated cytokine levels, and bone marrow dysfunction. Symptoms include fatigue, easy bruising and bleeding, night sweats and fever. Approximately 17% of ET patients who have CALR mutations progress to MF. We believe there exists at least a $5 billion addressable market in the United States for mutCALR driven ET and MF.

We believe that DMR-001 has the potential to become a best-in-class anti-mutCALR therapy due to two differentiating features compared to marketed therapies and therapies in development, including INCA033989. First, our preclinical studies demonstrated that DMR-001 is a more potent inhibitor of mutCALR-dependent cell proliferation compared to a reference mutCALR targeted monoclonal antibody. This is especially relevant with regard to patients with Type 2 mutCALR, which represent about a third of mutCALR patients. Whereas Type 1 mutations are characterized by a deletion of 52 base pairs in the gene for CALR, Type 2 mutations have an insertion of 5 base pairs. Our preclinical assays demonstrated that DMR-001 has approximately ten-fold higher potency on Type 2 mutCALR than a reference mutCALR antibody with the same mechanism of action as INCA033989. Second, DMR-001 was engineered to have an increased half-life in circulation through the incorporation

of sequence modifications that have previously been shown to improve pharmacokinetics in humans. Our preclinical data generated in NHPs, confirmed the improved half-life of DMR-001 compared to a reference antibody.

The expected combination of increased clinical activity and longer half-life is predicted to enable the delivery of sufficient amounts of DMR-001 via subcutaneous injection to match and potentially exceed the reported efficacy of INCA033989 that was intravenously administered in Incyte's Phase 1 trial. We believe such a subcutaneous formulation is critically important because it provides a more convenient dosing option for ET and MF patients, most of whom have a long life expectancy after diagnosis and thus require long-term treatment. We intend to file an IND or CTA for DMR-001 in mid-2026 and initiate a Phase 1 trial in ET and MF patients with a subcutaneous formulation thereafter, subject to regulatory approval, with two proof-of-concept readouts expected beginning mid-2027.

In addition, we are developing DMR-002 and DMR-003, both anti-mutCALR-based therapies, with the intent to ultimately address the full spectrum of mutCALR MPN patients. We intend to file an IND or CTA for DMR-002 in the second half of 2026 and for DMR-003 in 2027.

We periodically evaluate our product pipeline to assess whether development of certain assets in our portfolio align with our strategic objectives. Following a recent review of our product candidate portfolio, we have determined to focus on our mutCALR portfolio to address the full mutCALR MPN disease spectrum and have deprioritized continued development of GB3226, a small molecule inhibitor of ENL-YEATS and FLT3 for the treatment of AML. We intend to explore entering into one or more corporate partnerships or collaboration arrangements to advance the development and commercialization of our legacy assets, including GB3226, GB1211 (galectin-3 inhibitor candidate), and GB2064 (LOXL-2 inhibitor candidate).

Our operations to date have been financed primarily from our initial public offering, the issuance of common stock, convertible preferred stock and convertible notes. Since inception, we have had significant operating losses. Our net losses were $209.8 million and $21.4 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $487.4 million and $257.6 million in cash and cash equivalents.

Based on current estimates of our expenses going forward, we believe that our existing cash and cash equivalents of $257.6 million as of December 31, 2025 will be sufficient to fund our operations into Phase 3 development of DMR-001. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon successful development, approval, and commercialization of our product candidates and upon achievement of sufficient revenues to support our cost structure.

On August 29, 2024, we effected a 1-for-25 reverse stock split of our issued and outstanding common stock. Accordingly, unless otherwise noted, all share and per share amounts for all periods presented in this Annual Report on Form 10-K have been adjusted retroactively, where applicable, to reflect this reverse stock split. All fractional shares resulting from the reverse stock split were rounded up to the nearest whole number.

Recent Developments

Acquisition of Damora Therapeutics, Inc.

On November 10, 2025, we effected the Asset Acquisition to acquire Pre-Acquisition Damora in accordance with the terms of the Acquisition Agreement. Pursuant to the Acquisition Agreement, First Merger Sub merged with and into Pre-Acquisition Damora, pursuant to which Pre-Acquisition Damora was the surviving corporation and became a wholly owned subsidiary of the Company. Immediately following the First Merger, Pre-Acquisition Damora merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity.

The Asset Acquisition was structured as a stock-for-stock transaction pursuant to which all of Pre-Acquisition Damora's outstanding equity interests were exchanged based on a fixed exchange ratio of 1-for-1.6366, for consideration of a combination of 265,309 shares of common stock, 16,366 shares of Series B Preferred Stock (or 16,366,000 shares on an as-converted-to-common stock basis), and 4,241 shares of Series C Preferred Stock (or 4,241,000 shares on an as-converted-to-common stock basis), in addition to the assumption of outstanding and unexercised stock options to purchase 434,508 shares of common stock from the Damora Therapeutics, Inc. 2025 Equity Incentive Plan.

Concurrently with the Asset Acquisition, we entered into the Securities Purchase Agreement for a private investment with the Investors to raise $285 million in which the Investors were issued 39,641 shares of Series C Preferred Stock (or 39,641,000 shares on an as-converted-to-common stock basis) at a price of $7,186.90 per share (or $7.1869 per share on an

as-converted-to-common stock basis). The PIPE closed on November 12, 2025. The Transactions were approved by our board of directors and the board of directors and stockholders of Pre-Acquisition Damora. The closings of the Transactions were not subject to the approval of our stockholders. Subject to certain beneficial ownership limitations set by each holder, each share of Series B Preferred Stock and Series C Preferred stock will be convertible at the option of the holder into 1,000 shares of common stock. Except as otherwise required by law (e.g. voting on a change to the authorized shares of Series B Preferred Stock or the rights of such shares as required by the DGCL) and the Series B Certificate of Designation, the Series B Preferred Stock does not have voting rights. Except as otherwise required by law (e.g. voting on a change to the authorized shares of Series C Preferred Stock or the rights of such shares as required by DGCL) and the Series C Certificate of Designation, the Series C Preferred Stock does not have voting rights. On February 9, 2026, we held a special meeting of stockholders of the company and received stockholder approval of, among other proposals, (i) the issuance of shares of common stock upon conversion of the Series B Preferred Stock and Series C Preferred Stock and (ii) the Share Increase of Amendment to increase the number of authorized shares of common stock from 300,000,000 to 500,000,000. Following the special meeting of stockholders of the company, on February 9, 2026, 42,005 shares of Series C Preferred Stock were automatically converted into 42,005,000 shares of common stock. On February 9, 2026, we filed with the Secretary of State of the State of Delaware the Share Increase Amendment to increase the number of authorized shares of common stock from 300,000,000 to 500,000,000.

Shelf Registration Statement, ATM Offering Program and February 2026 Public Offering

On February 10, 2026, we filed an automatically effective shelf registration statement (the "Registration Statement") with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units.

On February 10, 2026, we entered into the ATM Agreement, pursuant to which we may sell, from time-to-time, shares of our common stock under an ATM offering program for up to $150.0 million. As of the date of this filing, we have not made any sales under the ATM offering program and have $150.0 million in remaining capacity under the ATM offering program.

On February 10, 2026, we also entered into an underwriting agreement with certain underwriters to issue and sell 14,473,685 shares of our common stock, including the full exercise by the underwriters of their option to purchase an additional 2,171,052 shares, at a public offering price of $19.00 per share. The net proceeds from this offering were approximately $297.3 million, after deducting underwriting discounts and commissions and expenses of the offering. The underwritten offering closed on February 12, 2026.

We intend to use the net proceeds from this offering to advance our preclinical studies, clinical trials, and manufacturing in support of our antibody programs, as well as for additional research and development activities, working capital, and general corporate purposes. We may also use a portion of the proceeds to license, acquire or invest in new product candidates or for drug development activities related to such product candidates, complementary businesses, technology or assets.

The underwritten offering was made pursuant to the Registration Statement. A final prospectus supplement dated February 10, 2026 relating to and describing the terms of the underwritten offering was filed with the SEC on February 11, 2026.

Name Change

On March 6, 2026, we filed with the Secretary of State of the State of Delaware an amendment to our amended and restated certificate of incorporation to change the name of the Company from "Galecto, Inc." to "Damora Therapeutics, Inc." (the "Name Change Amendment"). The Name Change Amendment became effective at 12:01 a.m. Eastern Time on March 10, 2026.

Business and Macroeconomic Conditions

The extent of the impact of macroeconomic events and conditions, including inflation, increasing interest rates, increasing financial market volatility and uncertainty, the impacts of geopolitical instabilities and government actions, including the ongoing military conflict in Ukraine, conflict between Israel and various other parties, conflicts in the Middle East, geopolitical tensions between China and the United States, and the implementation of tariffs, sanctions, export or import controls, and other measures that restrict international trade by the United States, China or other governments, and their potential supply chain impact, and public health pandemics on our operational and financial performance will continue to depend on certain developments, including the impact on our clinical studies, employee or industry events, and effect on our suppliers and manufacturers, all of which are uncertain and cannot be predicted. Adverse effects of these large macroeconomic conditions have been prevalent in many of the areas where we and our suppliers or third-party business partners conduct business, and as a result, we may experience disruptions in our operations. We may experience disruptions or delays due to these factors as well as delays due to labor shortages and supply chain disruptions in distribution of clinical trial materials, trial monitoring and data analysis that could materially adversely impact our business, results of operations and overall financial performance in future periods. As of the filing date of this Annual Report,

the extent to which these macroeconomic events and conditions may impact our financial condition, results of operations or guidance is uncertain. The effect of these macroeconomic events and conditions may not be fully reflected in our results of operations and overall financial performance until future periods. See Part I, Item 1A "Risk Factors" for further discussion of the possible impact of these macroeconomic conditions on our business.

Components of Operating Results

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for the development of our product candidates and our drug discovery efforts, which include:

- personnel costs, which include salaries, benefits and equity-based compensation expense;
- expenses incurred under agreements with consultants, and third-party contract organizations that conduct research and development activities on our behalf;
- direct and pass through costs associated with research conducted under the Paragon Option Agreement;
- costs related to sponsored research service agreements;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials;
- laboratory supplies and equipment used for internal research and development activities; and
- acquired in-process research and development programs.

We expense all research and development costs in the periods in which they are incurred, including for acquired in-process research and development. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

For the year ended December 31, 2025, we recognized $22.1 million of research and development expenses in connection with services provided by Paragon under the Paragon Option Agreement in our consolidated statement of operations and comprehensive loss.

We have historically met the requirements to receive a tax credit in Denmark of up to $0.8 million per year for losses resulting from research and development costs of up to approximately $3.9 million per year. The tax credit is reported as a reduction to research and development expense in the consolidated statements of operations. We recorded a reduction to research and development expense of $0.8 million in each of the years ended December 31, 2025 and 2024. The credits are available the following year, in 2026 and 2025, respectively.

Our direct research and development expenses are not currently tracked on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to the continued development of our programs, developing any future programs, including investments in manufacturing, as we advance any program we may identify and continue to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. Product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that if we pursue further development and testing of our product candidates, our

research and development expenses will increase as our product candidates advance into clinical development and/or later stages of clinical development.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs through commercialization. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates, including DMR-001, DMR-002, DMR-003 and any our other product candidates we develop in the future;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA, regulatory authorities in Europe or other regulatory agencies of regulatory filings for DMR-001, DMR-002, DMR-003 and any future product candidates;
- maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

Acquired In-process Research and Development Activities

Our acquired in-process research and development activities consist of payments pursuant to our business development transactions, including asset acquisitions. In-process research and development that is acquired in a transaction that does not qualify as a business combination under U.S. GAAP and that does not have an alternative future use is recorded to "Acquired in-process research and development expenses" ("AIPR&D") in our consolidated statements of income in the period in which it is acquired. We present the cost to acquire AIPR&D within our "Cash flows from operating activities" in our consolidated statements of cash flows.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, depreciation expense and other expenses for outside professional services, including legal, human resources, audit and accounting services and facility-related fees not otherwise included in research and development expenses. Personnel costs consist of salaries, benefits and stock-based compensation expense, for our personnel in executive, finance and accounting, business operations and other administrative functions. We expect that our general and administrative expenses will increase substantially for the foreseeable future as we increase our headcount and further establish our office space to support our expected growth. We also expect to incur increased expenses as a public company, including increased costs of accounting, audit, legal, regulatory and tax related services associated with maintaining compliance with SEC requirements, additional director and officer insurance costs, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Restructuring Costs

Our restructuring costs consist primarily of expenses related to employee severance and notice period payments, benefits and related costs and other expenses including non-cash stock-based compensation expense related to the accelerated vesting of certain share-based awards, lease commitments and legal expenses. We anticipate that we will not incur any additional restructuring costs in the near future.

