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 001-39782

4D Molecular Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-3506994**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5858 Horton Street #455 Emeryville, CA	**94608**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 505-2680

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	FDMT	The Nasdaq Global Select Market

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or Section 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 shares of common stock on The Nasdaq Global Select Market on June 30, 2025 was $166,461,070.

The number of shares of registrant's Common Stock outstanding as of March 16, 2026 was 51,051,487. This number does not include 16,935,665 shares of common stock issuable upon the exercise of pre-funded warrants outstanding as of March 16, 2026 (which are immediately exercisable at an exercise price of $0.0001 per share of common stock, subject to beneficial ownership limitations).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the 2026 Annual Meeting of Stockholders are incorporated herein by reference in Parts II and III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2025.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements concern our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our development activities, preclinical studies and clinical trials, including our clinical trials for 4D-150, 4D-175, 4D-710 and 4D-725;
- the number, size and design of our planned clinical trials, and what regulatory authorities may require to obtain marketing approval;
- the timing of Investigational New Drug Application (“IND”) enabling studies and results from such studies;
- the timing and success of lead optimization for our product candidates in lead optimization;
- the translation of our preclinical results and data into future clinical trials in humans;
- the timing of any manufacturing runs for materials to be used in patient trials;
- the timing or likelihood of regulatory filings and approvals;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates, if approved;
- the success of competing products or platform technologies that are or may become available;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain approval;
- future agreements with third parties in connection with the commercialization of our product candidates;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- existing regulations and regulatory developments in the United States and foreign countries;
- the expected potential benefits of strategic collaboration agreements, including our relationships with Otsuka Pharmaceutical Co., Ltd. and Cystic Fibrosis Foundation, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- potential claims relating to our intellectual property and third-party intellectual property;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;

- the pricing and reimbursement of our product candidates, if approved;
- the potential effects of public health emergencies to our preclinical and clinical programs and our business;
- our ability to attract and retain key managerial, scientific and medical personnel;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing; and
- our financial performance.

These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this Annual Report on Form 10-K.

SUMMARY RISK FACTORS

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. The following is a summary of the principal risks that could seriously harm our business, all of which are more fully described in Part I. Item 1A. "Risk Factors" in this Annual Report on Form 10-K. This summary should be read in conjunction with the other risk factors included in the "Risk Factors" section and should not be relied upon as an exhaustive summary of the material risks facing our business.

- We are in the late stages of drug development for our lead program and have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- We have had recurring net losses, and we expect to continue to incur significant net losses for the foreseeable future.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- All of our product candidates are based on a novel AAV genetic medicine technology with which there is limited regulatory and clinical experience to date, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. Further, the regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities.
- Adverse public perception or regulatory scrutiny of genetic medicine technology may negatively impact the developmental progress or commercial success of products that we develop alone or with collaborators.

- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization, which could seriously harm our business.
- Gene therapies are novel, complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs, limit the supply of our products or otherwise seriously harm our business.
- The regulatory approval processes of the FDA, European Medicines Agency ("EMA") and comparable foreign regulatory authorities are lengthy, expensive, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our product candidates may be dependent on our licensors.
- Our employees, independent contractors, consultants, research or commercial partners or collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

PART I

Item 1. Business.

Overview

We are a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with the potential to transform treatment paradigms and provide unprecedented benefits to patients. Our products are developed with customized and evolved adeno-associated virus (“AAV”) vectors invented from our proprietary vector discovery platform, Therapeutic Vector Evolution (“TVE”) which was designed to generate vectors with properties that overcome the limitations of conventional AAV vectors. TVE applies the principles of directed evolution in non-human primate (“NHP”) models to select vectors that target tissues of diseases with high unmet need using routine and local routes of administration. We are focused on clinical-stage product candidates in retina and lung utilizing vectors invented with TVE and believe the clinical results to date validate the platform.

Our lead product candidate 4D-150 utilizes our proprietary R100 vector and a transgene encoding anti-VEGF biologics (inhibitors of vascular endothelial growth factor): aflibercept (targeting VEGF-A, VEGF-B and placental growth factor) and an RNA interference (RNAi) approach targeting VEGF-C. The goal for our development and potential commercialization of 4D-150 is to transform the standard of care for large market retinal vascular diseases with a safe, in-office, and durable lifelong backbone therapy, substantially reducing treatment burden and improving long-term vision outcomes. 4D-150 is initially being developed for the treatment of wet age-related macular degeneration (“wet AMD”) and diabetic macular edema (“DME”).

