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: 001-38541

Dianthus Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**81-0724163**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7 Times Square, 43rd Floor New York, New York	**10036**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (929) 999-4055

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	DNTH	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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 Registrant's shares of Common Stock on The Nasdaq Capital Market on June 30, 2025, was $599.4 million.

The number of shares of the Registrant's Common Stock outstanding as of March 4, 2026 was 44,471,094.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be included in Part III of this Annual Report on Form 10-K is set forth in, and incorporated by reference from, the Registrant's definitive proxy statement for its 2026 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after December 31, 2025.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K are forward-looking statements, including, without limitation, statements concerning our plans, objectives, goals, expectations, hopes, beliefs, intentions, assumptions, projections, estimates or strategies and any underlying assumptions regarding the future, our future results of operations and financial position, including the sufficiency of our existing cash resources to fund our operations for as long as anticipated, our liquidity, capital resources, costs and expenses, capital requirements, commitments and contingencies, the development or commercial potential of claseprubart, DNTH212, or any other product candidate, our anticipated preclinical and clinical drug development activities, in particular with respect to claseprubart and DNTH212, and any timelines, developments or results in connection therewith, including the timing of data, the efficacy, safety profile, dosing amount or frequency, method of delivery or other potential therapeutic benefits of claseprubart and DNTH212, the receipt or timing of potential regulatory designations, approvals and commercialization of any product candidates, market size or addressable patient population and other statements, including those included under the sections titled "*Risk Factors,*" "*Business,*" "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and elsewhere in this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terms such as "aim," "may," "might," "will," "would," "shall," "objective," "intend," "target," "should," "could," "can," "expect," "anticipate," "believe," "design," "estimate," "forecast," "predict," "project," "potential," "possible," "plan," "seek," "contemplate," "goal," "likely" or "continue" or the negative of these terms and similar expressions intended to identify forward-looking statements, but the absence of these terms does not mean that a statement is not forward-looking. Forward-looking statements are not historical facts and are based on our current expectations and beliefs with respect to future events and their potential effects and impacts. There can be no assurance that future events affecting us will be those that have been anticipated. Given the significant risks and uncertainties, you should not place undue reliance on these forward-looking statements.

There are a number of risks, uncertainties and other factors that could cause our actual results or outcomes, or the timing of our results or outcomes, to differ materially from the forward-looking statements expressed or implied in this Annual Report on Form 10-K. Such risks, uncertainties and other factors include, among others, the following:

- expectations regarding the strategies, prospects, plans, expectations and objectives of our management for future operations of the Company;
- risks associated with our ability to manage expenses and unanticipated spending and costs that could reduce our cash resources;
- risks related to our ability to correctly estimate our operating expenses and other events;
- changes in our capital resource requirements;
- our ability to obtain, maintain and protect our intellectual property rights, in particular those related to our product candidates;
- our ability to advance the development of claseprubart, DNTH212, and our other potential product candidates or preclinical activities under the timelines we anticipate in planned and future clinical trials;
- our ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of our product candidates;
- our ability to realize the anticipated benefits of our current or future research and development programs, strategic partnerships, licensing programs or other collaborations;
- regulatory requirements or developments, and our ability to obtain necessary approvals from the U.S. Food and Drug Administration (the "FDA") or other regulatory authorities;
- our ability to manufacture product candidates in conformity with the FDA's or other regulatory authorities' requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- changes to clinical trial designs and regulatory pathways;
- developments and projections relating to our expected or existing competitors or industry;

- legislative, regulatory, political, geopolitical and macroeconomic developments beyond our control, including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy or foreign currency exchange rates, changes in trade policies including tariffs and other trade restrictions or the threat of such actions, instability in financial institutions, the impact of a prolonged shutdown of the U.S. federal government, the ongoing conflict in Ukraine, conflict in the Middle East and rising tensions between China and Taiwan, the attacks on marine vessels traversing the Red Sea and the responses thereto, and supply chain disruptions;

- success in retaining, recruiting or changes in, our officers, key employees or directors;

- the liquidity and trading of our securities;

- regulatory actions with respect to our product candidates or our competitors' products and product candidates;

- our ability to successfully develop and commercialize any technology that we have in-licensed or may in-license or products we have acquired or may acquire;

- our ability to successfully operate in non-U.S. jurisdictions in which we may choose to do business, including compliance with applicable regulatory requirements and laws;

- our reliance on third-party contract development and manufacturer organizations to manufacture and supply product candidates;

- our ability to establish satisfactory pricing and obtain adequate reimbursement from government and third-party payors of our products and product candidates that receive regulatory approvals, if any;

- our ability to successfully commercialize our product candidates, if approved, and the rate and degree of market acceptance of such product candidates;

- risks related to our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities;

- our inability to continue to grow and manage our growth effectively; and

- our inability to comply with, and the effect on our business of, evolving legal standards and regulations, including those concerning data protection, consumer privacy and sustainability and evolving labor standards.

There may be other factors that may cause our actual results or outcomes, or the timing of those results or outcomes, to differ materially from the forward-looking statements expressed or implied in this Annual Report on Form 10-K, including factors disclosed in the sections titled "*Risk Factors,*" "*Business,*" "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and elsewhere in this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission (the "SEC"). You should evaluate all forward-looking statements made in this Annual Report on Form 10-K in the context of these risks and uncertainties.

We caution you that the risks, uncertainties and other factors referred to above and elsewhere in this Annual Report on Form 10-K may not contain all of the risks, uncertainties and other factors that may affect our future results, operations and outcomes. Moreover, new risks emerge from time to time. It is not possible for us to predict all risks. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Past performance is not indicative of future performance.

Any forward-looking statements contained in this Annual Report on Form 10-K apply only as of the date of this Annual Report on Form 10-K and are expressly qualified in their entirety by the cautionary statements included in this Annual Report on Form 10-K. Except as required by law, we disclaim any intent to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changes in assumptions or otherwise.

Explanatory Note

Unless context otherwise requires, references to "we," "our," "us," "Dianthus," the "Company," or the "combined company" in this Annual Report on Form 10-K refer to Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.) for the period after the completion of the Reverse Merger (as defined below) and refer to Dianthus Therapeutics OpCo, Inc. for the period before the completion of the Reverse Merger. The term "Former Dianthus" also refers to Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.), and the term "Magenta" refers to the Company prior to completion of the Reverse Merger. On September 11, 2023, we completed a business combination with Former Dianthus pursuant to which, among other matters, Former Dianthus became a wholly owned subsidiary of ours (the "Reverse Merger").

PART I

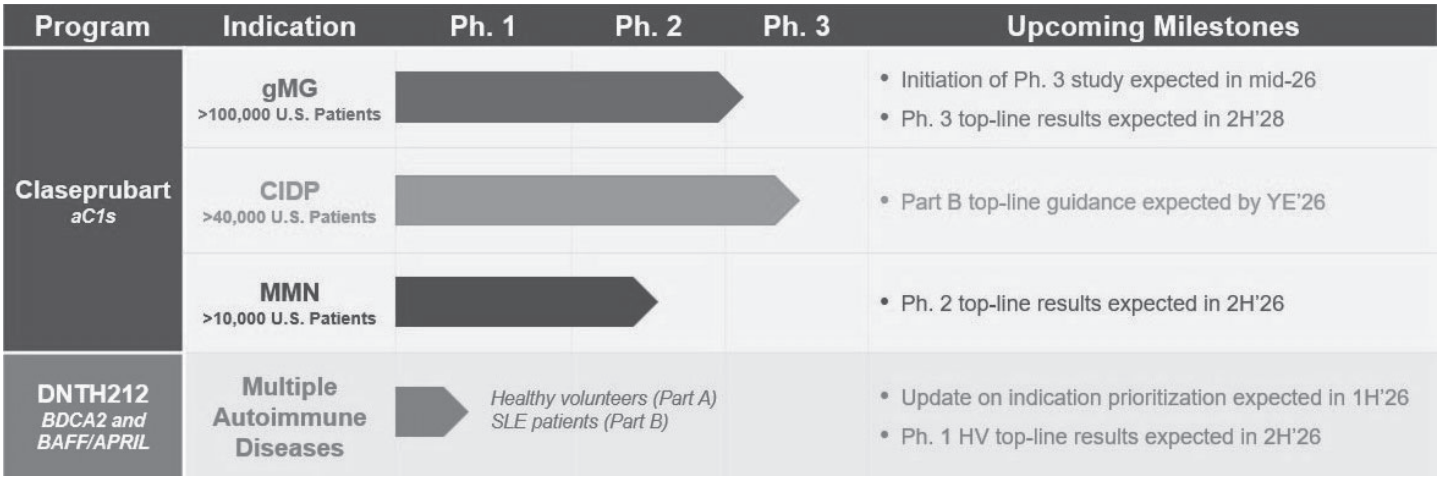
Item 1. Business.

Overview

We are a clinical-stage biotechnology company dedicated to developing potentially best-in-class therapies for patients living with severe autoimmune diseases. Our lead clinical-stage candidate, claseprubart, is a monoclonal antibody that is purposefully engineered with extended half-life, improved potency, and high selectivity for only the active C1s complement protein ("C1s") – enabling less frequent and more convenient self-administered subcutaneous ("S.C.") injections suitable for a pre-filled pen. Additionally, selective inhibition of the classical complement pathway may lower patient risk of infection from encapsulated bacteria by preserving immune activity of the lectin and alternative pathways. We believe claseprubart has the potential to address a broad array of complement-dependent diseases as currently available therapies and those in development leave room for improvements in efficacy, safety, and/or dosing convenience.

Our second clinical-stage candidate, DNTH212, is a first and potentially best-in-class, bifunctional fusion protein that targets plasmacytoid dendritic cell ("pDC") BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. By targeting both the innate and adaptive immune systems via two clinically validated pathways that are known drivers of autoimmune disease pathogenesis, this complementary and differentiated approach has the potential to address multiple autoimmune indications with improved outcomes. DNTH212 is also designed with the potential for patient friendly convenient, infrequent, self-administered S.C. injections suitable for a pre-filled pen.

Our Pipeline



Our Pipeline-in-a-Product Potential for Claseprubart, a Next-Generation Complement Therapeutic

Our most advanced product candidate, claseprubart, is a clinical-stage, highly potent, highly selective and fully human monoclonal immunoglobulin G4 with picomolar binding affinity that is designed to selectively bind only to the active form of C1s. The active form of C1s is generated during complement activation by cleavage of the inactive proC1s. As a validated complement target in the autoimmune and inflammatory field, C1s inhibition prevents further progression of the classical pathway cascade. Claseprubart is engineered with YTE half-life extension technology, a specific three amino acid change in the Fc domain, and has a pharmacokinetic ("PK") profile designed to support less frequent, lower dose, self-administration as a convenient S.C. injection.

We are currently conducting three mid- to late-stage clinical trials with claseprubart in generalized Myasthenia Gravis ("gMG"), Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"), and Multifocal Motor Neuropathy ("MMN").

Overview of Development Plans of Claseprubart in Target Indications

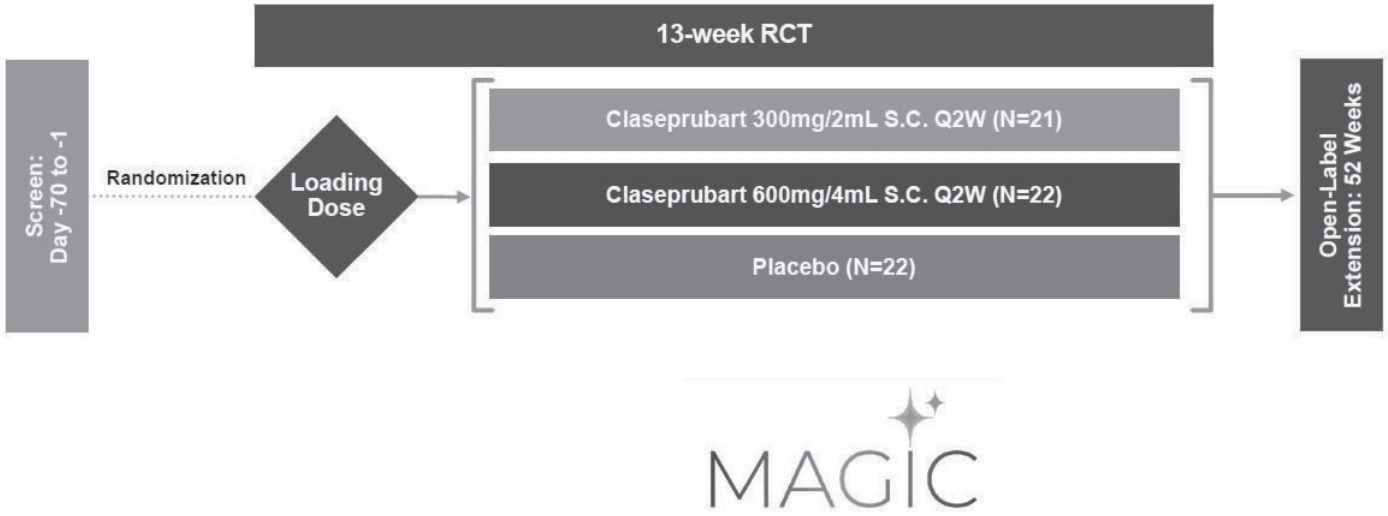
In September 2025, we reported positive top-line results from the Phase 2 MaGic trial of claseprubart in patients with gMG and subsequently held an end-of-Phase 2 meeting with the FDA in the first quarter of 2026. We expect to initiate a Phase 3 registrational trial in gMG in mid-2026 and report top-line results in the second half of 2028.

In March 2026, we made an early GO announcement in the interim responder analysis for our Phase 3 CAPTIVATE trial of claseprubart in patients with CIDP due to achieving a target of 20 confirmed responders with less than the planned 40 participants completing Part A.

Claseprubart is also being evaluated in the Phase 2 MoMeNtum trial for patients with MMN, and we anticipate initial top-line results from this trial will be available in the second half of 2026.

MAGIC

The MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial of claseprubart that enrolled 65 acetylcholine receptor positive ("AChR+") participants with gMG. Following an initial loading dose, claseprubart was administered every two weeks ("Q2W") via S.C. injection at a dose of 300mg/2mL or 600mg/4mL. The initial randomized treatment duration was 13 weeks, followed by a 52-week open-label extension ("OLE"). The primary endpoint of the study was safety and tolerability. Secondary and exploratory efficacy endpoints included Myasthenia Gravis Activities of Daily Living Scale ("MG-ADL") and Quantitative Myasthenia Gravis ("QMG") score assessments, as well as Minimal Symptom Expression ("MSE"), Myasthenia Gravis Composite ("MGC") score, and the Myasthenia Gravis Quality of Life Scale ("MG-QOL-15r").



In September 2025, we announced positive top-line data from the Phase 2 MaGic trial. Claseprubart 300mg and 600mg demonstrated rapid, statistically significant and clinically meaningful improvements over placebo as measured by both MG-ADL and QMG, including at week 1 and at week 13. The claseprubart 300mg Q2W dose was also statistically significant and clinically meaningful across other key efficacy endpoints, including MSE, MGC, and MG-QoL-15r.

Claseprubart was generally well tolerated with no drug-related serious adverse events ("SAE") or discontinuations due to any related adverse event. Claseprubart had a favorable clinical safety profile comparable to placebo with no treatment-related serious bacterial infections and no clinical symptoms of emergent autoimmune disorders observed.

Efficacy Results

MG-ADL

- Claseprubart dosed at 300mg S.C. Q2W achieved a statistically significant and clinically meaningful mean improvement from baseline of 4.6 points in MG-ADL score at Week 13 (placebo-adjusted improvement: 1.8 points; P=0.0113). A statistically significant improvement in the MG-ADL was also seen as early as Week 1 with 300mg.

- Claseprubart dosed at 600mg S.C. Q2W achieved a statistically significant and clinically meaningful mean improvement from baseline of 5.4 points in MG-ADL score at Week 13 (placebo-adjusted improvement: 2.6 points; P=0.0006). A statistically significant improvement in the MG-ADL was also seen as early as Week 1 with 600mg.

- As expected, there was no statistically significant difference between the claseprubart 300mg and 600mg arms in MG-ADL score at any time point.

QMG

- Claseprubart dosed at 300mg S.C. Q2W achieved a statistically significant and clinically meaningful mean improvement from baseline of 4.4 points in QMG score at Week 13 (placebo-adjusted improvement: 2.4; P=0.0144). A statistically significant improvement in QMG was also seen as early as Week 1 with 300mg.

- Claseprubart dosed at 600mg S.C. Q2W achieved a statistically significant and clinically meaningful mean improvement from baseline of 4.5 points in QMG score at Week 13 (placebo-adjusted improvement: 2.5; P=0.0111). A statistically significant improvement in QMG was also seen as early as Week 1 with 600mg.

- As expected, there was no statistically significant difference between the claseprubart 300mg and 600mg arms in QMG score at any time point.

Efficacy Summary at Week 13

	Placebo N=22	**Claseprubart 300mg Q2W N=21**		**Claseprubart 600mg Q2W N=22**	
		Absolute	**Placebo-Adjusted**	**Absolute**	**Placebo-Adjusted**
MG-ADL mean change from baseline	-2.8	-4.6	-1.8 *(P=0.0113)**	-5.4	-2.6 *(P=0.0006)**
QMG mean change from baseline	-2.0	-4.4	-2.4 *(P=0.0144)**	-4.5	-2.5 *(P=0.0111)**
MSE	14%	37%	23% *(P=0.0550)**	27%	13% *(P=0.1031)*
MGC mean change from baseline	-3.1	-8.7	-5.6 *(P=0.0008)**	-8.6	-5.5 *(P=0.0008)**
MG-QoL-15r mean change from baseline	-3.9	-6.1	-2.2 *(P=0.0414)**	-5.4	-1.5 *(P=0.1122)*

*One-sided p-values are presented for comparisons of claseprubart vs placebo, with any p-value below 0.1 considered nominally statistically significant.

Safety and Tolerability Results

- Claseprubart was generally well tolerated and demonstrated a clinical safety profile in both treatment arms comparable to placebo.

- No infection signal was observed, including no related serious bacterial infections in the treatment arms; the only related SAE of infection occurred in the placebo arm.

- There were no symptoms indicative of autoimmune activation.

- Injection site reactions ("ISRs") were infrequent and generally mild, and there were no claseprubart discontinuations from randomized controlled trial ("RCT") due to related adverse events.

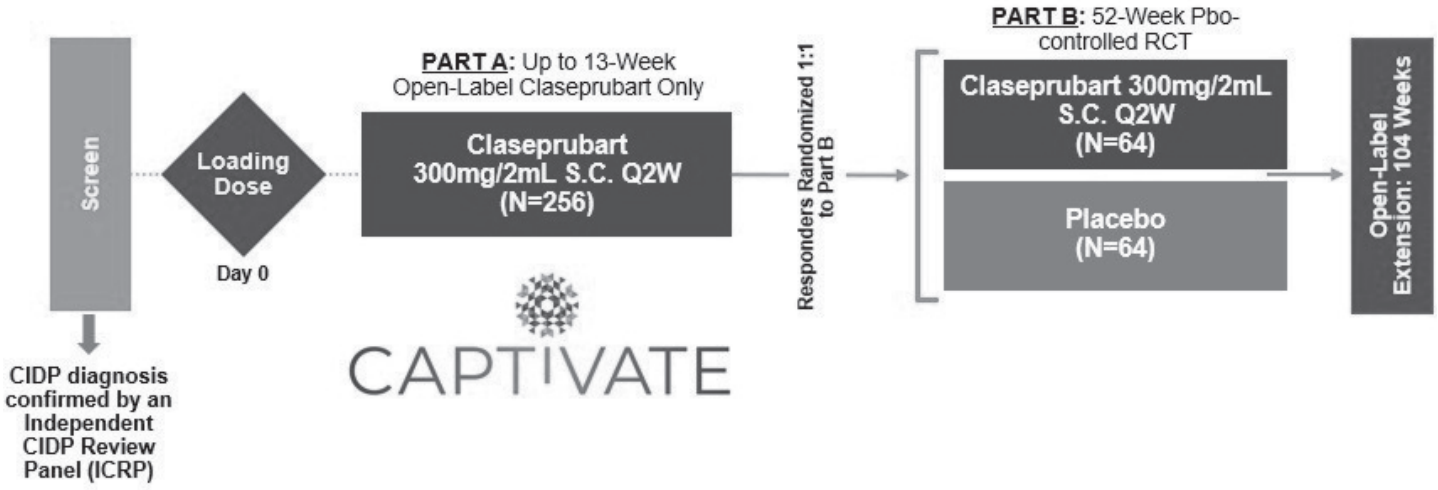
In the OLE portion of the MaGic trial, patients who were on placebo during the randomized controlled portion of the trial received claseprubart 600mg Q2W without a loading dose. Data from the OLE demonstrate that after two doses of claseprubart 600mg Q2W, participants experienced robust reductions in MG-ADL and QMG at PK levels far below the steady state of the 300mg Q2W dose, supporting the potential for dosing of 300mg claseprubart every four weeks ("Q4W").

Based on the outcome of our end-of-Phase 2 meeting with the FDA held in the first quarter of 2026, we expect to initiate a registrational Phase 3 trial of claseprubart evaluating 300mg Q2W and 300mg Q4W in gMG patients in mid-2026 and report top-line results in the second half of 2028.

CAPTIVATE

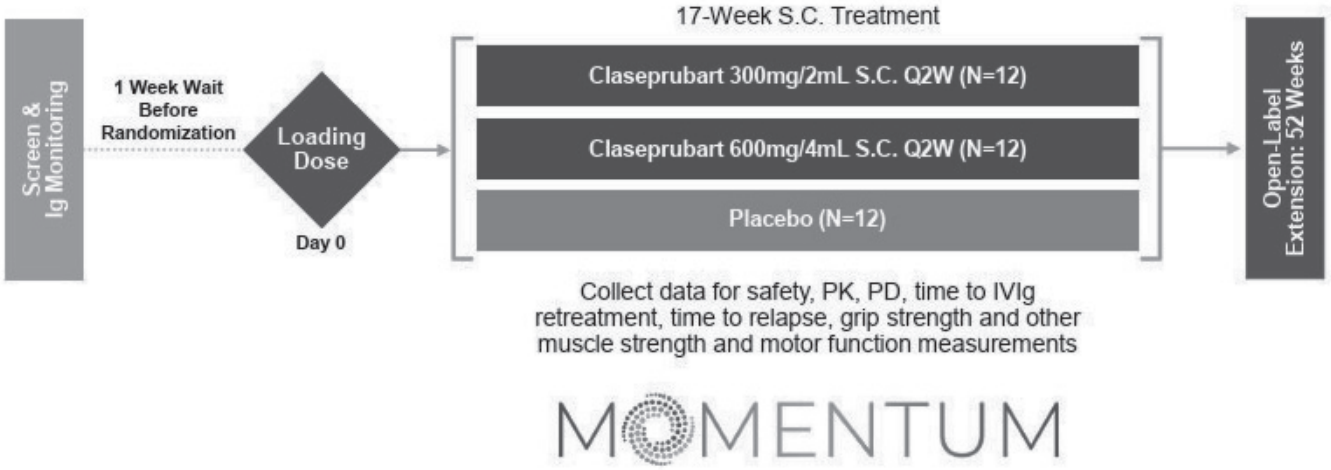
The CAPTIVATE trial is a single, two-part, randomized withdrawal global Phase 3 trial of claseprubart in patients with CIDP. In the open label Part A of this trial, participants will be administered claseprubart with a loading dose followed by 300mg/2mL administered Q2W via S.C. injection for up to 13 weeks. Only participants who respond to claseprubart in Part A, as measured as greater than or equal to one point decrease (improvement) in adjusted Inflammatory Neuropathy Cause and Treatment ("INCAT") disability score compared to Part A baseline, are randomized into Part B, a double-blind, placebo-controlled treatment period of up to 52 weeks, where they will be assessed for prevention of relapse, safety and tolerability, followed by an OLE period. Part A included an interim responder analysis of the first 40 participants to complete Part A. Our target for the Part A interim responder analysis was a response rate of 50% or greater (i.e., ≥20 confirmed responders out of first 40 participants to complete Part A) based on precedent set with aC1s inhibition. In March 2026, we announced that we achieved our target of 20 confirmed responders in Part A early, with less than 40 participants completing Part A. We believe that this single pivotal trial will support a Biologics License Application ("BLA") filing in adult patients with CIDP.

Based on the interim responder analysis for Part A, we plan to seek regulatory approval to revise the study design for the CAPTIVATE trial, as shown below.



MOMENTUM

The MoMeNtum trial is a global, randomized, double-blind, placebo-controlled Phase 2 study designed to evaluate the safety, tolerability, and efficacy of claseprubart in 36 patients with MMN. Following determination of immunoglobulin ("Ig") dependency and responsiveness, patients will be randomized to receive placebo or claseprubart with a loading dose followed by 300mg/2mL or 600mg/4mL administered Q2W via S.C. injection. The initial S.C. treatment duration is 17 weeks followed by a 52-week OLE. The primary endpoint of this study is safety and tolerability. Secondary endpoints include time to intravenous immunoglobulin ("IVIg") retreatment, time to relapse, and assessments of muscle and grip strength. We anticipate initial top-line results from this trial will be available in the second half of 2026.



Claseprubart Phase 1 Healthy Volunteer Data

Data from the Phase 1 clinical trial of claseprubart in 60 healthy volunteers across eight dose cohorts validates the extended half-life and potent classical pathway inhibition and supports a potentially differentiated safety profile of claseprubart. The top-line data confirmed its approximately 60-day half-life and highly potent classical pathway inhibition with Q2W S.C. dosing of 300mg/2mL surpassing the serum concentration required to surpass 90% classical pathway inhibition in a hemolytic assay estimated to be 87ug/mL, establishing claseprubart's best-in-class potential to be the first self-administered S.C. injection dosed infrequently to treat a range of autoimmune disorders. Claseprubart was generally well tolerated with no SAEs or complement-related infections.

Our First and Potentially Best-In-Class Bifunctional BDCA2 and BAFF/APRIL Inhibitor (DNTH212)

On October 16, 2025, we entered into an exclusive license agreement with Nanjing Leads Biolabs Co., Ltd. ("Leads") for DNTH212, a first and potentially best-in-class bifunctional BDCA2 and BAFF/APRIL inhibitor.

DNTH212 is an investigational, extended half-life bifunctional fusion protein targeting plasmacytoid dendritic cell BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. By targeting both the innate and adaptive immune systems via two clinically validated pathways that are known drivers of autoimmune disease pathogenesis, this complementary and differentiated approach has the potential to address multiple autoimmune indications with improved outcomes.

A two-part Phase 1 study in China in healthy volunteers (Part A) and patients with systemic lupus erythematosus (Part B) was initiated in December 2025, with top-line results in healthy volunteers expected in the second half of 2026.

Our Strategy

Our goal is to continue to develop potentially best-in-class therapies for patients living with severe autoimmune diseases. The key components of our strategy are as follows:

- Initiate a global Phase 3 clinical trial of claseprubart in gMG in mid-2026, and expect to report top-line results in the second half of 2028.
- Continue enrollment of claseprubart in our global Phase 3 clinical trial in CIDP.
- Continue enrollment of claseprubart in our global Phase 2 clinical trial in MMN to report top-line results in the second half of 2026.
- Explore claseprubart in a broad range of diseases where the classical pathway plays a significant role in the disease pathology, beyond gMG, CIDP and MMN.

- Continue to advance our second clinical candidate, DNTH212, as a potentially best-in-class bifunctional BDCA2 and BAFF/APRIL inhibitor for severe autoimmune diseases.

- Internally develop or in-license additional next-generation product candidates designed to have distinct advantages over existing therapies.

- Collaborate strategically to maximize the value of our product candidates.