Other Income (Expense), Net

Our other income (expense), net is comprised of:

- Interest income: The interest income earned on our cash and cash equivalents is recorded in our statements of operations.
- Foreign exchange: The functional currency of our subsidiaries in Denmark and Sweden is the Euro. Transactions denominated in currencies other than the Euro result in exchange gains and losses that are recorded in our consolidated statements of operations.

Results of Operations – Comparison of the Years Ended December 31, 2025 and 2024

The following sets forth our results of operations for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		Change	
	2025	2024	Amount	Percent
			(in thousands)	
Operating expenses				
Research and development	$ 26,877	$ 6,398	$ 20,479	320%
Acquired in-process research and development	174,310	4,395	169,915	3866%
General and administrative	9,685	10,499	(814)	-8%
Restructuring costs	—	968	(968)	-100%
Total operating expenses	210,872	22,260	188,612	847%
Loss from operations	(210,872)	(22,260)	(188,612)	-847%
Other income, net	1,083	862	221	26%
Loss before income tax expense	(209,789)	(21,398)	(188,391)	-880%
Income tax expense	(50)	(41)	(9)	-22%
Net loss	$ (209,839)	$ (21,439)	$ (188,400)	-879%

Research and Development Expenses

Research and development expenses were comprised of:

	Year Ended December 31, 2025	2024	Change
		(in thousands)	
Paramora Warrant	$ 9,362	—	$ 9,362
Preclinical studies and clinical trial-related activities	6,803	1,544	5,259
Chemistry, manufacturing and control	6,195	464	5,731
Personnel	$ 542	$ 2,657	$ (2,115)
Consultants and other costs	3,975	1,733	2,242
Total research and development expenses	$ 26,877	$ 6,398	$ 20,479

Research and development expenses were $26.9 million for the year ended December 31, 2025, compared to $6.4 million for the year ended December 31, 2024. The increase of $20.5 million was primarily related to costs related to the Paramora Warrant of $9.4 million, increased preclinical studies and clinical trial-related expenses of $5.3 million, increased chemistry, manufacturing and control ("CMC") activities of $5.7 million and increased consulting related costs and other research and development costs of $2.2 million; partially offset by decreased personnel costs of $2.1 million.

Acquired In-Process Research and Development Costs

Acquired in-process research and development costs were $174.3 million for the year ended December 31, 2025, compared to $4.4 million for the year ended December 31, 2024. This increase in costs relate to the Asset Acquisition. The Asset Acquisition was structured as a stock-for-stock transaction pursuant to which all of Pre-Acquisition Damora's outstanding equity interests were exchanged based on a fixed exchange ratio of 1-for-1.6366, for consideration of a combination of 265,309 shares of common stock, 16,366 shares of Series B Preferred Stock, and 4,241 shares of Series C Preferred Stock, in addition to the assumption of outstanding and unexercised stock options to purchase 434,508 shares of common stock from the Damora Therapeutics, Inc. 2025 Equity Incentive Plan. The acquired in-process research and development costs include the fair value of the common stock of $4.6 million, the fair value of the preferred stock of $148.1 million, the assumed assets of $0.2 million, the assumed specified liabilities of $19.5 million, and transaction costs of $2.3 million.

General and Administrative Expenses

General and administrative expenses were $9.7 million for the year ended December 31, 2025, compared to $10.5 million for the year ended December 31, 2024. The decrease of $0.8 million was primarily related to decreased stock-based compensation costs of $1.6 million; partially offset by increased personnel costs of $0.5 million and other general and administrative costs, net of $0.3 million.

Restructuring Costs

There were no restructuring costs for the year ended December 31, 2025. Restructuring costs were $1.0 million for the year ended December 31, 2024, primarily attributable to a reduction-in-force in the second quarter of 2024.

Other Income (Expense), Net

Other income, net was $1.1 million for the year ended December 31, 2025, compared to $0.9 million for the year ended December 31, 2024. The increase of $0.2 million was primarily due to increased interest income, net; offset by increased foreign exchange loss, net.

Liquidity and Capital Resources

Sources of Liquidity

Our operations to date have been financed primarily through our initial public offering, the sale and issuance of common stock and preferred shares and, prior to becoming a public company, convertible notes. During the year ended December 31, 2025, we raised $266.8 million in financing through the sale of Series C Preferred Stock in the PIPE completed in November 2025 in connection with the Asset Acquisition. In February 2026, we entered into the ATM Agreement, pursuant to which we may sell,

from time-to-time, shares of our common stock under an ATM offering program for up to $150.0 million. As of the date of this filing, we have not made any sales under the ATM offering program and have $150.0 million in remaining capacity under the ATM offering program. In February 2026, we also entered into an underwriting agreement with certain underwriters to issue and sell 14,473,685 shares of our common stock, including the full exercise by the underwriters of their option to purchase an additional 2,171,052 shares, at a public offering price of $19.00 per share. The net proceeds from this offering were approximately $297.3 million, after deducting underwriting discounts and commissions and expenses of the offering.

Since inception, we have had significant operating losses. Our net losses were $209.8 million and $21.4 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $487.4 million and $257.6 million in cash and cash equivalents. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (6,726)	$ (18,623)
Net cash (used in) provided by investing activities	(17,374)	11,650
Net cash provided by financing activities	266,844	—
Net increase (decrease) in cash and cash equivalents	$ 242,744	$ (6,973)

Net Cash Used in Operating Activities

Cash used in operating activities of $6.7 million during the year ended December 31, 2025 was attributable to our net loss of $209.8 million and a net increase of $18.4 million in our working capital, offset by a net increase in non-cash items of $184.7 million principally with respect to non-cash in-process research and development costs in connection with the Asset Acquisition, non-cash issuance of the Paramora Warrant and non-cash stock-based compensation.

Cash used in operating activities of $18.6 million during the year ended December 31, 2024 was attributable to our net loss of $21.4 million and a net decrease of $2.7 million in our working capital, offset by a net increase in non-cash items of $5.5 million principally with respect to non-cash stock-based compensation, non-cash issuance of common stock and preferred stock in connection with the asset purchase agreement with Bridge Medicines LLC and non-cash amortization of the right of use lease asset.

Net Cash Used in Investing Activities

Cash used in investing activities of $17.4 million for the year ended December 31, 2025 was attributable to Damora Asset Acquisition costs, net of cash assumed.

Cash provided by investing activities of $11.7 million for the year ended December 31, 2024 was attributable to proceeds from the sale of marketable securities.

Net Cash Provided by Financing Activities

Cash provided by financing activities of $266.8 million for the year ended December 31, 2025 was primarily attributable to the sale of Series C Preferred Stock in the PIPE completed in November 2025 in connection with the Asset Acquisition.

We had no financing activities for the year ended December 31, 2024.

Funding Requirements

Since inception, we have not generated any revenue from product sales. We do not expect to generate any meaningful product revenue unless and until we obtain regulatory approval of and commercialize DMR-001, DMR-002, DMR-003 or any future product candidates, and we do not know when, or if, that will occur. Until we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop DMR-001, DMR-002, DMR-003 or any future product candidates and fund operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities. We are subject to all the risks involved in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may harm our business. We expect to incur significant costs as we implement our development plans for DMR-001, DMR-002 and DMR-003 and we will need to obtain substantial additional funding to finance our continuing operations.

In order to complete the development of DMR-001, DMR-002, DMR-003 or any future product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize product candidates, if approved, we will require substantial additional capital. Accordingly, until such time that we can generate a sufficient amount of revenue from product sales or other sources, if ever, we expect to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through equity financings, such as our ATM offering program, or convertible debt securities, the ownership interest of our stockholders 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, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If we raise capital through collaborations, partnerships, and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional capital from these sources on favorable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from bank failures, other general macroeconomic conditions and otherwise. Our failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to seek other alternatives which may include, among others, a delay or termination of our clinical trials or the development of our product candidates, temporary or permanent curtailment of our operations, a sale of our assets, or other alternatives with strategic or financial partners. We cannot provide assurance that we will ever generate positive cash flow from operating activities.

Our primary uses of capital are, and we expect will continue to be, costs related to third-party clinical research, manufacturing and development services; laboratory expenses and costs for related supplies; clinical costs; compensation-related expenses; legal and other regulatory expenses; costs to operate as a public company; and general overhead costs.

Based on current estimates of our expenses going forward, we believe that our existing cash and cash equivalents of $257.6 million as of December 31, 2025 will be sufficient to fund our operations into Phase 3 development of DMR-001. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the related disclosures of assets and liabilities at the date of the consolidated 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, and 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. 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 involving management's judgments and estimates.

Research and Development Costs

We incur expenses associated with the development of our product candidates to conduct preclinical studies and clinical trials. Accounting for clinical trials relating to activities performed by CROs, CMOs and other external vendors requires management to exercise estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs, CMOs and other vendors in connection with preclinical studies and clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided by the CRO, CMOs and other vendors but not yet invoiced and include these costs in the accrued and other current liabilities or prepaid expenses on the balance sheets and within research and development expense on the consolidated statements of operations. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, compensation arrangements and services received attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided, and in accordance with agreements established with our collaboration partners and third-party service providers. We make estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Stock-based Compensation

We have issued stock-based compensation awards through the granting of stock awards, which generally vest over a four-year period. We account for stock-based compensation in accordance with Accounting Standards Codification ("ASC") 718, *Compensation-Stock Compensation* ("ASC 718"). In accordance with ASC 718, compensation cost is measured at estimated fair value and is recognized as compensation expense over the vesting period during which service is provided in exchange for the award.

We use a Black-Scholes option pricing model to determine fair value of our stock options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of stock options, the expected volatility based on the historical volatility of a publicly traded set of peer companies and the expected risk-free interest rate. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control. As a result, if other assumptions had been used, stock-based compensation cost could have been materially impacted. Furthermore, if we use different assumptions for future grants, share-based compensation cost could be materially impacted in future periods.

The fair value of our awards in the year ended December 31, 2025 has been estimated using Black-Scholes based on the following assumptions: term of 6.4 years; volatility of 101.9%; risk-free rate of 3.9%; and no expectation of dividends. The fair value of our awards in the year ended December 31, 2024 has been estimated using Black-Scholes based on the following assumptions: term of 6.0 years; volatility of 95.3%; risk-free rate of 4.0%; and no expectation of dividends.

We will continue to use judgment in evaluating the assumptions utilized for our equity-based compensation expense calculations on a prospective basis. In addition to the assumptions used in the Black-Scholes model, the amount of equity-based compensation expense we recognize in our consolidated financial statements includes stock option forfeitures as they occurred. We recognize forfeitures as they occur, and the compensation expense is reversed in the period that the forfeiture occurs.

Income Taxes

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 losses and tax

credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Based on the level of historical operating results and projections for the taxable income for the future, we have determined that it is more likely than not that our net deferred tax assets will not be realized. Accordingly, we have recorded a full valuation allowance to reduce our deferred tax assets.

We recognize tax benefits from uncertain tax positions only if (based on the technical merits of the position) it is more likely than not that the tax positions will be sustained on examination by the tax authority. The tax benefits recognized in the financial statements from such positions are measured based on the largest amount that is more than 50% likely to be realized upon ultimate settlement. We have not recorded any uncertain tax positions as of December 31, 2025 or 2024. We do not believe there will be any material changes in our unrecognized tax positions over the next 12 months. In the event we are assessed interest or penalties at some point in the future, they will be classified in the consolidated financial statements as a component of income tax expense. We have not incurred any interest or penalties.

We operate in multiple jurisdictions, both within and outside the United States, and may be subject to audits from various tax authorities. Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We will monitor the extent to which our deferred tax assets may be realized and adjust the valuation allowance accordingly.

Recently Adopted Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to our consolidated financial statements for the years ended December 31, 2025 and 2024 for a discussion of recent accounting pronouncements.