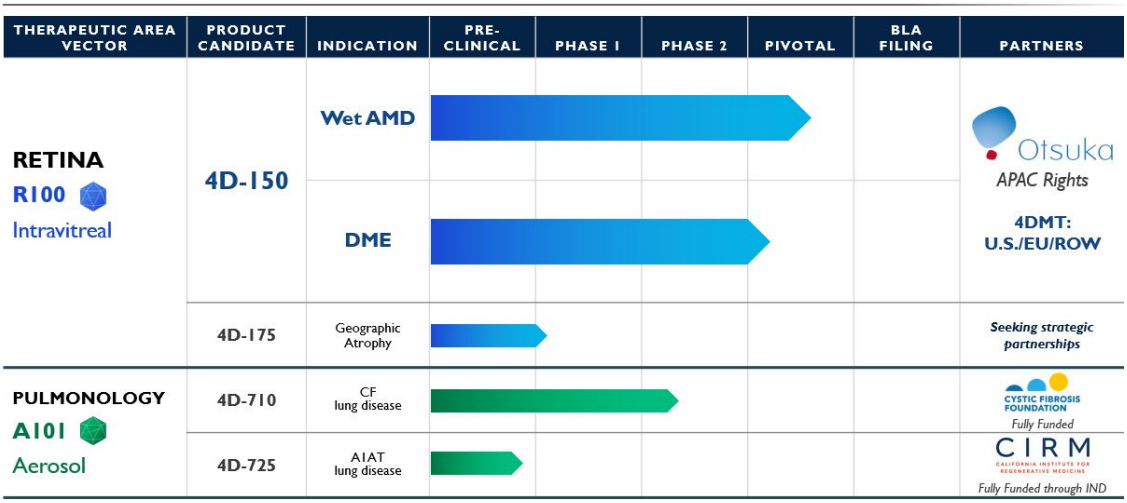
Our other pipeline programs include 4D-710, which we believe is the first known genetic medicine to demonstrate successful delivery and durable expression of the cystic fibrosis transmembrane conductance regulator (“CFTR”) transgene in the lungs of people with cystic fibrosis ("CF") and is currently in Phase 2 development. We believe these results will translate into durable clinical improvements in people with CF, including improved lung function and quality of life.

We believe we are well positioned to discover, develop, manufacture and if approved, commercialize targeted genetic medicines with the potential to transform the lives of patients suffering from debilitating diseases.

Our Product Candidate Pipeline & Strategy

We have developed a pipeline of product candidates in two therapeutic areas, retina and pulmonology, focusing on disease areas of high unmet need and commercial potential. Our strategy focuses on advancing our lead product candidate 4D-150 through Phase 3 trials in wet AMD and DME and if successful, commercialization, while advancing our early-stage programs in retina and pulmonology through clinical proof-of-concept. We believe these product candidates are differentiated and can not only provide meaningful benefit to patients, but also are suitable for scalable, global adoption by physicians and payors.

Below is a summary of our product candidate pipeline:



Retina Therapeutic Area

Introduction

We are developing product candidates to treat severe retinal diseases with our customized and evolved vector, R100. R100 was developed for in-office intravitreal injection to deliver transgene payloads to all major cell layers of the retina, with potentially lifelong transgene expression. We believe leveraging the same novel vector in multiple product candidates will increase product development efficiencies, decrease development risks and inform the clinical development of subsequent product candidates using the same vector. We believe our product candidates targeting large-market retina diseases such as wet AMD and DME have the potential to reshape the standard of care, resulting in substantial benefit for patients.

Our lead retina product candidate 4D-150 is currently in Phase 3 development for wet AMD and is preparing to enter Phase 3 development in DME.

Our second retina product candidate is 4D-175 for geographic atrophy and has an open IND. Further development for 4D-175 is currently pending financing, including potential strategic partnerships.

4D-150 for Wet AMD and DME

Disease Background, Unmet Medical Need, and Target Patient Population

Wet AMD is a highly prevalent disease with an estimated 5 million patients affected in the United States, major European markets, and Japan, and is expected to continue growing with the aging global population. Wet AMD is a type of macular degeneration where abnormal blood vessels (choroidal neovascularization or "CNV") grow into the macula, the central area of the retina. CNV causes swelling and edema of the retina, bleeding and scarring, which can result in visual distortion and reduced acuity. The proliferation and leakage of abnormal blood vessels is stimulated by protein members of the VEGF family, such as VEGF-A, -B, -C, and placental growth factor (“PIGF”). This process distorts and can potentially destroy central vision and may progress to blindness without treatment.