Overview of the Complement System

The Complement System—Three Main Pathways

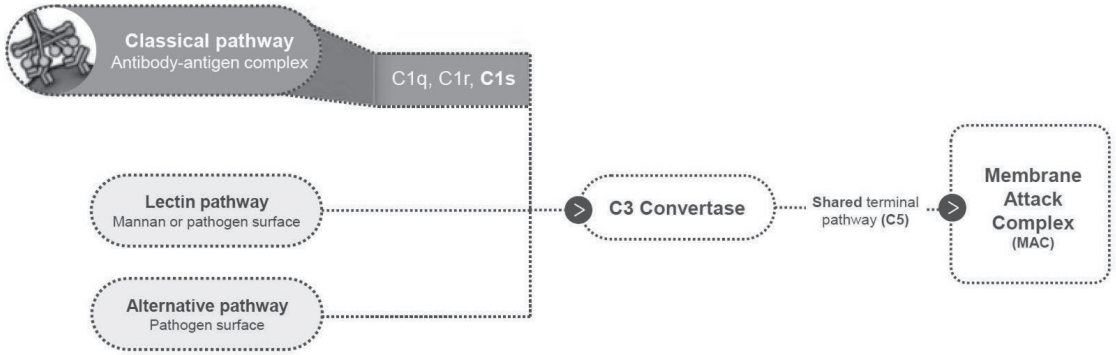
The complement system plays a critical role in maintaining an active innate immune system, including as the first line of defense against microbial pathogens, eliminating apoptotic cells and tissue debris, and modulating the adaptive B and T cell response. However, uncontrolled complement activation can also be a key contributor to the pathophysiology of numerous inflammatory and autoimmune conditions.

The complement system includes more than 30 component proteins, regulators, and receptors. The figure below illustrates the three complement activation pathways, each of which has a unique trigger for initiating a cascade of events:

- *Classical Pathway*: Activated primarily by immune complexes.

- *Lectin Pathway*: Activated by mannose binding lectin interaction with sugars on the surface of pathogens or injured cells.

- *Alternative Pathway*: Automatically activated in a conformational, non-enzymatic process that leads to amplification of the classical and lectin pathways.

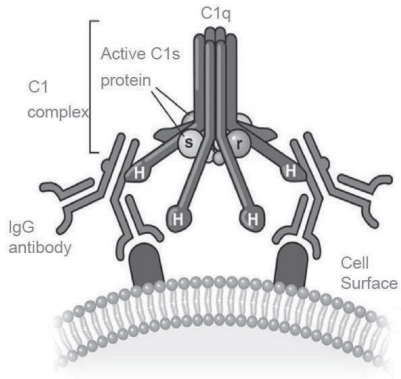


Regardless of the activation event, all complement pathways converge at common pathway components, known as C3 and C5. When the C3 and C5 proteins are activated, they enable three principal immune responses: inflammation, opsonization and formation of the membrane attack complex ("MAC"), a pore forming structure that leads to the lysis of targeted cells. In a normal immune response, C3b fragments act to mark pathogens for removal from tissues or the bloodstream by phagocytes in a process known as opsonization. C3a or C5a cleaved fragments cause inflammation in the surrounding tissues, attracting phagocytes to ingest opsonized pathogens. Downstream, C5b fragments initiate the formation of the MAC on pathogens, causing cell death and elimination. However, under conditions of excessive or uncontrolled activation, the complement system is believed to play a key role in the incidence and progression of several autoimmune and inflammatory diseases. Under these conditions, healthy cells may become part of a trigger for complement activation and/or become opsonized and destroyed.

Classical Pathway and the Role of C1s

The classical pathway of the complement system bridges innate and adaptive immunity. Classical pathway activation is initiated by the C1 complex. The C1 complex consists of a binding protein, C1q, and two inactive proenzymes, C1r ("proC1r") and C1s ("proC1s"). Initiation of the classical pathway cascade occurs when C1q binds to the Fc portion of immunoglobulin G ("IgG") or immunoglobulin M ("IgM"), as part of an immune complex as depicted in the image below. During an immune response, C1q binding to IgM or IgG antibodies that coat the surface of a cell triggers the autoactivation of proC1r, which in turn cleaves proC1s to generate

the active form of C1s. In its active form, C1s is responsible for cleaving and activating C4 and C2, which leads to the downstream cascade that culminates in the terminal pathway and MAC formation.



C1s is unique to the classical pathway and thus provides a therapeutic opportunity to selectively target antibody-driven autoimmune and inflammatory disorders mediated by the classical pathway while leaving the lectin and alternative pathways intact. This may result in distinct safety advantages over current FDA-approved downstream complement inhibitors, such as those approved for the treatment of gMG, which inhibit MAC formation from all three complement pathways and currently have an FDA Boxed Warning for serious meningococcal infections and an associated Risk Evaluation and Mitigation Strategy ("REMS") program.

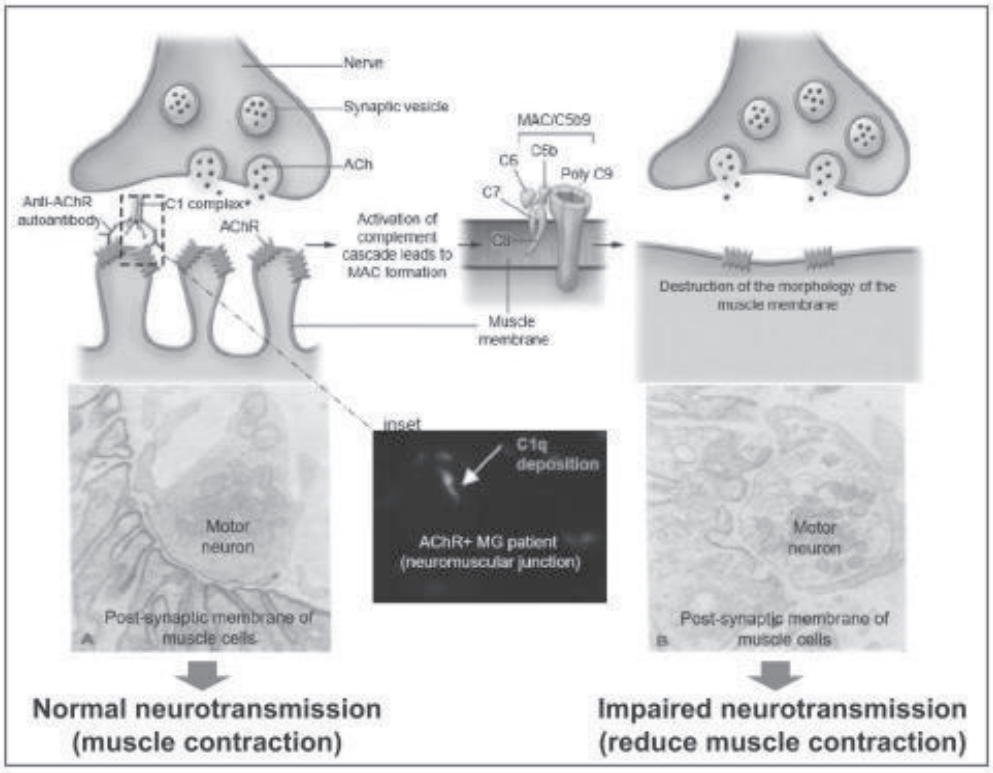
Claseprubart for the Treatment of Generalized Myasthenia Gravis

Overview of Myasthenia Gravis

Myasthenia Gravis ("MG") is a rare, chronic autoimmune disease characterized by muscle weakness due to inhibition of acetylcholine mediated muscle contraction. In MG, patients have autoantibodies directed against specific proteins of the neuromuscular endplate. MG is most commonly diagnosed in women between 20 and 39 years of age, and in men between 50 and 70 years of age. Clinically, MG can be classified as either ocular or generalized. In ocular MG, impairment is limited to the eye muscles, with symptoms such as diplopia and ptosis. Approximately 80% of ocular MG cases progress to gMG. Based on Komodo claims data, we believe there are more than 100,000 individuals in the United States with acetylcholine receptor antibody-positive gMG. Common symptoms of gMG include weakness of limb muscles and dysphagia (difficulty swallowing) or slurred speech resulting from weakness of oropharyngeal muscles (those involved in jaw and throat movement). Weakness of respiratory muscles is of particular concern, as it may lead to myasthenic crisis, a life-threatening condition requiring ventilatory support that occurs in approximately 15-20% of gMG patients. Patients with gMG may experience impaired vision, speech, and mobility, shortness of breath, difficulty swallowing and eating, and fatigue, all of which can have a profound negative effect on activities of daily life. Measures of both mental and physical health indicate a substantially lower quality of life for patients with gMG compared with the general population. Quality of life can be further negatively impacted in patients with refractory MG in terms of disease exacerbations, emergency department visits, and hospitalizations.

Role of Classical Pathway and C1s in the Pathogenesis of Myasthenia Gravis

In approximately 85% of gMG cases, antibodies to the acetylcholine receptors are identified (AChR+ gMG patients). These autoantibodies bind to the acetylcholine receptor and activate C1q which activates C1r. C1r in turn activates C1s which undergoes a conformational change allowing it to cleave C4 and initiating the classical complement pathway. Classical pathway activation ultimately results in MAC associated destruction at the motor end plate. As illustrated in the figure below, antibody-mediated classical complement activation leads to significant damage at the neuromuscular junction in patients with gMG, with the loss of characteristic anatomical folds.



Current gMG Treatments and their Limitations

The acetylcholinesterase inhibitor pyridostigmine has been used to treat neuromuscular symptoms of gMG since the 1950s. However, most patients require additional immunosuppressants such as steroids, azathioprine, mycophenolate, cyclosporine A, or rituximab. Although these therapies have shown some success, many patients continue to have unmet need and experience undesirable side effects, and none of these therapies have been approved for gMG. The treatment landscape for MG has continued to evolve. Plasmapheresis ("PLEX") and IVIg therapy are therapeutic options, although these are more invasive treatments often reserved for MG crisis. FcRn targeted therapy is another treatment for gMG. FcRn promotes activity of pathogenic autoantibodies by protecting IgG from degradation. Efgartigimod, marketed as Vyvgart, is a humanized anti-FcRn-IgG1 Fc fragment that is designed to reduce the level of all serum IgG and AChR antibodies and was approved by the FDA for the treatment of gMG in adult patients who are AChR antibody positive in 2021. Vyvgart's current dosing paradigm is 10 mg/kg administered as an I.V. infusion over one hour once weekly for four weeks. In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion. A S.C. formulation of Vyvgart, Vyvgart Hytrulo, was approved by the FDA in 2023. Vyvgart Hytrulo can either be administered as a single-dose vial of 1008 mg per injection once weekly for four weeks over approximately thirty to ninety seconds by a healthcare professional only or as a single-dose prefilled syringe of 1000 mg per injection once weekly for four weeks over approximately twenty to thirty seconds by patients and/or caregivers. For both formulations, subsequent treatment cycles are based on clinical evaluation.

Complement inhibitors for the treatment of AChR antibody-positive gMG emerged in 2017 with eculizumab, marketed as Soliris, a recombinant humanized monoclonal antibody against complement protein C5. More recently, another C5 inhibitor, ravulizumab, marketed as Ultomiris, was approved by the FDA for the treatment of adult patients with gMG who are AChR antibody positive in 2022. These treatments require higher dose I.V. infusions and carry the risk of life-threatening infections such as meningococcal infections due to being terminal complement inhibitors, and, as a result, have an FDA Boxed Warning and an associated REMS program.

As such, we believe claseprubart has the potential to meaningfully transform the standard of care in gMG as a potent, lower dose, lower frequency, self-administered S.C. injection with no FDA Boxed Warning, REMS, or requirement for cycling of treatment such as with FcRn inhibitors. As it is designed to be a more patient-friendly, predictable, convenient and a less burdensome biologic, claseprubart has the potential to become a first-line biologic treatment option. Thus, claseprubart could compete for early treatment of AChR positive gMG patients versus IVIg, terminal complement inhibitors and FcRn inhibitors, as well as for use in patients that do not adequately respond to other biologics, such as IVIg or FcRn inhibitors.

Claseprubart for the Treatment of Other Autoimmune and Inflammatory Diseases

The classical pathway is activated through interaction of the C1 complex with antibody-antigen complexes. We believe it is therefore rational to propose that compounds specifically targeting the classical pathway and specifically C1s, such as claseprubart, would be well-suited for the potential treatment of autoimmune or inflammatory disease conditions where autoantibodies are implicated, such as CIDP and MMN.

Overview of CIDP

CIDP is an autoimmune and inflammatory disorder affecting the myelin that insulates and protects peripheral nerves. CIDP is estimated to affect more than 40,000 people in the United States. Common symptoms of the disease include weakness, loss of balance, and sensation changes in the arms or legs. In the classic or typical CIDP, there is symmetric involvement of both upper and lower limbs, characterized by weakness in the proximal (for example, shoulder region or hip region) as well as distal (for example, wrist or ankle) muscle groups. In addition, there is sensory involvement. There are several atypical forms of CIDP, characterized by varying levels of motor and sensory involvement with overlap. CIDP follows a relapsing-remitting or a progressive clinical course, which can result in substantial disability, loss of motor and sensory function, and negative impact on quality of life.

Role of Classical Pathway and C1s in the Pathogenesis of CIDP

The pathogenesis of CIDP involves a complex interplay of multiple aberrant immune responses, inflicting damage on the myelin sheath. The complement system appears to play a role in promoting macrophage-mediated demyelination. Complement deposition in sural nerve biopsies, as well as signs of increased complement activation in serum and cerebrospinal fluid of patients with CIDP, suggest complement involvement in CIDP. A recently developed human-on-a-chip conduction model (with CIDP and MMN phenotype) suggests that complement activation by CIDP and MMN patient serum is sufficient to mimic neurophysiological features of each disease and that C1s inhibition is sufficient to rescue these pathological effects. Additionally, riliprubart, a C1s inhibitor in development by Sanofi, reported positive Phase 2 clinical data beginning in the fourth quarter of 2023 across three patient groups: (a) Standard of Care-Treated; (b) Standard of Care-Refractory; and (c) Standard of Care-Naïve. These data provide additional proof of concept and validation of the role of C1s for the treatment of CIDP and the potential use of a C1s inhibitor as a first-line targeted biologic.

Current CIDP Treatments and their Limitations

Over 70% of CIDP patients require ongoing treatment with immunosuppressants such as IVIg, S.C. immune globulin, PLEX or steroids. In June 2024, Vyvgart Hytrulo, marketed by argenx, was approved for the treatment of CIDP. Vyvgart Hytrulo can either be administered as a single-dose vial of 1008 mg per injection once weekly over approximately thirty to ninety seconds by a healthcare professional only or as a single-dose prefilled syringe of 1000 mg per injection once weekly over approximately twenty to thirty seconds by patients and/or caregivers. Despite treatment, a significant number of patients do not achieve clinical remission and there remains a significant unmet clinical need for this disease. Given the role of the complement system in the disease pathology, patients may benefit from a selective C1s inhibitor.

Overview of MMN

MMN is a pure motor neuropathy associated with asymmetric deficits with predilection for upper limb involvement. It is an underrecognized disease with U.S. prevalence estimates of approximately 10,000 individuals. MMN predominantly affects males as compared to females (3:1). Clinical symptoms consist of progressive or stepwise muscle weakness in the distribution of affected peripheral nerves, without loss of sensory modalities. The muscle weakness is asymmetric and causes predominantly upper limb weakness, such as weakness in hand grip, finger movements or wrist drop. The disease is progressive and can cause substantial disability and loss of function, due to the involvement of upper limbs.

Role of Classical Pathway and C1s in the Pathogenesis of MMN

Approximately 50% of patients have an IgM autoantibody against GM1, a genetic disorder that progressively destroys nerve cells in the brain and spinal cord, that is found at nodes of Ranvier mainly in peripheral motor nerves, causing immune mediated motor neuropathy with variable conduction block. There is evidence to support the role of complement in the pathophysiology of MMN. Sera from MMN patients has been shown to activate complement in vitro. There is complement deposition in the affected nerves, and the degree of complement deposition correlates with the response to Ig therapy. As described above, inhibition of C1s reverses the pathological effects in a recently developed MMN model.

Current MMN Treatments and their Limitations

Intravenous and S.C. Ig therapy is approved by the FDA for treatment of adult patients with MMN. Most patients require chronic long-term therapy with immunoglobulins with variable response in up to 80% of patients. Steroids and PLEX are generally ineffective and can worsen clinical symptoms. Other immunosuppressants, such as rituximab, have been used with variable efficacy. Treatment options are limited and there remains a significant unmet clinical need for this disease, such as a selective C1s inhibitor in patients with MMN.

Intellectual Property

As of February 10, 2026, we wholly own the patent portfolio covering our C1s selective antibodies, including two issued U.S. patents, three pending PCT applications, three pending non-provisional applications in the United States and pending foreign patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, Mexico, New Zealand, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan and United Arab Emirates. Our rights under the patent applications in China, Hong Kong and Taiwan are licensed to Tenacia Biotechnology (Hong Kong) Co., Limited, as further described below. The applications are directed to, among other things, antibodies that selectively bind to active C1s and methods of using these antibodies, including methods of treating C1s mediated disorders, and pharmaceutical formulations comprising these antibodies. Patents issuing from these applications covering claseprubart would be expected to expire no earlier than 2043, subject to any disclaimers or extensions. We continue to develop additional pharmaceutical formulations for claseprubart and will file patent applications to protect the same as appropriate.

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 the company's stage of development, we currently do not have a commercial organization for the marketing, sales and distribution of pharmaceutical products.

We are currently a party to a license agreement with Tenacia Biotechnology (Hong Kong) Co., Limited ("Tenacia") for claseprubart, pursuant to which Tenacia has development and commercialization rights in the People's Republic of China, including Hong Kong, Macau, and Taiwan ("Greater China"). Additionally, we are party to a license agreement with Leads for DNTH212, pursuant to which Leads has development and commercialization rights in Greater China. Outside of Greater China, we currently hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates.

Manufacturing

We do not currently own or operate facilities for product manufacturing, testing, storage, and distribution. We contract with third parties for the manufacture and distribution of our product candidates. Because we rely on contract manufacturers, we employ personnel with extensive technical, manufacturing, analytical and quality experience. Our staff has strong knowledge and understanding of the extensive regulations that govern manufacturing, documentation, quality assurance, and quality control of drug supply that are required to support our regulatory filings.

In light of the recently enacted BIOSECURE Act, which prohibits federal agencies from entering into procurement contracts with an entity that uses biotechnology equipment or services from a biotechnology company of concern, we are strengthening our supply chain in the event that WuXi Biologics or one of our other manufacturers is impacted by the BIOSECURE Act or any similar legislation. We will closely monitor whether the BIOSECURE Act or new legislation may impact our future manufacturing strategy, and we will implement mitigations and supply chain redundancies, as needed. See the risk factor entitled *"We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture claseprubart, DNTH212 and any other product candidates, and we may rely on third parties to produce and process 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."*

Competition

We expect to face intense competition from other biopharmaceutical companies that are developing agents for the treatment of autoimmune and inflammatory diseases.

Generalized Myasthenia Gravis

There is significant competition in gMG. AstraZeneca's Soliris® and Ultomiris®, both I.V. C5 inhibitors, argenx's Vyvgart® (efgartigimod) and Vyvgart® Hytrulo, an I.V. and S.C. FcRn inhibitor, respectively, UCB S.A. Rystiggo® (rozanolixizumab), a weekly S.C. infusion FcRn inhibitor and Zilbrysq® (zilucoplan), a daily S.C. injection C5 inhibitor, Johnson and Johnson's Imaavy, an I.V. FcRn inhibitor, and Amgen's Uplizna, an I.V. CD19-directed cytolytic antibody, are approved by the FDA for the treatment of gMG in patients who are AChR positive. There are several other companies developing compounds in mid- to late-stage clinical development for the treatment of gMG using various approaches and modalities.

Chronic Inflammatory Demyelinating Polyneuropathy

There is significant competition in CIDP, including, among others, Pfizer's PANZYGA®, a 10% Immune Globulin Infusion (Human), CSL Behring's Hizentra®, a 20% Immune Globulin S.C. (Human), and Grifols Therapeutics' Gamunex-C®, a 10% Immune Globulin Injection (Human) and argenx's Vyvgart® Hytrulo, an FcRn inhibitor, approved by the FDA for CIDP. Sanofi is conducting two Phase 3 clinical trials of riliprubart (SAR445088), a C1s inhibitor. argenx's empasiprubart (ARGX-117), an I.V. C2 inhibitor that blocks both the classical and lectin pathways, is being evaluated in two Phase 3 clinical trials.

Multifocal Motor Neuropathy

Currently, Takeda's Gammagard Liquid, a 10% Immune Globulin Infusion (Human), is the only therapy approved by the FDA for MMN. However, there are few agents in development for MMN. argenx's empasiprubart (ARGX-117), an I.V. C2 inhibitor that blocks both the classical and lectin pathways, is in a Phase 3 clinical trial.

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, as well as academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors.

Accordingly, competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for any of our targeted indications by a competitor could render our product candidates non-competitive or obsolete, or reduce the demand for our product candidates before we can recover our development and commercialization expenses.

Collaboration, License and Services Agreements

Zenas BioPharma, Inc.

In September 2020, we entered into an option agreement (the "Zenas Option") with Zenas BioPharma, Inc. (formerly Zenas BioPharma Limited) ("Zenas"), under which we agreed to grant Zenas an exclusive option for an exclusive license under certain patents and know-how with respect to antibody sequences generated in a research program directed towards the research of monoclonal antibody antagonists targeting the human Complement C1s and C2 proteins, or another human protein (each, a "Research Program"). In consideration for the option grant, we were issued Zenas common stock equivalent to one percent of its shares outstanding prior to their Series A financing. On a Research Program-by-Research Program basis, Zenas also agreed to pay us a one-time payment of $1 million upon exercising the option to enter into a license agreement with respect to such Research Program. The option may only be exercised for up to two Research Programs.

On June 10, 2022, in connection with Zenas's exercise of the option, we entered into a license agreement with Zenas (the "Zenas License Agreement" and together with the Zenas Option, the "Zenas Agreements"), under which we granted Zenas an exclusive, sublicensable license under certain patents and know-how to research, develop, manufacture, and commercialize monoclonal antibody antagonists targeting the human Complement C1s protein (including the antibody sequence of claseprubart) and, if and when the option is exercised, the human Complement C2 protein, in Greater China (the "Territory"). As consideration for the license, we were eligible to receive: (i) development milestone payments of up to $11.0 million; (ii) an approximate $1.1 million payment for reimbursement of a portion of development costs we previously incurred; (iii) reimbursement of a portion of costs related to chemistry, manufacturing, and controls ("CMC") and expenses for the first antibody sequence through the manufacture of the first two batches of drug product; and (iv) reimbursement of a portion of certain non-CMC-related costs and expenses. Additionally, we were eligible to receive royalty payments based on a percentage of the annual net sales of the licensed products sold on a region-by-region basis in the Territory. The royalty rate varied from the mid-single digits to the low teens based on different tiers of annual net sales of the licensed products. Zenas was obligated to make royalty payments to us for the royalty term of the Zenas License Agreement.

Tenacia Biotechnology (Hong Kong) Co., Limited

On October 21, 2024, Zenas assigned the Zenas License Agreement to its affiliated entity, Zenas BioPharma (HK) Limited ("Zenas HK"). After the assignment, we entered into a novation agreement (the "Novation Agreement") with Zenas HK and Tenacia, and an amendment to the Zenas License Agreement, now with Tenacia (as amended, the "Tenacia License Agreement"), pursuant to which Tenacia replaced Zenas HK as a party to the Zenas Agreements, and certain economic terms under the Zenas License Agreement with respect to cost sharing and development milestones were amended.

Except as noted below, the economic terms of the Zenas License Agreement were unchanged when novated by the Novation Agreement and amended by the Tenacia License Agreement. The Tenacia Option (as described below) and Tenacia License Agreement are collectively referred to as the "Tenacia Agreements."

Under the Zenas License Agreement, Zenas also had the right to exercise an option with respect to a second antibody sequence, which is now held by Tenacia (the "Tenacia Option"). Pursuant to the Tenacia Option, if Tenacia exercises the option and pays us the option exercise fee related to the second antibody sequence, we will grant Tenacia an exclusive license to the sequences and licensed products under this second antibody sequence. The economic terms with respect to this second antibody sequence were unchanged by the amendment to the Zenas License Agreement.

As consideration for the license, which replaced the consideration of the Zenas License Agreement with respect to the first antibody sequence, we are eligible to receive (i) a $2.5 million upfront payment, which was paid to us by Tenacia in October 2024 upon execution of the Tenacia License Agreement; (ii) reimbursement of a portion of certain clinical costs; (iii) development milestones totaling up to $15.0 million; and (iv) royalties on net sales ranging from the mid-single digits to the low teen percentages. Tenacia is also responsible for paying local development costs in Greater China and a portion of central development costs based on the number of patients enrolled from China in our global Phase 3 studies. Tenacia is obligated to make royalty payments to us for the royalty term of the Tenacia License Agreement.

Biologics Master Services Agreement — WuXi Biologics (Hong Kong) Limited

On March 22, 2021, we entered into a biologics master services agreement (the "WuXi Biologics MSA") with WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"). The WuXi Biologics MSA governs development activities and good manufacturing practices ("GMP") manufacturing and testing for claseprubart, as well as potential future candidates, on a work order basis. Under the WuXi Biologics MSA, we are obligated to pay WuXi Biologics a service fee and all non-cancellable obligations, including potential milestone payments, in the amount specified in each work order associated with the agreement for the provision of services.

The WuXi Biologics MSA terminates on the later of (i) March 22, 2028 or (ii) the completion of services under all work orders executed by the parties prior to March 22, 2026, unless terminated earlier. The term of each work order terminates upon completion of the services under such work order, unless terminated earlier. We can terminate the WuXi Biologics MSA or any work order at any time upon 30 days' prior written notice and immediately upon written notice if WuXi Biologics fails to obtain or maintain required material governmental licenses or approvals. Either party may terminate a work order (i) at any time upon six months' prior notice with reasonable cause, provided however that if WuXi Biologics terminates a work order in such manner, no termination or cancellation fees shall be paid by us and (ii) immediately for cause upon (a) the other party's material breach that remains uncured for 30 days after notice of such breach, (b) the other party's bankruptcy or (c) a force majeure event that prevents performance for a period of at least 90 days.

Cell Line License Agreement — WuXi Biologics (Hong Kong) Limited

On March 22, 2021, we entered into a cell line license agreement (the "Cell Line License Agreement") with WuXi Biologics. Under the Cell Line License Agreement, we received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials and media and feeds to make, have made, use, sell and import certain drug products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products").

In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of $150,000. Additionally, if we manufacture all of our commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer (the "Royalty"). If we manufacture part of our commercial supplies of the WuXi Biologics Licensed Products with WuXi Biologics or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon six months' prior written notice and our payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

License Agreement with Nanjing Leads Biolabs Co. Ltd.

On October 16, 2025, we entered into a license and collaboration agreement (the "Leads License Agreement") with Leads, pursuant to which we received a royalty-bearing, exclusive license outside of Greater China from Leads to develop, manufacture, commercialize, or otherwise exploit DNTH212, a bifunctional fusion protein being developed in China by Leads as LBL-047. We also obtained certain non-exclusive rights to perform development and manufacturing activities in Greater China to support DNTH212 outside of Greater China. DNTH212 is an investigational, extended half-life bifunctional fusion protein targeting plasmacytoid dendritic cell BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. On December 23, 2025, we and Leads jointly announced the initiation of a Phase 1 clinical trial for LBL-047 (DNTH212).

Under the terms of the Leads License Agreement, we will pay Leads up to $38.0 million, comprised of $30.0 million in upfront and near-term milestone payments, plus an additional $8.0 million milestone, payable in cash or shares of our common stock at our election, upon the initiation of a Dianthus-led Phase 1 study, for exclusive rights to develop and commercialize DNTH212 globally outside of Greater China. Leads will also be eligible to receive up to $962.0 million in development and regulatory approval milestones across three key geographies and sales-based milestones across five indications, as well as tiered royalties from mid-single digits up to a low double-digit on ex-Greater China net sales. During the three months ended December 31, 2025, we paid Leads $25.0 million in upfront and near-term milestone payments. In addition, we recorded $5.0 million of milestone payments within the accounts payable line item on our consolidated balance sheet as of December 31, 2025.

The Leads License Agreement will remain in effect on a country-by-country and product-by-product basis until expiration of the applicable royalty term, unless earlier terminated. Each party has customary termination rights, including for uncured material breach, insolvency, patent challenge, or, in our case, for convenience.