Contractual Obligations

We enter into contracts in the normal course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. We have not included our payment obligations under these contracts in the table, as these contracts generally provide for termination upon notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material and we cannot reasonably estimate the timing of if and when they will occur. We could also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

Smaller Reporting Company Status

We are a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, and smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Effects of Inflation

Our assets are primarily monetary, consisting of cash and cash equivalents. Because of their liquidity, these assets are not directly affected by inflation. Since we intend to retain and continue to use our equipment, furniture, fixtures and office equipment, computer hardware and software and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expense and use of our resources. We continue to monitor the impact of inflation on these costs in order to minimize its effects through productivity improvements and cost reductions. There can be no assurance, however, that our operating results will not be affected by inflation in the future.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 305(e) of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

Our independent public accounting firm is EY Godkendt Revisionspartnerselskab, Copenhagen, Denmark, PCAOB Auditor ID 1757.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our periodic and current reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Inherent Limitations of Internal Controls

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. 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 policies or procedures may deteriorate. Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our evaluation under that framework, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report on our internal control over financial reporting from our independent registered public accounting firm due to our status as a smaller reporting company.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the three months ended December 31, 2025, none of the Company's directors or officers adopted, materially modified, or terminated any contract, instruction, or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders in the sections titled "Director Biographies," "Executive Officers," "The Board of Directors and its Committees," and "Corporate Governance" and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders in the sections titled "Executive Officer Compensation" and "Director Compensation" 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 included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders in the sections titled "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" and "Equity Compensation Plan Information" 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 included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders in the sections titled "Certain Relationships and Related Person Transactions" and "The Board of Directors and its Committees – Board Independence" and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders in the sections titled "Ratification of the Selection of Independent Registered Public Accounting Firm–Independent Registered Public Accounting Firm Fees" and "Ratification of the Selection of Independent Registered Public Accounting Firm–Pre-Approval Policies and Procedures" and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1)For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2)Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3)Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File / Reg. Number
2.1†	Asset Purchase Agreement by and between the Registrant and Bridge Medicines LLC.	Form 8-K (Exhibit 2.1)	October 7, 2024	001-39655
2.2†	Agreement and Plan of Merger, dated November 10, 2025, by and among the Registrant, Daylight Merger Sub I, Inc., Daylight Merger Sub II, LLC and Damora Therapeutics, Inc.	Form 8-K (Exhibit 2.1)	November 10, 2025	001-39655
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	Form 8-K (Exhibit 3.1)	November 4, 2020	001-39655
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (Reverse Stock Split).	Form 8-K (Exhibit 3.1)	September 5, 2024	001-39655
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (Authorized Share Increase).	Form 8-K (Exhibit 3.1)	February 10, 2026	001-39655
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (Name Change).	Form 8-K (Exhibit 3.1)	March 10, 2026	001-39655
3.5	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock.	Form 8-K (Exhibit 3.1)	October 7, 2024	001-39655
3.6	Certificate of Designation of Series B Non-Voting Convertible Preferred Stock.	Form 8-K (Exhibit 3.1)	November 10, 2025	001-39655
3.7	Certificate of Designation of Series C Non-Voting Convertible Preferred Stock.	Form 8-K (Exhibit 3.2)	November 10, 2025	001-39655
3.8	Certificate of Correction to the Certificate of Designation of the Series C Non-Voting Convertible Preferred Stock.	Form 8-K/A (Exhibit 3.3)	December 9, 2025	001-39655
3.9	Amended and Restated By-laws of the Registrant.	Form 8-K (Exhibit 3.2)	November 4, 2020	001-39655
3.10	Certificate of Amendment to Amended and Restated By-laws of the Registrant.	Form 10-K (Exhibit 3.5)	March 19, 2025	001-39655
4.1	Specimen Common Stock Certificate.	Form S-1/A (Exhibit 4.1)	October 22, 2020	333-249369
4.2*	Description of Capital Stock.			
4.3	Registration Rights Agreement, dated November 12, 2025, by and among the Registrant and several investors signatory thereto.	Form 8-K (Exhibit 10.2)	November 10, 2025	001-39655

4.4	Warrant to Purchase Common Stock, dated December 31, 2025.	Form 8-K (Exhibit 4.1)	January 6, 2026	001-39655
10.1#	2020 Stock Option and Grant Plan.	Form S-1/A (Exhibit 10.1)	October 22, 2020	333-249369
10.2#	2020 Equity Incentive Plan and forms of award agreements.	Form 10-K (Exhibit 10.2)	March 8, 2024	001-39655
10.3#*	Damora Therapeutics, Inc. 2025 Equity Incentive Plan and forms of award agreements.			
10.4#	Senior Executive Cash Incentive Bonus Plan.	Form S-1/A (Exhibit 10.3)	October 22, 2020	333-249369
10.5#	Executive Separation Benefits Plan.	Form 8-K (Exhibit 10.1)	July 6, 2021	001-39655
10.6#	Form of Officer Indemnification Agreement between the Registrant and each of its executive officers.	Form S-1/A (Exhibit 10.4)	October 22, 2020	333-249369
10.7#	Form of Director Indemnification Agreement between the Registrant and each of its directors.	Form S-1/A (Exhibit 10.5)	October 22, 2020	333-249369
10.8*	Non-Employee Director Compensation Policy, as amended.	Form 10-K (Exhibit 10.7)	March 19, 2025	001-39655
10.9#	Service Agreement between Galecto Biotech ApS and Hans Schambye, dated April 23, 2013.	Form S-1/A (Exhibit 10.7)	October 22, 2020	333-249369
10.10#*	Retention Agreement between Galecto Biotech ApS and Hans Schambye, dated November 10, 2025.			
10.11#*	Separation Agreement between Galecto Biotech ApS and Hans Schambye, dated February 9, 2026.			
10.12#	Offer Letter between the Registrant and Sherwin Sattarzadeh, dated December 31, 2025.	Form 8-K (Exhibit 10.1)	January 6, 2026	001-39655
10.13#*	Offer Letter between the Registrant and Becker Hewes, dated December 31, 2025.			
10.14#	Offer Letter between the Registrant and Garrett Winslow, dated April 12, 2021.	Form 10-Q (Exhibit 10.1)	August 12, 2024	001-39655
10.15#*	Retention Compensation Agreement between the Registrant and Garrett Winslow, dated November 10, 2025.			
10.16#*	Offer Letter between the Registrant and Lori Firmani, dated September 29, 2020.			
10.17#*	Retention Compensation Agreement between the Registrant and Lori Firmani, dated November 10, 2025.			
10.18+	Antibody Discovery and Option Agreement, dated as of October 7, 2025, by and among Paragon Therapeutics, Inc., Paramora Holding LLC and Damora Therapeutics, Inc.	Form S-3 (Exhibit 10.1)	February 10, 2026	333-293343

10.19+	License Agreement between Bridge Medicines LLC and Rockefeller University, dated February 3, 2020.	Form 10-K (Exhibit 10.15)	March 19, 2025	001-39655
10.20	English language summary of Lease Agreement between Galecto Biotech ApS and COBIS A/S, dated November 11, 2024.	Form 10-K (Exhibit 10.16)	March 19, 2025	001-39655
10.21	Sales Agreement, dated as of February 10, 2026, by and between the Registrant and TD Securities (USA) LLC.	Form S-3 (Exhibit 1.2)	February 10, 2026	333-293343
19.1	Statement of Company Policy on Insider Trading and Disclosure.	Form 10-K (Exhibit 19.1)	March 19, 2025	001-39655
21.1*	List of Subsidiaries of the Registrant.			
23.1*	Consent of EY Godkendt Revisionspartnerselskab, independent registered public accounting firm.			
24.1*	Power of Attorney (included on signature page to this Annual Report on Form 10-K).			
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1**	Certification of Principal Executive 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 Recovery Policy.	Form 10-K (Exhibit 97)	March 8, 2024	001-39655
101.INS	Inline XBRL Instance Document			
101.SCH	Inline XBRL Taxonomy Extension Schema Document			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)			

* Filed herewith.

** Furnished herewith. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference.

# Indicates management contract or any compensatory plan, contract or arrangement.

† Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

+ Certain portions have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) is the type that the Registrant treats as private or confidential.

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, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Damora Therapeutics, Inc.

Date: March 19, 2026 By: /s/ Sherwin Sattarzadeh
Sherwin Sattarzadeh
Chief Operating Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Sherwin Sattarzadeh and Garrett Winslow, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to 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, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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

Name	Title	Date
/s/ Sherwin Sattarzadeh Sherwin Sattarzadeh	Chief Operating Officer (Principal Executive Officer)	March 19, 2026
/s/ Lori Firmani Lori Firmani	Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2026
/s/ Carl Goldfischer Carl Goldfischer, M.D.	Chairman	March 19, 2026
/s/ Julianne Bruno Julianne Bruno	Director	March 19, 2026
/s/ Christopher Cain Christopher Cain, Ph.D.	Director	March 19, 2026
/s/ Jayson Dallas Jayson Dallas, M.D.	Director	March 19, 2026
/s/ Peter Harwin Peter Harwin	Director	March 19, 2026
/s/ Amit Munshi Amit D. Munshi	Director	March 19, 2026

DAMORA THERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Damora Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Damora Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

	Acquired option obligation
Description of the Matter	As disclosed in Notes 1, 3, 4 and 13 of the consolidated financial statements, on November 10, 2025, the Company (formerly known as Galecto, Inc.) acquired Damora Therapeutics, Inc. The total fair value of consideration transferred was $152.7 million. The transaction was accounted for as an asset acquisition under ASC 805-50. Substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, consisting of rights to license in-process research and development with no alternative future use. In connection with the asset acquisition, the Company recognized an option obligation liability of $3.7 million related to a service provider's contractual right to receive future warrant grants. Auditing the Company's accounting for the asset acquisition was complex due to the estimation uncertainty in determining the fair value of the option obligation liability. The Company used an option pricing model to measure the acquired option obligation. The fair value determination of the option obligation liability required management to make estimates and significant assumptions regarding the expected term of the warrants and volatility of the underlying shares.

How We Addressed the Matter in Our Audit	To test the value of the option obligation liability, our procedures included, among others, reading the relevant agreements related to the asset acquisition and research services to understand the terms and conditions of the option. We assessed the reasonableness of management's significant assumptions and evaluated the completeness and accuracy of the data used in supporting the assumptions, including the actual historical volatility of the underlying shares and related adjustments. With the assistance of our internal valuation specialists, we evaluated the reasonableness of the methodology assumptions applied by the Company, including in the determination of the expected term and volatility. We also assessed the appropriateness of the related disclosures included in the consolidated financial statements.

/s/ EY Godkendt Revisionspartnerselskab

We have served as the Company's auditor since 2019.

Copenhagen, Denmark
March 19, 2026

DAMORA THERAPEUTICS, INC.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 257,624	$ 14,175
Prepaid expenses and other current assets	2,799	2,664
Total current assets	260,423	16,839
Operating lease right-of-use asset	68	73
Equipment, net	36	57
Other assets, noncurrent	—	163
Total assets	$ 260,527	$ 17,132
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 444	$ 377
Accrued expenses and other current liabilities	2,401	820
Related party accounts payable and other current liabilities	17,221	—
Total current liabilities	20,066	1,197
Operating lease liabilities, noncurrent	53	61
Other liabilities, noncurrent	28	43
Total liabilities	20,147	1,301
Commitments and contingencies (Note 11)		
Mezzanine equity		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares authorized at December 31, 2025 and 2024; 159 shares issued and outstanding as of December 31, 2025 and 161 shares issued or outstanding as of December 31, 2024	1,341	1,360
Stockholders' equity		
Series B non-voting convertible preferred stock, par value of $0.00001 per share; 16,366 shares authorized at December 31, 2025; 16,366 shares issued and outstanding as of December 31, 2025 and no shares issued or outstanding as of December 31, 2024	117,621	—
Series C non-voting convertible preferred stock, par value of $0.00001 per share; 43,882 shares authorized at December 31, 2025; 43,882 shares issued and outstanding as of December 31, 2025 and no shares issued or outstanding as of December 31, 2024	297,291	—
Common stock, par value of $0.00001 per share; 500,000,000 shares authorized at December 31, 2025 and 2024; 1,597,321 and 1,316,989 shares issued and outstanding at December 31, 2025 and 2024, respectively	—	—
Additional paid-in capital	310,688	291,898
Accumulated deficit	(487,363)	(277,524)
Accumulated other comprehensive income	802	97
Total stockholders' equity	240,380	15,831
Total liabilities and stockholders' equity	$ 260,527	$ 17,132

See accompanying notes to the consolidated financial statements.

DAMORA THERAPEUTICS, INC.

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

	Year Ended December 31,	
	2025	2024
Operating expenses		
Research and development	$ 26,877	$ 6,398
Acquired in-process research and development	174,310	4,395
General and administrative	9,685	10,499
Restructuring costs	—	968
Total operating expenses	210,872	22,260
Loss from operations	(210,872)	(22,260)
Other income (expense), net		
Interest income, net	1,167	844
Foreign exchange transaction gain (loss), net	(84)	18
Total other income, net	1,083	862
Loss before income tax expense	(209,789)	(21,398)
Income tax expense	(50)	(41)
Net loss	$ (209,839)	$ (21,439)
Net loss per share, basic and diluted, Series B Preferred Stock	$ (23,816.00)	$ —
Weighted-average Series B non-voting convertible preferred stock outstanding, basic and diluted	2,332	—
Net loss per share, basic and diluted, Series C Preferred Stock	$ (23,816.00)	$ —
Weighted-average Series C non-voting convertible preferred stock outstanding, basic and diluted	6,252	—
Net loss per share, basic and diluted, common stock	$ 3.98	$ (18.53)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	1,363,005	1,157,149
Other comprehensive income (loss), net of tax		
Currency translation gain (loss)	$ 705	$ (283)
Other comprehensive income (loss), net of tax	705	(283)
Total comprehensive loss	$ (209,134)	$ (21,722)

See accompanying notes to the consolidated financial statements.

DAMORA THERAPEUTICS, INC.