Diabetic eye disease (diabetic retinopathy, including DME) is the leading cause of vision loss and blindness in working-age adults in developed countries. Diabetic retinopathy is a complication of diabetes that arises from chronic hyperglycemia–induced damage to retinal blood vessels, leading to increased vascular permeability and angiogenic signaling. Specifically, DME affects an estimated 4 million patients in the United States, major European markets, and Japan, and is expected to grow with the rapidly increasing prevalence of diabetes. DME is a vision-threatening complication of diabetic retinopathy characterized by macular fluid accumulation. The development of DME is driven by upregulation of VEGF and inflammatory mediators that promote vascular leakage and macular edema, ultimately leading to vision loss.

The current treatment paradigm for both wet AMD and DME requires frequent intravitreal bolus injections of patients with anti-VEGF biologics that inhibit blood vessel leakage and proliferation of new blood vessels, reducing edema and bleeding risk, and allowing in many instances some visual acuity to be recovered. Each anti-VEGF injection requires an in-office visit, which carries significant burden and discomfort to patients, and when patients miss injections, they may experience vision decline due to undertreatment. Based on real world data for wet AMD, approximately 40% of patients discontinue treatment by year one, and early vision gains are followed by steady long-term vision decline, which is associated with declining injection frequency. Even with frequent treatment, the disease can often be under poor control, with higher variability in retina anatomy associated with vision loss. Bolus anti-VEGF treatment of retinal vascular diseases represents global branded therapeutic markets of over $16 billion, with wet AMD and DME comprising approximately $14 billion.

We believe these major chronic retinal vascular diseases are ideal applications for genetic medicines. Multiple products on the market validate the efficacy of the anti-VEGF biologics therapeutic approach. A single dose genetic medicine delivering potentially lifelong expression of anti-VEGF biologics as a backbone therapy delivered with a routine in-office intravitreal injection could transform the standard of care for these diseases. In addition, we expect the relatively low doses required to allow for favorable manufacturing scalability, cost of goods sold, and pricing flexibility compared to conventional IV genetic medicines.

Our Solution

4D-150 is a genetic medicine designed to be a backbone therapy for chronic retinal vascular diseases.

The product candidate combines our proprietary R100 vector designed for efficient intravitreal delivery to the retina with a dual transgene payload expressing aflibercept and VEGF-C RNAi. Sustained expression of 4D-150 transgenes has the potential to reduce the treatment burden of repeated visits for anti-VEGF injections required to maintain optimal visual outcomes. Intravitreal delivery of biologics into the eye is a routine in-office injection, which we believe allows for seamless adoption into retina clinic workflows.

Differentiation of 4D-150

AAV genetic medicine approaches are being developed by several companies to treat wet AMD by delivering a copy of a transgene encoding an anti-VEGF biologic by either subretinal surgery or suprachoroidal injection with a conventional AAV vector, or intravitreal administration with a mouse-evolved vector. It remains to be demonstrated whether conventional AAVs or mouse-evolved vectors can deliver significant retinal coverage while limiting toxicities. In comparison, our customized and evolved vectors are invented and tested in primates whose eyes more closely resemble the anatomy of the human eye than of mouse eyes. Compared to subretinal or suprachoroidal delivery, we believe that our R100 vector-based products provide comprehensive retinal coverage via an intravitreal injection, while delivering an improved tolerability profile with limited inflammation compared to other intravitreal approaches.

In addition, to our knowledge, 4D-150 is the first genetic medicine product candidate for the eye designed to directly inhibit four different angiogenic growth factor targets, VEGF A, B, and C plus PlGF. We therefore believe there is significant differentiation between our genetic medicine product candidate and other AAV genetic medicines in development in this therapeutic area.

In addition to genetic medicine approaches, other product candidates designed for extended durability are in development, with the potential to extend dosing intervals by several weeks. We believe a backbone therapy, like 4D-150, designed to provide potentially lifelong benefit with a one-time treatment, would be paradigm-shifting and highly differentiated from interval extension approaches.