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 third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Generally, before a new therapeutic product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity and potency, or a small molecule drug candidate's quality, safety and efficacy, 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.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications from the sponsor, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions,

fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Biologics Regulation

In the United States, biological products 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") regulation;
- submission to the FDA of an Investigational New Drug application ("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 ("cGMP");
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations and current Good Clinical Practices ("cGCP") 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 BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- 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 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 cGCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for a particular indication(s) 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. In April 2025, the FDA published a roadmap to reduce animal testing in preclinical safety studies, including those required in INDs, with scientifically validated new approach methodologies. 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 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.

In addition to the IND submission process, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or

synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment and such review may result in some delay before initiation of a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study 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 study 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 study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with cGCP requirements, 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 study through an onsite inspection if the FDA deems such inspection necessary. The cGCP 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.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted, except that the PREA will apply to an original BLA for a new active ingredient that is orphan-designated if the biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

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 ten 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 assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCPs. 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 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.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and data demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. 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. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if there is evidence it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

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

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product candidate. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same approved use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the same use or indication for which the already-approved or licensed product was approved or licensed. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

There is some uncertainty with respect to the FDA's interpretation of the scope of orphan drug exclusivity. Historically, exclusivity was specific to the orphan indication for which the drug was approved. As a result, the scope of exclusivity was interpreted as preventing approval of a competing product. However, in 2021, the federal court in *Catalyst Pharmaceuticals, Inc. v. Becerra* suggested that orphan drug exclusivity covers the full scope of the orphan-designated "disease or condition" regardless of whether a drug obtained approval for a narrower use.

Regulation of Combination Products

Certain therapeutic products are comprised of multiple components, such as drug components, biologic components, and device components, that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug/biologic-device combination product is attributable to the drug or biological product, the FDA center responsible for premarket review of the drug or biological product would have primary jurisdiction for the combination product. The FDA has also established the Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute. A combination product with a primary mode of action attributable to the drug or biologic component generally would be reviewed and approved pursuant to the drug or biologic approval processes set forth in the FDCA. In reviewing the new drug application or BLA for such a product, however, FDA reviewers would consult with their counterparts in the FDA's Center for Devices and Radiological Health to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products with both device and drug/biologic components are subject to cGMP requirements applicable to both drugs and devices, including the Quality Management System Regulation applicable to medical devices.

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 the 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 agencies, and are subject to periodic unannounced inspections by the FDA and certain

state agencies 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 agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, 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 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 study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. 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 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 twelve 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. 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 new 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, the latter of the effective date of an IND and issue date of the patent for which extension is sought, and 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 U.S.

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. 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 commercial activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, for persons in a position to refer or recommend federally reimbursable healthcare business that may be alleged to be intended to induce prescribing, purchasing or recommending, and may be subject to scrutiny if they do not qualify for an exception or regulatory safe harbor. Qualifying for a statutory exception or regulatory safe harbor requires satisfying all of the criteria for the 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, but it does increase the risk of regulatory scrutiny. Ultimately, 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.

The FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibits, 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.

We are also subject to federal price reporting laws and federal consumer protection and unfair competition laws. Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

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 and 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 Act ("HITECH"), and their respective implementing regulations impose data 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 ("PHI") for or on behalf of such covered entities. These requirements imposed by HIPAA and HITECH on covered entities and business associates include entering into agreements that require business associates protect 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, that 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 ("CCPA"), as amended by the California Privacy Rights Act of 2020 ("CPRA"), 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/CPRA 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, 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 and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. The CCPA and numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, exempt PHI that is subject to HIPAA; and others exempt covered entities and business associates 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.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. 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. Additionally, our use of artificial intelligence and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence/machine learning, controlling for data bias, and anti-discrimination.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as

Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

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. Factors payors consider in determining reimbursement are based on whether the product is: a covered benefit under its health plan; safe, effective and medically necessary; cost-effective; and neither experimental nor investigational.

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.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. 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 29, 2023, HHS announced the list of the first ten drugs subject to price negotiations. These price negotiations occurred in 2024. In January 2025, CMS announced a list of 15 additional 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.

In addition, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union ("EU") provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

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 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.

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 May 2025, the Trump Administration renewed the idea of international reference pricing through an executive order entitled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," which, among other things, directs the HHS and other agencies to communicate most-favored-nation ("MFN") price targets to pharmaceutical manufacturers to bring prices for U.S. patients in line with comparably developed nations and to facilitate direct-to-consumer purchasing programs. The HHS subsequently issued guidance indicating the MFN target price will be the lowest price paid in an Organisation for Economic Co-operation and Development country with a gross domestic product ("GDP") per capita of at least 60% of the U.S. GDP per capital. In addition, in December 2025, CMS proposed new drug payment models to lower drug prices for Medicare beneficiaries; under the models, CMS would explore potential adjustments to Medicare drug inflation rebate calculations by comparison to international drug pricing information. It is currently unclear whether and to what extent these measures will be implemented and what impact any such implementation would have on our business.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect government authorities 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.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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 processing of personal data, including health-related personal data in the European Economic Area ("EEA") is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 ("GDPR") and related data protection laws in individual EEA countries. In the United Kingdom ("UK"), the processing of personal data is mainly governed by the GDPR as incorporated into UK law pursuant to the European Union (Withdrawal) Act 2018 (the "UK GDPR"). The GDPR and UK GDPR impose a number of strict obligations and requirements for the processing, including collecting, analyzing and transferring, of personal data of individuals in the EEA or in the UK, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR and the UK GDPR include 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 personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and obligations relating to the security and confidentiality of the personal data. EEA countries may also impose additional requirements in relation to the processing of 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 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 the appropriate safeguards, data exporters, with the assistance of the date importers, 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 safeguards 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 the EEA to the UK, based on the EC's adequacy decision of June 28, 2021 and subsequent renewals, personal data may continue to flow freely from the EEA to the UK on the basis that the UK is deemed to provide an adequate level of data protection until December 27, 2031. The adequacy decisions will automatically expire unless renewed.

With respect to transfers from the UK to other countries, these transfers are also subject to specific transfer rules under the UK regime. These UK international transfer rules broadly mirror the EU 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 ("UK Addendum") and a document setting out transitional provisions. The IDTA and UK Addendum came into force on March 21, 2022 and are the primary UK-approved mechanisms for putting in place appropriate safeguards for UK restricted transfers, subject to transitional arrangements for legacy SCCs. Regarding transfers from the UK to the EEA, the UK Information Commissioner's Office ("ICO") guidance indicates that organizations do not need new arrangements. 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 UK Extension to the EU-US Data Privacy Framework, 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 recipient is a United States organization certified to the EU-US Data Privacy Framework and participating in the UK Extension to the EU-US Data Privacy Framework.

Failure to comply with the requirements of the GDPR or UK GDPR and the related national data protection laws of the EEA countries may result in significant monetary fines for noncompliance of up to €20.0 million or £17.5 million (as applicable), 4% of the total worldwide annual turnover (for higher-tier infringements). This is enforced by ICO and is entirely separate from fines under EU GDPR. In addition, violations of national laws can trigger additional administrative penalties, investigations, corrective orders, temporary or definitive bans, and, in some jurisdictions, 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 EEA countries 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 EEA.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including public disclosure obligations provided in the EU Clinical Trials Regulation No. 536/2014 ("CTR"), European Medical 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.

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 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 EU/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 CTR, a sponsor is able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the "Clinical Trials Information System" or "CTIS"). One national regulatory authority (the reporting EU member state proposed by the applicant) will take the lead in validating and evaluating the application, 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, including a layperson's summary. 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. As of January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive were required to comply with the CTR and have to be transitioned to CTIS.

Under the CTR, national laws, regulations, and the applicable cGCP 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 ("ICH") guidelines on Good Clinical Practice and the ethical principles that have their origin in the Declaration of Helsinki. 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 National Competent Authority and to the Ethics Committees of the EU member state where they occur.

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 an MA. To obtain an MA of a drug under EU 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 granted by the Medicines and Healthcare Products Regulatory Agency ("MHRA") under the Human Medicines Regulations 2012 (SI 2012/1916), as amended. MA applications are submitted electronically via the MHRA Submissions Portal. Under the MHRA's national assessment procedure, the MHRA generally aims to reach a decision within 210 "clock-on" days, excluding any "clock-stops" while the applicant prepares responses to the MHRA questions.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Recognition 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 specific 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 (AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune diseases and other immune dysfunctions, and viral diseases). For medicinal products containing a new active substance not yet authorized in 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 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 the 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 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. Following Windsor Framework changes, which became effective January 1, 2025, EU authorizations are no longer valid in Northern Ireland and centrally authorized products are instead authorized by the MHRA under UK-wide marketing authorizations; existing licenses for product licensed by the MHRA that covers Great Britain only become geographically valid UK-wide while retaining their license number/prefix.

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 member states of the EU, 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 ("ATMPs") 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 is valid for one year and 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 an MA or placing the product on the market. New Chemical Entities ("NCE") 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 pre-clinical 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 EU's regulatory authorities to include a 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 and negotiations are still ongoing. The timing for finalization of these negotiations and entry into force are unclear.

The current drafts envisage a shortening of the periods of data exclusivity from eight to six years (with transferrable vouchers for an additional year of market protection as an incentive for the development of new antibiotics), earlier regulatory guidance and extension of market exclusivity for orphan medicines (depending on certain conditions), four-year data exclusivity for additional indications of existing products, and rules governing the availability of products (including shortage prevention plans and some supply obligations for manufacturers).

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. The EMA grants orphan drug designation if the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the EU (prevalence criterion). In addition, Orphan Drug Designation can be granted if, for economic reasons, the medicinal product would be unlikely to be developed without incentives and if there is no other satisfactory method approved in the EU of diagnosing, preventing, or treating the condition, or if such a method exists, the proposed medicinal product is a significant benefit to patients affected by the condition. An application for orphan drug designation (which is not a MA, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an application for MA of the medicinal product is submitted. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the MA is submitted, and sponsors must submit an annual report to EMA summarizing the status of development of the medicine. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Designated orphan medicines are eligible for conditional MA.

The EMA's Committee for Orphan Medicinal Products reassesses the orphan drug designation of a product in parallel with the review for a MA; for a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of MA review by the EMA and approval by the EC. Additionally, any MA granted for an orphan medicinal product must only cover the therapeutic indication(s) that are covered by the orphan drug designation. Upon the grant of an MA, orphan drug designation provides up to ten years of market exclusivity in the orphan indication.

During the 10-year period of market exclusivity, with a limited number of exceptions, the regulatory authorities of the EU Member States and the EMA may not accept applications for MA, accept an application to extend an existing MA or grant MA for other similar medicinal products for the same therapeutic indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan medicinal product can also obtain an additional two years of market exclusivity for an orphan-designated condition when the results of specific studies are reflected in the Summary of Product Characteristics ("SmPC") addressing the pediatric population and completed in accordance with a fully compliant Pediatric Investigation Plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation (i.e., the condition prevalence or financial returns criteria under Article 3 of Regulation (EC) No. 141/2000 on orphan medicinal products). When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a MA may be granted to a "similar medicinal product" (orphan or not) for the same or overlapping indication subject to certain requirements.

In the UK, following the post-Brexit transition period, a system for incentivizing the development of orphan medicines was introduced. Overall, the requirements for orphan designation largely replicate the requirements in the EU and the benefit of market exclusivity has been retained. Products with an orphan designation in the EU can be considered for an orphan MA in Great Britain and, marketing authorizations granted for products that fulfill UK orphan criteria are valid UK-wide regardless of whether there is an EU orphan designation. The MHRA will review applications for orphan designation at the time of an MA, and will offer incentives, such as market exclusivity and full or partial refunds for MA fees to encourage the development of medicines in rare diseases. Separately, the MHRA has stated that it is considering updating its licensing framework for orphan medicines, with a draft framework expected by spring 2026.

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a 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 a 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. From January 1, 2025, EU pediatric requirements are addressed via Windsor Framework categorization: for Category 2 products, both UK and EU pediatric requirements apply, and an EU-agreed PIP must also be in place (unless waived).

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 MAA 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 MAs. 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 an 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 IV 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 EU 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 ("EU GMP"). These requirements include compliance with EU GMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. 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 EU 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 EU GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with EU GMP.

On October 27, 2025, the Council of the EU approved a framework for compulsory licensing of crisis-relevant products (including medicinal products) in crisis situations. While the proposal focuses on voluntary agreements with intellectual property rights holders, it includes rules on compulsory licensing as a measure of last resort upon activation/declaration of a crisis or emergency mode. The European Parliament has not yet voted on the proposal.

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 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 MA 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 EU 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 its 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. 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 EU. 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 become 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 ten 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 ("TCA"), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP issued 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 (the "MMDA") to enable the UK's 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.

For other countries outside of the EU, 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 cGCP 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.

Additional Regulation

In addition to the foregoing, local, state and federal laws regarding such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and waste generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous or biohazardous substances, we could be liable for damages, environmental remediation, and/or governmental fines. We believe that we are in material compliance with applicable environmental laws and occupational health and safety laws that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees and Human Capital Resources

As of March 4, 2026, we had 92 employees, all of whom were employed full time and 66 of whom were engaged in research and development activities. 25 of our employees hold Ph.D. or M.D. degrees. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Available Information

Our corporate website is *www.dianthustx.com*, and our investor relations website is *investor.dianthustx.com*. Copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports are available free of charge on our investor relations website as soon as reasonably practicable after we file or furnish such material electronically with the SEC. The SEC also maintains a website that contains our SEC filings at *www.sec.gov*. We do not intend for the information contained in, or available through, our website to be part of this Annual Report on Form 10-K. Similarly, please note that any Internet addresses provided in this Annual Report on Form 10-K are for informational purposes only and are not intended to be hyperlinks. Accordingly, no information found and/or provided at such Internet addresses is intended or deemed to be incorporated by reference herein.

Item 1A. Risk Factors.

In evaluating our business, you should carefully consider the following discussion of material risks, events and uncertainties that make an investment in us speculative or risky in addition to the other information included in this Annual Report on Form 10-K. A manifestation of any of the following risks and uncertainties could, in circumstances we may or may not be able to accurately predict, materially and adversely affect our business and operations, growth, reputation, prospects, operating and financial results, financial condition, cash flows, liquidity and stock price. Some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future. The risks and uncertainties described below are not the only ones we face. Our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our business. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

SUMMARY OF RISK FACTORS

- We have a limited operating history, have not completed any late-stage clinical trials and have no products approved for commercial sale, which may make it difficult for you 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 or eliminate clinical trials, product development programs or future commercialization efforts;

- We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable;

- We face competition from entities that have developed or may develop programs for the diseases we plan to address with claseprubart, DNTH212 or other product candidates;

- Claseprubart, DNTH212 and our other programs are in varying stages of development and may fail in development or suffer delays that materially and adversely affect their commercial 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 our most advanced product candidate, claseprubart, and our anticipated clinical trials of such candidate may not be successful;

- If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of claseprubart, DNTH212 or any other product candidates may be delayed and our expenses may increase and our stock price may decline;

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

- 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;

- If we encounter difficulties enrolling patients in our current or future clinical trials, our clinical development activities could be delayed or otherwise adversely affected;

- We have collaborations with third parties, including our existing license and development collaborations with Tenacia and Leads. If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected;

- 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;

- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage;

- 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, such product candidates, and our ability to generate revenue will be materially impaired;

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

- Our product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated;

- The market price of our common stock may be volatile, the market price of our common stock may drop, and an active trading market for our common stock may not be sustained and our stockholders may not be able to sell their shares of common stock for a profit, if at all;

- Provisions in our certificate of incorporation and bylaws and under Delaware law could make an acquisition of us more difficult and may discourage any takeover attempts which stockholders may consider favorable, and may lead to entrenchment of management; and

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

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

We have a limited operating history, have not completed any late-stage clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biotechnology company with limited operating history that has incurred significant operating losses. We have utilized substantially all of our resources conducting research and development activities (including with respect to our claseprubart program), business planning, developing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities. We have limited experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our current and future clinical trials will begin or be completed on time, if at all. In addition, while we are conducting two Phase 2 clinical trials and one Phase 3 clinical trial with claseprubart in patients with gMG, MMN and CIDP, respectively, we have not completed a late-stage clinical trial (including Phase 3 or other pivotal clinical trials) for any product candidate, have no products approved for commercial sale and have not yet demonstrated our ability to successfully complete late-stage clinical trials, obtain regulatory or marketing 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. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made 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 continue the transition 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 or eliminate clinical trials, product development programs or future commercialization efforts.

Developing biotechnology products is a very long, time-consuming, expensive and uncertain process that takes years to complete. Since our inception in 2019, we historically have funded our operations with proceeds from the sale of capital stock and have incurred significant recurring losses, including net losses of $162.3 million and $85.0 million for the years ended December 31, 2025 and 2024, respectively.

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct multiple Phase 2 and Phase 3 clinical trials, prepare for additional IND and other regulatory filings, potentially initiate additional clinical trials, and continue to research, develop and conduct preclinical studies of our other potential product candidates. In addition, if we obtain regulatory approval for any product candidate for commercial sale, including claseprubart and DNTH212, we anticipate incurring significant commercialization expenses related to product manufacturing, marketing, sales 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 those that we currently anticipate. Because the design and outcome of our current and future 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 product candidate we develop. Our future capital requirements depend on many factors, including factors that are not within our control.

We will also continue to incur additional costs associated with operating as a public company that we did not incur as a private company. Accordingly, we will require substantial additional funding to continue our operations. Based on our current operating plan, we believe that our existing cash, cash equivalents and investments should be sufficient to fund our operations into 2028. This estimate is based on assumptions that may prove to be materially wrong, including assumptions regarding the timing, cost and success of our clinical trials and other development activities, and we could use our available capital resources sooner than we currently expect. Our existing cash, cash equivalents and investments may be used more quickly than anticipated due to changes in our development plans, regulatory requirements, manufacturing needs or other factors. Our future capital requirements will depend on many factors, including:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we pursue;
- our ability to establish an acceptable safety profile with IND-enabling toxicology studies to enable clinical trials;
- successful patient enrollment in, and the initiation and completion of, larger and later-stage clinical trials;
- per subject trial costs;
- the number, extent and scope of trials required for regulatory approval;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects in clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the extent to which we encounter any serious adverse events in our clinical trials;
- the timing of receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;

- the extent to which we establish collaborations, strategic partnerships, or other strategic arrangements with third parties, if any, and the performance of any such third party;

- hiring and retaining research and development personnel;

- our arrangements with our contract development and manufacturing organizations ("CDMOs"), and contract research organizations ("CROs");

- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercial launch;

- the impact of any business interruptions to our operations or to those of the third parties with whom we work; and

- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

We do not have any committed external sources of funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, including through our effective shelf registration statement or ATM program, debt financings, collaborations and licensing arrangements or other sources. 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. For example, in September 2025, we completed an underwritten public offering of our common stock in which we issued 7,627,879 shares of common stock and pre-funded warrants to purchase up to 1,112,121 shares of common stock to certain institutional and accredited investors, which resulted in dilution to our stockholders that did not participate in the offering, and, to the extent that the pre-funded warrants are exercised, our stockholders' ownership interests will be further diluted. As of the date of this filing, we have sold 2,626,834 shares of our common stock under our ATM program.

If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to product development programs, 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, including resulting from public health crises, the conflict between Russia and Ukraine or the conflicts in the Middle East, over which we may have no or little control. 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 clinical trials, product development programs or future commercialization efforts.

We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable.

Investment in biotechnology product development is a highly speculative undertaking and entails substantial upfront expenditures and significant risks that any program will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, we have not generated any revenue from product sales to date, and we 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 clinical development and obtain regulatory approval of, and then successfully commercialize, at least one product candidate. We may never succeed in these activities and, even if we do, may never generate product revenue or revenues that are significant or large enough to achieve profitability. If we are unable to 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 inception. Our net losses were $162.3 million and $85.0 million for the years ended December 31, 2025 and 2024, respectively. We expect to continue to incur significant 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 programs through preclinical and clinical development, including expansion into additional indications;

- seek to identify additional programs and additional product candidates;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- seek regulatory and marketing approvals for product candidates;
- seek to identify, establish and maintain additional collaborations and license agreements;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drug products for which we may obtain marketing approval, either by ourselves or in collaboration with others;
- seek to generate revenue from commercial sales of products for which we receive marketing approval;
- hire additional personnel including research and development, clinical and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support product development;
- acquire or in-license products, intellectual property and technologies;
- develop and manufacture our clinical supplies and access commercial-scale cGMP capacity and capabilities through third-parties or our own manufacturing facility; and
- continue to operate as a public company.

In addition, our expenses will increase if, among other things, we are required by the FDA or other regulatory authorities to perform 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 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 marketing approval for, and are successful in commercializing, one or more product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional programs 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 the value of our company 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 company could also cause you to lose all or part of your investment.

Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. There is no assurance that adequate additional financing needed to allow us to continue as a going concern will be available to us on acceptable terms, or at all. The perception that we may not be able to continue as a going concern may cause others to choose not to do business with us due to concerns about our ability to meet our contractual obligations.

Risks Related to Discovery, Development and Commercialization

We face competition from entities that have developed or may develop programs for the diseases we plan to address with claseprubart, DNTH212 or other product candidates.

The development and commercialization of drugs is highly competitive. If approved, claseprubart, DNTH212 or our other product candidates 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, as well as 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 marketing approved products than we do. 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, medical and management personnel, establishing clinical trial sites, patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, claseprubart, DNTH212 or our other product candidates.

Our competitors have developed, are developing or may develop programs and processes competitive with claseprubart, DNTH212 or our other product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. 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 any products we may develop, if any, or if competitors develop competing products or if biosimilars enter the market more quickly than we are able to, if at all, and are able to gain market acceptance. See the section titled "*Business — Competition*" for a more detailed description of our competitors and the factors that may affect the success of the products that we develop.

In addition, because of the competitive landscape for autoimmune and inflammatory indications, we may also face competition for 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 programs that are under development for the same indications as our programs. An increase in the number of approved products for the indications we are targeting with our product candidates may further exacerbate this competition. Our inability to enroll a sufficient number of patients could, among other things, delay our development timeline, which may further harm our competitive position.

Claseprubart, DNTH212 and our other programs are in varying stages of development and may fail in development or suffer delays that materially and adversely affect their commercial 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 products on the market and claseprubart, DNTH212 and our other programs are in varying stages of development. As a result, we expect it will be many years before we commercialize a product candidate, if any. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, claseprubart, DNTH212 or other product candidates either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any product candidates. We have limited experience as a company in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or comparable foreign regulatory authorities. We have also 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 product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of such product candidates.

We or our collaborators may experience delays in initiating or completing clinical trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that we could conduct that could

delay or prevent our ability to receive marketing approval or commercialize claseprubart, DNTH212 or any other product candidates, including:

- IRBs, the FDA or other regulators, or ethics committees 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 CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, 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 product development programs;
- the number of subjects required for clinical trials of any of our product candidates may be larger than we anticipate, especially if regulatory bodies require completion of non-inferiority or superiority trials, 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 drop out of the trial, which may require that we add new clinical trial sites or investigators;
- 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 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 complete a given clinical trial;
- our inability to manufacture sufficient quantities of our product candidates for use in clinical trials, or delays in manufacturing or distribution;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate 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 additional 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 or similar application and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that 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 equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the EU.

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, claseprubart, DNTH212 or any other product candidates. We or our current or future collaborators' inability to complete development of, or commercialize, claseprubart, DNTH212 or any other product candidates or significant delays in doing so, could have a material and adverse effect on our business, financial condition, results of operations, cash flows, and prospects.

We are substantially dependent on the success of our most advanced product candidate, claseprubart, and our anticipated clinical trials of such candidate may not be successful.

Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our most advanced product candidate, claseprubart. We are investing a majority of our efforts and financial resources into the research and development of this candidate. We are executing global Phase 2 clinical trials of claseprubart in gMG and MMN and a global Phase 3 clinical trial of claseprubart in CIDP. The success of claseprubart may depend on having a potentially differentiated safety profile, comparable efficacy profile and a more favorable dosing schedule (i.e., less frequent dosing) and more patient-friendly administration (i.e., S.C. self-administration using a pen or other prefilled device) to products currently approved or in development for the indications we are pursuing or may in the future pursue.

Claseprubart will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales, if any. We are not permitted to market or promote this product candidate, or any other product candidates, before we receive marketing approval from the FDA and/or comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of claseprubart 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 and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot guarantee that we will ever be able to generate revenue through the sale of this product candidate, even if approved. If we are not successful in commercializing claseprubart, or we are significantly delayed in doing so, our business will be materially harmed.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of claseprubart, DNTH212 or any other product candidates may be delayed and our expenses may increase and, as a result, our stock price may 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, preclinical studies and clinical trials and the submission of regulatory filings. We have publicly announced and may in the future 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 some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of claseprubart, DNTH212 or any other product candidates may be delayed or never achieved and, as a result, 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.

Our approach to the discovery and development of product candidates 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 claseprubart leverages clinically validated mechanisms of action and incorporates advanced antibody engineering properties designed to overcome limitations of existing therapies. Claseprubart is purposefully designed to improve upon currently approved products and existing product candidates. However, the scientific research that forms the basis of our efforts to develop a product candidate using only the classical complement pathway and half-life extension technologies is ongoing and may not result in viable product candidates. The long-term safety and efficacy of these technologies and exposure profile of claseprubart compared to currently approved products is unknown.

We may ultimately discover that our technologies for our specific targets and indications and claseprubart, DNTH212 or any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. We currently have only preclinical data and data from our Phase 1 and Phase 2 clinical trials of claseprubart and the same results may not be seen in patients in our later stage trials. In addition, product candidates using technologies may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. This technology and claseprubart, DNTH212 or 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.

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 activities fail to identify novel targets or technologies for drug discovery, or such targets 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 claseprubart, DNTH212 or any other product candidates. 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 claseprubart, DNTH212 or any other product candidates prove to be ineffective, unsafe or commercially unviable, our product candidates and pipeline may have little, if any, value, which may have a material and adverse effect on our business, financial condition, results of operations, cash flows, and prospects.

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.

Before obtaining marketing 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 non-human primates ("NHPs") to conduct certain preclinical studies that we are required to complete prior to submitting an IND or foreign equivalent, initiating clinical development or submitting a marketing application. During the past several years, there was a global shortage of NHPs available for drug development. If similar shortages occur in the future, the cost of obtaining NHPs for our future preclinical studies may increase significantly and the availability of NHPs may decrease. A shortage could result in delays to our development timelines.

Additionally, our ongoing claseprubart Phase 3 clinical trial in CIDP contains an "open-label" trial design for Part A of the trial before patients are randomized into Part B, a double-blind placebo-controlled treatment period. We may also initiate future open-label trials with claseprubart, DNTH212 or other product candidates. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial, including with respect to Part A of our claseprubart Phase 3 clinical trial, may not be predictive of future clinical trial results, including with respect to Part B of our claseprubart Phase 3 clinical trial in CIDP, or with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Furthermore, a failure of one or more clinical trials can occur at any stage of testing. 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 marketing approval of their product candidates. In addition, we expect to rely on patients to provide feedback on measures, 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 plan. If the FDA or comparable 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, a Clinical Trial Application ("CTA"), or similar 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 at each clinical trial site; difficulties in patient enrollment in our clinical trials for a variety of reasons; 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 cGCPs or regulations or applicable regulations or regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance 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 larger-scale facilities operated by third-party CDMOs and delays or failure by our CDMOs 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 placed on clinical hold, suspended or terminated by us, the FDA, the competent authorities of the EU, member states or other regulatory authorities or the IRBs or ethics committees of the institutions in which such trials are being conducted, if a clinical trial is recommended for suspension or termination by the data safety monitoring board or equivalent body for such trial, or on account of changes to federal, state, or local laws. If we are required to conduct additional clinical trials or other testing of claseprubart, DNTH212 or any other product candidates beyond those that we contemplate, if we unable to successfully complete clinical trials of claseprubart, DNTH212 or any other 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 may be adversely affected and we may incur significant additional costs.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

A key part of our business strategy is to identify and develop additional product candidates. Our preclinical research and clinical trials may initially show promise in identifying potential product candidates yet fail to yield product candidates for clinical development for a number of reasons. For example, we may be unable to identify or design additional product candidates with the pharmacological and pharmacokinetic drug properties that we desire, including, but not limited to, extended half-life, acceptable safety profile or the potential for the product candidate to be delivered in a convenient formulation. Research programs to identify new product candidates require substantial technical, financial, and human resources. If we are unable to identify additional product candidates for preclinical and clinical development, we may not be able to successfully implement our business strategy, and may have to delay, reduce the scope of, suspend or eliminate one or more of our product candidates, clinical trials or future commercialization efforts, which would negatively impact our financial condition.