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

	Mezzanine Equity		Stockholders' Equity									
	Preferred Stock		Series B Non-Voting Convertible Preferred Stock		Series C Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2023	—	—	—	—	—	—	1,084,509	—	288,036	(256,085)	380	32,331
Stock-based compensation expense	—	—	—	—	—	—	—	—	3,239	—	—	3,239
Issuance of common stock in connection with vesting of restricted stock units	—	—	—	—	—	—	6,828	—	93	—	—	93
Issuance of preferred and common stock in connection with an Asset Purchase Agreement	161	1,360	—	—	—	—	62,594	—	530	—	—	1,890
Round-up shares from the 1-for-25 reverse split effective August 29, 2024	—	—	—	—	—	—	163,058	—	—	—	—	—
Other comprehensive loss, net	—	—	—	—	—	—	—	—	—	—	(283)	(283)
Net loss	—	—	—	—	—	—	—	—	—	(21,439)	—	(21,439)
Balance at December 31, 2024	161	$ 1,360	—	$ —	—	$ —	1,316,989	$ —	$ 291,898	$ (277,524)	$ 97	$ 15,831
Stock-based compensation expense									998			998
Issuance of Series B and C non-voting convertible preferred and common stock in connection with the asset acquisition of Damora Therapeutics, Inc.	—	—	16,366	117,621	4,241	30,480	265,309	—	4,576	—	—	152,677
Issuance of Series C non-voting convertible preferred stock in connection with private placement, net of issuance costs	—	—	—	—	39,641	266,811	—	—	—	—	—	266,811
Issuance of Paramora Warrant	—	—	—	—	—	—	—	—	13,125	—	—	13,125
Issuance of preferred and common stock in connection with an Asset Purchase Agreement	(2)	(19)	—	—	—	—	2,201	—	19	—	—	—
Issuance of common stock in connection with vesting of restricted stock units	—	—	—	—	—	—	8,022	—	39	—	—	39
Exercise of stock options	—	—	—	—	—	—	4,800	—	33	—	—	33
Other comprehensive loss, net	—	—	—	—	—	—	—	—	—	—	705	705
Net loss	—	—	—	—	—	—	—	—	—	(209,839)	—	(209,839)
Balance at December 31, 2025	159	$ 1,341	16,366	$ 117,621	43,882	$ 297,291	1,597,321	$ —	$ 310,688	$ (487,363)	$ 802	$ 240,380

See accompanying notes to the consolidated financial statements.

DAMORA THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (209,839)	$ (21,439)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation of equipment	22	21
Stock-based compensation	998	3,239
Issuance of common stock in connection with vesting of restricted stock units	39	93
Issuance of preferred and common stock in connection with an Asset Purchase Agreement	—	1,890
In-process research and development costs in connection with Damora Asset Acquisition	174,310	—
Issuance of Paramora Warrant, net of cost assumed in Damora Asset Acquisition	9,362	—
Amortization of premiums and discounts on marketable securities	—	70
Amortization of right of use lease asset	12	160
Accretion of lease liability	6	10
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(138)	954
Other assets, noncurrent	166	970
Accounts payable	51	(1,325)
Accrued expenses and other current liabilities	1,099	(3,139)
Related party accounts payable and other current liabilities	17,221	—
Operating lease liabilities	(20)	(170)
Other liabilities, noncurrent	(15)	43
Net cash used in operating activities	(6,726)	(18,623)
Cash flows from investing activities		
Damora Asset Acquisition costs, net of cash assumed	(17,374)	—
Proceeds from sale of marketable securities	—	11,650
Net cash (used in) provided by investing activities	(17,374)	11,650
Cash flows from financing activities		
Proceeds from issuance of preferred stock in connection with private placement, net of issuance costs	266,811	—
Proceeds from issuance of common stock in connection with stock option exercise	33	—
Net cash provided by financing activities	266,844	—
Net increase (decrease) in cash and cash equivalents	242,744	(6,973)
Effect of exchange rate changes on cash and cash equivalents	705	(317)
Cash and cash equivalents, beginning of year	14,175	21,465
Cash and cash equivalents, end of year	$ 257,624	$ 14,175
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ 5	$ —
Supplemental disclosures of noncash activities:		
Fair value of the Series B Preferred Stock issued in connection with the Damora Asset Acquisition	$ 152,677	$ —
Operating lease liability arising from obtaining right-of-use assets	$ —	$ 75

See accompanying notes to the consolidated financial statements.

DAMORA THERAPEUTICS, INC.

Notes to the Consolidated Financial Statements

1. DESCRIPTION OF BUSINESS, ORGANIZATION AND LIQUIDITY

Business

Damora Therapeutics, Inc. (formerly known as Galecto, Inc.) is a biopharmaceutical company developing therapies for the treatment of hematological malignancies. As used in these financial statements, unless the context otherwise requires, references to the "Company," "we," "us," and "our" refer to Damora Therapeutics, Inc. and its subsidiaries.

As of December 31, 2025, the Company's wholly owned subsidiaries were PharmAkea, Inc., a Delaware corporation ("PharmAkea"), Damora Securities Corporation, a Massachusetts corporation, Damora Therapeutics, LLC, a Delaware limited liability company, and Galecto Biotech AB, a Swedish company. Galecto Biotech ApS, a Danish operating company, is a wholly-owned subsidiary of Galecto Biotech AB.

Recent developments

In October 2024, the Company entered into an asset purchase agreement with Bridge Medicines LLC ("Bridge Medicines") to acquire the global rights to Bridge Medicines' BRM-1420 (currently referred to as GB3226) program, a novel dual ENL-YEATS and FLT3 inhibitor for multiple genetic subsets of acute myeloid leukemia ("AML"), and assumed certain of Bridge Medicines' liabilities associated with the acquired assets (the "Asset Purchase"). For additional details, see Note 3.

On November 10, 2025, the Company acquired Damora Therapeutics, Inc., a Delaware corporation ("Pre-Acquisition Damora"), in accordance with the terms of the Agreement and Plan of Merger, dated November 10, 2025 (the "Acquisition Agreement"), by and among the Company, Daylight Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("First Merger Sub"), Daylight Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Second Merger Sub"), and Pre-Acquisition Damora. Pursuant to the Acquisition Agreement, First Merger Sub merged with and into Pre-Acquisition Damora, pursuant to which Pre-Acquisition Damora was the surviving corporation and became a wholly owned subsidiary of the Company (the "First Merger"). Immediately following the First Merger, Pre-Acquisition Damora merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity (together with the First Merger, the "Asset Acquisition"). The Asset Acquisition is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Under the terms of the Acquisition Agreement, following the closing of the Asset Acquisition (the "Closing"), the Company issued to the stockholders of Pre-Acquisition Damora (i) 265,309 shares of the common stock of the Company, par value $0.00001 per share (the "Common Stock"), (ii) 16,366 shares of Series B Non-Voting Convertible Preferred Stock, par value $0.00001 per share (the "Series B Preferred Stock") (as described below), and (iii) 4,241 shares of Series C Non-Voting Convertible Preferred Stock, par value $0.00001 per share (the "Series C Preferred Stock") (as described below), in the case (ii) and (iii), each share of which is convertible into 1,000 shares of Common Stock, subject to certain conditions described below.

In connection with the Asset Acquisition, the Company also entered into a significant private investment in public equity ("PIPE") transaction. The Company agreed to sell 39,641 shares of Series C Preferred Stock in the PIPE for approximately $285 million in gross proceeds. The PIPE closed on November 12, 2025. The Series C Preferred Stock are convertible into Common Stock at a ratio of 1,000 shares of Common Stock per share of Series C Preferred Stock, subject beneficial-ownership limitations. In addition, the Company entered into a registration rights agreement requiring the filing of a resale registration statement within 45 days of closing, and certain participating holders agreed to a 180-day lock-up on resales of their securities.

On February 9, 2026, the Company's stockholders approved, among other proposals, the issuance of shares of Common Stock upon conversion of the Series B Preferred Stock and Series C Preferred Stock. Following the special meeting of the stockholders of the Company, 42,005 shares of Series C Preferred Stock were automatically converted into 42,005,000 shares of Common Stock.

On February 10, 2026, we also entered into an underwriting agreement with certain underwriters to issue and sell 14,473,685 shares of Common Stock, including the full exercise by the underwriters of their option to purchase an additional 2,171,052 shares, at a public

offering price of $19.00 per share. The underwritten offering closed on February 12, 2026. The net proceeds from this offering were approximately $297.3 million, after deducting underwriting discounts and commissions and expenses of the offering of $19.0 million.

Following a recent review of the Company's product candidate portfolio, the Company has determined to focus on its mutant forms of the calcium binding protein calreticulin ("mutCALR") portfolio to address the full mutCALR myeloproliferative neoplasm ("MPN") disease spectrum and have deprioritized continued development of GB3226. The Company intends to explore entering into one or more corporate partnerships or collaboration arrangements to advance the development and commercialization of the Company's legacy assets, including GB3226, GB1211 (galectin-3 inhibitor candidate), and GB2064 (LOXL-2 inhibitor candidate).

Risks and uncertainties

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities.

The Company's product candidates are in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

Liquidity and management plans

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, recruiting management and technical staff and raising capital, and has financed its operations primarily through the issuance of preferred shares, debt financings, the Company's initial public offering and sales of Common Stock.

As of December 31, 2025, the Company had an accumulated deficit of $487.4 million, from recurring losses since inception in 2011. The Company has incurred recurring losses and has not generated revenue as no products have obtained the necessary regulatory approval in order to market products. The Company expects to continue to incur losses as a result of costs and expenses related to the Company's clinical development and corporate general and administrative activities. The Company had negative cash flows from operating activities during the years ended December 31, 2025 and 2024 of $6.7 million and $18.6 million, respectively, and current projections indicate that the Company will have continued negative cash flows for the foreseeable future as it continues to fund operating expenses. Net losses incurred for the years ended December 31, 2025 and 2024 amounted to $209.8 million and $21.4 million, respectively.

At December 31, 2025, the Company's cash and cash equivalents amounted to $257.6 million, current assets amounted to $260.4 million and current liabilities amounted to $20.1 million. At December 31, 2024, the Company's cash and cash equivalents amounted to $14.2 million, current assets amounted to $16.8 million and current liabilities amounted to $1.2 million.

Based on current operating plans, the Company has sufficient resources to fund operations for at least one year from the issuance date of these financial statements with existing cash and cash equivalents. The Company will need to secure additional financing in the future to fund additional research and development, and before a commercial drug can be produced, marketed and sold. If the Company is unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on the Company.

Reverse stock split

On August 29, 2024, the Company effected a 1-for-25 reverse stock split of its issued and outstanding Common Stock. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split. All fractional shares resulting from the reverse stock split were rounded up to the nearest whole number.

Increase in authorized shares

On February 9, 2026, the Company filed with the Secretary of State of the State of Delaware a certificate of amendment to its amended and restated certificate of incorporation to increase the number of authorized shares of common stock from 300,000,000 to 500,000,000.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with United States generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP, as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of consolidation

The Company's consolidated financial statements for 2025 and 2024 include Damora Therapeutics, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. The Company bases its estimates on historical experience and various other assumptions that management believes to be reasonable under the circumstances. Significant items subject to such estimates and assumptions include contract research accruals, accounting for stock-based compensation and valuation of the Company's deferred tax assets. Changes in estimates are recorded in the period in which they become known. The Company's actual results could differ from those estimates.

Currency and currency translation

The consolidated financial statements are presented in U.S. dollars, the Company's reporting currency. Damora Therapeutics, Inc., Damora Securities Corporation, Damora Therapeutics, LLC and PharmAkea's functional currency is the U.S. dollar. The functional currency of the Company's subsidiary Galecto Biotech AB, and its subsidiary Galecto Biotech ApS, is the Euro. Adjustments that arise from exchange rate changes on transactions of each group entity denominated in a currency other than the functional currency are included in other income and expense in the consolidated statements of operations. Assets and liabilities of Galecto Biotech AB and Galecto Biotech ApS recorded in their Euro functional currency are translated into the U.S. dollar reporting currency of the Company at the exchange rate on the balance sheet date. Revenue and expenses of Galecto Biotech AB and Galecto Biotech ApS recorded in their Euro functional currency are translated into the U.S. dollar reporting currency of the Company at the average exchange rate prevailing during the year. Resulting translation adjustments are recorded to accumulated other comprehensive income (loss) ("OCI").

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents are stated at fair value and may include money market funds, U.S. Treasury and U.S. government-sponsored agency securities, corporate debt, commercial paper and certificates of deposit. The Company had money market funds of $200.6 and $5.9 million as of December 31, 2025 and 2024, respectively, which are included in cash and cash equivalents and reported at fair value (Note 6).