We have received Regenerative Medicine Advanced Therapy ("RMAT") from the U.S. Food and Drug Administration (the “FDA”) and PRIority MEdicine ("PRIME") designation from the European Medicines Agency (the “EMA”) for 4D-150 for the treatment of wet AMD and RMAT designation for 4D-150 for treatment of DME, which highlights recognition from regulatory bodies of the potential of 4D-150 to address significant unmet medical needs for both wet AMD and DME.

Clinical Development of 4D-150 in Wet AMD: PRISM Phase 1/2 and 4FRONT Phase 3 Program

4D-150 is currently being evaluated in wet AMD in the ongoing PRISM Phase 1/2 clinical trial and ongoing 4FRONT global Phase 3 registrational program, which includes two Phase 3 clinical trials (4FRONT-1 and 4FRONT-2).

PRISM enrolled patients with severe, recalcitrant disease with high anti-VEGF treatment burden (Phase 1/2a, 25 patients dosed with Phase 3 dose of 3E10 vg/eye) and with broad disease activity and treatment burden (Phase 2b, 30 patients dosed with Phase 3 dose). Within the Phase 2b Phase 3 dose arm, a subgroup of 15 recently diagnosed patients were enrolled, which is most comparable to our Phase 3 population. In addition, 16 patients were dosed with 3E10 vg/eye in the Phase 2 Alternate Steroids cohort. In total, 71 patients have been dosed with the Phase 3 dose of 3E10 vg/eye.

Interim Data from 4D-150 PRISM Clinical Trial in Wet AMD

In November 2025, we reported positive long-term interim results from Phase 1/2a and 2b of PRISM. As of the most recent data cutoff date (August 22, 2025):

- 4D-150 demonstrated consistent and durable benefit across all three patient cohorts as evidenced by maintenance of visual acuity, control of retinal anatomy and reduction of treatment burden at all time points with up to 2 years of follow-up. Treatment burden reduction results were as follows:

Treatment Burden Reduction Following 4D-150
(Mean Supplemental Injections vs Comparator)

Cohorts:	Through Year 1	Through Year 1.5 (Phase 2b) & Year 2 (Phase 1/2a)
Phase 2b[1] Subgroup: Recently Diagnosed (Ph 3 comparable)	94%	92%
Phase 2b[1]: Broad	83%	82%
Phase 1/2a[2]: Severe, Recalcitrant	83%	79%

[1]Compared to projected aflibercept 2mg Q8 weeks (Phase 3 comparator)
[2]Compared to mean injections in prior 12 months

- Durability was Maintained Consistently Across 6-Month Intervals Through 1.5 to 2 Years:

Mean Supplemental Anti-VEGF Injections per Patient by 6-month Segments Post-4D-150

Cohorts:	0 to 6 Months *Includes impact of 4D-150 & aflibercept loading dose(s)**	6 to 12 Months	12 to 18 Months	18 to 24 Months
Phase 2b Subgroup: Recently Diagnosed (Ph 3 comparable)	*0.1*	0.2	0.4	*pending*
Phase 2b: Broad	*0.4*	0.6	0.6	*pending*
Phase 1/2a: Severe, Recalcitrant	*0.5*	1.3	1.2	1.2

*Week –1 in Phase 1/2a, Week –1 & 4 in Phase 2b

- 4D-150 continued to be well tolerated with no new safety or intraocular inflammation findings, with up to 3.5 years of follow-up
    - Within approximately the first 28 weeks post-4D-150 dosing, 2.8% (2 of 71) of patients had 4D-150-related 1+ (mild) intraocular inflammation (IOI) (SUN/NEI scales), which were transient 1+ vitreous cells noted at a single timepoint
    - Following the first 28 weeks post-4D-150 dosing, no new cases of inflammation with approximately 1.5 to more than 3.5 years of follow-up on all patients as of the data cutoff
    - 99% (70 of 71) completed steroid prophylaxis taper on schedule and remained completely off steroids
    - No 4D-150-related hypotony, endophthalmitis, vasculitis, occlusive/non-occlusive retinal vasculitis or choroidal effusions observed to date

4FRONT Global Phase 3 Registration Program in Wet AMD

The 4FRONT global Phase 3 registration program consists of two multicenter, randomized, double masked, aflibercept Q8W comparator-controlled trials, with the primary endpoint of BCVA noninferiority of 4D-150 3E10 vg/eye to aflibercept 2mg Q8W at 52 weeks. The first trial 4FRONT-1 is being conducted in North America and is enrolling a treatment-naïve population and the second trial 4FRONT-2 is being conducted globally and is enrolling both treatment-naïve and previously treated, recently diagnosed population. Target enrollment per study is 480 patients randomized 1:1 to 4D-150 or the aflibercept comparator arm, providing approximately 90% power with a noninferiority margin of 4 letters as aligned with the Japan Pharmaceuticals and Medical Devices Agency and EMA and over 90% power with a noninferiority margin of 4.5 letters per FDA guidance.