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

We may experience difficulties in patient enrollment in our 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 its conclusion. The enrollment of patients in current or future trials for claseprubart, DNTH212 or any other product candidates will depend on many factors, including 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. Additionally, the number of patients required for clinical trials of claseprubart, DNTH212 or any other product candidates may be larger than we anticipate, especially if regulatory bodies require the completion of non-inferiority or superiority trials. Even if we are able to enroll a sufficient number of patients for our 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 marketing approvals and increased development costs or may require us to abandon one or more clinical trials altogether.

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

We have publicly disclosed and may in the future publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and 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 top-line 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 top-line data should be viewed with caution until the final data is available. We have publicly disclosed and may in the future 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 agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of a particular product candidate and us in general. 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. If the preliminary, top-line 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, claseprubart, DNTH212 or any other product candidate may be harmed, which could harm our business, financial condition, results of operations, cash flows, and prospects.

Our current or 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 claseprubart, DNTH212 or any of our other product candidates or result in potential product liability claims.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While our completed preclinical studies in NHPs and our Phase 1 clinical trial in humans have not shown any such characteristics, we cannot assure you that such characteristics will not be observed in our or our partner's current or future clinical trials with claseprubart or DNTH212. If significant adverse events or other side effects are observed in any of our or our partner's current or future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, patients may be harmed, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether, including claseprubart or DNTH212. We, the FDA, EU member states, or other applicable regulatory authorities, or an IRB or ethics committee, may suspend any clinical trials of claseprubart, DNTH212 or any other product candidates 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 that do not present themselves in clinical trials in humans. Even if the side effects do not preclude a product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of an approved product due to its tolerability versus other therapies. In addition, a half-life extension could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Treatment-emergent adverse events 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 claseprubart, DNTH212 or any other product candidates, may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from claseprubart, DNTH212 or any other 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, cash flows, and prospects significantly.

In addition, even if we successfully advance claseprubart, DNTH212 or any other product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to such product candidates. As a result, we cannot be assured that adverse effects of claseprubart, DNTH212 or any other product candidates will not be uncovered when a significantly larger number of patients are exposed to such product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidate over a multi-year period.

If any of the foregoing events occur or if claseprubart, DNTH212 or any other product candidates prove to be unsafe, our entire pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations, cash flows, and prospects.

We may expend our limited resources to pursue a particular product candidate, such as claseprubart, and fail to capitalize on candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus our research and development efforts on certain selected product candidates. For example, we are initially focused on our most advanced product candidate, claseprubart. As a result, we may forgo or delay pursuit of opportunities with other potential candidates that may 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 programs 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 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 candidate.

Even if regulatory approval is obtained, any approved products resulting from claseprubart, DNTH212 or any other product candidate 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 claseprubart, DNTH212 or any other product candidates, they may not gain market acceptance among physicians, 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. There are several approved products and product candidates in later stages of development for the treatment of gMG, MMN and CIDP. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic with a target product profile such as that of claseprubart or for its targeted indications, 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 product candidates developed by us or our existing or future collaborators. An extended half-life may make it more difficult for patients to change treatments and there is a perception that half-life extension could exacerbate side effects, each of which may adversely affect our ability to gain market acceptance. Market acceptance of claseprubart, DNTH212 or any other product candidates will depend on many factors, including factors that are not within our control.

Sales of 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 any of our approved products are safe, therapeutically effective, cost effective or less burdensome as compared with competing treatments. If claseprubart, DNTH212 or any other 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 and may not become or remain profitable.

We have never commercialized a product candidate and may lack the necessary expertise, personnel and resources to successfully commercialize a product candidate on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, which we may license to others, we may rely on the assistance and guidance of those collaborators. For a product candidate for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. Factors that may affect our ability to commercialize a product candidate, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidate, ensuring regulatory compliance of our employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of a product candidate upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of an approved product candidate, we may not generate revenues from them or be able to reach or sustain profitability.

We have never completed any late-stage clinical trials and we may not be able to file an IND, a CTA or other applications for regulatory approval to commence additional clinical trials on the timelines we expect, and, even if we are able to, the FDA, EMA or comparable foreign regulatory authorities may not permit us to proceed and could also suspend/terminate the trial after it has been initiated.

We are early in our development efforts and will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA, EMA, or comparable foreign regulatory approval to market our product candidates. Carrying out clinical trials and the submission of a successful IND or CTA is a complicated process. As an organization, we have limited experience in preparing, submitting and prosecuting regulatory filings. We may experience manufacturing delays or other delays with IND- or CTA-enabling studies, including with suppliers, study sites, or third-party contractors and vendors on whom we depend. Moreover, we cannot be sure that submission of an IND or a CTA or submission of a trial to an IND or a CTA will result in the FDA or EMA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that lead us to suspend or terminate clinical trials. For example, upon submission or after approval of an IND or CTA for a clinical trial of claseprubart or DNTH212, the FDA, EMA or comparable foreign regulatory authorities may recommend or require changes to our protocol or study designs that could adversely affect our study timelines and/or ability to enroll patients. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of our product candidates. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a CTA, such regulatory authorities may change their requirements in the future. The FDA, EMA or comparable foreign regulatory authorities may require the analysis of data from trials assessing different doses of the product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of large trials in a specific indication. Any delays or failure to file INDs or CTAs, initiate clinical trials, or obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. We are subject to similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

Risks Related to Our Reliance on Third Parties

We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture claseprubart, DNTH212 and any other product candidates, and we may rely on third parties to produce and process 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 lease or own any facility that may be used as our clinical-scale manufacturing and processing facility and currently rely on a CDMO, WuXi Biologics (as defined below), to manufacture our lead product candidate, claseprubart. We currently have a sole source relationship with WuXi Biologics for our supply of claseprubart (see Item 1. *"Business—Collaboration, License and Services Agreements*" in this Annual Report on Form 10-K for additional information on Dianthus' relationship with WuXi Biologics). If there should be any disruption in such supply arrangement, including any adverse events affecting our sole supplier, Wuxi Biologics, it could have a negative effect on the clinical development of claseprubart and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partner for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of claseprubart. We perform periodic audits of each CDMO facility that supports our supply of claseprubart and review/approve all claseprubart cGMP-related documentation. We also have a quality agreement with WuXi Biologics that documents our mutual agreement on compliance with cGMPs and expectations on quality-required communications to us. Beyond this, we have no control over the ability of our CDMO to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities and the associated Quality Management System for the manufacture of claseprubart or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability to develop, obtain regulatory approval for or market claseprubart, if approved. Similarly, our failure, or the failure of our CDMO, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension 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 claseprubart and harm our business and results of operations. In addition, we have not yet caused claseprubart to be manufactured on a commercial scale and may not be able to do so, if approved.

Moreover, our CDMO may experience manufacturing difficulties due to resource constraints, governmental restrictions or as a result of labor disputes or unstable political environments. Supply chain issues, including those resulting from the ongoing military conflicts between Russian and Ukraine and Israel and surrounding areas and the attacks on marine vessels traversing the Red Sea, may affect our third-party vendors and cause delays. Furthermore, since we have engaged WuXi Biologics, a manufacturer located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments or political unrest or unstable economic conditions in China. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. For example, in the event that we need to transfer from WuXi Biologics, which is our sole manufacturing source for claseprubart, we anticipate that the complexity of the manufacturing process may materially impact the amount of time it would take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer, if we are able to identify an alternative source, could negatively affect our ability to supply product candidates, including claseprubart, in a timely manner or within budget. If any CDMO on which we will rely fails to manufacture quantities of claseprubart at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition, cash flows, and prospects could be materially and adversely affected. In addition, our CDMO and/or distribution partners 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 our CDMO 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 claseprubart by the FDA, result in higher costs or adversely impact commercialization of claseprubart.

In addition, we currently rely on foreign CROs and CDMOs, including WuXi Biologics, and will likely continue to rely on foreign CROs and CDMOs in the future. Foreign CDMOs may be subject to U.S. legislation, including the BIOSECURE Act, enacted into law in December 2025 as part of the National Defense Authorization Act for fiscal year 2026. The BIOSECURE Act prohibits U.S. federal executive agencies from contracting with any entity where the biotechnology equipment or services of a "biotechnology company of concern" ("BCOC") would be used in the performance of that contract. Generally, a BCOC is a biotechnology company that is subject to the jurisdiction, direction, control, or operates on behalf of a foreign adversary's government and poses a risk to the national security of the U.S. BCOCs include entities listed on the Department of Defense Section 1260H list of "Chinese military companies" and additional entities to be designated through an interagency process led by the Office of Management and Budget

("OMB"). OMB has not yet identified any BCOCs. The BIOSECURE Act has the potential to severely restrict our ability to purchase services or products from, or otherwise collaborate with, certain Chinese BCOCs without losing the ability to contract with, or otherwise receive funding from, the U.S. government, and could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material. We do business with companies in China and it is possible some of our contractual counterparties could be impacted by the legislation described above and alternative arrangements may need to be made.

Foreign CDMOs may also be subject to sanctions, trade restrictions and other foreign regulatory requirements. For example, 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. Evolving changes in China's public health, economic, political, and social conditions 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 development programs. It is unknown whether and to what extent new tariffs, export controls, trade restrictions, or other new laws or regulations imposed by either the new U.S. administration or by China will be adopted, or the effect that any such actions would have on us or our industry. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S.-based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on our CDMO and other service providers that operate in China. For example, the BIOSECURE Act could prohibit, among other things, the use of U.S. government executive agency contract, grant, or loan funding to provide or to enter into, extend or renew contracts involving the use of certain equipment or services produced or provided by certain Chinese companies, which could cause us to reevaluate our relationship with our current CDMO, WuXi Biologics, which is located in China. While we have not started commercialization of drug candidates, any unfavorable government policies on international trade, such as export controls, capital controls, tariffs or other trade restrictions, may affect the demand for our drug products, the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our preclinical studies and clinical trials, particularly with respect to our manufactured product candidates that we import from China, including pursuant to our manufacturing arrangements and license agreement with WuXi Biologics. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

If our CDMO, WuXi Biologics, is unable to obtain sufficient raw and intermediate materials on a timely basis or if our CDMO experiences other supply difficulties, our business may be materially and adversely affected.

We work closely with our CDMO, WuXi Biologics, to ensure their suppliers have continuity of supply of raw and intermediate materials but cannot guarantee these efforts will always be successful. Our CDMO has experienced, and may experience in the future, raw and intermediate materials supply shortages, which could contribute to manufacturing delays and impact the progress of our clinical trials. Further, while we work with our CDMO to diversify their sources of raw and intermediate materials, in certain instances they acquire raw and intermediate materials from a sole supplier, and there can be no assurance that they will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates in a timely or cost-effective manner and could delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates.

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 utilize 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 cGCP regulations, which are guidelines enforced by the FDA and comparable foreign regulatory authorities for any product candidate in clinical development. If we or any of these third parties fail to comply with applicable cGCP 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 provide assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product generated under cGMP regulations. Our failure to comply with these regulations 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.

Any third parties conducting our clinical trials will not be with 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 product candidates. These third parties 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 claseprubart, DNTH212 or other product candidates.

We have collaborations with third parties, including our existing license and development collaboration with Tenacia for claseprubart and Leads for DNTH212. If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have various collaboration and license arrangements, including with Tenacia for the development and commercialization of claseprubart in Greater China, and with Leads for the development and commercialization of DNTH212 in Greater China. Further, we may in the future form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates. 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, licensors or licensees experience delays in performance of, or fail to perform their obligations under, their applicable agreements with us, disagree with our interpretation of the terms of such agreement or terminate their agreement with us, our pipeline of product candidates would 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, licensors or licensees may have the right to terminate our 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 such agreements or may face other penalties under our agreements. Our collaborators, licensors or licensees may also fail to properly maintain or defend the intellectual property we have licensed from, if required by our agreement with them, or even infringe upon our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to commercialize our product candidates. Further, any of these relationships may require us to increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. 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 provide development or commercialization capabilities that complement our own. 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 that perceive us to be a competitor may be unwilling to assign or license rights to us. 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 do 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 Related to Our Business and Operations

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

We have experienced and expect to continue 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, regulatory affairs and, potentially, sales and marketing. 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 we 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, including our Chief Executive Officer, executive officers and other members of our leadership team. 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 and adversely affect our business, financial condition, cash flows, 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 on 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 claseprubart, DNTH212 or other product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any product candidates before we receive regulatory approval from the applicable foreign regulatory authority, and we may never receive such regulatory approval for any 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 claseprubart, DNTH212 or other product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of claseprubart, DNTH212 or other product candidates will be harmed, and our business will be adversely affected. Moreover, even if we obtain approval of claseprubart, DNTH212 or other product candidates and ultimately commercialize such 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 employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, 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, CDMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. 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, CDMOs, other contractors, third party service providers or consultants or potential future collaborators, may fail or experience cybersecurity incidents or data privacy breaches or other unauthorized or improper access to, use of, or destruction of 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).

Although we maintain cybersecurity controls and safeguards designed 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, CDMOs, other contractors (including sites performing our clinical trials), third party service providers and supply chain companies, and consultants, as well as other partners, 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 cybersecurity incidents arising from inadvertent or intentional actions by employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise system infrastructure or lead to the loss, destruction, alteration or unauthorized dissemination of, or damage to, 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, supply chain, and ability to produce, sell and distribute our goods and services. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Cybersecurity incidents, including phishing attacks and attempts to misappropriate or compromise confidential or proprietary information or sabotage enterprise IT systems are becoming increasingly frequent and more sophisticated. Cybersecurity incidents increasingly involve the use of artificial intelligence and machine learning to launch more automated, targeted and coordinated attacks on targets. The information and data processed and stored in our technology systems, and those of our strategic partners, contract research organizations, contract manufacturers, suppliers, distributors or other third parties for which we depend to operate our business, may be vulnerable to loss, damage, denial-of-service, unauthorized access or misappropriation.

To the extent that any disruption or cybersecurity incident were to result in a 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 claseprubart, DNTH212 or other 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.

As our employees work remotely and utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations, there are risks to our information technology systems and data. 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, including risks present in integrating acquired entities' systems, controls and technologies.

To date, we have not experienced a cybersecurity incident that has materially affected our business, financial condition, or results of operations; however, we have experienced and expect to continue to experience attempted cybersecurity threats and incidents. There can be no assurance that any future cybersecurity incident will not be material.

The cybersecurity controls and safeguards we have implemented may not be effective. While we maintain cybersecurity risk management and governance processes, as described in Item 1C. "*Cybersecurity*", these processes may not be effective in preventing or mitigating all cybersecurity incidents. 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 regulators, affected individuals and other relevant stakeholders of security incidents. Such cybersecurity incidents and related notifications and 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); increased investigation and compliance costs; financial loss; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential patients) to stop supporting our platform, deter patients 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 or from disruptions 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, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information and personal data.

Issues in the use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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 with whom we work, 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 are changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or 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, cash flows, and results of operations. See the sections titled "*Business—Government Regulation—Data Privacy and Security*" and "*—Other Government Regulation Outside of the United States*" located elsewhere in this Annual Report on Form 10-K for a more detailed description of the laws that may affect our ability to operate.

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 acquire businesses 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 we 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 the 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, at times 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 can at times exceed 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 on March 10, 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. For example, we could not access assets held in our account with Silicon Valley Bank for a period in March 2023, which required us to obtain a short-term loan to fund our operations. 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 Intellectual Property

Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

We rely or may rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from competing with us. Our success depends in large part on our ability to obtain and maintain patent protection for platform technologies, product candidates and their uses, as well as the ability to operate without infringing on or violating the proprietary rights of others. We own three pending U.S. patent applications, two issued U.S. patents, three pending PCT (Patent Cooperation Treaty) applications, and twenty-four pending foreign applications in United Arab Emirates, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, Mexico, New Zealand, Saudi Arabia, Singapore, South Africa, South Korea, and Taiwan. Our rights under the patent applications in China and Taiwan are licensed to Tenacia Biotechnology (Hong Kong) Co., Limited, as further described below. We additionally expect to continue to file patent applications in the United States and abroad related to discoveries and technologies that are important to our business. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on product candidates worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions may be less extensive than those in the United States. As such, we do not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Competitors may operate in countries where we do not have patent protection and could then freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where patent protection has not been requested.

Our intellectual property portfolio is at an early stage, and we currently only own one issued patent covering claseprubart, which is expected to expire in 2043, without taking any potential patent term extension into account. Our pending and future 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, 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 United States Patent and Trademark Office ("USPTO"). Further, if we encounter delays in any clinical trials or delays in obtaining regulatory approval, the period of time during which we could market product candidates under patent protection would be reduced. Thus, the patents that we may own or license may not afford any meaningful 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 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 the market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with 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 foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake 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 markets of interest and our business may be adversely affected.

We may not be successful in obtaining or maintaining necessary rights to product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may 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 product candidates. 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 investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product candidate, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and prospects.

While we will normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to a product candidate, there may be times when the filing and prosecution activities for patents and patent applications relating to a product candidate are controlled by future licensors or collaboration partners. If any of these future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering a product candidate, we could lose rights to the intellectual property or exclusivity with respect to those rights, our ability to develop and commercialize such candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution and patent applications which may be licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of licensees, future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to future in-licensed patents, they may be able to license such patents to our competitors, and the competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, cash flows, 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 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 technology, product candidates, or the methods for manufacturing the same, 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, cash flows, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology or manufacturing methods, our product candidates, or future methods or product candidates, resulting in either an injunction prohibiting manufacture or future sales, or, with respect to future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. For example, we are aware of a certain U.S. patent owned by a third party with claims that are directed to a method of inhibiting complement C1s activity in an individual with an antibody that selectively binds active form of complement component C1s compared to inactive C1s and inhibits complement C1s activity by at least 60% in a protease assay. Although we do not believe that this is a valid patent, this patent could be construed to cover our anti-C1s antibodies.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues; whether and to what 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 creations or use of intellectual property by future licensors and us and/or our partners; and the priority date of an invention of patented technology.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing 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, if found to be valid and enforceable, could be alleged to render one or more of such product candidates infringing. If a third party successfully brings a claim

against us, 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 theft) 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 patents owned or licensed by us will not be challenged by others in the course of litigation. 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 and on the market price of our common stock.

Competitors may infringe or otherwise violate our 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 it infringes 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 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 received may not be commercially valuable.

Further, we may be required to protect our patents 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 U.S. 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 and other parties with whom we had 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 and 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.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that 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 and may engage in the services of consultants to assist in the development of our product candidates. Many of these consultants, and many of our employees, were or may have been 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 ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. 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, financial condition and prospects. 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 any future in-licensed patent applications and the maintenance, enforcement or defense of our owned and any future in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. 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 16, 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 16, 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 could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and prospects.

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 twenty-six 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 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 recent precedential court decisions. 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. 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, the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and weaken our ability to protect, defend and enforce our patent rights in the future.

Geopolitical actions 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. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations, cash flows, and prospects may be adversely affected.

In addition, a European Unified Patent Court (the "UPC") came into force June 1, 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the EU. This enables 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 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 for 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 the patents and patent applications 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 and the patent's prosecution history. 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 pending applications or any future issued patents, 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 patent applications or patents, 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 and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents 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 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 product candidates 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 or academic institutions, 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 conditions, results of operations, cash flows, and prospects.

Patent terms may be inadequate to protect our competitive position on 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 its 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 future 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 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 the licensed technology in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We may in the future collaborate with academic institutions to accelerate our preclinical research or development. While it is our policy to avoid engaging university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in-technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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, such 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 our most advanced product candidate, claseprubart, we must demonstrate through lengthy, complex and expensive preclinical and clinical trials that such 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, a product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other data. A product candidate 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 its 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 a product candidate; we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its 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 a product candidate 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 a product candidate; 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 foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market claseprubart, DNTH212 or other product candidates, which would significantly harm our business, results of operations and prospects. If we were to obtain approval, regulatory authorities may approve any such product candidate 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 a product candidate, we will not be able to commercialize, or will be delayed in commercializing, such product candidate and our ability to generate revenue will be materially impaired.

Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business.

The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including disruptions caused by government shutdowns and public health crises, or layoffs of federal workers by the federal government. Disruptions at the FDA, other agencies, and authorities may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, foreign regulatory authorities, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown or other disruption 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. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 synthesizing the active ingredient, developing an acceptable formulation, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, meeting facility, process and testing validation requirements, and demonstrating that our drug products meet stability requirements. Meeting these CMC requirements is a complex task that requires specialized expertise. If we are not able to meet the CMC requirements, we may not be successful in getting our products approved.

We intend to deliver our product candidates via a drug delivery device that will have its own regulatory, development, supply and other risks.

We intend to deliver our product candidates via a drug delivery device, such as an injector or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and/or dose volume requirements. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some drug delivery devices are provided by single-source unaffiliated third-party companies. We may be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

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

We conducted our Phase 1 clinical trial for claseprubart in New Zealand, we are currently conducting our Phase 2 clinical trials and our Phase 3 clinical trial for claseprubart in the United States and outside the United States, and we may in the future choose to conduct more of our clinical trials outside the United States. 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 its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, 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. Even if the FDA 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 to continue such trials once initiated.

Other risks inherent in conducting international clinical trials include: foreign regulatory requirements, differences in healthcare services, and differences in cultural customs that could restrict or limit our ability to conduct our clinical trials; administrative burdens of conducting clinical trials under multiple sets of foreign regulations; foreign exchange fluctuations; diminished protection of intellectual property in some countries; and political and economic risks relevant to foreign countries.

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

The ACA, includes a subtitle called the 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.

Our investigational biological products, if approved, could be considered reference products entitled to 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 a product candidate to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Even if we receive regulatory approval of claseprubart, DNTH212 or other 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 claseprubart, DNTH212 or other product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of such product candidates, 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 REMS in order to approve a product candidate, 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. In addition, if the FDA or comparable foreign regulatory authorities approve a product candidate, the products 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 ongoing compliance with current cGMPs and cGCPs 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 discover 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, restrictions on our ability to conduct clinical trials, 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, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize claseprubart, DNTH212 or other product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

We may face difficulties from healthcare legislative reform measures.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of claseprubart, DNTH212 or other 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 marketing approval that we may have obtained and we may not achieve or sustain profitability. See the section titled "*Business—Government Regulation—Healthcare Reform*" located elsewhere in this Annual Report on Form 10-K for a more detailed description of healthcare reforms measures that may prevent us from being able to generate revenue, attain profitability, or commercialize product candidates.

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. See the section titled "*Business—Government Regulation—Other Healthcare Laws and Compliance Requirements*" located elsewhere in this Annual Report on Form 10-K for a more detailed description of the laws that may affect our ability to operate.

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 claseprubart, DNTH212 or other product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such products at competitive prices which would seriously harm our business.

We intend to seek approval to market claseprubart, DNTH212 and other product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for such 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 products 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. For example, an executive order issued by the White House on May 12, 2025, directs the HHS to implement a "Most Favored Nation" drug pricing policy. And the recently-enacted One Big Beautiful Bill Act imposes new restrictions on funding for government health care programs and on individual eligibility for coverage under those programs, which may lead to lower reimbursements for drugs covered by those programs. 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. Additionally, if any of our product candidates are approved and we are found to have improperly promoted off-label uses of those programs, we may become subject to significant liability, which would materially adversely affect our business and financial condition. See the sections titled "*Business—Government*

Regulation—Coverage and Reimbursement" and "*—Regulation in the European Union*" located elsewhere in this Annual Report on Form 10-K for a more detailed description of the government regulations and third-party payor practices that may affect our ability to commercialize our product candidates.

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. 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 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 member states of the EU, 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 marketing 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 member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of a product 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 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, cash flows, or prospects could be materially and adversely affected. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the UK determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs.

If we decide to pursue a Fast Track Designation or Orphan Drug Designation by the FDA, it may not lead to a faster development or regulatory review or approval process.

We may seek Fast Track Designation or Orphan Drug Designation for one or more product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant such designations, so even if we believe a particular product candidate is eligible for such designations, we cannot guarantee that the FDA would decide to grant it. Even if we do receive Fast Track Designation or Orphan Drug Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation or Orphan Drug Designation if it believes that the designation is no longer supported by data from a clinical development program. See the section titled "*Business—Government Regulation—Expedited Development and Review Programs*" located elsewhere in this Annual Report on Form 10-K for a more detailed description of the process for seeking Fast Track Designation or Orphan Drug Designation.

General Risk Factors

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.

We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical 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 approved for commercial sale, the current and 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, 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 believe we currently maintain adequate product liability insurance for claseprubart, DNTH212 and other product candidates, 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, cash flows, and prospects.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, such as the conflict between Russia and Ukraine, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations, cash flows, 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, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve raised interest rates multiple times in response to concerns about inflation and, although it recently lowered interest rates, there is no guarantee that it will continue to lower rates or that it will not raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, rising tensions between China and Taiwan, the ongoing conflict in Israel and surrounding areas, the attacks on marine vessels traversing the Red Sea and the ongoing military conflict between Russia and Ukraine and in the Middle East have created 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.

The market price of our common stock may be volatile, and the market price of our common stock may drop.

The market price of our common stock has been and is likely 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 of the investment community or that we may provide to the public;
- 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, and the markets for biotechnology and biopharmaceutical companies in particular, 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 will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will continue to incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"). Some of our executive officers have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. 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.

If we no longer qualify as 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 requires, 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, we currently qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, which allows us to take advantage of many exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. Once we are no longer a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with 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.

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 our 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. As a private company, we were never required to test our internal controls within a specified period. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

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.

Our certificate of incorporation and bylaws and provisions under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our common stockholders 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 our Board of Directors will be responsible for appointing the members of 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 stockholders to replace members of our Board of Directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board of Directors;
- limit the manner in which stockholders can remove directors from the Board of Directors;
- establish 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 our 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 our Board of Directors; and
- require the approval of the holders of at least 66.67% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the Board of Directors, which is responsible for appointing the members of management.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our charter or our bylaws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, which for purposes of this risk factor refers to herein as the "Delaware Forum Provision." The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended (the "Securities Act") and the Exchange Act. Our bylaws further provide that, unless we consent in writing to an alternative forum, federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which for purposes of this risk factor refers to herein as the "Federal Forum Provision." In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived its compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on our stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders.

We do not anticipate paying 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 your sole source of gain, if any, for the foreseeable future.

An active trading market for our common stock may not be sustained and our stockholders may not be able to sell their shares of common stock for a profit, if at all.

An active trading market for our shares of common stock may not be sustained. If an active market for our common stock is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

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

If securityholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. In addition, shares of common stock that are subject to outstanding options or warrants of Dianthus are 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 any of the foregoing shares of common stock are sold, the trading price of our common stock could decline.

Our executive officers, directors and principal stockholders will 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 approximately 31% of our outstanding shares of common stock as of March 4, 2026. 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.

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

The trading market for our common stock will be 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 the event we do have equity research analyst coverage, we will 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 ceases coverage of us or fails 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.

We have broad discretion in the use of our cash, cash equivalents and investments and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We have broad discretion over the use of our cash, cash equivalents and investments. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these cash resources. You will not have the opportunity to influence our decisions on how to use our cash resources.

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

The rules dealing with 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 and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We will 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 will make 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 IRA, 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 15 years for research activities conducted outside the United States. On 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 Internal Revenue Service 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 general business condition.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes is expected to be limited.