Concentrations of credit risk and off-balance sheet risk

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. Substantially all of the Company's cash is held at financial institutions that management believes to be of high-credit quality. The Company maintains its cash in bank deposit and checking accounts that at times exceed insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

Investments in marketable securities

The Company invests excess cash balances in short-term and long-term marketable debt securities. The Company classifies investments in marketable debt securities as either held-to-maturity or available-for-sale based on the facts and circumstances present at the time of purchase and re-evaluates classification at each balance sheet date. All investments in marketable debt securities at each balance sheet date presented, are generally considered as available-for-sale. Marketable debt securities with maturities of twelve months or less are classified as short-term investments and marketable debt securities with maturities greater than twelve months are classified based on their availability for use in current operations.

The Company reports available-for-sale debt securities at fair value at each balance sheet date and includes any unrealized holding gains and losses (the adjustment to fair value), net of applicable taxes, in accumulated other comprehensive income (loss), a component of stockholders' equity. The cost of debt securities is adjusted for the amortization of premium and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Realized gains and losses are determined using the specific identification method and are included in other income (expense). If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other than temporary," including the intention to sell and, if so, marks the investment to market through a charge to the Company's consolidated statements of operations and comprehensive loss. The Company had no debt securities as of December 31, 2025 and 2024.

Fair value of financial instruments

Fair value is defined as the price the Company would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are as follows:

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

Level 2—Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and

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

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3.

The Company monitors the availability of inputs that are significant to the measurement of fair value to assess the appropriate categorization of financial instruments within the fair value hierarchy. Changes in economic conditions or model-based valuation techniques may require the transfer of financial instruments from one fair value level to another. In such instances, our policy is to recognize significant transfers between levels at the end of the reporting period. The significance of transfers between levels is evaluated based upon the nature of the financial instrument and size of the transfer relative to total net assets available for benefits.

Leases

The Company determines whether an arrangement is or contains a lease at the time it enters into a contract. For all leases, the Company determines the classification as either operating leases or finance leases. Operating leases are included in operating lease right-of-use ("ROU") assets and accrued expenses and other current liabilities and operating lease liabilities, noncurrent in the Company's consolidated balance sheets. The Company has not entered into any financing leases.

Lease recognition occurs at the commencement date and lease liability amounts are based on the present value of lease payments over the lease term. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. If a lease does not provide information to determine an implicit interest rate, the Company uses the Company's incremental borrowing rate in determining the present value of lease payments. ROU assets represent the right to use an

underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments under the lease. ROU assets also include any lease payments made prior to the commencement date and exclude lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term. The depreciable life of assets and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option reasonably certain of exercise. Lease agreements with both lease and non-lease components, are generally accounted for together as a single lease component. Refer to Note 8 for further details.

Property and equipment, net

Property and equipment are recorded at cost. Costs associated with maintenance and repairs are expensed as incurred. Depreciation is provided using the straight-line method over the estimated useful lives:

Asset Category	Useful Life
Equipment	5-7 years
Furniture and fixtures	5 years
Leasehold improvements	Lesser of 10 years or the remaining term of the respective lease

Impairment of long-lived assets

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying value, an impairment loss is recorded for the difference between the carrying value and fair value of the asset. Refer to Note 14 for further details.

Research and development expenses

Research and development costs are expensed as incurred. The Company's research and development expenses consist primarily of costs incurred for the development of its product candidates and include expenses incurred under agreements with contract manufacturing organizations ("CMOs"), contract research organizations, investigative sites and consultants to conduct clinical trials and preclinical and non-clinical studies, costs to acquire, develop and manufacture supplies for clinical trials and other studies, salaries and related costs, including stock-based compensation, depreciation and other allocated facility-related and overhead expenses and licensing fees and milestone payments incurred under product license agreements where no alternative future use exists.

The Company has met the requirements to receive a tax credit in Denmark for losses resulting from research and development costs of up to $3.9 million and $3.5 million for the years ended December 31, 2025 and 2024, respectively. The tax credit is reported as a reduction to research and development expense in the consolidated statements of operations. For the years ended December 31, 2025 and 2024, research and development expenses include refundable tax credits of $0.8 million for both periods.

The Company has qualified for the R&D Expenditure Credit ("RDEC") in United Kingdom for preclinical laboratory and in-patient clinical trials. The RDEC net tax benefit is reported as a reduction to research and development expense in the consolidated statements of operations. For the year ended December 31, 2024, the Company recorded an overall reduction for the RDEC, net of the UK corporation tax rate of $0.06 million. The amount recorded as of December 31, 2024 includes relief for that tax year. The Company recorded no RDEC amount for the year ending December 31, 2025.

Acquired in-process research and development expenses

Acquired in-process research and development activities include payments pursuant to our business development transactions, including asset acquisitions. In-process research and development that is acquired in a transaction that does not qualify as a business combination under U.S. GAAP and that does not have an alternative future use is recorded to "Acquired in-process research and development expenses" ("AIPR&D") in our consolidated statements of income in the period in which it is acquired. The Company presents the cost to acquire AIPR&D within our "Cash flows from operating activities" in our consolidated statements of cash flows.

Accrued research and development costs

Substantial portions of the Company's preclinical and clinical trials are performed by third-party laboratories, medical centers, contract research organizations and other vendors (collectively, "CROs"). These CROs generally bill monthly for services performed, or bill based upon milestone achievement. For preclinical studies, the Company accrues expenses based upon estimated percentage of

work completed and the contract milestones remaining. For clinical studies, expenses are accrued based upon the number of patients enrolled and the duration of the study. The Company monitors patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported to the Company by the CROs, and correspondence with the CROs and clinical site visits. The Company's estimates depend on the timeliness and accuracy of the data provided by the CROs regarding the status of each program and total program spending. The Company periodically evaluates the estimates to determine if adjustments are necessary or appropriate based on information it receives.

Stock-based compensation

The Company accounts for stock awards granted in accordance with ASC 718, *Compensation-Stock Compensation* ("ASC 718"). In accordance with ASC 718, compensation expense is measured at the estimated fair value of the stock options at grant date and is included as compensation expense over the vesting period during which an employee provides service in exchange for the award.

All share-based awards granted are measured based on the fair value on the date of the grant and compensation expense is recognized with respect to those awards over the requisite service period, which is generally the vesting period of the respective award. The Company reverses any previously recognized compensation cost associated with forfeited awards in the period the forfeiture occurs.

Equity-based compensation expense is classified in the Company's consolidated statement of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes model. The following summarizes the inputs used:

Expected volatility—The Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies because we lack company-specific historical and implied volatility information due in part to the limited time in which we have operated as a publicly traded company. We expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price.

Expected term—The expected term of the Company's stock options has been determined based on the expected time to liquidity. The Company uses the simplified method prescribed by the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of options granted because we lack company-specific historical and implied expected term information due in part to the limited time in which we have operated as a publicly traded company.

Risk-free interest rate—The risk-free interest rate is based on the implied yield on a U.S. Treasury security at a constant maturity with a remaining term equal to the expected term of the option granted.

Dividends—Expected dividend yield is zero because the Company does not pay cash dividends on common shares and does not expect to pay any cash dividends in the foreseeable future.

Income taxes

Deferred income tax assets and liabilities arise from temporary differences associated with differences between the financial statements and tax basis of assets and liabilities, as measured by the enacted tax rates, which are expected to be in effect when these differences reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company has generated net losses since inception and accordingly has not recorded a material provision for income taxes.

The Company follows the provisions of ASC 740-10, *Uncertainty in Income Taxes* ("ASC 740-10"). The Company has not recognized a liability as a result of the implementation of ASC 740-10. A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there is no unrecognized benefit since the date of adoption. The Company has not recognized interest expense or penalties as a result of the implementation of ASC 740-10. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits and penalties in income tax expense.

The Company has identified the United States, Denmark and United Kingdom as its major tax jurisdictions. Refer to Note 13 for further details.

Net loss per share

The Company computes net loss per share of common stock, Series B Preferred Stock, and Series C Preferred Stock using the two-class method required for multiple classes of common stock and other participating securities.

The two-class method is an earnings (loss) allocation method under which earnings (loss) per share is calculated for each class of common stock. The Company has determined that the Series B Preferred Stock and Series C Preferred Stock do not have preferential rights when compared to the Company's common stock and therefore it must allocate losses to these other classes of common stock. Refer to Note 16 for further details.

Basic and diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares and pre-funded warrants outstanding during the period, without consideration of potential dilutive securities. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potential shares of common stock would be anti-dilutive.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker ("CODM"), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment.

Other comprehensive gain (loss)

Other comprehensive gain (loss) ("OCI") is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's OCI includes currency translation and unrealized gain or (loss) on marketable securities.

Smaller reporting company status

The Company is a "smaller reporting company," meaning that the market value of its shares held by non-affiliates is less than $700 million and its annual revenue was less than $100 million during the most recently completed fiscal year. The Company may continue to be a smaller reporting company if either (i) the market value of its shares held by non-affiliates is less than $250 million or (ii) its annual revenue was less than $100 million during the most recently completed fiscal year and the market value of its shares held by non-affiliates is less than $700 million. As a smaller reporting company, the Company may choose to present only the two most recent fiscal years of audited financial statements in its Annual Report on Form 10-K, and smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently adopted accounting standards

In November 2023, the FASB issued 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASC 280"), which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses and segment profit or loss. The ASU also requires entities with a single reportable segment to provide all segment disclosures under ASC 280, including the new required disclosures under the ASU. The ASU is effective for all public entities with fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The ASU must be applied retrospectively. The adoption of ASU No. 2023-07 during the year ended December 31, 2024 did not have a material impact on the financial statements.

On December 14, 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 amends ASC 740, Income Taxes to expand income tax disclosures and requires that the Company disclose (i) the income tax rate reconciliation using both percentages and reporting currency amounts; (ii) specific categories within the income tax rate reconciliation; (iii) additional information for reconciling items that meet a quantitative threshold; (iv) the composition of state and local income taxes by jurisdiction; and (v) the amount of income taxes paid disaggregated by jurisdiction. The Company adopted ASU 2023-09 for the year ended December 31, 2025 on a prospective basis. See Note 14 Income Taxes for additional information.

Recently issued accounting standards

The Company reviewed all other recently issued accounting pronouncements and have concluded they are not applicable or not expected to be significant to the accounting for its operations.

Recently tax legislation

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions and allows immediate expensing of certain domestic research and experimental expenditures under new Section 174A of the Internal Revenue Code. The Company does not expect the impact of the OBBBA to be material to its consolidated financial statements.

3. ASSET ACQUISITIONS

Bridge Medicines

On October 7, 2024, the Company entered into an Asset Purchase Agreement (the "Bridge Purchase Agreement") with Bridge Medicines pursuant to which the Company acquired global rights to Bridge Medicines' BRM-1420 program, a novel dual ENL-YEATS and FLT3 inhibitor for multiple genetic subsets of AML, and assumed certain of Bridge Medicines' liabilities associated with the Asset Purchase. As consideration to Bridge Medicines for the Asset Purchase, the Company (a) issued to Bridge Medicines (i) 62,594 shares of Common Stock and (ii) 160.562 shares of the Company's newly designated Series A non-voting convertible preferred stock, par value $0.00001 per share (the "Series A Preferred Stock") and (b) assumed specified liabilities. The closing of the Asset Purchase occurred on October 7, 2024. The total cost of the Asset Purchase was $4.4 million, including the fair value of the Common Stock, the fair value of the Series A Preferred Stock, the assumed specified liabilities and transaction costs.

The following table sets forth the activity for the Bridge Purchase Agreement during the year ended December 31, 2024 (in thousands):

Fair value of Common Stock	$	530
Fair value of Series A Preferred Stock		1,360
Transaction costs		2,505
Total costs	$	4,395

The terms of the Series A Preferred Stock are as set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock (the "Series A Certificate of Designation"). Each share of Series A Preferred Stock is convertible into 1,000 shares of Common Stock at the election of the holder of such Series A Preferred Stock. Except as required by law, the Series A Preferred Stock has no voting rights, provided that the Company shall not, without the affirmative vote or written consent of the holders of majority of then outstanding Preferred Stock, among other things, alter or change adversely the power, preferences or rights given to the Series A Preferred Stock, amend the Series A Certificate of Designation, issue additional shares of Series A Preferred Stock, or amend or fail to comply with certain provisions of the Bridge Purchase Agreement.

Carl Goldfischer, Chairman of the Company's board of directors is also the Executive Chairman of Bridge Medicines.

Damora Therapeutics

On November 10, 2025, the Company entered into the Asset Acquisition pursuant to the Acquisition Agreement.

Pre-Acquisition Damora was incorporated on August 8, 2025, under the direction of Peter Harwin, a managing member of Fairmount Funds Management LLC ("Fairmount"), for the purpose of holding option rights to certain intellectual property being developed by Paragon Therapeutics, Inc. ("Paragon"). Paragon was founded by Fairmount as its discovery engine for biologics. Prior to the Asset Acquisition, Pre-Acquisition Damora had no employees, no revenue-generating activities, and no substantive operations.