In March 2025, we initiated 4FRONT-1. Subsequently in February 2026, we announced enrollment completion within an approximately 11-month period, ahead of initial projections, with the trial overenrolled and expected to exceed 500 patients randomized, reflecting strong interest from investigators and patients. We continue to anticipate topline data with the 52-week primary endpoint in the first half of 2027.

In June 2025, we initiated 4FRONT-2, with enrollment completion expected in the second half of 2026. We anticipate topline data with the 52-week primary endpoint in the second half of 2027.

Clinical Development of 4D-150 in DME: SPECTRA Phase 1/2 Clinical Trial

The SPECTRA Phase 1/2 clinical trial assesses 4D-150 in patients with DME. The trial design consists of a Dose Confirmation cohort (Part 1) followed by a randomized, masked Dose Expansion cohort (Part 2). In the Dose Confirmation cohort, patients were sequentially enrolled to one of three dose arms of 4D-150 (5E9, 1E10 and 3E10 vg/eye). In the Dose Expansion cohort (Part 2, N=54), patients were to be randomized 1:1:1 to one of two doses of 4D-150 or aflibercept. In January 2025, we announced FDA feedback that based on interim data and plans reviewed to-date, we may proceed into Phase 3 and Part 2 was no longer necessary. We do not currently intend to enroll Part 2.

Interim Data from Part 1 of 4D-150 SPECTRA Clinical Trial in DME

In July 2025, we announced positive 60-week topline interim data from Part 1 of the SPECTRA clinical trial. Based on the results, 3E10 vg/eye was selected as the Phase 3 dose. As of the most recent data cutoff date (May 2, 2025):

- Safety (n=22):
  - 4D-150 was well tolerated with no intraocular inflammation at any timepoint
  - All patients completed the 16-week topical corticosteroid taper on schedule and remained completely off steroids
  - No hypotony, endophthalmitis, vasculitis, choroidal effusions or retinal artery occlusions

- Efficacy Results Through 60 Weeks:
  - Phase 3 Dose (N=9):
    - Sustained gain of BCVA of +9.7 letters
    - Sustained reduction of CST, as measured by OCT, of -174 µm
  - Supplemental injections:
    - Post-aflibercept loading doses (3), patients treated with Phase 3 dose required substantially fewer supplemental injections compared to patients receiving lower doses (1E10 and 5E9 vg/eye, N=11 evaluable) or projected on-label aflibercept 2mg Q8W (expected Phase 3 comparator):
      - Mean injections per patient:
        - Phase 3 dose: 1.6
        - Lower doses: 3.7
        - Projected on-label aflibercept 2mg Q8W: 7.0
        - Dose response observed for Phase 3 dose vs. lower doses (58% fewer injections)
        - Phase 3 dose demonstrated a reduction of 78% vs. projected on-label aflibercept 2mg Q8W
      - 0-1 injections:
        - 5 of 9 overall (Phase 3 dose) vs. 2 of 11 (lower doses)
      - Injection-free:
        - 4 of 9 overall (Phase 3 dose) vs. 1 of 11 overall (lower doses)

In January 2025, we also announced alignment with the FDA that a single Phase 3 clinical trial would be acceptable as the basis of a biologics license application ("BLA") submission for 4D-150 in DME. This decision was based on the data generated for 4D-150 in both the SPECTRA and PRISM clinical trials combined with data from the two planned Phase 3 clinical trials in the 4FRONT wet AMD program. Per FDA feedback, we may proceed to Phase 3 and are aligned with key design elements of a Phase 3 clinical trial with approximately 300-400 patients total with a primary endpoint of BCVA noninferiority vs. on-label aflibercept 2mg (5 loading doses and Q8W), and revised supplemental injection criteria (less stringent compared to Part 1 SPECTRA, in line with prior successful Phase 3 DME clinical trials). Protocol alignment across global agencies is ongoing and a single global Phase 3 clinical trial is expected to initiate in the third quarter of 2026.