As of December 31, 2025, we had federal net operating loss carryforwards of $475.9 million, of which $458.3 million can be carried forward indefinitely. As of December 31, 2025, we had state net operating loss carryforwards of $419.0 million, which will begin to expire in 2038. As of December 31, 2025, we had federal, state, and foreign tax credit carryforwards of approximately $26.4 million, $4.3 million and nil, respectively. All tax credits have a limited carryforward period and will begin to expire in 2038.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income or tax liabilities is expected to be limited. 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.

In general, our ability to use our federal and state net operating loss and credits carryforwards to reduce future taxable liabilities is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income or tax liabilities to use all of our carryforwards. Under current law, federal net operating loss carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but for taxable years beginning after December 31, 2020 the deductibility of such net operating loss carryforwards is limited to 80% of taxable income. Federal net operating losses generated prior to December 31, 2017, however, have a 20-year carryforward period, but are not subject to the 80% limitation. Similar state law limitations may apply.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), federal net operating loss and credit carryforwards may become subject to an annual limitation in the event 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 (referred to as an "ownership change"). Similar state law limitations may apply. There may also be periods during which the use of net operating loss carryforwards and other tax attributes are suspended or otherwise limited, which could accelerate or permanently increase taxes owed. We have experienced ownership changes in the past and may experience additional ownership changes in the future, as a result of subsequent changes in our stock ownership, some of which are outside our control; however, we have not completed an analysis to determine whether any such limitations have been triggered. Accordingly, we may not be able to utilize a material portion of our net operating loss carryforwards, even if we achieve profitability.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We take cyber risk seriously as a part of modern enterprise risk management, protecting our stakeholders and assets, and building resilient processes. The modern threat landscape requires us to consider cyber risks, and make determinations regarding how to treat the risks. We evaluate cybersecurity risks alongside other operational, financial and compliance risks.

In the ordinary course of our business, we collect, use, store, and transmit digitally confidential, sensitive, proprietary, personal, and health-related information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To that end, we rely on a multidisciplinary team (including from our IT function, senior management, and third-party service providers, as described further below) to assess how identified cybersecurity threats could impact our business. These assessments may leverage, among other processes, industry tools and metrics designed to assist in the assessment of risks from such cybersecurity threats. Our cybersecurity risk assessment processes are integrated into our broader risk management and disclosure processes.

Senior management is directly involved with our efforts to prevent, detect, and mitigate cybersecurity incidents by overseeing preparation of cybersecurity policies and procedures, testing incident response plans and engaging vendors to conduct penetration testing and other security assessments. Senior management participates in cybersecurity incident response efforts by being part of the incident response team and helping direct our response to cybersecurity incidents. Our incident response procedures include defined escalation protocols and cross-functional evaluation involving information security, legal and senior management to assess the severity and potential materiality of cybersecurity incidents and to determine appropriate response and disclosure actions.

To augment internal knowledge, we have engaged a virtual Chief Information Security Officer ("vCISO") from a third-party firm that has provided IT and security services for over 19 years and utilizes industry expertise to recommend and implement best practice solutions for operational needs. The service provides a named vCISO as part of an advisory team to assess and help manage our cybersecurity program; including acting as a dedicated point of contact for incident response, triage, continued improvement, and program maturity.

Cybersecurity risks are identified and processed in a Risk Register by an information security team that includes the vCISO and internal management. We conduct risk assessments, penetration testing, vulnerability scanning, receive alerts from security tools, and engage in an ongoing discussion of business processes and policy management. We use advanced tools to track governance, risk, and compliance tied to a security framework tailored from industry standards and best practices, and we test our tools and policies regularly.

Third parties also play a role in our cybersecurity. We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges. These evaluations include testing both the design and operational effectiveness of security controls. We have implemented and maintain information security processes designed to identify, assess, and manage material risks from cybersecurity threats to critical computer networks, third-party hosted services, communications systems, hardware, software, and our critical data including confidential, personal, proprietary, and sensitive data. Accordingly, we maintain risk assessment processes intended to identify cybersecurity threats, determine their likelihood of occurring, and assess any potential material impact to our business. Based on our assessment, we implement and maintain risk management processes to our information assets and mitigate harm to our business.

In addition to internal systems and concerns, we manage risks from third parties that are a part of business operations. This includes assessing cybersecurity risks during the vetting process and recurring assessments during the life of the engagements. Relative levels of assessment are considered with regard to business criticality of the relevant third parties. We rely heavily on our third party CROs and CDMOs to manage our clinical trials and manufacture our investigational products, and a cybersecurity incident at a CRO, CMDO or other third party upon which we rely could materially adversely impact us. Since the beginning of the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our business strategy, results of operations or financial condition, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. See "*Item 1A. Risk Factors*" in this Annual Report on Form 10-K for additional information on cybersecurity risks we face.

Information from the risk management process is managed by the Information Security Team and is reported to the Board of Directors on a regular basis. We provide cybersecurity updates to our Audit Committee on a quarterly basis. In the case of an incident, relevant members of the Information Security Team are involved to assess and oversee incident response operations as needed, including adequate reporting of material incidents if/when appropriate. Cybersecurity incidents are evaluated under our disclosure controls and procedures.

Notwithstanding the approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. While we maintain cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured.

Item 2. Properties.

We are currently a remote-based company, and a majority of our employees work remotely. We currently lease space for administrative offices in Waltham, Massachusetts and New York, New York. Our space in Waltham is approximately 2,750 square feet under a lease that expires in January 2027 and our space in New York is approximately 3,367 square feet under a lease that expires in February 2031. Our New York office is our corporate headquarters. As the company expands, we believe suitable additional, or substitute space will be available as and when needed.

Item 3. Legal Proceedings.

From time to time, we may be involved in litigation and other legal proceedings arising in the ordinary course of our business. We are not currently a party to or aware of any legal proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition, results of operations or cash flows. The outcome of any claims or litigation, regardless of the merits, is inherently uncertain. Regardless of the outcome, litigation and other legal proceedings can have a material adverse impact on us, our business, financial condition, results of operations or cash flows because of defense and settlement costs, diversion of management resources, in the case of intellectual property claims, requirements to change our product candidates, change our business practices, pay monetary damages or enter into short- or long-term royalty or licensing agreements, and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "DNTH".

Common Stockholders

As of March 4, 2026, there were approximately 5 stockholders of record of our common stock based on information provided by our transfer agent. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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 to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination to pay dividends will be at the discretion of the Board of Directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions and restrictions imposed by applicable laws and other factors the Board of Directors deems relevant.

Recent Sales of Unregistered Equity Securities

There were no unregistered sales of our common stock during the quarter ended December 31, 2025.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended December 31, 2025.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "*Special Note Regarding Forward Looking Statements*" included elsewhere in this Annual Report on Form 10-K. Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "*Item 1A. Risk Factors*" included elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical-stage biotechnology company dedicated to developing potentially best-in-class therapies for patients living with severe autoimmune diseases. Our lead clinical-stage candidate, claseprubart, is a monoclonal antibody that is purposefully engineered with extended half-life, improved potency, and high selectivity for only the active C1s complement protein ("C1s") – enabling less frequent and more convenient self-administered subcutaneous ("S.C.") injections suitable for a pre-filled pen. Additionally, selective inhibition of the classical complement pathway may lower patient risk of infection from encapsulated bacteria by preserving immune activity of the lectin and alternative pathways. We believe claseprubart has the potential to address a broad array of complement-dependent diseases as currently available therapies and those in development leave room for improvements in efficacy, safety, and/or dosing convenience.

Our second clinical-stage candidate, DNTH212, is a first and potentially best-in-class, bifunctional fusion protein that targets plasmacytoid dendritic cell ("pDC") BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. By targeting both the innate and adaptive immune systems via two clinically validated pathways that are known drivers of autoimmune disease pathogenesis, this complementary and differentiated approach has the potential to address multiple autoimmune indications with improved outcomes. DNTH212 is also designed with the potential for patient friendly convenient, infrequent, self-administered S.C. injections suitable for a pre-filled pen.

Our Pipeline-in-a-Product Potential for Claseprubart, a Next-Generation Complement Therapeutic

Our most advanced product candidate, claseprubart, is a clinical-stage, highly potent, highly selective and fully human monoclonal immunoglobulin G4 with picomolar binding affinity that is designed to selectively bind only to the active form of C1s. The active form of C1s is generated during complement activation by cleavage of the inactive proC1s. As a validated complement target in the autoimmune and inflammatory field, C1s inhibition prevents further progression of the classical pathway cascade. Claseprubart is engineered with YTE half-life extension technology, a specific three amino acid change in the Fc domain, and has a pharmacokinetic ("PK") profile designed to support less frequent, lower dose, self-administration as a convenient S.C. injection.

We are currently conducting three mid- to late-stage clinical trials with claseprubart in generalized Myasthenia Gravis ("gMG"), Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"), and Multifocal Motor Neuropathy ("MMN").

In September 2025, we reported positive top-line results from the Phase 2 MaGic trial of claseprubart for patients with gMG and subsequently held an end-of-Phase 2 meeting with the FDA in the first quarter of 2026. We expect to initiate a Phase 3 registrational trial in gMG in mid-2026 and report top-line results in the second half of 2028.

In March 2026, we made an early GO announcement in the interim responder analysis for our Phase 3 CAPTIVATE trial of claseprubart in patients with CIDP due to achieving a target of 20 confirmed responders with less than the planned 40 participants completing Part A.

Claseprubart is also being evaluated in the Phase 2 MoMeNtum trial for patients with MMN, and we anticipate initial top-line results from this trial will be available in the second half of 2026.

MAGIC

The MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial of claseprubart that enrolled 65 acetylcholine receptor positive ("AChR+") participants with gMG. Following an initial loading dose, claseprubart was administered every two weeks ("Q2W") via S.C. injection at a dose of 300mg/2mL or 600mg/4mL. The initial randomized treatment duration was 13 weeks, followed by a 52-week open-label extension ("OLE"). The primary endpoint of the study was safety and tolerability. Secondary and exploratory efficacy endpoints included Myasthenia Gravis Activities of Daily Living Scale ("MG-ADL") and Quantitative Myasthenia Gravis ("QMG") score assessments, as well as Minimal Symptom Expression ("MSE"), Myasthenia Gravis Composite ("MGC") score, and the Myasthenia Gravis Quality of Life Scale ("MG-QOL-15r").

In September 2025, we announced positive top-line data from the Phase 2 MaGic trial. Claseprubart 300mg and 600mg demonstrated rapid, statistically significant and clinically meaningful improvements over placebo as measured by both MG-ADL and QMG, including at week 1 and at week 13. The claseprubart 300mg Q2W dose was also statistically significant and clinically meaningful across other key efficacy endpoints, including MSE, MGC, and MG-QoL-15r.

Claseprubart was generally well tolerated with no drug-related serious adverse events ("SAE") or discontinuations due to any related adverse event. Claseprubart had a favorable clinical safety profile comparable to placebo with no treatment-related serious bacterial infections and no clinical symptoms of emergent autoimmune disorders observed.

In the OLE portion of the MaGic trial, patients who were on placebo during the randomized controlled portion of the trial received claseprubart 600mg Q2W without a loading dose. Data from the OLE demonstrate that after two doses of claseprubart 600mg Q2W, participants experienced robust reductions in MG-ADL and QMG at PK levels far below the steady state of the 300mg Q2W dose, supporting the potential for dosing of 300mg claseprubart every four weeks ("Q4W").

Based on the outcome of our end-of-Phase 2 meeting with the FDA held in the first quarter of 2026, we expect to initiate a registrational Phase 3 trial of claseprubart evaluating 300mg Q2W and 300mg Q4W in gMG patients in mid-2026 and report top-line results in the second half of 2028.

CAPTIVATE

The CAPTIVATE trial is a single, two-part, randomized withdrawal global Phase 3 trial of claseprubart in patients with CIDP. In the open label Part A of this trial, participants will be administered claseprubart with a loading dose followed by 300mg/2mL administered Q2W via S.C. injection for up to 13 weeks. Only participants who respond to claseprubart in Part A, as measured as greater than or equal to one point decrease (improvement) in adjusted Inflammatory Neuropathy Cause and Treatment ("INCAT") disability score compared to Part A baseline, are randomized into Part B, a double-blind, placebo-controlled treatment period of up to 52 weeks, where they will be assessed for prevention of relapse, safety and tolerability, followed by an OLE period. Part A included an interim responder analysis of the first 40 participants to complete Part A. Our target for the Part A interim responder analysis was a response rate of 50% or greater (i.e., ≥20 confirmed responders out of first 40 participants to complete Part A) based on precedent set with aC1s inhibition. In March 2026, we announced that we achieved our target of 20 confirmed responders in Part A early, with less than 40 participants completing Part A. We believe that this single pivotal trial will support a Biologics License Application ("BLA") filing in adult patients with CIDP.

MOMENTUM

The MoMeNtum trial is a global, randomized, double-blind, placebo-controlled Phase 2 study designed to evaluate the safety, tolerability, and efficacy of claseprubart in 36 patients with MMN. Following determination of Ig dependency and responsiveness, patients will be randomized to receive placebo or claseprubart with a loading dose followed by 300mg/2mL or 600mg/4mL administered Q2W via S.C. injection. The initial S.C. treatment duration is 17 weeks followed by a 52-week OLE. The primary endpoint of this study is safety and tolerability. Secondary endpoints include time to intravenous immunoglobulin ("IVIg") retreatment, time to relapse, and assessments of muscle and grip strength. We anticipate initial top-line results from this trial to be available in the second half of 2026.

Our First and Potentially Best-In-Class Bifunctional BDCA2 and BAFF/APRIL Inhibitor (DNTH212)

On October 16, 2025, we entered into an exclusive license agreement with Nanjing Leads Biolabs Co., Ltd. ("Leads") for DNTH212, a first and potentially best-in-class bifunctional BDCA2 and BAFF/APRIL inhibitor.

DNTH212 is an investigational, extended half-life bifunctional fusion protein targeting plasmacytoid dendritic cell BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. By targeting both the innate and adaptive immune systems via two clinically validated pathways that are known drivers of autoimmune disease pathogenesis, this complementary and differentiated approach has the potential to address multiple autoimmune indications with improved outcomes.

A two-part Phase 1 study in China in healthy volunteers (Part A) and patients with systemic lupus erythematosus (Part B) was initiated in December 2025, with top-line results in healthy volunteers expected in the second half of 2026.

Corporate Update

September 2025 Public Offering

On September 9, 2025, we entered into an underwriting agreement with certain underwriters to issue and sell 7,627,879 shares of our common stock, including the full exercise by the underwriters of their option to purchase an additional 1,140,000 shares, at a public offering price of $33.00 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase 1,112,121 shares of our common stock at a public offering price of $32.999 per share, which represented the per share public offering price for the common stock less the $0.001 per share exercise price for each pre-funded warrant. The gross proceeds from the underwritten offering were $288.4 million, before underwriting discounts and commissions and expenses of the offering. The underwritten offering closed on September 11, 2025.

The pre-funded warrants are exercisable at any time after the date of issuance. A holder of the pre-funded warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 4.99%, 9.99%, or 19.99%, as applicable to each holder, of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of the pre-funded warrants may increase or decrease this percentage to a percentage not in excess of 19.99% by providing us with at least 61 days' prior notice.

We intend to use the net proceeds from this underwritten offering to advance our preclinical and clinical development activities, as well as for 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 a shelf registration statement, which became effective on October 9, 2024. A final prospectus supplement dated September 9, 2025 relating to and describing the terms of the underwritten offering was filed with the SEC on September 11, 2025.

Global and Macroeconomic Developments

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with legislative, regulatory, political, geopolitical and macroeconomic developments beyond our control, including inflationary pressures, a general economic slowdown or a recession, high interest rates, changes in monetary policy or foreign currency exchange rates, changes in trade policies, including tariffs and other trade restrictions or the threat of such actions, instability in financial institutions, the ongoing conflict in Ukraine, conflicts in the Middle East, rising tensions between China and Taiwan, the attacks on marine vessels traversing the Red Sea and the responses thereto, and supply chain disruptions. While we are closely monitoring the impact of the current macroeconomic conditions on all aspects of our business, including the impacts on participants in our clinical trials, employees, suppliers, vendors, business partners and regulators, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period of time. We will continue to evaluate the nature and extent of the potential impacts to our business, results of operations, liquidity and capital resources. For additional information, see the section titled "*Item 1A. Risk Factors*" found elsewhere in this Annual Report on Form 10-K.

Components of Results of Operations

Revenues

Since inception, we have not generated any revenue from product sales, and we do not expect to generate any revenue from the sales of products in the foreseeable future. We have recognized revenues attributable to upfront payments, milestone payments and cost reimbursements under our license agreements.

If our development efforts for claseprubart, DNTH212, or any other future product candidates, if any, are successful and result in regulatory approval, we may generate revenue from future product sales. If we enter into license or collaboration agreements for claseprubart, DNTH212, or any other future product candidates, if any, or intellectual property, revenue may be generated in the future from such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of claseprubart, DNTH212, or any other future product candidates or from license or collaboration agreements. We may never succeed in obtaining regulatory approval for claseprubart, DNTH212, or any other future product candidates.

Licensing Agreements

In June 2022, we executed a license agreement with Zenas BioPharma, Inc. (formerly Zenas BioPharma Limited) ("Zenas"), a former related party, which provided Zenas with a license in Greater China for the development and commercialization of certain sequences and products under an identified antibody sequence (the "Zenas License Agreement"). The Zenas License Agreement included the following payments from Zenas: (i) a non-refundable upfront payment of $1.0 million; (ii) an approximately $1.1 million reimbursement payment for a portion of development costs previously incurred by us; (iii) reimbursement of a portion of all chemistry, manufacturing and control ("CMC")-related costs and expenses for the first antibody sequence through the manufacture of the first two batches of drug product; (iv) reimbursement of a portion of all non-CMC-related costs and expenses for the development of the first antibody sequence through the first regulatory approval; (v) development milestones totaling up to $11.0 million; and (vi) royalties on net sales ranging from the mid-single digits to the low teen percentages.

On October 21, 2024, Zenas assigned the Zenas License Agreement to its affiliated entity, Zenas BioPharma (HK) Limited ("Zenas HK"). After the assignment, we entered into a novation agreement (the "Novation Agreement") with Zenas and Tenacia Biotechnology (Hong Kong) Co., Limited ("Tenacia") and an amendment to the Zenas License Agreement, now with Tenacia (as amended, the "Tenacia License Agreement"), pursuant to which Tenacia replaced Zenas HK as a party to the Zenas Agreements and certain economic terms under the Zenas License Agreement with respect to cost sharing and development milestones were amended.

Except as stated otherwise, the economic terms of the Zenas License Agreement were unchanged when novated by the Novation Agreement and amended by the Tenacia License Agreement.

The consideration under the Tenacia License Agreement, which replaced the consideration of the Zenas License Agreement, related to the first antibody sequence includes the following payments by Tenacia to us: (i) a $2.5 million upfront payment, which was paid by Tenacia to us in October 2024 upon execution of the Tenacia License Agreement; (ii) reimbursement of a portion of certain clinical costs; (iii) development milestones totaling up to $15.0 million; and (iv) royalties on net sales ranging from the mid-single digits to the low teen percentages. Tenacia is also responsible for paying local development costs in Greater China and a portion of central development costs based on the number of patients enrolled from China in our global Phase 3 studies. No milestones were achieved under the Zenas Agreements prior to novation. During the year ended December 31, 2025, we achieved $6.0 million of milestone payments under the Tenacia Agreements (as defined below), which were added to the transaction price. We had not recorded any royalty revenue under the Zenas Agreement prior to novation, and we have not recorded any royalty revenue under the Tenacia Agreements.

Under the Zenas License Agreement, Zenas also had the right to exercise an option with respect to a second antibody sequence, which is now held by Tenacia (the "Tenacia Option" and, together with the Tenacia License Agreement, the "Tenacia Agreements"). Pursuant to the Tenacia Option, if Tenacia exercises the option and pays us the option exercise fee related to the second antibody sequence, we will grant Tenacia an exclusive license to the sequences and licensed products under this second antibody sequence. The economic terms with respect to this second antibody sequence were unchanged by the amendment to the Zenas License Agreement.

For the years ended December 31, 2025 and 2024, we recognized related party license revenue totaling nil and $5.9 million, respectively, associated with the Zenas Agreements.

For the years ended December 31, 2025 and 2024, we recognized license revenue totaling $2.0 million and $0.3 million, respectively, associated with the Tenacia Agreements.

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of claseprubart, DNTH212 and other potential product candidates.

External expenses include:

- payments to third parties in connection with research and development, including agreements with third parties, such as contract research organizations ("CROs"), clinical trial sites and consultants;
- the cost of manufacturing products for use in our clinical trials and preclinical studies, including payments to contract development and manufacturing organizations ("CDMOs") and consultants; and

- payments to third parties in connection with the preclinical development of other potential product candidates, including for outsourced professional scientific development services, consulting research and collaborative research.

Internal expenses include:

- personnel-related costs, including salaries, bonuses, related benefits and stock-based compensation expenses for employees engaged in research and development functions; and

- depreciation, supplies, travel expenses and other allocated expenses.

We recognize research and development expenses in the periods in which they are incurred. Our internal resources, employees and infrastructure are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We utilize CROs for research and development activities and CDMOs for manufacturing activities and we do not have laboratory or manufacturing facilities. Therefore, we have no material facilities expenses attributed to research and development.

Product candidates in later stages of development generally have higher development costs than those in earlier stages. As a result, we expect that our research and development expenses will increase substantially over the next several years as we advance claseprubart into larger and later-stage clinical trials, develop DNTH212, work to discover and develop additional product candidates, seek to expand, maintain, protect and enforce our intellectual property portfolio and hire additional research and development personnel.

The successful development of claseprubart, DNTH212, or any other future product candidates, if any, is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, claseprubart, DNTH212, or any other future product candidates, if any. To the extent claseprubart, DNTH212, or any other future product candidates advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. The duration, costs and timing of development of claseprubart, DNTH212, or any other future product candidates are subject to numerous uncertainties and will depend on a variety of factors, including:

- the timing and progress of our preclinical and clinical development activities;

- the number and scope of preclinical and clinical programs we pursue;

- our ability to establish a favorable safety profile with Investigational New Drug application (“IND”)-enabling toxicology studies to enable clinical trials;

- successful patient enrollment in, and the initiation and completion of, larger and later-stage clinical trials;

- per subject trial costs;

- the number and extent of our clinical trials required for regulatory approval;

- the countries in which our clinical trials are conducted;

- the length of time required to enroll eligible subjects in our clinical trials;

- the number of subjects that participate in our clinical trials;

- the drop-out and discontinuation rate of subjects in our clinical trials;

- potential additional safety monitoring requested by regulatory agencies;

- the duration of subject participation in our clinical trials and follow-up;

- the extent to which we encounter any serious adverse events in our clinical trials;

- the timing of receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;
- the extent to which we establish collaborations, strategic partnerships, or other strategic arrangements with third parties, if any, and the performance of any such third party;
- hiring and retaining research and development personnel;
- our arrangements with our CDMOs and CROs;
- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercial launch;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work; and
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

Any of these factors could significantly impact the costs, timing and viability associated with the development of claseprubart, DNTH212, or any other future product candidates.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, bonuses, related benefits, and stock-based compensation expense for personnel in executive, finance, and administrative functions; professional fees for legal, consulting, accounting, and audit services; and travel expenses, technology costs, and other allocated expenses. General and administrative expenses also include corporate facility costs, including insurance, rent, utilities, depreciation, and maintenance, not otherwise included in research and development expenses. We recognize general and administrative expenses in the periods in which they are incurred.

We expect that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercial preparation activities for the product candidates and, if any product candidate receives marketing approval, commercialization activities. In addition, we will continue to incur expenses associated with being a public company, including expenses related to accounting, audit, legal, regulatory, public company reporting and compliance, director and officer insurance, investor and public relations, and other administrative and professional services.

Other Income/(Expense)

Other income/(expense) consists primarily of interest and investment income generated from earnings on invested cash and investment securities.

Income Tax

Since inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for our earned research tax credits due to uncertainty of realizing a benefit from those items. We maintain a full valuation allowance on our federal and state deferred tax assets as we have concluded that it is more likely than not that the deferred assets will not be utilized.

Results of Operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2025 compared to the year ended December 31, 2024 is presented below. A discussion regarding our financial condition and results of operations for the year ended December 31, 2024 compared to the year ended December 31, 2023 can be found in "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in our Annual Report on Form 10-K filed with the SEC on March 11, 2025.

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations and other comprehensive loss for the periods indicated:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Revenues:		
License revenue - former related party	$ —	$ 5,909
License revenue	2,036	326
Total revenues	2,036	6,235
Operating expenses:		
Research and development	145,638	83,105
General and administrative	34,331	24,994
Total operating expenses	179,969	108,099
Loss from operations	(177,933)	(101,864)
Other income/(expense):		
Interest and investment income	16,119	17,365
Gain on investment in former related party	508	148
Loss on currency exchange, net	(57)	(64)
Other expense	(974)	(554)
Total other income	15,596	16,895
Net loss	$ (162,337)	$ (84,969)

Revenues

Under the terms of the Zenas Agreements, we recognized related party license revenue of nil and $5.9 million during the years ended December 31, 2025 and 2024, respectively. Additionally, under the terms of the Tenacia Agreements, we recognized license revenue of $2.0 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively. The decrease in total revenues was due to a decrease of reimbursable costs associated with claseprubart's ongoing clinical trials that were subject to the Zenas Agreements and are subject to the Tenacia Agreements.

Research and Development Expenses

Research and development expenses were $145.6 million for the year ended December 31, 2025, as compared to $83.1 million for the year ended December 31, 2024, an increase of $62.5 million. This increase was due to: (1) a $47.7 million increase in external research and development costs, consisting of clinical operation activities, CMC activities, preclinical study costs, discovery expenses and licensing and milestone payments; and (2) a $14.8 million increase in internal research and development costs, consisting of personnel and related costs, stock-based compensation expense and other costs.

The $47.7 million increase in external research and development costs was due to a $30.0 million increase in expenses related to discovery activities and a $17.7 million increase in expenses related to claseprubart. The increase in discovery activities related primarily to the upfront and clinical development milestone payments of $30.0 million for the DNTH212 program. The increase in expenses related to claseprubart were due to increases of $24.1 million in clinical operations activities and $1.5 million in licensing and milestone payments, partially offset by decreases of $4.9 million in preclinical study costs and $3.0 million in CMC activities. The changes related to claseprubart's ongoing Phase 2 clinical trials in gMG and MMN and Phase 3 clinical trial in CIDP.

The $14.8 million increase in internal research and development costs was due to increases of $9.3 million in personnel and related costs, $4.5 million in stock-based compensation expense and $1.0 million in other expenses. The increases were due to the

buildout of our internal research and development function to support our Phase 2 and Phase 3 clinical trials in claseprubart and development of DNTH212.

General and Administrative Expenses

General and administrative expenses were $34.3 million for the year ended December 31, 2025, as compared to $25.0 million for the year ended December 31, 2024, an increase of $9.3 million. The increase was primarily due to increases of $5.4 million in stock-based compensation expense, $3.3 million in personnel and related costs and $0.6 million in other administrative costs. The increases in costs were due to the buildout of our general and administrative function to support our Phase 2 and Phase 3 clinical trials in claseprubart and development of DNTH212.

Other Income/(Expense)

Other income was $15.6 million for the year ended December 31, 2025, as compared to $16.9 million for the year ended December 31, 2024, a decrease of $1.3 million. The decrease was primarily due to a decrease of $1.3 million in interest income from a lower average investment balance and lower interest rates on investments and an increase of $0.4 million in other expense, partially offset by $0.4 million increased gain on an investment in a former related party.

Income Tax

The provision for income taxes consists primarily of income taxes related to federal and state jurisdictions in which we conduct business. We maintain a full valuation allowance on our federal and state deferred tax assets as we have concluded that it is more likely than not that the deferred assets will not be utilized.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our lead product candidate, claseprubart, DNTH212, or any other future product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for our lead product candidate, claseprubart, DNTH212, or any other future product candidates to support potential future commercialization and providing general and administrative support for our operations, including the costs associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. See the section titled "*Risk Factors*" found elsewhere in this Annual Report on Form 10-K for additional risks associated with our substantial capital requirements.