The Company evaluated whether the Asset Acquisition met the definition of a business under ASC 805. ASC 805-10-55-5A through 55-5C provides a screen test to determine whether an acquired set of assets and activities is not a business. The Company concluded that substantially all (in excess of 90%) of the fair value of the gross assets acquired was concentrated in a single identifiable asset, consisting of Pre-Acquisition Damora's option rights to license in-process research and development ("IPR&D") intellectual property

pursuant to its agreement with Paragon (the "Paragon Option Agreement"). Accordingly, the Asset Acquisition was accounted for as an asset acquisition rather than a business combination.

In accordance with the Acquisition Agreement, the Company issued the following equity consideration to former Pre-Acquisition Damora security holders in exchange for 100% of the equity interests of Pre-Acquisition Damora:

- 265,309 shares of Common Stock;
- 16,366 shares of Series B Preferred Stock; and
- 4,241 shares of Series C Preferred Stock.

Each share of Series B and Series C Preferred Stock is convertible into 1,000 shares of Common Stock, applicable beneficial ownership limitations. On February 9, 2026, the Company received stockholder approval of, among other proposals, the issuance of shares of Common Stock upon conversion of the Series B Preferred Stock and Series C Preferred Stock.

The fair value of the equity consideration issued was determined based on the Common Stock trading price at the Closing date and the estimated fair value of the Series B Preferred Stock and Series C Preferred Stock sold to third parties. The total fair value of consideration transferred was approximately $152.7 million.

The Company accounted for the Asset Acquisition under the asset acquisition guidance in ASC 805-50. The cost to acquire the assets was measured based on the fair value of the equity consideration issued. Direct transaction costs in the amount of $2.3 million were included in the total cost to acquire the asset.

The total cost to acquire the asset was as follows (in millions):

Description		Amount
Fair value of equity consideration issued	$	152.7
Transaction fees		2.3
Total cost to acquire asset	$	155.0

As an asset acquisition, the total cost was allocated to the identifiable assets acquired and liabilities assumed based on their relative fair values. The Company acquired cash and assumed certain current liabilities at the acquisition date, both of which were recorded at their carrying values, as they approximated fair value. The excess of the consideration transferred over the fair value of acquired assets and liabilities assumed was allocated to acquired IPR&D.

The allocation of the purchase price was as follows (in millions):

Description		Amount
Acquired in-process research and development	$	174.3
Acquired cash		0.2
Assumed current liabilities		(19.5)
Total cost to acquire asset	$	155.0

The acquired IPR&D represents early-stage research programs that had not yet reached technological feasibility at the acquisition date. The Company determined that the acquired IPR&D had no alternative future use, as the intellectual property was in the pre-clinical stage and was specific to the underlying research programs. Accordingly, the full amount allocated to IPR&D was expensed as research and development expense on the acquisition date.

4. RELATED PARTY TRANSACTIONS

Bridge Medicines

In October 2024, the Company entered into the Bridge Purchase Agreement pursuant to which the Company acquired global rights to Bridge Medicines' BRM-1420 program, a novel dual ENL-YEATS and FLT3 inhibitor for multiple genetic subsets of AML, and assumed certain of Bridge Medicines' liabilities associated with the acquired assets. Pursuant to the Bridge Purchase Agreement, as consideration to Bridge Medicines for the Asset Purchase, the Company issued to Bridge Medicines 62,594 shares of Common Stock

and 160.562 shares of Series A Preferred Stock. Carl Goldfischer, Chairman of the Company's board of directors is also the Executive Chairman of Bridge Medicines. For further details of the Bridge Purchase Agreement, see Note 3.

During the year ended December 31, 2024, except as noted above, the Company had no material related party transactions.

Paragon and Paramora Holding LLC

Paragon and Paramora Holding LLC ("Paramora") each beneficially own less than 5% of the Company's capital stock through their respective holdings of Common Stock. Fairmount Funds Management LLC ("Fairmount") beneficially owns more than 5% of the Company's capital stock on an as-converted basis, has three seats on the board of directors and beneficially owns more than 5% of Paragon. Fairmount appointed Paragon's board of directors and has the contractual right to approve the appointment of any executive officers. Paramora is an entity formed by Paragon as a vehicle to hold equity in Pre-Acquisition Damora (and, as a result of the Asset Acquisition, the Company) in order to share profits with certain employees of Paragon.

In connection with the Asset Acquisition, the Company assumed the rights and obligations of Pre-Acquisition Damora under the Paragon Option Agreement. Under the Paragon Option Agreement, Pre-Acquisition Damora (and, as a result of the Asset Acquisition, the Company) is obligated to compensate Paragon for its services performed under each research program based on the actual costs incurred with mark-up costs pursuant to the terms of the Paragon Option Agreement. As of the date of the Asset Acquisition, Pre-Acquisition Damora had incurred total expenses of $15.2 million under the Paragon Option Agreement since inception, all of which was reimbursable expenses under the Paragon Option Agreement for historical costs owed to Paragon. As of the Closing date, $15.2 million was unpaid and was assumed by the Company through the Asset Acquisition.

For the year ended December 31, 2025, the Company recognized expenses related to services provided by Paragon subsequent to the Asset Acquisition totaling $22.0 million, which included $9.4 million of stock-based compensation expense, and were recorded as Research and development expenses in the consolidated statements of operations. As of December 31, 2025, $17.2 million was unpaid and was included in Related party accounts payable and other current liabilities on the Company's consolidated balance sheets.

For the year ended December 31, 2025, the Company made payments totaling $10.6 million to Paragon.

December 31,	2025	2024
Reimbursable costs under the Paragon Option Agreement	$ 12.7	$ —

On December 12, 2025, the Company exercised the Option available under the Paragon Option Agreement with respect to the DMR-001 research program, and expects to enter into the DMR-001 License Agreement.

Following the execution of the DMR-001 License Agreement, the Company will be obligated to pay Paragon up to $22.0 million upon the achievement of specific development, regulatory and clinical milestones for the first product under each agreement, respectively, that achieves such specified milestones. Upon execution of the DMR-001 License Agreement, we expect to pay Paragon a $1.5 million fee for nomination of a development candidate, as applicable, and the Company expects to be obligated to make a further milestone payment of $2.5 million upon the first dosing of a human patient in a Phase 1 trial.

The following is the summary of Related party accounts payable and other current liabilities (in millions):

	December 31, 2025	December 31, 2024
Reimbursable costs under the Paragon Option Agreement	$ 12.7	$ —
Related party accounts payable and other current liabilities	$ 17.2	$ —

Paramora option obligation

On November 10, 2025, in connection with the Asset Acquisition, the Company assumed the obligation to issue Paramora (the "Paramora Option Obligation") an annual equity grant of warrants for Paramora to purchase 1% of the then outstanding shares of Common Stock, on a fully diluted basis, on the last business day of each calendar year during the term of the Paragon Option Agreement, at the fair market value determined by the board of directors of the Company. The Company determined that the 2025 and 2026 grants are two separate grants, as there would be no obligation for the 2026 grant had the Company exercised or terminated all of the options under the Paragon Option Agreement prior to December 31, 2026. The service inception period for the grant precedes the grant date, with the full award being vested as of the grant date with no post-grant date service requirement. Accordingly, a liability

related to the Paramora Option Obligation was recorded pursuant to the amended Paragon Option Agreement during 2025 interim periods. The Company determined that the grant date of the award was December 31, 2025, as all terms of the award, including number of shares and exercise price, were known by all parties. Accordingly, the Company measured the grant-date fair value of the warrants granted at approximately $13.1 million as an equity-classified award, of which $3.7 million was recognized as part of the liabilities assumed with the Asset Acquisition on November 10, 2025. For the year ended December 31, 2025, $9.4 million was recognized as stock compensation expense related to the Paramora Option Obligation. There was no similar expense for the year ended December 31, 2024.

As of December 31, 2025, there was no unamortized expense related to the Paramora Option Obligation.

The Company settled its 2025 obligations under the Paramora Option Obligation by issuing Paramora 628,302 warrants to purchase Common Stock, with a $23.01 per share exercise price of each warrant. As of December 31, 2025, none of the warrants issued under the Paramora Option Obligation have been exercised.

The following table summarizes the assumptions used in calculating the fair value of the warrant obligation for the year ended December 31, 2025:

	Year Ended December, 2025
Expected volatility	100.0%
Expected term (in years)	10.0
Risk-free interest rate	4.2%
Expected dividend yield	—%

5. INVESTMENTS IN MARKETABLE SECURITIES

Cash in excess of the Company's immediate requirements is invested in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

The Company had no available-for-sale investments as of December 31, 2025 and 2024.

6. FAIR VALUE MEASUREMENTS

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs.

The Company classified its money market funds within Level 1 because their fair values are based on their quoted market prices. The Company classified its debt securities within Level 2 because their fair values are determined using alternative pricing sources or models that utilized market observable inputs.

A summary of the assets that are measured at fair value as of December 31, 2025 and 2024 is as follows (in thousands):

		Fair Value Measurement at December 31, 2025		
Assets:	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds[(1)]	$ 200,628	$ 200,628	$ —	$ —
Debt securities	—	—	—	—
Total	$ 200,628	$ 200,628	$ —	$ —

Assets:	Carrying Value	Fair Value Measurement at December 31, 2024 Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds[1]	$ 5,926	$ 5,926	$ —	$ —
Debt securities	—	—	—	—
Total	$ 5,926	$ 5,926	$ —	$ —

(1)Money market funds with maturities of 90 days or less at the date of purchase are included within cash and cash equivalents in the accompanying consolidated balance sheets and are recognized at fair value.

7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2025	2024
Contract research and development costs	$ 1,198	$ 1,103
Research and development tax credit receivable	875	836
Prepaid insurance costs	577	590
Value-added tax refund receivable	24	45
Other	125	90
Total prepaid expenses and other current assets	$ 2,799	$ 2,664

8. LEASES

The Company has the following operating leases:

Location	Primary Use	Lease Expiration Date	Renewal Option
Copenhagen, Denmark	Corporate headquarters	November 2029	None

The Company has no finance leases and has elected to apply the short-term lease exception to all leases of one year or less. Rent expense for years ended December 31, 2025 and 2024 was $54,000 and $254,000, respectively.

Quantitative information regarding the Company's leases for the years ended December 31, 2025 and 2024 is as follows (in thousands):

	Year Ended December 31, 2025	2024
Lease Cost:		
Operating lease cost	$ 20	$ 224
Other Information:		
Operating cash flows paid for amounts included in the measurement of lease liabilities	$ 20	$ 223
Operating lease liabilities arising from obtaining right-of-use assets	$ —	$ —

As of December 31, 2025 and 2024, the weighted average remaining lease term for operating leases was 3.9 years and 4.9 years, respectively.

As of December 31, 2025 and 2024, the weighted average discount rate for operating leases was 8% for both periods.

Operating lease liabilities are as follows at December 31, 2025 (in thousands):

	Operating Leases
2026	$ 20
2027	20
2028	20
2029	19
2030	—
Total lease payments	79
Less: imputed interest	(11)
Total lease liabilities	$ 68

9. PROPERTY AND EQUIPMENT, NET

Equipment as of December 31, 2025 and 2024 consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Equipment	$ 108	$ 107
Less: accumulated depreciation	(72)	(50)
Equipment, net	$ 36	$ 57

Depreciation expense for the years ended December 31, 2025 and 2024 was $22,000 and $21,000, respectively.

10. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	December 31, 2025	2024
Employee compensation costs	$ 442	$ 204
Contract research and development costs	277	117
Lease liabilities, current	15	12
Legal costs	587	11
Other current liabilities	1,080	476
Total accrued expenses and other current liabilities	$ 2,401	$ 820

11. COMMITMENTS AND CONTINGENCIES

Lease commitments

The Company's commitments related to lease agreements are disclosed in Note 8.

Paragon option agreement

The Company's commitments related to the Paragon Option Agreement are disclosed in Note 4.

Legal proceedings

From time to time, the Company may be party to litigation arising in the ordinary course of its business. The Company was not subject to any material legal proceedings during the years ended December 31, 2025 and 2024, and, to its knowledge, no material legal proceedings are currently pending or threatened.

Indemnification agreements

The Company, as permitted under Delaware law and in accordance with its certification of incorporation and by-laws and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, which the officer or director is or was serving at the Company's request in such capacity.

The Company enters into certain types of contracts that contingently require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's by-laws, under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the Company's products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on the Company's future business, operating results or financial condition. It is not possible to estimate the maximum amount potentially payable under these contracts since the Company has no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

12. STOCKHOLDERS' EQUITY

The Company's authorized capital stock consists of 500,000,000 shares of Common Stock, and 10,000,000 shares of preferred stock, of which 200 shares were designated as Series A Preferred Stock, 16,366 shares were designated as Series B Preferred Stock, and 43,882 shares were designated as Series C Preferred Stock.