We have an open market 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 for an aggregate sales price of up to $200 million. Any sales of our common stock pursuant to the ATM Agreement are made under our registration statement on Form S-3 which was deemed effective by the SEC on October 9, 2024. As of the date of this filing, we have sold 2,626,834 shares of our common stock under the ATM offering program and have $100.1 million in remaining capacity under the ATM offering program. There were no sales under the ATM offering program during the three months ended December 31, 2025.

We historically have funded our operations with proceeds from the sale of capital stock. As of the date of this filing, we have raised aggregate gross proceeds of $288.4 million from public offerings, $423.5 million from private placements, and $99.9 million from our ATM offering program.

Future Capital Requirements

Since inception, we have devoted substantially all of our resources to conducting research and development activities (including with respect to the claseprubart program and DNTH212) and undertaking preclinical studies, conducting clinical trials and the manufacturing of the product used in our clinical trials and preclinical studies, business planning, developing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities.

We do not own or operate, and currently have no plans to establish, any significant laboratory or manufacturing facilities. We rely, and expect to continue to rely, on third parties for the testing and manufacture of our product candidates, as well as for commercial manufacturing should any of our product candidates obtain marketing approval. We believe this strategy allows us to maintain a more efficient infrastructure by eliminating the need to invest in our own significant laboratory and manufacturing facilities, equipment, and personnel while also enabling us to focus expertise and resources on the development of our product candidates.

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 claseprubart, DNTH212, or any other future product candidates, and we do not know when, or if, that will occur. In order to complete the development of claseprubart, DNTH212, or any other 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.

Historically, we have funded our operations with proceeds from the sale of capital stock. As of the date of this filing, we have raised aggregate gross proceeds of $288.4 million from public offerings, $423.5 million from private placements, and $99.9 million from our ATM offering program. However, we have incurred significant recurring losses. We generated net losses of $162.3 million and $85.0 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $336.7 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors, including the timing, scope and results of our research and development activities. As of December 31, 2025, we had cash, cash equivalents and investments of $514.4 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and investments as of December 31, 2025 should be sufficient to fund our operations into 2028. Until we achieve profitability, we plan to fund our operations and capital expenditures with cash on hand and 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. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us.

We based projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress, results, and costs of researching and developing claseprubart, and conducting larger and later-stage clinical trials;
- the scope, timing, progress, results, and costs of researching and developing DNTH212 or any other future product candidates that we may pursue;
- the costs, timing, and outcome of regulatory review of our product candidates;

- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish, maintain, and derive value from collaborations, partnerships or other marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the capital requirements associated with such operating plans.

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	$ (129,060)	$ (78,180)
Net cash used in investing activities	(122,833)	(286,812)
Net cash provided by financing activities	280,125	255,623
Increase/(decrease) in cash, cash equivalents and restricted cash	$ 28,232	$ (109,369)

Cash Flows from Operating Activities

For the year ended December 31, 2025, net cash used in operating activities consisted of a net loss of $162.3 million, partially offset by net non-cash operating expenses of $16.5 million and a decrease in net operating assets and liabilities of $16.7 million. The non-cash operating expenses consisted primarily of stock-based compensation expense of $22.8 million, amortization of right-of-use operating lease assets of $0.3 million and depreciation expense of $0.1 million, partially offset by accretion of discount on investment securities of $6.2 million and a gain on an investment in a former related party of $0.5 million. The decrease in net operating assets and liabilities was primarily attributable to increases in accounts payable, accrued expenses and operating lease liabilities of $11.3 million and deferred revenue of $4.6 million and decreases in receivables from Zenas of $0.8 million and other assets of $0.3 million, partially offset by increases in prepaid expenses and other current assets of $0.2 million and accounts receivable of $0.1 million.

For the year ended December 31, 2024, net cash used in operating activities consisted of a net loss of $85.0 million and an increase in net operating assets and liabilities of $0.4 million, partially offset by net non-cash operating expenses of $7.1 million. The increase in net operating assets and liabilities was primarily attributable to increases in other assets of $8.2 million, prepaid expenses and other current assets of $1.6 million, and receivables from a former related party of $0.5 million, partially offset by increases in accounts payable, accrued expenses and operating lease liabilities of $8.2 million and deferred revenue of $1.5 million and a decrease in unbilled receivable from a former related party of $0.2 million. The non-cash operating expenses consisted primarily of stock-based compensation expense of $12.9 million and amortization of right-of-use operating lease assets of $0.3 million, partially offset by accretion of discount on investment securities of $6.0 million and a gain on an investment in a former related party of $0.1 million.

Cash Flows from Investing Activities

For the year ended December 31, 2025, net cash used in investing activities consisted primarily of $435.0 million of purchases of investment securities and capital expenditures of $0.2 million, partially offset by $312.4 million of proceeds from sales and maturities of investment securities.

For the year ended December 31, 2024, net cash used in investing activities consisted primarily of $413.7 million of purchases of investment securities and capital expenditures of $0.1 million, partially offset by $127.0 million of proceeds from sales and maturities of investment securities.

Cash Flows from Financing Activities

For the year ended December 31, 2025, net cash provided by financing activities consisted of $271.9 million of net proceeds from a public offering, $7.9 million of proceeds from the exercise of stock options and $0.3 million of proceeds from the issuance of stock under the employee stock purchase plan.

For the year ended December 31, 2024, net cash provided by financing activities consisted of $215.3 million of net proceeds from the private placement, $39.2 million of net proceeds from the ATM offering program and $1.1 million of proceeds from the exercise of stock options.

Contractual Obligations and Commitments

Lease Obligations

We lease administrative office space under operating lease agreements in New York, New York, and Waltham, Massachusetts, which expire in February 2031 and January 2027, respectively.

Research and Development and Manufacturing Agreements

We enter into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with CDMOs and development and clinical trial services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not presented separately.

License and Collaboration Agreements

In October 2025, we entered into a license agreement with Leads, pursuant to which Leads granted us a royalty-bearing, exclusive license outside Greater China to develop, manufacture, commercialize, or otherwise exploit DNTH212, a bifunctional fusion protein being developed in China by Leads as LBL-047. We also obtained certain non-exclusive rights to perform development and manufacturing activities in Greater China to support DNTH212 outside of Greater China. DNTH212 is an investigational, extended half-life bifunctional fusion protein targeting plasmacytoid dendritic cell BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. We are obligated to pay Leads up to $38.0 million, comprised of $30.0 million in upfront and near-term milestone payments plus an additional $8.0 million milestone, payable in cash or our common stock at our election, upon the initiation of a Dianthus-led Phase 1 study, for exclusive rights to develop and commercialize DNTH212 globally outside of Greater China. We are also obligated to pay up to $962.0 million in development and regulatory approval milestones across three key geographies and sales-based milestones across five indications, as well as tiered royalties from mid-single digits up to a low double-digit on ex-Greater China net sales.

During the three months ended December 31, 2025, we paid Leads $25.0 million in upfront and near-term milestone payments. In addition, we recorded $5.0 million of milestone payments within the accounts payable line item on our consolidated balance sheet as of December 31, 2025.

In July 2020, we entered into a collaborative research agreement with IONTAS Limited (“IONTAS”) to perform certain milestone-based research and development activities under our first development program. We are obligated to pay development and commercial milestone payments of up to £5.4 million (approximately $7.3 million based on the December 31, 2025 exchange rate) with the first development program, which has been selected for the claseprubart program.

In August 2019, we entered into a license agreement with Alloy Therapeutics, LLC (“Alloy”) for (i) a worldwide, non-exclusive license to use the Alloy technology solely to generate Alloy antibodies and platform assisted antibodies for internal, non-clinical

research purposes, and (ii) with respect to Alloy antibodies and platform assisted antibodies that are selected by us for inclusion into a partnered antibody program, a worldwide, assignable license to make, have made, use, offer for sale, sell, import, develop, manufacture, and commercialize products comprising partnered antibody programs selected from Alloy antibodies and platform assisted antibodies in any field of use. In addition to annual license fees, we are obligated to pay development and commercial milestone payments of up to $12.8 million for the first partnered antibody, which has been selected for the claseprubart program.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The preparation of the financial statements and related disclosures requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate estimates and assumptions on a periodic basis. Our actual results may differ materially from these estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on 10-K, we believe that the following accounting policies are critical to understanding our historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses

Research and development expenses are recorded as an expense, as incurred. Research and development expenses consists of: (i) costs to engage contractors who specialize in our development activities; (ii) external research and development costs incurred under arrangements with third parties, such as CROs, CDMOs and consultants; and (iii) costs associated with preclinical and clinical activities and regulatory operations.

We enter into consulting, research, and other agreements with commercial firms, researchers, and others for the provision of goods and services. Under such agreements, we may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date, whereas payments are dictated by the terms of each agreement. As such, depending on the timing of payment relative to the receipt of goods or services, we may record either prepaid expenses or accrued services. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research and development activities on our behalf.

We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. There may also be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued or prepaid research and development expenses.

Revenue Recognition - Licensing Agreements

We analyze our licensing agreements pursuant to ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. As part of the accounting for contracts with customers, management develops assumptions that require judgment to determine whether promised goods and services represent distinct performance obligations and the standalone selling price for each performance obligation identified in the contract. This evaluation is subjective and requires us to make judgments about the promised goods and services and whether those goods and services are separable from other aspects of the

contract. Further, determining the standalone selling price for performance obligations requires significant judgment, and when an observable price of a promised good or service is not readily available, we consider relevant assumptions to estimate the standalone selling price, including, as applicable, market conditions, development timelines, probabilities of technical and regulatory success and forecasted revenues.

We evaluate the performance obligations promised in the contract that are based on goods and services that will be transferred to the customer and determine whether those obligations are both (i) capable of being distinct and (ii) distinct in the context of the contract. Goods or services that meet these criteria are considered distinct performance obligations. We estimate the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of potential transaction price and the likelihood that the transaction price will be received. We utilize either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

We apply judgment in determining whether a combined performance obligation is satisfied at a point in time or over time, and, if over time, concluding upon the appropriate method of measuring progress to be applied for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, as estimates related to the measure of progress change, related revenue recognition is adjusted accordingly. Changes in the estimated measure of progress are accounted for prospectively as a change in accounting estimate.

When two or more contracts are entered into with the same customer at or near the same time, we evaluate the contracts to determine whether the contracts should be accounted for as a single arrangement. Contracts are combined and accounted for as a single arrangement if one or more of the following criteria are met: (i) the contracts are negotiated as a package with a single commercial objective; (ii) the amount of consideration to be paid in one contract depends on the price or performance of the other contract; or (iii) the goods or services promised in the contracts (or some goods or services promised in each of the contracts) are a single performance obligation.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Where applicable, amounts are recorded as unbilled revenue when our right to consideration is unconditional. We do not assess whether a contract with a customer has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

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

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Dianthus Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Dianthus 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 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of 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 accounting principles generally accepted in the United States of America.

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 critical audit matters does not alter in any way our opinion on the 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.

Research and Development Expenses related to contract research organizations and contract development and manufacturing organizations — *Refer to Note 2 to the financial statements*

Critical Audit Matter Description

The Company incurs certain research and development expenses from third-party contract research organizations ("CROs") and contract development and manufacturing organizations ("CDMOs"). The Company may pay for services on a monthly, quarterly, project or other basis. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the service providers and vendors, whereas payments are dictated by the terms of each agreement. As such, depending on the timing of payment relative to the receipt of goods or services, management may record either prepaid expenses or accrued services.

We identified research and development expenses related to CROs and CDMOs as a critical audit matter because of the judgments necessary for the Company to estimate the extent of service performed and the associated expense incurred. A high degree of auditor judgment and an increased extent of effort was required when auditing the Company's estimates of the extent of services performed and expenses incurred and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to research and development expenses related to CROs and CDMOs included the following, among others:

- We evaluated the Company's overall estimation methodology and assumptions to estimate the research and development expenses related to CROs and CDMOs and evaluated management's conclusions compared to the evidence obtained.
- We made selections and tested on a sample basis the research and development expenses related to CROs and CDMOs by:
  - Obtaining and reading the related contracts to understand key provisions and agree them to the Company's analysis.
  - Obtaining and inspecting third-party documents such as service contracts, status reports, and other correspondence received from the vendors related to the services provided and comparing them to the Company's schedule of estimated expenses incurred to date.
  - Obtaining and inspecting confirmations from select vendors confirming the accuracy and completeness of the data and information provided to the Company.
  - Testing the mathematical accuracy of the underlying analyses used in the estimates of the services provided.
- We examined subsequent invoices received from vendors and cash disbursements made subsequent to December 31, 2025 and inquired of individuals within the clinical and manufacturing operations of the Company to corroborate the applicable service period in order to evaluate completeness of the research and development expenses related to CROs and CDMOs.

/s/ Deloitte & Touche LLP
Morristown, New Jersey
March 8, 2026
We have served as the Company's auditor since 2022.

DIANTHUS THERAPEUTICS, INC.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 51,087	$ 22,792
Short-term investments	353,208	252,449
Receivable from former related party	—	807
Accounts receivable, net	52	—
Prepaid expenses and other current assets	5,091	4,856
Total current assets	409,438	280,904
Long-term investments	110,135	81,728
Property and equipment, net	296	194
Right-of-use operating lease assets	1,337	1,553
Other assets and restricted cash	9,716	9,629
Total assets	$ 530,922	$ 374,008
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,725	$ 4,579
Accrued expenses	19,452	13,074
Current portion of deferred revenue	1,188	479
Current portion of operating lease liabilities	367	320
Total current liabilities	30,732	18,452
Deferred revenue	5,770	1,908
Long-term operating lease liabilities	1,019	1,171
Total liabilities	37,521	21,531
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; authorized shares – 10,000,000 at December 31, 2025 and 2024; issued and outstanding – none at December 31, 2025 and 2024	—	—
Common stock; $0.001 par value per share; authorized shares – 150,000,000 at December 31, 2025 and 2024; issued and outstanding shares – 43,223,090 and 31,115,341 at December 31, 2025 and 2024, respectively	43	31
Additional paid-in capital	829,598	526,732
Accumulated deficit	(336,729)	(174,392)
Accumulated other comprehensive income	489	106
Total stockholders' equity	493,401	352,477
Total liabilities and stockholders' equity	$ 530,922	$ 374,008

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

DIANTHUS THERAPEUTICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2025	**2024**
Revenues:		
License revenue - former related party	$ —	$ 5,909
License revenue	2,036	326
Total revenues	2,036	6,235
Operating expenses:		
Research and development	145,638	83,105
General and administrative	34,331	24,994
Total operating expenses	179,969	108,099
Loss from operations	(177,933)	(101,864)
Other income/(expense):		
Interest and investment income	16,119	17,365
Gain on investment in former related party	508	148
Loss on currency exchange, net	(57)	(64)
Other expense	(974)	(554)
Total other income	15,596	16,895
Net loss	$ (162,337)	$ (84,969)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.20)	$ (2.55)
Weighted-average number of shares of common stock outstanding including shares issuable under equity-classified pre-funded warrants, used in computing net loss per share of common stock, basic and diluted	38,617,580	33,313,849
Comprehensive loss:		
Net loss	$ (162,337)	$ (84,969)
Other comprehensive income:		
Unrealized gain on marketable securities	383	59
Total other comprehensive income	383	59
Total comprehensive loss	$ (161,954)	$ (84,910)

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

DIANTHUS THERAPEUTICS, INC.
Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Paid-in Capital	Deficit	Income	Equity
Balance, December 31, 2023	14,817,696	$ 15	$ 258,231	$ (89,423)	$ 47	$ 168,870
Issuance of common stock and pre-funded warrants in connection with the private placement, net of issuance costs of $14,665	14,500,500	14	215,319	—	—	215,333
Issuance of common stock in connection with at-the-market offering ("ATM"), net of issuance costs	1,503,708	2	39,198	—	—	39,200
Exercise of pre-funded warrants	210,316	—	—	—	—	—
Exercise of stock options	83,121	—	1,090	—	—	1,090
Stock-based compensation expense	—	—	12,894	—	—	12,894
Net loss	—	—	—	(84,969)	—	(84,969)
Unrealized gain on marketable securities	—	—	—	—	59	59
Balance, December 31, 2024	31,115,341	$ 31	$ 526,732	$ (174,392)	$ 106	$ 352,477
Issuance of common stock and pre-funded warrants in connection with public offering, net of issuance costs of $404	7,627,879	8	271,856	—	—	271,864
Exercise of pre-funded warrants	3,833,921	4	(3)	—	—	1
Exercise of stock options	627,148	—	7,903	—	—	7,903
Issuance of common stock under employee stock purchase plan	18,801	—	317	—	—	317
Stock-based compensation expense	—	—	22,793	—	—	22,793
Net loss	—	—	—	(162,337)	—	(162,337)
Unrealized gain on marketable securities	—	—	—	—	383	383
Balance, December 31, 2025	43,223,090	$ 43	$ 829,598	$ (336,729)	$ 489	$ 493,401

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

DIANTHUS THERAPEUTICS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (162,337)	$ (84,969)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	111	96
Stock-based compensation expense	22,793	12,894
Accretion of discount on investment securities	(6,163)	(6,018)
Amortization of right-of-use operating lease assets	317	316
Gain on investment in former related party	(507)	(148)
Changes in operating assets and liabilities:		
Receivable from former related party	807	(513)
Unbilled receivable from former related party	—	184
Accounts receivable, net	(52)	—
Prepaid expenses and other current assets	(235)	(1,601)
Other assets	358	(8,163)
Accounts payable, accrued expenses and operating lease liabilities	11,277	8,191
Deferred revenue	4,571	2,387
Deferred revenue - former related party	—	(836)
Net cash used in operating activities	(129,060)	(78,180)
Cash flows from investing activities:		
Capital expenditures	(213)	(105)
Purchases of investment securities	(435,013)	(413,707)
Proceeds from sales and maturities of investment securities	312,393	127,000
Net cash used in investing activities	(122,833)	(286,812)
Cash flows from financing activities:		
Proceeds from public offering	272,268	—
Payment of issuance costs in connection with public offering	(364)	—
Proceeds from exercise of stock options	7,903	1,090
Proceeds from issuance of common stock under employee stock purchase plan	317	—
Proceeds from exercise of pre-funded warrants	1	—
Proceeds from private placement	—	229,998
Payment of issuance costs in connection with private placement	—	(14,665)
Proceeds from issuance of common stock pursuant to ATM offering, net of issuance costs	—	39,200
Net cash provided by financing activities	280,125	255,623
Increase/(decrease) in cash, cash equivalents and restricted cash	28,232	(109,369)
Cash, cash equivalents and restricted cash, beginning of period	23,022	132,391
Cash, cash equivalents and restricted cash, end of period	$ 51,254	$ 23,022
Supplemental Disclosure		
Cash and cash equivalents	$ 51,087	$ 22,792
Restricted cash	167	230
Total cash, cash equivalents and restricted cash	$ 51,254	$ 23,022
Cash paid for interest	$ —	$ —
Cash paid for taxes	$ —	$ —
Issuance costs in connection with public offering included in accrued expenses	$ 40	$ —
Additions to right-of-use lease assets from new operating lease liabilities	$ 101	$ 1,253

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

1. Organization, Description of Business and Liquidity

Business

Dianthus Therapeutics, Inc. (the "Company" or "Dianthus") is a clinical-stage biotechnology company dedicated to developing potentially best in class therapies for patients living with severe autoimmune diseases. The Company's corporate headquarters are in New York, New York.

Currently, the Company is devoting substantially all efforts and resources toward product research and development of its product candidates. The Company has incurred losses from operations and negative operating cash flows since its inception. There can be no assurance that its research and development programs will be successful, that products developed, if any, will obtain necessary regulatory approval, or that any approved product, if any, will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its key employees, consultants, and advisors.

Reverse Merger and Pre-Closing Financing

On September 11, 2023, the Company completed its business combination with Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.) ("Former Dianthus") in accordance with the terms of the Agreement and Plan of Merger, dated as of May 2, 2023 (the "Merger Agreement"), by and among the Company, Dio Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and Former Dianthus, pursuant to which, among other matters, Merger Sub merged with and into Former Dianthus, with Former Dianthus surviving as a wholly owned subsidiary of the Company (the "Reverse Merger"). In connection with the completion of the Reverse Merger, the Company changed its name from "Magenta Therapeutics, Inc." to "Dianthus Therapeutics, Inc.," and the business conducted by the Company became primarily the business conducted by Former Dianthus. Unless context otherwise requires, references herein to "Dianthus," the "Company," or the "combined company" refer to Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.) after completion of the Reverse Merger, the term "Former Dianthus" refers to Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.), and the term "Magenta" refers to the Company prior to completion of the Reverse Merger. The Company was incorporated in June 2015, and Former Dianthus was incorporated in May 2019.

Immediately prior to the effective time of the Reverse Merger, the Company effected a 1-for-16 reverse stock split of its common stock (the "Reverse Stock Split"). Unless noted otherwise, all references herein to share and per share amounts reflect the Reverse Stock Split.

At the effective time of the Reverse Merger, the Company issued an aggregate of 11,021,248 shares of common stock to the Former Dianthus stockholders, based on the exchange ratio of approximately 0.2181 shares of common stock for each share of Former Dianthus common stock, including those shares of Former Dianthus common stock issued upon the conversion of Former Dianthus preferred stock and those shares of the Former Dianthus common stock issued in the pre-closing financing (as defined below), resulting in 14,817,696 shares of common stock being issued and outstanding following the effective time of the Reverse Merger.

At the effective time of the Reverse Merger, the 2019 Stock Plan (as discussed in Note 11) was assumed by the Company, and each outstanding and unexercised option to purchase shares of Former Dianthus common stock immediately prior to the effective time of the Reverse Merger was assumed by the Company and converted into an option to purchase shares of common stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio, and each outstanding and unexercised warrant to purchase shares of Former Dianthus common stock immediately prior to the effective time of the Reverse Merger (including the Former Dianthus pre-funded warrants sold in the pre-closing financing) was converted into a warrant to purchase shares of common stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio.

The Reverse Merger was accounted for as a reverse recapitalization in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). Under this method of accounting, Former Dianthus was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the expectation that, immediately following the Reverse Merger: (i) Former Dianthus' stockholders would own a substantial majority of the voting rights in the combined company; (ii) Former Dianthus' largest stockholders would retain the largest interest in the combined company; (iii) Former Dianthus would designate a majority (six of eight) of the initial members of the board of directors of the combined company; and (iv) Former Dianthus' executive management team would become the management team of the combined company. Accordingly, for accounting purposes: (i) the Reverse Merger was treated as the equivalent of Former Dianthus issuing stock to acquire the net assets of Magenta; (ii) the net assets of Magenta were recorded at their acquisition-date fair value in the consolidated financial statements of Former Dianthus and (iii) the reported historical operating results of the combined company prior to the Reverse Merger are those of Former Dianthus. Historical common stock figures of Former Dianthus have been retroactively restated based on the exchange ratio of approximately 0.2181.

On September 11, 2023, prior to the effective time of the Reverse Merger, the Company entered into a contingent value rights agreement (the "CVR Agreement") with a rights agent, pursuant to which pre-Reverse Merger holders of Magenta common stock received one non-transferable contingent value right (each, a "CVR") for each outstanding share of Magenta common stock held by such stockholder immediately prior to the effective time of the Reverse Merger on September 11, 2023. Subject to, and in accordance with, the terms and conditions of the CVR Agreement, each CVR represents the contractual right to receive a pro rata portion of the proceeds, if any, received by the Company as a result of (i) contingent payments made to the Company, such as milestone, royalty or earnout, when received under any pre-Reverse Merger disposition agreements related to Magenta's pre-Reverse Merger assets and (ii) the Company's sale of assets after the effective date of the Reverse Merger and prior to December 31, 2023, in each case, received within a three-year period following the closing of the Reverse Merger.

The Company believes that the achievement of the milestones outlined in the CVR Agreement are highly susceptible to factors outside the Company's influence that are not expected to be resolved for a long period of time, if at all. In particular, these amounts are primarily influenced by the actions and judgments of third parties and the buyers of such assets and are based on the buyers of such assets progressing the in-process research and development assets into clinical trials, and in the case of one of the agreements, to a regulatory milestone. If the Company were to record a receivable for such contingent payments, it would also record a corresponding liability. As of December 31, 2025, no receivables were recorded on the consolidated balance sheet relating to such contingent payments.

Concurrently with the execution and delivery of the Merger Agreement, and in order to provide Former Dianthus with additional capital for its development programs, Former Dianthus entered into a subscription agreement, as amended (the "Subscription Agreement"), with certain investors named therein (the "Investors"), pursuant to which, subject to the terms and conditions of the Subscription Agreement, immediately prior to the effective time of the Reverse Merger, Former Dianthus issued and sold, and the Investors purchased, (i) 2,873,988 shares of Former Dianthus common stock and (ii) 210,320 pre-funded warrants, exercisable for 210,320 shares of Former Dianthus common stock, at a purchase price of approximately $23.34 per share or $23.34 per warrant, for an aggregate purchase price of approximately $72.0 million (the "pre-closing financing").

2024 Private Placement

On January 22, 2024, the Company entered into a securities purchase agreement for a private placement with certain institutional and accredited investors. At the closing of the private placement on January 24, 2024, the Company sold and issued 14,500,500 shares of common stock at a price per share of $12.00, and pre-funded warrants to purchase 4,666,332 shares of common stock at a purchase price of $11.999 per pre-funded warrant, which represents the per share purchase price of the common stock less the $0.001 per share exercise price for each pre-funded warrant, for an aggregate purchase price of approximately $230.0 million. The pre-funded warrants are exercisable at any time after the date of issuance. A holder of pre-funded warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of pre-funded warrants may increase or decrease this percentage to a percentage not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

Shelf Registration Statement and ATM Offering Program

On October 1, 2024, the Company filed a registration statement with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of $500.0 million. On October 9, 2024, the registration statement was declared effective by the SEC. The registration statement includes an ATM offering program for the sale of up to $200.0 million of shares of the Company's common stock. The Company sold 1,503,708 shares of its common stock under the ATM offering program during the year ended December 31, 2024, resulting in net proceeds of $39.2 million. No sales were made under the ATM offering program during the year ended December 31, 2025. As of the date of this filing, the Company has sold 2,626,834 shares of its common stock under the ATM offering program and has $100.1 million in remaining capacity under the ATM offering program.

On January 28, 2026, the Company filed a registration statement with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of $600.0 million. On January 30, 2026, the registration statement was declared effective by the SEC.

September 2025 Underwritten Public Offering

On September 9, 2025, the Company entered into an underwriting agreement with certain underwriters to issue and sell 7,627,879 shares of the Company's common stock, including the full exercise by the underwriters of their option to purchase an additional 1,140,000 shares, at a public offering price of $33.00 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase 1,112,121 shares of the Company's common stock at a public offering price of $32.999 per share, which represented the per share public offering price for the common stock less the $0.001 per share exercise price for each pre-funded warrant. The gross proceeds from the underwritten offering were $288.4 million, before underwriting discounts and commissions and estimated expenses of the offering. The underwritten offering closed on September 11, 2025.

The pre-funded warrants are exercisable at any time after the date of issuance. A holder of the pre-funded warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 4.99%, 9.99%, or 19.99%, as applicable to each holder, of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of the pre-funded warrants may increase or decrease this percentage to a percentage not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

The Company intends to use the net proceeds from this underwritten offering to advance the Company's preclinical and clinical development activities, as well as for working capital and general corporate purposes. The Company 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 a shelf registration statement, which became effective on October 9, 2024. A final prospectus supplement dated September 9, 2025 relating to and describing the terms of the underwritten offering was filed with the SEC on September 11, 2025.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on its key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing and compliance with government regulations. If the Company does not successfully commercialize any of its product candidates, it will be unable to generate recurring product revenue or achieve profitability.

The Company's current product candidates, as well as any future product candidates, 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 and infrastructure, and extensive compliance-reporting capabilities. Even if its product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales.

Liquidity

In accordance with Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (Subtopic 205-40), the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements were issued (the "issuance date"):

- Since its inception, the Company has funded its operations primarily with outside capital and has incurred significant recurring losses, including net losses of $162.3 million and $85.0 million for the years ended December 31, 2025 and 2024, respectively. In addition, the Company had an accumulated deficit of $336.7 million as of December 31, 2025;

- The Company expects to continue to incur significant recurring losses and rely on outside capital to fund its operations for the foreseeable future; and

- As of the issuance date, the Company expects that its existing cash, cash equivalents and investments on hand will be sufficient to fund its obligations as they become due for at least twelve months beyond the issuance date. The Company expects that its research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for its existing product candidates and any future product candidates to support commercialization and providing general and administrative support for its operations, including the costs associated with operating as a public company.

In the event the Company is unable to secure additional outside capital, management will be required to seek other alternatives which may include, among others, a delay or termination of clinical trials or the development of its product candidates, temporary or permanent curtailment of the Company's operations, a sale of assets, or other alternatives with strategic or financial partners.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ materially from those estimates.

Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates including the following: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Significant estimates are used in the following areas, among others: the recognition of research and development expense and revenue recognition.

Cash and Cash Equivalents

All short-term, highly liquid investments with original maturities of 90 days or less are considered to be cash and cash equivalents. The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents are valued at cost, which approximates fair value.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and investments. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. The Company invests its excess cash primarily in money market funds, U.S. treasury securities, U.S. government agency securities and corporate debt securities in accordance with the Company's investment policy. The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. The Company has not experienced any significant realized losses related to its cash, cash equivalents and investments and management believes the Company is not exposed to significant risks of losses.

Investments

The Company's investments consist of marketable securities classified as available-for-sale and reported at fair value on the consolidated balance sheets. Management of the Company determines the appropriate classification of the securities at the time they are

acquired and evaluates the appropriateness of such classifications at each balance sheet date. Investments in marketable securities with remaining maturities when purchased of greater than three months and less than one year are classified as current. Investments with a remaining maturity date greater than one year are classified as non-current. Unrealized gains and losses on available-for-sale securities are reported as a component of accumulated other comprehensive income/(loss) on the consolidated balance sheets. Interest earned on securities that are classified as available-for-sale are included in interest income. Realized gains and losses and declines in value judged to be other than temporary are included as a component of interest and investment income in the consolidated statements of operations and comprehensive loss, based on the specific identification method.

When the fair value is below the amortized cost of a marketable security, an estimate of expected credit losses is made in accordance with ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The credit-related impairment amount is recognized in the consolidated statements of operations and comprehensive loss. Credit losses are recognized through the use of an allowance for credit losses account in the consolidated balance sheet and subsequent improvements in expected credit losses are recognized as a reversal of an amount in the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, then the allowance for the credit loss is written-off and the excess of the amortized cost basis of the asset over its fair value is recorded in the consolidated statements of operations and comprehensive loss. There were no credit losses recorded during the years ended December 31, 2025 or 2024.

Additional information regarding investments is included in Note 4.

Receivable from Former Related Party and Unbilled Receivable from Former Related Party

The receivable from former related party and the unbilled receivable from former related party results from the option and license agreements with Zenas BioPharma, Inc. (formerly Zenas BioPharma Limited) ("Zenas"). The Company previously considered Zenas to be a related party. See Notes 12 and 17 for more information. The receivable represents amounts earned and billed to Zenas but not yet collected as of period end while the unbilled receivable represents amounts earned but not yet billed to Zenas as of period end. The receivable and unbilled receivable are reported at net realizable value. The Company evaluated the creditworthiness of Zenas and their financial condition and did not require collateral from Zenas. No allowance for doubtful accounts is recorded as all accounts are considered collectible.

Accounts Receivable

Accounts receivable relates to the license agreement with Tenacia Biotechnology (Hong Kong) Co., Limited ("Tenacia"). See Note 12 for more information. The receivable represents amounts earned and billed to Tenacia but not yet collected as of period end. The receivable are reported at net realizable value. The Company evaluated the creditworthiness of Tenacia and their financial condition and did not require collateral from Tenacia. No allowance for doubtful accounts is recorded as all accounts are considered collectible.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over estimated useful lives of three years for computer equipment and five years for furniture and fixtures. Expenditures for major renewals and betterments that extend the useful lives are capitalized. Expenditures for normal maintenance and repairs are expensed as incurred. The cost of assets sold or abandoned, and the related accumulated depreciation are eliminated from the accounts and any gains or losses are recognized in the accompanying consolidated statements of operations and comprehensive loss of the respective period.

Leases

Operating leases are accounted for in accordance with ASU 2016-02, *Leases*, as amended ("ASC 842"). Right-of-use lease assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. As the Company's leases do not provide an implicit rate, management used the Company's incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The right-of-use asset is based on the measurement of the lease liability and includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. Rent expense for operating leases is recognized on a straight-line basis over the lease term. The Company does not have any leases classified as finance leases. Management has elected the practical expedient to exclude short-term leases from right-of-use assets and lease liabilities.

The Company's leases do not have significant rent escalation, holidays, concessions, material residual value guarantees, material restrictive covenants or contingent rent provisions. The Company's leases include both lease (e.g., fixed payments including rent, taxes,

and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as management has elected the practical expedient to group lease and non-lease components for all leases.

Additional information and disclosures required under ASC 842 are included in Note 9.

Restricted Cash

In accordance with ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, restricted cash is included as a component of cash, cash equivalents and restricted cash in the accompanying consolidated statements of cash flows. Restricted cash serves as collateral for a letter of credit securing office space. Restricted cash is recorded within the prepaid expenses and other current assets and the other assets and restricted cash line items in the accompanying consolidated balance sheets.

Fair Value Measurements

The Company calculates the fair value of assets and liabilities that qualify as financial instruments and includes additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments.

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"), defines fair value 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 at the measurement date. ASC 820 establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect management's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality.

The three levels of the fair value hierarchy are described below:

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

- Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

To the extent that a 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 management in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Management has segregated all financial assets and liabilities that are measured at fair value on a recurring basis into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date. The Company's valuation techniques for its Level 2 financial assets included using quoted prices for similar assets in active markets and quoted prices for similar assets in markets that are not active.

The estimated fair value of receivable from former related party, accounts receivable, accounts payable and accrued expenses approximate their carrying amounts due to the relatively short maturity of these instruments.

Additional information regarding fair value measurements is included in Note 7.

License Revenues

To date, the Company's only revenue has been attributable to upfront payments and cost reimbursements under the Company's licensing agreements. The Company has not generated any revenue from product sales and does not expect to generate any revenue from product sales for the foreseeable future.

The Company recognizes revenue pursuant to ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identifies the contract with a customer; (ii) identifies the performance obligations in the contract; (iii) determines the transaction price; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when the performance obligation is satisfied.

The Company evaluates the performance obligations promised in a contract that are based on goods and services that will be transferred to the customer and determines whether those obligations are both (i) capable of being distinct and (ii) distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, the Company applies judgment to determine whether promised goods and services are both capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential transaction price and the likelihood that the transaction price will be received. Variable consideration is included in the transaction price if, in management's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. The Company then allocates the transaction price to each performance obligation and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months, the related deferred revenue is classified in current liabilities.

Additional information and disclosures required under ASC 606 are included in Note 12.

Research and Development Costs

Research and development expenses are recorded as expense, as incurred. Research and development expenses consists of (i) costs to engage contractors who specialize in the development activities of the Company; (ii) external research and development costs incurred under arrangements with third parties, such as contract research organizations, contract development and manufacturing organizations and consultants; and (iii) costs associated with preclinical and clinical activities and regulatory operations.

The Company enters into consulting, research, and other agreements with commercial firms, researchers, and others for the provision of goods and services. Under such agreements, the Company may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the service providers and vendors or our estimate of the level of service that has been performed at each reporting date, whereas payments are dictated by the terms of each agreement. As such, depending on the timing of payment relative to the receipt of goods or services, management may record either prepaid expenses or accrued services. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company.

Patent Costs

Patent costs are expensed as incurred and recorded within general and administrative expenses.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes (*"ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities and for loss and credit carryforwards using enacted tax rates anticipated to be in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of December 31, 2025 and 2024, the Company did not have any material uncertain tax positions. The Company recognizes interest and penalties related to uncertain tax positions, if any exist, in income tax expense.

Additional information and disclosures required under ASC 740 are included in Note 13.

Stock-Based Compensation

The Company accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation – Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments, including grants of stock options and restricted stock, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values. All of the stock-based awards are subject only to service-based vesting conditions. Management estimates the fair value of the stock option awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (a) the fair value of the Company's common stock, (b) the expected stock price volatility, (c) the calculation of expected term of the award, (d) the risk-free interest rate and (e) expected dividends. Management estimates the fair value of the restricted stock awards, if any, using the fair value of the Company's common stock. Forfeitures are recognized as they are incurred.

Management uses the simplified method, as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term. The risk-free interest rate is based on observed interest rates appropriate for the term of the awards. The dividend yield assumption is based on history and expectation of paying no dividends.

Compensation expense related to stock-based awards is calculated on a straight-line basis by recognizing the grant date fair value, over the associated service period of the award, which is generally the vesting term.

Additional information regarding stock-based compensation is included in Note 11.

Comprehensive Loss

The only component of comprehensive loss other than net loss is change in unrealized gains related to marketable securities.

Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares of common stock outstanding includes the weighted average effect of outstanding pre-funded warrants for the purchase of shares of common stock for which the remaining unfunded exercise price is $0.001 or less per share.

Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as stock options and warrants for the purchase of common stock, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock outstanding is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. For all periods presented, basic and diluted net loss per share were the same, as any additional share equivalents would be anti-dilutive.

Additional information is included in Note 15.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740), Improvements to Income Tax Disclosures*, to enhance the transparency and decision usefulness of income tax disclosures. The enhancement provides information to better assess how an entity's operations and related tax risks and tax planning and operational opportunities affect its tax rate and prospects for future cash flows. On January 1, 2025, the Company adopted ASU 2023-09 on a prospective basis. Refer to Note 13 to these consolidated financial statements for additional discussion.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The amendments in ASU No. 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact ASU No. 2024-03 may have on its consolidated financial statements and related disclosures.

3. Segment Reporting

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 (the "CODM") in deciding how to allocate resources and in assessing the Company's performance. The Company operates as a single operating segment and has one reportable segment which focuses on developing next-generation therapies to transform the treatment of severe autoimmune diseases.

The Company's CODM is its Chief Executive Officer. The CODM manages the Company's operations on a consolidated basis as one operating segment for the purposes of evaluating financial performance and allocating resources.

The Company has not yet generated any revenue from product sales. The CODM assesses the financial performance of the segment and decides how to allocate resources based on net loss on a consolidated basis. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

The CODM uses net loss predominantly in the annual operating budget and in the strategic planning and forecasting process. Such profit or loss measure is used to monitor budget versus actual results on an ongoing basis by the CODM and determines how resources are allocated to the various activities of the Company. The CODM also uses net loss to evaluate the Company's performance and considers net loss when determining management's incentive compensation.

All of the Company's tangible assets are held in the United States. The Company views its operations and manages its business in one operating segment, operating exclusively in the United States.

The table below provides a summary of the segment profit or loss, including significant segment expenses:

	Year Ended December 31,	
	2025	2024
Revenues:		
License revenue - former related party	$ —	$ 5,909
License revenue	2,036	326
Total revenues	2,036	6,235
Research and development expenses:		
Claseprubart program-related expenses:		
Clinical operation activity costs	49,870	25,764
CMC activity costs	16,570	19,494
Preclinical study activity costs	3,563	8,537
Other costs	2,069	600
Total claseprubart program-related expenses	72,072	54,395
Discovery expenses[1]	32,070	2,117
Personnel and related costs	26,008	16,638
Stock-based compensation expense	10,090	5,576
Other costs	5,398	4,379
Total research and development expenses	145,638	83,105
General and administrative expenses:		
Stock-based compensation expense	12,703	7,318
Personnel and related costs	11,531	8,249
Other costs	10,097	9,427
Total general and administrative expenses	34,331	24,994
Other income, net	15,596	16,895
Net loss	$ (162,337)	$ (84,969)

(1) For the year ended December 31, 2025, discovery expenses include $30.0 million related to the upfront and near-term milestone payments pursuant to the Leads License Agreement (as defined below in Note 16) related to DNTH212. Additional information is included in Note 16.

4. Cash Equivalents and Marketable Securities

The Company's investments consist of marketable securities classified as available-for-sale. The following tables provide a summary of the estimated fair value of the Company's cash equivalents and marketable securities:

	December 31, 2025				Classification	
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value	Short-term	Long-term
Cash equivalents:						
Money market funds	$ 50,247	$ —	$ —	$ 50,247	$ 50,247	$ —
Total cash equivalents	$ 50,247	$ —	$ —	$ 50,247	$ 50,247	$ —
Marketable securities:						
U.S. treasury securities	$ 345,668	$ 402	$ —	$ 346,070	$ 274,152	$ 71,918
Certificate of deposit	6,112	9	—	6,121	6,121	—
U.S. government agency securities	17,053	17	(7)	17,063	7,521	9,542
Corporate debt securities	89,709	81	(15)	89,775	61,100	28,675
Commercial paper	4,312	2	—	4,314	4,314	—
Total marketable securities	$ 462,854	$ 511	$ (22)	$ 463,343	$ 353,208	$ 110,135

	December 31, 2024				Classification	
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value	Short-term	Long-term
Cash equivalents:						
Money market funds	$ 19,742	$ —	$ —	$ 19,742	$ 19,742	$ —
Corporate debt securities	2,204	—	—	2,204	2,204	—
Total cash equivalents	$ 21,946	$ —	$ —	$ 21,946	$ 21,946	$ —
Marketable securities:						
U.S. treasury securities	$ 257,334	$ 198	$ (130)	$ 257,402	$ 186,552	$ 70,850
U.S. government agency securities	6,946	2	(5)	6,943	3,928	3,015
Corporate debt securities	69,791	45	(4)	69,832	61,969	7,863
Total marketable securities	$ 334,071	$ 245	$ (139)	$ 334,177	$ 252,449	$ 81,728

As December 31, 2024, marketable securities within the corporate debt securities line item includes both commercial paper and corporate debt securities. Commercial paper held at December 31, 2024 was classified as short-term securities.

Interest and Investment Income

The following table provides a summary of the components of interest and investment income:

	Year Ended December 31,	
	2025	2024
Interest income	$ 9,956	$ 11,347
Accretion of discount on marketable securities, net	6,163	6,018
Total interest and investment income	$ 16,119	$ 17,365

5. Prepaid Expenses and Other Current Assets

The following table provides a summary of prepaid expenses and other current assets:

	December 31,	
	2025	2024
Prepaid materials, supplies and research and development services	$ 3,033	$ 3,035
Prepaid subscriptions, software and other administrative services	1,274	770
Prepaid insurance	698	696
Other current assets	86	355
Prepaid expenses and other current assets	$ 5,091	$ 4,856

6. Property and Equipment

The following table provides a summary of property and equipment:

	December 31,	
	2025	2024
Computer equipment	$ 543	$ 333
Furniture and fixtures	57	54
Subtotal	600	387
Less: accumulated depreciation	(304)	(193)
Property and equipment, net	$ 296	$ 194

Depreciation expense was $0.1 million for each of the years ended December 31, 2025 and 2024.

7. Fair Value of Financial Instruments

The following table provides a summary of financial assets measured at fair value on a recurring basis:

Description	Fair Value at December 31, 2025	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents:				
Money market funds	$ 50,247	$ 50,247	$ —	$ —
Short-term investments:				
U.S. treasury securities	274,152	274,152	—	—
Certificate of deposit	6,121	6,121	—	—
U.S. government agency securities	7,521	—	7,521	—
Corporate debt securities	61,100	—	61,100	—
Commercial paper	4,314	—	4,314	—
Long-term investments:				
U.S. treasury securities	71,918	71,918	—	—
U.S. government agency securities	9,542	—	9,542	—
Corporate debt securities	28,675	—	28,675	—
Other assets and restricted cash:				
Investment in former related party	656	656	—	—
Total assets measured at fair value	$ 514,246	$ 403,094	$ 111,152	$ —

Description	Fair Value at December 31, 2024	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents:				
Money market funds	$ 19,742	$ 19,742	$ —	$ —
Corporate debt securities	2,204	—	2,204	—
Short-term investments:				
U.S. treasury securities	186,552	186,552	—	—
U.S. government agency securities	3,928	—	3,928	—
Corporate debt securities	61,969	—	61,969	—
Long-term investments:				
U.S. treasury securities	70,850	70,850	—	—
U.S. government agency securities	3,015	—	3,015	—
Corporate debt securities	7,863	—	7,863	—
Other assets and restricted cash:				
Investment in former related party	148	148	—	—
Total assets measured at fair value	$ 356,271	$ 277,292	$ 78,979	$ —

There were no transfers between levels for the years ended December 31, 2025 or 2024. The weighted-average maturity of the securities held at December 31, 2025 was less than 12 months.

As of December 31, 2024, marketable securities within the corporate debt securities line item included both commercial paper and corporate debt securities. Commercial paper held at December 31, 2024 was classified as short-term securities and classified within Level 2 of the fair value hierarchy.

8. Accrued Expenses

The following table provides a summary of accrued expenses:

	December 31,	
	2025	2024
Accrued compensation	$ 9,517	$ 5,154
Accrued external research and development	8,589	6,996
Accrued professional fees	215	271
Other accrued expenses	1,131	653
Accrued expenses	$ 19,452	$ 13,074

9. Leases

The Company leases space under operating leases for administrative offices in New York, New York, and Waltham, Massachusetts. The Company previously leased wet laboratory space in Watertown, Massachusetts, but this lease terminated in March 2025.

The following table provides a summary of the components of lease costs and rent:

	Year Ended December 31,	
	2025	2024
Operating lease cost	$ 396	$ 422
Variable lease cost	44	32
Total operating lease costs	$ 440	$ 454

Cash paid for amounts included in the measurement of operating lease liabilities was $0.3 million and $0.4 million for the years ended December 31, 2025 and 2024, respectively.

The Company recorded operating lease costs of $0.4 million within the general and administrative expenses line item in the consolidated statements of operations and comprehensive loss during each of the years ended December 31, 2025 and 2024. The Company recorded operating lease costs of $24 thousand and $58 thousand within the research and development expenses line item in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2025 and 2024, respectively.

Maturities of operating lease liabilities as of December 31, 2025 are as follows:

2026	$ 367
2027	323
2028	318
2029	321
2030	324
Thereafter	54
Total undiscounted operating lease payments	1,707
Less: imputed interest	(321)
Present value of operating lease liabilities	$ 1,386
Balance sheet classification:	
Current portion of operating lease liabilities	$ 367
Long-term operating lease liabilities	1,019
Total operating lease liabilities	$ 1,386

The weighted-average remaining term of operating leases was 58 months and the weighted-average discount rate used to measure the present value of operating lease liabilities was 8.40% as of December 31, 2025.

10. Stockholders' Equity

September 2025 Underwritten Public Offering

At the closing of an underwritten public offering on September 11, 2025, the Company issued and sold 7,627,879 shares of its common stock, including the full exercise by the underwriters of their option to purchase an additional 1,140,000 shares, and pre-funded warrants to purchase 1,112,121 shares of its common stock with a $0.001 per share exercise price. The gross proceeds from this underwritten public offering were $288.4 million, before underwriting discounts and commissions and estimated expenses related to this public offering.

The pre-funded warrants are exercisable at any time after the date of issuance and will not expire. As of December 31, 2025, there were 1,112,121 pre-funded warrants outstanding related to this underwritten public offering.

Shelf Registration Statement and ATM Offering Program

On October 1, 2024, the Company filed a registration statement with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of $500.0 million. On October 9, 2024, the registration statement was declared effective by the SEC. The registration statement includes an ATM offering program for the sale of up to $200.0 million of shares of the Company's common stock. The Company sold 1,503,708 shares of its common stock under the ATM offering program during the year ended December 31, 2024, resulting in net proceeds of $39.2 million. No sales were made under the ATM offering program during the year ended December 31, 2025. As of the date of this filing, the Company has sold 2,626,834 shares of its common stock under the ATM offering program and has $100.1 million in remaining capacity under the ATM offering program.

On January 28, 2026, the Company filed a registration statement with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of $600.0 million. On January 30, 2026, the registration statement was declared effective by the SEC.

Private Placement Offering

At the closing of the private placement on January 24, 2024, the Company issued 14,500,500 shares of common stock and pre-funded warrants to purchase 4,666,332 shares of common stock with a $0.001 per share exercise price. The pre-funded warrants are exercisable at any time after the date of issuance and will not expire. As of December 31, 2025, there were 832,333 pre-funded warrants outstanding related to this private placement.

Preferred Stock

As of December 31, 2025, the Company was authorized to issue up to 10,000,000 shares of preferred stock at a par value of $0.001. As of December 31, 2025, no shares of preferred stock were issued and outstanding.

Common Stock

As of December 31, 2025, the Company was authorized to issue up to 150,000,000 shares of common stock at a par value of $0.001. As of December 31, 2025, the Company had issued and outstanding 43,223,090 shares of common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any. No dividends have been declared or paid by the Company through December 31, 2025.

The Company had the following shares of common stock reserved for future issuance:

	December 31,	
	2025	2024
Issuance of common stock upon exercise of stock options	5,991,343	4,499,702
Equity awards available for grant under stock award plans	1,888,479	1,917,501
Shares available for issuance under employee stock purchase plan	143,277	99,578
Issuance of common stock upon exercise of warrants	1,949,131	4,671,009
Total common stock reserved for future issuance	9,972,230	11,187,790

11. Stock-Based Compensation

2018 Stock Option and Incentive Plan

The Company grants stock-based awards under the Second Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan, which originally became effective on June 19, 2018 as the Magenta Therapeutics, Inc. 2018 Stock Option and Incentive Plan and was amended and restated in September 2023 and renamed the Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (the "Prior 2018 Incentive Plan").

On May 23, 2024, the Company's stockholders approved an amendment and restatement of the Prior 2018 Incentive Plan and it was renamed the Second Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (the "2018 Amended Plan") to:

- provide for an increase in the number of shares of common stock reserved for issuance thereunder by 2,931,820 shares;
- increase the Evergreen Provision (as described below) from 4% to 5% of issued and outstanding shares of common stock on December 31 of the preceding calendar year; and
- extend the expiration date until March 14, 2034.

The 2018 Amended Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, cash-based awards, and dividend equivalent rights. The 2018 Amended Plan is administered by either the board of directors or the compensation committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the administrator, except that the term of stock options and stock appreciation rights may not be greater than ten years (or five years for certain incentive stock options). Awards typically vest over 12 months to four years. The exercise price for stock options granted may not be less than the fair value of common stock as of the date of grant (or 110% of the fair value of common stock for certain incentive stock options). The fair value of common stock is based on quoted market prices.

The 2018 Amended Plan also provides for the assumption of shares remaining available for delivery under the 2019 Stock Plan (as defined below) pursuant to the terms of the Reverse Merger, and such shares will be available for the granting of awards under the 2018 Amended Plan in accordance with applicable stock exchange requirements. The Company also has outstanding stock options under the Magenta Therapeutics, Inc. 2016 Stock Option and Grant Plan, as amended (the "2016 Plan"), but is no longer granting awards under the 2016 Plan.

The 2018 Amended Plan provides that the number of shares reserved and available for issuance under the 2018 Amended Plan will automatically increase each January 1 by 5% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 (the "Evergreen Provision"), or such lesser number of shares as determined by the Company's board of directors or compensation committee of the board of directors.

Pursuant to the Evergreen Provision, the number of shares reserved for issuance under the 2018 Amended Plan increased by 1,555,767 on January 1, 2025. Shares of common stock underlying any awards under the 2018 Amended Plan, the 2019 Stock Plan and the 2016 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) will be available for future awards under the 2018 Amended Plan.

As of December 31, 2025, 1,174,479 shares of common stock were available for grant under the 2018 Amended Plan.

2019 Stock Plan

In July 2019, Former Dianthus's board of directors adopted, and the Former Dianthus's stockholders approved, the Dianthus Therapeutics, Inc. 2019 Stock Plan (the "2019 Stock Plan"). In connection with the Reverse Merger, the Company assumed options to purchase shares of Former Dianthus's common stock that were outstanding under the 2019 Stock Plan immediately prior to the Reverse Merger and such options were converted into options to purchase 1,273,454 shares of common stock (the "Assumed Options"). No further awards will be made under the 2019 Stock Plan; however, the Assumed Options will remain outstanding under the 2019 Stock Plan in accordance with their terms, as adjusted to reflect the Reverse Merger.

2019 Employee Stock Purchase Plan

Employees may elect to participate in the Dianthus Therapeutics, Inc. 2019 Employee Stock Purchase Plan, as amended (the "ESPP"). The purchase price of common stock under the ESPP is equal to 85% of the lower of the fair market value of the common stock on (i) the offering date or (ii) the exercise date. The six-month offering periods begin in January and July of each year. During the year ended December 31, 2025, the Company issued 18,801 shares of common stock pursuant to the ESPP, respectively. As of December 31, 2025, 143,277 shares remained available for issuance under the ESPP.

The ESPP provides that the number of shares reserved and available for issuance under the ESPP will automatically increase each January 1 through January 1, 2029, by the lesser of (i) 1% of the number of shares issued and outstanding on the immediately preceding December 31, (ii) 62,500 shares and (iii) such number of shares as determined by the Company's board of directors or its appointed administrator. The number of shares reserved for issuance under the ESPP increased by 62,500 on January 1, 2025.

Inducement Plan

In February 2024, the Company's board of directors approved the Dianthus Therapeutics, Inc. Equity Inducement Plan (the "Inducement Plan"), which provides for up to 300,000 shares of common stock for inducement awards. In December 2025, the Company's board of directors approved an amendment to the Inducement Plan (the "Amended Inducement Plan"), which increased the number of shares of common stock available for inducement awards to 900,000. As of December 31, 2025, 714,000 shares of common stock were available for grant under the Amended Inducement Plan.

Stock Options

The following table summarizes stock option activity for the year ended December 31, 2025:

	Number of Stock Options Outstanding	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at January 1, 2025	4,499,702	$ 17.19	8.7	$ 24,867
Options granted	2,432,800	23.77		42,437
Options exercised	(627,148)	12.60		14,919
Options forfeited	(314,011)	21.07		1,690
Balance at December 31, 2025	5,991,343	$ 20.14	8.3	$ 127,547
Exercisable options at December 31, 2025	2,336,600	$ 17.01	7.6	$ 57,823
Unvested options at December 31, 2025	3,654,743	$ 22.14	8.8	$ 69,724

The aggregate intrinsic value of options granted, options exercised and options forfeited represents the difference between (i) the exercise price of the option and (ii) the closing market price of the Company's common stock on (x) December 31, 2025, (y) the date of exercise, or (z) the date of forfeiture, respectively.

The weighted average grant-date fair value per share of stock options granted during the year ended December 31, 2025 was $18.27 per share.

The table below summarizes the assumptions used to determine the grant-date fair value of stock options issued, presented on a weighted average basis:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.2%	4.2%
Expected term (in years)	6.0	6.0
Expected volatility	91.5%	92.6%
Expected dividend yield	0.0%	0.0%

Stock Warrants

In April 2021, Former Dianthus issued 4,677 warrants for the purchase of common stock at an exercise price of $1.65 per share. The warrants vested on July 30, 2023 and had a grant date fair value of $1.16 per warrant. As of December 31, 2025, the warrants have a weighted average remaining contractual term of 5.3 years.

Stock-based Compensation Expense

The following table provides a summary of stock-based compensation expense:

	Year Ended December 31,	
	2025	2024
Research and development	$ 10,090	$ 5,576
General and administrative	12,703	7,318
Total stock-based compensation expense	$ 22,793	$ 12,894

As of December 31, 2025, there was $59.0 million of total unrecognized compensation cost related to granted stock options. The Company expects to recognize that cost over a remaining weighted average period of 2.7 years.

12. License Revenues

Zenas BioPharma, Inc.

In September 2020, the Company entered into an Option Agreement (the "Zenas Option") with Zenas, formerly considered a related party (See Note 17). Through the Zenas Option, the Company provided Zenas an option to enter into an exclusive license agreement for the development and commercialization of products arising from its research of monoclonal antibody antagonists targeting certain specific complement proteins.