As of December 31, 2025 and 2024, no Common Stock dividends had been declared by the board of directors. As of December 31, 2025, there were 158.361 shares of Series A Preferred Stock, 16,366 shares of Series B Preferred Stock and 43,882 shares of Series C Preferred Stock issued and outstanding. There were 161 shares of Series A Preferred Stock, and no shares of Series B Preferred Stock or Series C Preferred Stock issued and outstanding as of December 31, 2024.

November 2025 PIPE

In November 2025, in connection with the Asset Acquisition, the Company issued and sold 39,641 shares of Series C Preferred Stock at approximately $7,186.90 per share through a private placement to a group of accredited investors. The net proceeds from this offering were approximately $267.0 million, after deducting placement agent fees and offering costs of $18.1 million.

Shelf registration statement, at-the-market ("ATM") offering program and February 2026 public offering

On February 10, 2026, the Company filed an automatically effective shelf registration statement (the "Registration Statement") with the SEC for the issuance of Common Stock, preferred stock, warrants, debt securities, rights and units.

On February 10, 2026, the Company entered into a sales agreement (the "ATM Agreement"), pursuant to which it may sell, from time-to-time, shares of Common Stock under an ATM offering program for up to $150.0 million. As of the date of this filing, the Company has not made any sales under the ATM offering program and has $150.0 million in remaining capacity under the ATM offering program.

On February 10, 2026, the Company also entered into an underwriting agreement with certain underwriters to issue and sell 14,473,685 shares of Common Stock, including the full exercise by the underwriters of their option to purchase an additional 2,171,052 shares, at a public offering price of $19.00 per share. The underwritten offering closed on February 12, 2026. The net proceeds from this offering were approximately $297.3 million, after deducting underwriting discounts and commissions and expenses of $19.0 million.

Paramora warrants

The Company settled its 2025 obligations under the Paramora Option Obligation by issuing Paramora 628,302 warrants to purchase Common Stock, with a per share exercise price equal to $23.01. As of December 31, 2025, none of the warrants issued under the Paramora Option Obligation have been exercised. See Note 4 for additional information on the Paramora Option Obligation.

Common stock

Holders of Common Stock are entitled to one vote for each share of Common Stock held of record for the election of directors and on all matters submitted to a vote of stockholders. A majority vote of the holders of Common Stock is generally required to take action under our amended and restated certificate of incorporation, as amended, and amended and restated by-laws, as amended . Holders of Common Stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. Upon our dissolution, liquidation or winding up, holders of Common Stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of Common Stock have no preemptive, subscription, redemption or conversion rights and no sinking fund provisions are applicable to Common Stock. The rights, preferences and privileges of holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we have designated or may designate and issue in the future.

Preferred stock

Our board of directors has the authority, without action by the stockholders, to designate and issue up to an aggregate of 10,000,000 shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of Common Stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on Common Stock, diluting the voting power of Common Stock, impairing the liquidation rights of Common Stock, or delaying, deferring or preventing a change in control of us, which might harm the market price of our Common Stock.

Our board of directors will make any determination to issue such shares of preferred stock based on its judgment as to our best interests and the best interests of our stockholders.

Series A preferred stock

The Company has designated 200 shares of Series A Preferred Stock. As of December 31, 2025, 158.361 shares of Series A Preferred Stock were issued and outstanding. As of December 31, 2024, approximately 161 shares of Series A Preferred Stock were issued and outstanding. The Series A Preferred Stock is classified as mezzanine equity (temporary equity) because it is convertible at the option of the holder and contains provisions that could require the Company to issue a variable number of shares of Common Stock.

The Series A Preferred Stock was issued on October 7, 2024 in connection with an asset purchase agreement with Bridge Medicines LLC. Each share is convertible at the option of the holder into 1,000 shares of Common Stock, subject to a beneficial ownership limitation (the holder may not beneficially own more than a specified percentage, between 0% and 19.99%, of total outstanding Common Stock after giving effect to conversion). Stockholder approval for purposes of Nasdaq Stock Market Rules was obtained on June 18, 2025 (the “Series A Stockholder Approval”). Following that approval, certain shares were automatically converted into Common Stock on the third business day thereafter, subject to beneficial ownership limitations, and the remaining shares became convertible at the holder’s election. Upon conversion, Series A Preferred Stock is cancelled and retired and resumes the status of authorized but unissued preferred stock.

The Series A Preferred Stock has no voting rights, except as required by law or to protect the rights of the holders of Series A Preferred Stock. No liquidation preference applies. Dividends, if declared on Common Stock, are payable to holders of Series A Preferred Stock on an as-if-converted-to-common-stock basis in the same form.

Series B preferred stock

In connection with the Asset Acquisition completed on November 10, 2025, the Company issued 16,366 shares of Series B Preferred Stock. As of December 31, 2025, 16,366 shares of Series B Preferred Stock were issued and outstanding. The Series B Preferred Stock is classified within permanent stockholders' equity.

Each share of Series B Preferred Stock is convertible at the option of the holder into 1,000 shares of Common Stock (representing 16,366,000 shares of Common Stock in aggregate on an as-converted basis), subject to beneficial ownership limitations. The stockholder approval required for Nasdaq purposes ("Series B Stockholder Approval") was obtained on February 9, 2026. Upon conversion, the Series B Preferred Stock is cancelled and retired and resumes the status of authorized but unissued preferred stock.

The Series B Preferred Stock does not have general voting rights; however, for so long as at least 30% of the originally issued Series B Preferred Stock remains outstanding, the Company may not, without the affirmative vote of a majority of the then-outstanding Series B shares: (i) consummate a Fundamental Transaction (as defined) or a merger or consolidation resulting in a change of control; (ii) increase the size of the board of directors; (iii) adopt, amend, or repeal certain corporate authority policies unless approved unanimously by the board of directors; or (iv) replace the Company's registered independent public accounting firm, independent compensation consultant, or corporate counsel. The Series B Preferred Stock has no liquidation preference. Dividends, if declared on Common Stock, are payable to holders Series B Preferred Stock on an as-if-converted basis.

Series C preferred stock

In connection with the Asset Acquisition and a concurrent PIPE transaction completed in November 2025, the Company issued 43,882 shares of Series C Preferred Stock in aggregate (4,241 shares in the Asset Acquisition and 39,641 shares in the PIPE). As of December 31, 2025, 43,882 shares of Series C Preferred Stock were issued and outstanding. The Series C Preferred Stock is classified within permanent stockholders' equity.

Each share of Series C Preferred Stock is convertible into 1,000 shares of Common Stock (43,882,000 shares in aggregate on an as-converted basis), subject to beneficial ownership limitations. On February 9, 2026, the Company obtained the stockholder approval required for Nasdaq purposes ("Series C Stockholder Approval"). Following that approval, 42,005 shares of Series C Preferred Stock were automatically converted into 42,005,000 shares of Common Stock (the "Automatic Conversion"), with 1,877 shares remaining outstanding as of February 9, 2026. Each remaining share of Series C Preferred Stock may be converted at the option of the holder, subject to applicable beneficial ownership limitations. Upon conversion, shares are cancelled and retired.

The Series C Preferred Stock does not have general voting rights, except as required by law or to protect the rights of the Series C Preferred Stock. No liquidation preference applies. Dividends, if declared on Common Stock, are payable to holders of Series C Preferred Stock on an as-if-converted basis.

13. STOCK-BASED COMPENSATION

Employee equity plan

In March 2020, the Company's board of directors and stockholders approved the 2020 Stock Option and Grant Plan ("2020 Plan"). Holders of stock options under the 2020 Plan are entitled to exercise the vested portion of the stock option during the term of the grant. If a qualified exit, as defined in the 2020 Plan, occurs before the stock option vests, then all of the holders' unvested options shall vest immediately.

In October 2020, the Company's board of directors and stockholders approved the 2020 Equity Incentive Plan ("2020 Equity Plan"). Following the adoption of the 2020 Equity Plan, no further options are available to be issued under the 2020 Plan. Stock-based awards granted under the 2020 Equity Plan generally vest over a four-year period and expire ten years from the grant date. Shares available for grant under the 2020 Equity Plan cumulatively increase by 5% of the number of shares of Common Stock issued and outstanding on January 1st each year until 2030. At December 31, 2025, the Company had 174,141 options available for future grant under the 2020 Equity Plan.

The following table sets forth the activity for the Company's stock options during the periods presented:

	Number of Options	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2023	275,476	$ 114.38	6.7	$ —
Granted	90,020	7.71	—	—
Cancelled	(143,417)	103.19	—	—
Outstanding at December 31, 2024	222,079	78.37	7.2	—
Granted	473,948	7.04	—	—
Exercised	(4,800)	6.85	—	91,596
Cancelled	(20,387)	137.39	—	—
Outstanding at December 31, 2025	670,840	$ 26.69	8.8	$ 8,477,387
Vested and exercisable at December 31, 2025	543,867	$ 30.45	8.9	$ 6,763,679

On November 10, 2025, in connection with the Asset Acquisition, the Company assumed the Damora Therapeutics, Inc. 2025 Equity Incentive Plan (the "Damora Equity Plan") and its outstanding and unexercised stock options, which were converted to options to purchase 434,508 shares of Common Stock. The acquisition-date fair value of these grants will be recognized as an expense on a pro-rata basis over the vesting period.

The weighted-average grant date fair value of all stock options granted during the year ended December 31, 2025 was $14.37. The intrinsic value at December 31, 2025 and 2024 is based on the closing price of the Common Stock on that date of $23.01 and $4.65 per share, respectively.

The Company uses a Black-Scholes option pricing model to determine fair value of its stock options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of stock options, the expected volatility based on the historical volatility of a publicly traded set of peer companies and the expected risk-free interest rate based on the implied yield on a U.S. Treasury security. The fair values of the options granted were estimated based on the Black-Scholes model, using the following assumptions:

	2025	2024
Risk-free interest rate	3.9%	4.0%
Expected term (in years)	6.0	6.0
Expected volatility	102.1%	95.3%
Expected dividend yield	0%	0%

In November 2022, the Company's board of directors approved the 2022 Inducement Plan (the "Inducement Plan"), which allows for the grant of equity awards to be made to new employees where the equity award is a material inducement to an employee entering into employment with the Company. The Inducement Plan was adopted by the Company's board of directors without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). In December 2025, the Company's board of directors approved an increase of 7,990,000 shares of Common Stock reserved for issuance under the Inducement Plan. A total of 8,000,000 shares of the Common Stock have been reserved for issuance under the Inducement Plan. During the period ended December 31, 2025, 312,535 shares have been issued under the Inducement Plan at a weighted average exercise price of $32.00. The weighted average remaining contractual terms for the shares is 10 years. No shares were issues during the period ended December 31, 2024.

Paramora option obligation

On November 10, 2025, in connection with the Asset Acquisition, the Company assumed the Paramora Option Obligation which provided for an annual equity grant of warrants for Paramora to purchase 1% of the then outstanding shares of Common Stock, on a fully diluted basis, on the last business day of each calendar year during the term of the Paragon Option Agreement, at the fair market value determined by the board of directors of the Company. The Company determined that the 2025 and 2026 grants are two separate grants, as there would be no obligation for the 2026 grant had the Company exercised or terminated all of the options under the Paragon Option Agreement prior to December 31, 2026. The service inception period for the grant precedes the grant date, with the full award being vested as of the grant date with no post-grant date service requirement. Accordingly, a liability related to the Paramora Option Obligation was recorded pursuant to the amended Paragon Option Agreement during 2025 interim periods. The

Company determined that the grant date of the award was December 31, 2025, as all terms of the award, including number of shares and exercise price, were known by all parties. Accordingly, the Company measured the grant-date fair value of the warrants granted at approximately $13.1 million as an equity-classified award, of which $3.7 million was recognized as part of the liabilities assumed with the Asset Acquisition on November 10, 2025. For the year ended December 31, 2025, $9.4 million was recognized as stock compensation expense related to the Paramora Option Obligation. There was no similar expense for the year ended December 31, 2024.

As of December 31, 2025, there was no unamortized expense related to the Paramora Option Obligation.

The Company settled its 2025 obligations under the Paramora Option Obligation by issuing Paramora 628,302 warrants to purchase Common Stock, less the $23.01 per share exercise price of each warrant. As of December 31, 2025, none of the warrants issued under the Paramora Option Obligation have been exercised.

The following table summarizes the assumptions used in calculating the fair value of the warrant obligation for the year ended December 31, 2025:

	Year Ended December, 2025
Expected volatility	100.0%
Expected term (in years)	10.0
Risk-free interest rate	4.2%
Expected dividend yield	—%

Restricted stock units

In January 2024, the Company granted 34,200 restricted stock units ("RSUs") to its employees under the 2020 Equity Plan. The weighted average grant date fair value of the time-based RSUs was $17.75 for the year ended December 31, 2025. The RSUs vest 33% after one-year from the grant date and 17% every six-months thereafter, subject to continued service to the Company through the applicable vesting dates. For the year ended December 31, 2025, the Company recognized $0.2 million in expense related to the RSUs.