In October 2021, Zenas exercised its option for such clinical candidate under the Zenas Option. Zenas paid the Company a one-time payment of $1.0 million for the exercise of the corresponding option. In addition, in connection with the exercise of the Zenas Option, Zenas was required to reimburse the Company for a portion of CMC costs and expenses from the date of delivery of its option exercise notice through the execution of a license agreement.

In June 2022, pursuant to the Zenas Option, the Company negotiated in good faith a license agreement with Zenas (the "Zenas License Agreement" and, together with the Zenas Option, the "Zenas Agreements"). The Zenas License Agreement provided Zenas with a license in the People's Republic of China, including Hong Kong, Macau, and Taiwan ("Greater China") for the development and commercialization of sequences and products under the first antibody sequence. The Company was also obligated to perform certain research and development and CMC services and participated in a joint steering committee ("JSC").

The consideration under the Zenas Agreements included the following payments by Zenas to the Company: (i) a $1.0 million upfront payment upon the exercise of the corresponding option under the Zenas Option; (ii) an approximately $1.1 million reimbursement payment for a portion of development costs previously incurred by the Company; (iii) reimbursement of a portion of all CMC-related costs and expenses for the first antibody sequence through the manufacture of the first two batches of drug product; (iv) reimbursement of a portion of all non-CMC-related costs and expenses for the development of the first antibody sequence through the first regulatory approval; (v) development milestones totaling up to $11.0 million; and (vi) royalties on net sales ranging from the mid-single digits to the low teen percentages.

Tenacia Biotechnology (Hong Kong) Co., Limited

On October 21, 2024, Zenas assigned the Zenas Agreements to its affiliated entity, Zenas BioPharma (HK) Limited ("Zenas HK"). After the assignment, the Company entered into a novation agreement (the "Novation Agreement") with Zenas HK and Tenacia, and an amendment to the Zenas License Agreement, now with Tenacia (as amended, the "Tenacia License Agreement"), pursuant to which

Tenacia replaced Zenas HK as a party to the Zenas Agreements, and certain economic terms under the Zenas License Agreement with respect to cost sharing and development milestones were amended.

Except as otherwise noted below, the terms of the Zenas License Agreement were unchanged when novated by the Novation Agreement and amended by the Tenacia License Agreement.

The consideration under the Tenacia License Agreement, which replaced the consideration of the Zenas License Agreement, related to the first antibody sequence includes the following payments by Tenacia to the Company: (i) a $2.5 million upfront payment, which was paid to the Company in October 2024 upon execution of the Tenacia License Agreement; (ii) reimbursement of a portion of certain clinical costs; (iii) development milestones totaling up to $15.0 million; and (iv) royalties on net sales ranging from the mid-single digits to the low teen percentages. Tenacia is also responsible for paying local development costs in Greater China and a portion of the central development costs based on the number of patients enrolled from China in our global Phase 3 studies.

Under the Zenas Agreements, Zenas also had the right to exercise an option with respect to a second antibody sequence, which is now held by Tenacia (the "Tenacia Option" and, together with the Tenacia License Agreement, the "Tenacia Agreements"). Pursuant to the Tenacia Option, if Tenacia exercises the option and pays the Company the option exercise fee related to the second antibody sequence, the Company will grant Tenacia an exclusive license to the sequences and products under this second antibody sequence.

Accounting for the Zenas and Tenacia Agreements

Since the Zenas Agreements were negotiated with a single commercial objective, it was treated as a combined contract for accounting purposes. The Company assessed the Zenas Agreements in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), and concluded that it represented a contract with a customer and was within the scope of ASC 606. The Company determined that there was one combined performance obligation that consisted of the license and data transfer, the research and development and CMC services, and the participation in the JSC. The Company determined that Zenas' right to exercise an option with respect to a second antibody sequence did not represent a material right.

The Company determined that the combined performance obligation would be satisfied over time; therefore, the Company recognized the transaction price from the license agreement over the Company's estimated period to complete its activities. The Company concluded that it would utilize a cost-based input method to measure its progress toward the completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believed that this was the best measure of progress because other measures did not reflect how the Company transferred its performance obligation to Zenas. In applying the cost-based input method of revenue recognition, the Company used actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consisted primarily of third-party contract costs. Revenue was recognized based on the level of costs incurred relative to the total budgeted costs for the combined performance obligation. A cost-based input method of revenue recognition required management to make estimates of costs to complete the Company's performance obligation. In making such estimates, judgment was required to evaluate assumptions related to cost estimates.

The Company assessed the Tenacia Agreements in accordance with ASC 606 and applied the same considerations above to the Tenacia Agreements. With the exception of the cost sharing and development milestones noted below, the key terms of the Zenas License Agreement were unchanged when novated by the Novation Agreement and amended by the Tenacia License Agreement. Therefore, the Company determined that the accounting considerations and resulting conclusions noted above related to the Zenas Agreements also apply to the Tenacia Agreements.

The Company also determined that the milestone payments of $15.0 million (previously $11.0 million under the Zenas License Agreement) are variable consideration under ASC 606 which need to be added to the transaction price when it is probable that a significant revenue reversal will not occur. Based on the nature of the milestones, such as the regulatory approvals which are generally not within the Company's control, the Company will not consider achievement of each milestone to be probable until the uncertainty associated with such milestone has been resolved. Should it be probable that a significant reversal of revenue will not occur, the milestone payment will be added to the transaction price for which the Company recognizes revenue. No milestones were achieved under the Zenas Agreements prior to novation. During the year ended December 31, 2025, $6.0 million of milestones were achieved under the Tenacia Agreements and added to the transaction price. No milestones were achieved under the Tenacia Agreements during the year ended December 31, 2024.

There is a sales or usage-based royalty exception within ASC 606 that applies when a license of intellectual property is the predominant item to which the royalty relates. In accordance with this royalty exception, the Company will recognize royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). The Company has not recorded any royalty revenue to date.

The Company recognized related party license revenue totaling nil and $5.9 million during the years ended December 31, 2025 and 2024, respectively, associated with the Zenas Agreements. As of December 31, 2024, the Company recorded a related party receivable of $0.8 million on its consolidated balance sheet.

The Company recognized license revenue totaling $2.0 million and $0.3 million during the years ended December 31, 2025 and 2024, respectively, associated with the Tenacia Agreements. As of December 31, 2025, the Company recorded accounts receivable of $52 thousand, an unbilled receivable of $50 thousand within prepaid expenses and other current assets, current deferred revenue of $1.2 million and noncurrent deferred revenue of $5.8 million on its consolidated balance sheet.

13. Income Taxes

For the years ended December 31, 2025 and 2024, the Company recorded no current or deferred income tax expenses or benefits as it has incurred losses since inception and has provided a full valuation allowance against its deferred tax assets.

As further described in Note 2, the Company elected to prospectively adopt the guidance in ASU 2023-09. The following table is a reconciliation of the Company's effective income tax rate to the statutory federal income tax rate for the year ended December 31, 2025 in accordance with the guidance in ASU 2023-09:

	Year Ended December 31, 2025	
	Amount	Rate
Federal statutory income tax rate	$ (34,091)	21.0%
State taxes, net of federal benefit [1]	(12,453)	7.7%
Research tax credits	(7,331)	4.5%
Increase in deferred tax asset valuation allowance	53,688	(33.1)%
Nontaxable or non-deductible items:		
Disallowed compensation deductions	1,053	(0.6)%
Stock-based compensation	(866)	0.5%
Effective income tax rate	$ —	(0.0)%

(1) For the year ended December 31, 2025, state taxes in the following states made up the majority (greater than 50% of the tax effect): New York and Massachusetts.

The following table is a reconciliation of the Company's effective income tax rate to the statutory federal income tax 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
Federal statutory income tax rate	21.0%
State taxes, net of federal benefit	31.3%
Research tax credits	7.5%
Other	8.8%
Increase in deferred tax asset valuation allowance	(68.6)%
Effective income tax rate	(0.0)%

The following table provides a summary of net deferred tax assets:

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 132,723	$ 109,660
Capitalized research and development costs	52,153	35,142
Tax credit carryforwards	30,714	22,784
Stock-based compensation	13,243	9,151
Amortization of license fees	3,845	3,802
Accrued expenses	2,509	1,256
Deferred revenue	516	—
Lease liabilities	50	22
Other	20	15
Gross deferred tax assets	235,773	181,832
Valuation allowance	(235,293)	(181,605)
Total deferred tax assets	480	227
Deferred tax liabilities:		
Right-of-use lease assets	(77)	(18)
Other	(403)	(209)
Total deferred tax liabilities	(480)	(227)
Net deferred tax assets	$ —	$ —

As of December 31, 2025, the Company had federal net operating loss carryforwards of approximately $475.9 million, of which $458.3 million can be carried forward indefinitely. As of December 31, 2025, the Company had state tax net operating loss carryforwards of approximately $419.0 million, which will begin to expire in 2038. As of December 31, 2025, the Company had federal, state, and foreign tax credit carryforwards of approximately $26.4 million, $4.3 million and nil, respectively. All tax credits have a limited carryforward period and will begin to expire in 2038.

In assessing the realizability of the net deferred tax assets, management considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. Management believes that it is more likely than not that the Company's deferred income tax assets will not be realized. As a result of the analysis, the Company determined that a full valuation allowance against the deferred tax assets, net, was required.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2025 and 2024 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research tax credit carryforwards. During the years ended December 31, 2025 and 2024, capitalized research and development expenses increased pursuant to Section 174 of the Internal Revenue Code of 1986, as amended (the "Code"). The changes in the valuation allowance for the years ended December 31, 2025 and 2024 were as follows:

	Year Ended December 31,	
	2025	2024
Valuation allowance as of beginning of year	$ 181,605	$ 123,452
Net increases recorded to income tax provision	53,688	58,153
Valuation allowance as of end of year	$ 235,293	$ 181,605

The Company is subject to tax and will continue to file federal income tax returns in the United States as well as in certain state and local jurisdictions. The Company is subject to tax examinations for tax years ended December 31, 2022 and forward in all applicable income tax jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. In addition, the utilization of tax carryforwards, from periods prior to those previously mentioned may also be audited by the taxing authorities once utilized.

Net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service (the "IRS") and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

The Company has not recorded any liabilities for unrecognized tax benefits as of December 31, 2025 or 2024. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company has made no income tax payments and received no income tax refunds during the year. All payments made to taxing authorities were for non-income based tax liabilities and are outside the scope of ASC 740.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted. The OBBBA includes several significant tax 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 certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. On August 28, 2025, the IRS released procedural guidance (Rev. Proc. 2025-28) for implementing Section 174A and related elections for domestic research or experimental ("R&E") expenditures. Transition rules provide taxpayers with options to account for any remaining unamortized domestic R&E expenditures paid or incurred in taxable years beginning after December 31, 2021, and before January 1, 2025. Taxpayers may continue to amortize such unamortized amounts over the remaining five-year period; alternatively, they may elect to deduct any remaining unamortized domestic R&E expenditures either entirely in the first tax year beginning after December 31, 2024, or ratably over two taxable years (e.g., 2025 or ratably in 2025 and 2026). The Company has elected to continue to capitalize all domestic R&E expenditures and will continue to amortize previously capitalized and unamortized domestic R&E expenditures over the remaining five-year period. As of December 31, 2024, the Company had approximately $131.0 million of remaining unamortized domestic R&E expenditures, representing approximately $32.4 million of its gross deferred tax assets. As of December 31, 2025, the Company had approximately $191.0 million of remaining unamortized domestic R&E expenditures, representing approximately $50.4 million of its gross deferred tax assets.

14. Employee Benefit Plan

The Company maintains a defined contribution benefit plan under section 401(k) of the Code covering substantially all qualified employees of the Company (the "401(k) Plan"). Eligible employees are able to contribute 100% of their eligible compensation up to the maximum amount allowed under the Code. The Company matches 100% of each eligible employee's contributions up to 4% of total eligible compensation. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participant's directions. The 401(k) Plan currently does not offer the ability to invest in the Company's securities. Employees are immediately and fully vested in their contributions. The Company recorded expense of $1.0 million and $0.5 million representing employer contributions under the 401(k) Plan during the years ended December 31, 2025 and 2024, respectively.

15. Net Loss Per Share

Basic and diluted net loss per share of common stock were calculated as follows:

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (162,337)	$ (84,969)
Denominator:		
Weighted-average number of shares of common stock outstanding including shares issuable under equity-classified pre-funded warrants, used in computing net loss per share of common stock, basic and diluted	38,617,580	33,313,849
Net loss per share attributable to common stockholders, basic and diluted	$ (4.20)	$ (2.55)

Pre-funded warrants have been included in the computation of basic and diluted net loss per share of common stock as the pre-funded warrants are issuable for nominal consideration pursuant to their terms. There were outstanding pre-funded warrants of 1,944,454 and 4,666,332 as of December 31, 2025 and 2024, respectively. The outstanding pre-funded warrants increased the weighted-average number of shares of common stock outstanding by 3,302,164 shares and 4,546,993 shares for the year ended December 31, 2025 and 2024, respectively.

The Company's potential dilutive securities, which include stock options and warrants for the purchase of common stock, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following potential dilutive securities, presented on an as converted basis, were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	Year Ended December 31,	
	2025	2024
Stock options outstanding	5,991,343	4,499,702
Warrants for the purchase of common stock	4,677	4,677
Total	5,996,020	4,504,379

16. Commitments and Contingencies

License Agreement with Nanjing Leads Biolabs Co. Ltd.

On October 16, 2025, the Company entered into a License and Collaboration Agreement (the "Leads License Agreement") with Nanjing Leads Biolabs Co. Ltd. ("Leads"), pursuant to which Leads granted the Company a royalty-bearing, exclusive license outside of Greater China to develop, manufacture, commercialize, or otherwise exploit DNTH212, a bifunctional fusion protein being developed in China by Leads as LBL-047. The Company also obtained certain non-exclusive rights to perform development and manufacturing activities in Greater China to support DNTH212 outside of Greater China. DNTH212 is an investigational, extended half-life bifunctional fusion protein targeting plasmacytoid dendritic cell BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. On December 23, 2025, Leads and the Company jointly announced the initiation of a Phase 1 clinical trial for LBL-047 (DNTH212).

Under the terms of the Leads License Agreement, the Company will pay Leads up to $38.0 million, comprised of $30.0 million in upfront and near-term milestone payments plus an additional $8.0 million milestone, payable in cash or the Company's common stock at the Company's election, upon the initiation of a Dianthus-led Phase 1 study, for exclusive rights to develop and commercialize DNTH212 globally outside of Greater China. Leads will also be eligible to receive up to $962.0 million in development and regulatory approval milestones across three key geographies and sales-based milestones across five indications, as well as tiered royalties from mid-single digits up to a low double-digit on ex-Greater China net sales.

The Leads License Agreement will remain in effect on a country-by-country and product-by-product basis until expiration of the applicable royalty term, unless earlier terminated. Each party has customary termination rights, including for uncured material breach, insolvency, patent challenge, or, in the case of the Company, for convenience.

The Company recorded $30.0 million for amounts owed under the Leads License Agreement, including upfront and near-term milestone payments, within the research and development expenses line item in the consolidated statements of operations and comprehensive loss during the year ended December 31, 2025. During the three months ended December 31, 2025, the Company paid Leads $25.0 million in upfront and near-term milestone payments. In addition, the Company recorded $5.0 million of milestone payments within the accounts payable line item on its consolidated balance sheet as of December 31, 2025.

IONTAS Limited

In July 2020, the Company entered into a collaborative research agreement with IONTAS Limited ("IONTAS") to perform certain milestone-based research and development activities for the Company under its first development program. This agreement was amended in January 2023 to extend their services to additional development programs. IONTAS provides dedicated resources to perform the research and development activities and receives compensation for those resources as well as success-based milestone payments.

Upon the achievement, with the first development program with IONTAS, of (i) certain development milestones and (ii) certain commercial milestones, the Company is obligated to make payments to IONTAS of up to £3.1 million (approximately $4.2 million based on the December 31, 2025 exchange rate) and £2.3 million (approximately $3.1 million based on the December 31, 2025 exchange rate), respectively. Upon the achievement, with the second development program with IONTAS, of certain development milestones, the Company is obligated to make payments to IONTAS of up to £2.5 million (approximately $3.4 million based on the December 31, 2025 exchange rate). The Company recorded $1.7 million and $2.0 million for amounts owed under the IONTAS collaborative research license agreement, including milestone payments, within the research and development expenses line item in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2025 and 2024, respectively.

Alloy Therapeutics, LLC

In August 2019, the Company entered into a license agreement with Alloy Therapeutics, LLC ("Alloy"). The license agreement was amended in October 2022. The license agreement with Alloy grants to the Company the following:

- a worldwide, non-exclusive license to use the Alloy technology solely to generate Alloy antibodies and platform assisted antibodies for internal, non-clinical research purposes; and

- with respect to Alloy antibodies and platform assisted antibowedies that are selected by the Company for inclusion into a partnered antibody program, a worldwide, assignable license to make, have made, use, offer for sale, sell, import, develop, manufacture, and commercialize products comprising partnered antibody programs selected from Alloy antibodies and platform assisted antibodies in any field of use.

The Company pays annual license fees and annual partnered antibody program fees totaling $0.1 million to Alloy. The Company is also obligated to pay a $0.1 million fee to Alloy if the Company sublicenses a product developed with Alloy antibodies or platform assisted antibodies. Upon the achievement, with products developed with Alloy, of (i) certain development milestones and (ii) certain commercial milestones, the Company is obligated to make payments to Alloy of up to $1.8 million and $11.0 million, respectively. The Company recorded $1.1 million and $0.6 million for amounts owed under the Alloy license agreement, including milestone payments, within the research and development expenses line item in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2025 and 2024, respectively.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to employees, consultants, vendors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. To date, the Company has not incurred any material costs as a result of such indemnification agreements. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 or 2024.

Litigation

From time to time, the Company may be exposed to litigation relating to potential products and operations. The Company is not currently engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse effect on its financial condition, results of operations or cash flows.

Other

As of December 31, 2025, the Company had standing agreements with consultants, contractors or service providers that generally can be terminated by the Company with 30 to 60 days written notice, unless otherwise indicated.

17. Related Party Transactions

Zenas BioPharma, Inc.

The Company previously considered Zenas to be a related party because the sole member of Tellus BioVentures LLC ("Tellus"), who is a significant shareholder in the Company and was a member of the board of directors of the Company until May 2025, is a significant shareholder in Zenas and serves as Chief Executive Officer and Chairman of the board of directors of Zenas. As of May 2025, the Company no longer considers Zenas to be a related party. See Note 12 for more information.

In September 2020, Zenas issued 156,848 common shares to the Company in exchange for the Zenas Option. Previously, the Company used the measurement alternative as the measurement attribute for accounting for the Zenas common stock which did not require it to assess the fair value of the common stock at each reporting period as the fair value of the Zenas common stock was not readily determinable nor was there a reliable source for observable transactions from which the Company could determine a fair value. On September 12, 2024, Zenas announced the pricing of its initial public offering (the "Zenas IPO") of $17.00 per share, which also included a 1-for-8.6831 reverse stock split of its capital stock. Upon the Zenas IPO, the fair value of the Zenas common stock was deemed readily determinable. The Company reassesses the fair value of the investment at the end of each reporting period, with any adjustments to the fair value recorded as unrealized gains or losses within other income (loss) in the consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024, the fair value of the investment in Zenas was $0.7 million and $0.1 million, respectively, which was included within other assets and restricted cash on the Company's consolidated balance sheet.

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

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

As of December 31, 2025, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in its 2023 Internal Control-Integrated Framework. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption for "non-accelerated filers."

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(c) Trading Plans. The following table discloses any officer (as defined in Rule 16a-1(f) under the Exchange Act) or director who entered into, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K) during the quarter ended December 31, 2025:

Name (Title)	Action Taken (Date of Action)	Type of Trading Arrangement	Nature of Trading Arrangement	Duration of Trading Arrangement	Aggregate Number of Securities
Marino Garcia (President and Chief Executive Officer)	Adoption (November 17, 2025)	Rule 10b5-1 trading arrangement	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to the terms of the trading plan	Through and including December 31, 2026	Up to 122,918 shares
Edward Carr (Chief Accounting Officer)	Adoption (December 11, 2025)	Rule 10b5-1 trading arrangement	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to the terms of the trading plan	Through and including December 31, 2026	Up to 43,682 shares
Paula Soteropoulos (Director)	Adoption (December 23, 2025)	Rule 10b5-1 trading arrangement	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to the terms of the trading plan	Through and including December 31, 2026	Up to 28,792 shares
Ryan Savitz (Executive Vice President, Chief Financial Officer and Chief Business Officer)	Adoption (December 30, 2025)	Rule 10b5-1 trading arrangement	Exercises of vested stock options and sales of shares of the Company's common stock pursuant to the terms of the trading plan	Through and including March 31, 2027	Up to 153,840 shares

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as disclosed below, the information required under this item is incorporated herein by reference to our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of our fiscal year ended December 31, 2025 (the "Proxy Statement"), including under the heading "*Management and Corporate Governance"* and *"Delinquent Section 16(a) Reports."* We have adopted a Code of Business Conduct and Ethics (the "Code of Ethics") that applies to all of our directors, officers and employees, including our principal executive, principal financial and principal accounting officers, or persons performing similar functions. Our Code of Ethics is posted on our website at *investor.dianthustx.com*. We intend to disclose future amendments to certain provisions of the Code of Ethics, and waivers of the Code of Ethics granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

We have adopted an insider trading policy governing the purchase, sale, and/or other dispositions of our securities by our directors, officers, employees, contractors and by the Company itself that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and applicable exchange listing standards. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to the Proxy Statement, including under the heading *"Executive Compensation."*

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

The information required under this item is incorporated herein by reference to the Proxy Statement, including under the heading *"Security Ownership of Certain Beneficial Owners and Management."*

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

The information required under this item is incorporated herein by reference to the Proxy Statement, including under the headings *"Certain Relationships and Related Party Transactions"* and *"Management and Corporate Governance - Director Independence."*

Item 14. Principal Accountant Fees and Services.

The information required under this item is incorporated herein by reference to the Proxy Statement, including under the heading *"Information About Our Independent Accountants."*

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see the Index to the Consolidated Financial Statements on page 89 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, not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description
2.1†**	Agreement and Plan of Merger, dated as of May 2, 2023, by and among Magenta Therapeutics, Inc., Dio Merger Sub, Inc. and Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on July 31, 2023).
3.1**	Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
3.2**	Third Amended and Restated By-laws (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
4.1**	Form of Pre-Funded Warrant of Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
4.2**	Registration Rights Agreement, dated September 11, 2023, by and among Dianthus Therapeutics, Inc., Dianthus Therapeutics OpCo, Inc. and certain parties thereto (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
4.3**	Form of Pre-Funded Warrant of Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 22, 2024).
4.4**	Form of Registration Rights Agreement, dated January 22, 2024, by and among Dianthus Therapeutics, Inc. and certain parties thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on January 22, 2024).
4.5**	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
4.6**	Form of Pre-Funded Warrant of Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 11, 2025).
10.1**	Contingent Value Rights Agreement, dated September 11, 2023, by and between Dianthus Therapeutics, Inc. and the Rights Agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
10.2#**	Form of Indemnification Agreements for Directors of the Company (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
10.3#**	Form of Indemnification Agreements for Officers of the Company (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
10.4#**	Second Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 28, 2024).
10.5#**	Dianthus Therapeutics, Inc. 2019 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 8, 2024).
10.6#**	Form of Stock Option Agreement for Directors under the Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 filed with the SEC on October 4, 2023).
10.7#**	Form of Stock Option Agreement for Executives under the Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
10.8#**	Dianthus Therapeutics, Inc. 2019 Stock Plan (incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).

10.9#**	Form of Nonstatutory Stock Option Agreement under the Dianthus Therapeutics, Inc. 2019 Stock Plan (incorporated by reference to Exhibit 10.18 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).
10.10#**	Form of Incentive Stock Option Agreement under the Dianthus Therapeutics, Inc. 2019 Stock Plan (incorporated by reference to Exhibit 10.19 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).
10.11#**	Employment Agreement, dated October 23, 2021, by and between Dianthus Therapeutics, Inc. and Marino Garcia (incorporated by reference to Exhibit 10.13 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).
10.12#**	Amendment to Offer Letter, dated September 11, 2023, by and between Dianthus Therapeutics OpCo, Inc. and Marino Garcia (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
10.13#**	Offer Letter, as amended, dated March 11, 2022, by and between Dianthus Therapeutics, Inc. and Simrat Randhawa (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).
10.14#**	Amendment to Offer Letter, dated September 11, 2023, by and between Dianthus Therapeutics OpCo, Inc. and Simrat Randhawa (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
10.15#**	Offer Letter, dated January 18, 2022, by and between Dianthus Therapeutics, Inc. and Ryan Savitz (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).
10.16#**	Amendment to Offer Letter, dated September 11, 2023, by and between Dianthus Therapeutics OpCo, Inc. and Ryan Savitz (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
10.17#**	Director Compensation Letter, dated May 6, 2022, by and between Dianthus Therapeutics, Inc. and Paula Soteropoulos (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).
10.18††**	Biologics Master Services Agreement, dated as of March 22, 2021, by and between Dianthus Therapeutics, Inc. and WuXi Biologics (Hong Kong) Limited (incorporated by reference to Exhibit 10.24 to Amendment No. 2 to the Registrant's Registration Statement on Form S-4 filed with the SEC on July 17, 2023).
10.19††**	Cell Line License Agreement, dated as of March 22, 2021, by and between Dianthus Therapeutics, Inc. and WuXi Biologics (Hong Kong) Limited (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to the Registrant's Registration Statement on Form S-4 filed with the SEC on July 17, 2023).
10.20**	Securities Purchase Agreement, dated as of January 22, 2024, by and between the Company and each purchaser identified in Annex A thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 22, 2024).
10.21#*	Dianthus Therapeutics, Inc. Equity Inducement Plan (Amended and Restated on December 17, 2025).
10.22††*	License and Collaboration Agreement, dated as of October 16, 2025, by and between Dianthus Therapeutics, Inc. and Nanjing Leads Biolabs Co. Ltd.
19.1**	Dianthus Therapeutics, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 11, 2025).
21.1**	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm of Dianthus Therapeutics, Inc.
24.1*	Power of Attorney
31.1*	Principal Executive Officer Certification Pursuant to Rules 13a-14(a) or 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*	Principal Financial Officer Certification Pursuant to Rules 13a-14(a) or 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***	Certifications Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1#**	Dianthus Therapeutics, Inc. Rule 10D-1 Clawback Policy (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.

104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.
** Previously filed.
***Furnished herewith. The certifications on Exhibit 32.1 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.
† The annexes, schedules and certain exhibits to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Dianthus Therapeutics, Inc. hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.
†† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the SEC.
# Management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized**.**

DIANTHUS THERAPEUTICS, INC.

Date: March 9, 2026

By: /s/ Ryan Savitz
Ryan Savitz
Executive Vice President, Chief Financial Officer and Chief Business Officer
(Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Marino Garcia, Ryan Savitz and Adam Veness, and each of them, as true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for them and in their name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K, any and all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, and generally to do all such things in their names and behalf in their capacities as officers and directors to enable the Dianthus Therapeutics, Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the SEC, 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 requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their, his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Marino Garcia Marino Garcia	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 9, 2026
/s/ Ryan Savitz Ryan Savitz	Executive Vice President, Chief Financial Officer and Chief Business Officer *(Principal Financial Officer)*	March 9, 2026
/s/ Edward Carr Edward Carr	Chief Accounting Officer *(Principal Accounting Officer)*	March 9, 2026
/s/ Alison Lawton Alison Lawton	Director and Chair of the Board	March 9, 2026
/s/ Sujay Kango Sujay Kango	Director	March 9, 2026
/s/ Anne McGeorge Anne McGeorge	Director	March 9, 2026
/s/ Steven Romano, M.D. Steven Romano, M.D.	Director	March 9, 2026
/s/ Simon Read, Ph.D. Simon Read, Ph.D.	Director	March 9, 2026
/s/ Paula Soteropoulos Paula Soteropoulos	Director	March 9, 2026
/s/ Jonathan Violin, Ph.D. Jonathan Violin, Ph.D.	Director	March 9, 2026