The following table sets forth the activity for the Company's RSUs during the periods presented:

	Restricted Stock Units	Weighted-average grant date fair value
Total nonvested units at December 31, 2023	—	—
Granted	34,200	$ 17.75
Vested	(7,050)	17.75
Cancelled	(11,550)	17.75
Total nonvested units at December 31, 2024	15,600	17.75
Granted	—	—
Vested	7,800	17.75
Cancelled	—	—
Total nonvested units at December 31, 2025	7,800	$ 17.75

Stock-based compensation

The grant date fair value of stock awards vested during the years ended December 31, 2025 and 2024 was $0.8 million and $3.1 million, respectively. Total unrecognized compensation expense related to unvested options granted under the Company's stock-based compensation plan was $15.5 million at December 31, 2025, which is expected to be recognized over a weighted average period of 4.8 years. The Company recorded stock-based compensation expense related to the issuance of stock as follows (in thousands):

	For the Year Ended December 31,	
	2025	2024
Research and development	228	$ 896
General and administrative	770	2,343
Total Stock-based compensation	$ 998	$ 3,239

14. INCOME TAXES

As further described in Note 2, Summary of Significant Accounting Policies, the Company has elected to prospectively adopt the guidance in ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures or ASU 2023-09. The following table is a reconciliation of the U.S. federal statutory rate of 21% to the Company's effective tax rate for the year ended December 31, 2025 in accordance with the guidance in ASU No. 2023-09:

(In thousands, except percentages)	Year Ended December 31, 2025	
Provision for income taxes at U.S. federal statutory rate	$ (44,056)	21.0%
State income taxes, net of federal tax benefit	—	—
Changes in valuation allowances	4,648	(2.2)
Non-taxable or non-deductible items:		
Acquired IPR&D	36,605	(17.5)
Other reconciling Items	1,992	(0.9)
Foreign tax effects		
Denmark		
Nondeductible expenses	543	(0.3)
Foreign rate differential	(39)	—
Valuation allowance	306	(0.1)
Other reconciling Items	2	—
Effective income tax rate	$ —	—%

The following table is a reconciliation of the U.S. federal statutory rate of 21% to the Company's effective rate for the year ended December 31. 2024 in accordance with the guidance prior to the adoption of ASU 2023-09:

	Year Ended December 31, 2024
Income tax benefit at the statutory rate	% 21.0
Orphan Drug Credit	0.3
Permanent differences	(4.7)
State income taxes	1.7
Foreign rate differential	0.5
Change in valuation allowance	(18.8)
Total	—%

The Company had income tax expense of approximately $50,000 and $41,000 for the year ended December 31, 2025 and 2024, respectively. The Company has incurred net operating losses for all the periods presented. The Company has not reflected the benefit of any such net operating loss carryforwards in the accompanying financial statements. In 2019, the domicile of the reporting entity has changed from Denmark to the United States resulting in a tax rate of 21% in 2025 and 2024. This is discussed further below.

The components of net loss are as follows (in thousands):

	Year Ended December 31, 2025	2024
Domestic	$ (205,929)	$ (11,386)
Foreign	(3,910)	(10,053)
Total	$ (209,839)	$ (21,439)

Deferred taxes

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets and liabilities consisted of the following (in thousands):

	December 31, 2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 63,200	$ 55,193
Orphan Drug Credit	8,988	8,988
U.S. research and development credits	1,191	1,191
Stock-based compensation	914	748
Section 174 R&D costs	—	25
Amortization	1,061	1,041
Fixed assets	4	9
Accruals	70	31
Total deferred tax assets	$ 75,428	$ 67,226
Valuation allowance	(75,428)	(67,226)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The Company regularly assesses the likelihood that the deferred tax assets will be recovered from future taxable income. The Company considers projected future taxable income and ongoing tax planning strategies, then records a valuation allowance to reduce the carrying value of the net deferred taxes to an amount that is more-likely-than-not able to be realized. Based upon the Company's assessment of all available evidence, including the previous three years of taxable income and loss after permanent items, estimates of future profitability, the Company's overall prospects of future business and pursuant to the pursuit of strategic alternatives, the Company determined that it is more-likely-than-not that the Company will not be able to realize a portion of the deferred tax assets in the future. The Company will continue to assess the potential realization of deferred tax assets on an annual basis, or an interim basis if circumstances warrant. If the Company's actual results and updated projections vary significantly from the projections used as a basis for this determination, the Company may need to change the valuation allowance against the gross deferred tax assets. On the basis of this evaluation, a full valuation allowance at December 31, 2025 and December 31, 2024 was recorded of $75.4 million and $67.2 million, respectively, to reduce the net deferred tax assets to their estimated realizable value. The change in valuation allowance was $8.2 million.

The Company is subject to taxation in the United States, United Kingdom and Denmark. As of December 31, 2025, tax years 2019 and forward were generally open to examination by the United States and foreign tax authorities. There Company is not under examination by any taxing authorities.

As of December 31, 2025, the Company had gross U.S. federal net operating losses ("NOLs") of $65.6 million and federal research and development credits ("R&D credits") of $1.2 million and Orphan Drug Credit ("ODC") of $9.0 million to offset tax liabilities. The federal R&D credit and ODC carryforwards begin to expire in 2033 and 2042, respectively. All of the federal NOLs have an infinite life. The Company also had gross state NOLs of $57.0 million, which are available to offset state tax liabilities. The state NOLs begin to expire in 2040. The Company also had NOLs in Denmark of $208.2 million which have an indefinite life. Federal and state NOLs and R&D credit and ODC carryforwards are also subject to annual limitations in the event that cumulative changes in the ownership interests of significant stockholders exceed 50% over a three-year period, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986 (the "Code"). The Company has not completed an analysis to determine if the NOLs and R&D credits are limited due to a change in ownership.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted, reinstating full expensing of domestic R&D expenditures

under new Internal Revenue Code Section 174A, effective for tax years beginning after December 31, 2024. The legislation also provides taxpayers with the option to accelerate deductions for unamortized domestic R&D costs incurred during the 2022 to 2024 period. The Company intends to elect full expensing of 2025 costs and acceleration of prior-year unamortized costs in its 2025 tax return. As a result, the Company recorded a $0.03 million reduction in deferred tax liabilities in the year ended December 31, 2025. Final elections will be made with the 2025 tax return filing.

The Company recognizes accrued interest related to unrecognized tax benefits and penalties as income tax expense. The Company does not have any material unrecognized tax benefits which would affect the effective tax rate if recognized. The Company does not have any unrecognized tax benefits which would reverse within the next twelve months.

The Company is eligible for the Danish enhanced research and development tax allowance, providing for an increase in the deductible value of the amount of certain R&D expenditures. The deduction for R&D expenditures is set at 101.5% for 2019, 130% for 2020 through 2022, 108% for 2023 through 2025 and 114% for 2026.

The Company has qualified for the R&D Expenditure Credit ("RDEC") in United Kingdom for preclinical laboratory and in-patient clinical trials. The RDEC net tax benefit is reported as a reduction to research and development expense in the consolidated statements of operations. For the year ended December 31, 2024, the Company recorded an overall reduction for the RDEC, net of the UK corporation tax rate of $0.06 million. The amount recorded as of December 31, 2024 includes relief for the tax years December 31, 2021 through December 31, 2024. The Company recorded no RDEC amount for the year ending December 31, 2025.

15. RESTRUCTURING ACTIVITIES

In May 2024, the Company's board of directors approved a reduction of eight employees in an effort to conserve cash resources (the "May RIF").

Employees affected by the May RIF obtained involuntary termination benefits pursuant to a one-time benefit arrangement. For employees who have no requirements to provide future service, the Company recognized the liability for the termination benefits in full at fair value at the time of termination. For employees who are required to render services beyond a minimum retention period to receive their one-time termination benefits, the Company recognized the termination benefits ratably over their future service periods. For the May RIF, the Company recorded employee termination benefit charges during the year ended December 31, 2024 of $1.0 million and has included such charges as operating expenses in the Consolidated Statements of Operations and Comprehensive Loss.

Restructuring costs pertaining to the Restructuring Plan consist of the following (in thousands):

Balance at December 31, 2023	$	1,734
Restructuring expenses incurred		968
Payments		(2,702)
Balance at December 31, 2024	$	—

In September 2023, the board of directors approved arrangements designed to provide that the Company will have the continued dedication and commitment of its remaining employees, including executives, determined to be key to the Company's planned go-forward operations. The board of directors approved, and management implemented, a retention program for employees remaining with the Company which includes cash retention bonuses totaling $1.2 million for certain retained employees, provided that they remain within the Company through various requisite service periods. As a result, these cash retention bonuses were accrued over the requisite service period. The Company's arrangement with its then Chief Executive Officer specified that he was only entitled to a cash bonus upon the timely achievement of certain corporate and strategic milestones for the Company, which were not achieved by December 31, 2024.

In October 2024, the board of directors approved arrangements designed to provide that the Company will have the continued dedication and commitment of its remaining employees, including executives, determined to be key to the Company's planned go-forward operations. The board of directors approved, and management implemented, a retention program for employees remaining with the Company which includes cash retention bonuses totaling $0.6 million for certain retained employees, provided that they remain within the Company through various requisite service periods. As a result, these cash retention bonuses were accrued over the requisite service period. During the year ended December 31, 2024, the Company's retention accrual was $0.1 million.

In November 2025, the board of directors approved a retention program for employees remaining with the Company which includes cash retention bonuses totaling $0.8 million for certain retained employees, provided that they remain within the Company through

various requisite service periods. As a result, these cash retention bonuses were accrued over the requisite service period. During the year ended December 31, 2025, the Company's retention accrual was $0.3 million.

16. NET LOSS PER SHARE

Basic and diluted net loss per share of common stock, Series B Preferred Stock and Series C Preferred Stock is calculated as follows (in thousands except share and per share amounts):

	Year Ended December 31, 2025		
	Series B Preferred Stock	Series C Preferred Stock	Common Stock
Net loss per share, basic and diluted:			
Numerator			
Allocation of losses	$ (55,529)	$ (148,890)	$ (5,420)
Denominator			
Weighted-average shares outstanding	2,332	6,252	1,363,005
Net loss per share, basic and diluted	$ (23,816.00)	$ (23,816.00)	$ (3.98)

	Year Ended December 31, 2024		
	Series B Preferred Stock	Series C Preferred Stock	Common Stock
Net loss per share, basic and diluted:			
Numerator			
Allocation of losses	$ —	$ —	$ (21,439)
Denominator			
Weighted-average shares outstanding	—	—	1,157,149
Net loss per share, basic and diluted	$ —	$ —	$ (18.53)

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	Year Ended December 31,	
	2025	2024
Stock options to purchase Common Stock	983,375	222,079
Restricted stock units	7,800	15,600
Outstanding Paramora Warrant	628,302	—

17. DEFINED CONTRIBUTION PLAN

The Company has a 401(k)-defined contribution plan (the "401(k) Plan") for its U.S. based employees. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits. At the discretion of its board of directors, the Company may elect to match employee contributions. For the years ended December 31, 2025 and 2024, the Company paid a match of up to 6%, up to the maximum permitted by the Code, which amounted to $0.1 million during both periods and is expensed as personnel costs when incurred.

18. SEGMENT REPORTING

The Company has one reportable and one operating segment and manages its business activities primarily in Denmark and North America and on a consolidated basis. The Company's singular focus is on the development of its mutCALR portfolio to address the full mutCALR myeloproliferative neoplasm disease spectrum. All of the Company's tangible assets are held in Denmark and the United States.

The accounting policies of the Company are the same as those described in the summary of significant accounting policies.

The CODM is its chief executive officer, or in the absence of a chief executive officer, its chief operating officer. The CODM assesses performance for the Company and decides how to allocate resources based on net loss as reported on the consolidated statements of operations. The annual budgeting process is the primary mechanism used to make these decisions. The financial information also helps in making performance assessments using budgeted versus actual results.

The measure of segment assets is reported on the balance sheet as total consolidated assets.

19. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date on which the consolidated financial statements were issued. The Company has concluded that no subsequent events, other than already disclosed or described below, have occurred that require disclosure to the consolidated financial statements.

Shelf registration statement, ATM offering program and February 2026 public offering

On February 10, 2026, the Company filed the Registration Statement.

On February 10, 2026, the Company entered into the ATM Agreement, pursuant to which it may sell, from time-to-time, shares of Common Stock under an ATM offering program for up to $150.0 million. As of the date of this filing, the Company has made no sales of Common Stock under the ATM offering program and has $150.0 million in remaining capacity under the ATM offering program.

On February 10, 2026, the Company also entered into an underwriting agreement with certain underwriters to issue and sell 14,473,685 shares of Common Stock, including the full exercise by the underwriters of their option to purchase an additional 2,171,052 shares, at a public offering price of $19.00 per share. The underwritten offering closed on February 12, 2026. The net proceeds from this offering were approximately $297.3 million, after deducting underwriting discounts and commissions and expenses of the offering of $19.0 million.