Pulmonology Therapeutic Area

Introduction

We are developing product candidates to treat lung diseases. Our customized and evolved vector, A101, is used in all of our pulmonology disease product candidates. A101 was invented for aerosol delivery leading to transgene expression throughout all regions of the airways and alveoli, as well as resistance to pre-existing antibodies in humans. We believe that this modular product approach, utilizing A101 for multiple product candidates by switching the therapeutic transgene, increases product development efficiencies, decreases development risks and informs clinical development of subsequent product candidates using the same vector.

Our first pulmonology product candidate is 4D-710 for cystic fibrosis lung disease. We are currently enrolling the Phase 2 portion of the AEROW Phase 1/2 clinical trial in people with CF with funding from and in collaboration with the CF Foundation.

Our second pulmonology product candidate is 4D-725 for alpha-1 antitrypsin deficiency lung disease. 4D-725 is currently in preclinical development and fully funded by the California Institute for Regenerative Medicine through IND filing.

4D-710 for Cystic Fibrosis Lung Disease

Disease Background, Unmet Medical Need, and Target Patient Population

CF is the most common fatal inherited disease in the United States and results from mutations in the CFTR gene. CF causes impaired lung function, inflammation, and bronchiectasis and is commonly associated with repeat and persistent lung infections due to the inability to clear thickened mucus from the lung, often resulting in frequent exacerbations and hospitalizations and eventual end-stage respiratory failure. There is no cure for CF, and the median age of death for people is approximately 40 years in developed countries. CF is considered a rare, or orphan, disease by both the FDA and the EMA.

According to the CF Foundation, nearly 40,000 people in the United States and an estimated 105,000 people worldwide are living with CF, and approximately 1,000 new cases are diagnosed in the United States each year. People with CF require lifelong treatment with multiple daily medications, frequent hospitalizations and, ultimately, lung transplants. The quality of life for people with CF is further compromised as a result of spending significant time on self-care every day and frequent outpatient doctor visits and hospitalizations.

Until recently, approved therapies to treat people with CF were only designed to treat the manifestations of CF, for example by preventing and controlling infections that occur in the lungs, rather than addressing the underlying cause of the disease. Accordingly, antibiotics are frequently used along with mucus-thinning drugs.

More recently, a new class of drugs called modulators target CFTR for people with certain gene variants. Several therapies from Vertex Pharmaceuticals Inc. have been approved for marketing in the United States and the European Union based on their ability to improve lung function in genetically defined subsets of CF. In 2019, the FDA approved a triple drug therapy with Trikafta (elexacaftor/ivacaftor/tezacaftor), which Vertex believes would be applicable for up to 90% of people with CF, leaving at least 10% with no CFTR-targeted options. While these therapies improve lung function, they fall short of restoring it to the normal range in most people, and these chronic therapies require daily dosing for the person's lifetime. In addition, the existing CF drugs have been associated with tolerability issues, thus limiting their use in some people.

We believe there is a clinical need and market opportunity for a durable aerosolized therapy, delivered by breath-actuated nebulizer, that can restore normal CFTR function across all people with CF, including people who are receiving combination CFTR-modulator therapies and/or do not have appreciable CFTR protein expression and are therefore not amenable to CFTR modulators. We expect to explore single agent therapy with 4D-710 initially in people whose disease is not amenable to CFTR modulators (estimated to include approximately 15% of people with CF who have null variants or are unable to tolerate modulators), and to explore single agent or combination therapy with CFTR modulators for the remaining approximately 85% of people with CF.

Our Solution

We are developing 4D-710 as a durable, redosable, variant-agnostic disease-modifying therapy for people with CF lung disease. 4D-710 is designed for efficient aerosol delivery to the proximal and distal airways and alveoli, subsequent mucus barrier penetration, lung epithelial cell transduction, and resistance to pre-existing antibodies. The intended result is to achieve CFTR expression within lung epithelial cells for correction of CF lung disease. 4D-710 is comprised of our customized and evolved vector, A101, and a codon-optimized version of a synthetic truncated CFTR transgene *CFTRΔR*. *CFTRΔR* is a construct that retains the most critical functional components of the full-size CFTR gene and is small enough to fit within AAV vector packaging constraints, and is shown to have normal function and regulation in nonclinical studies. Based on nonclinical and clinical studies with other AAV programs, we expect redosing 4D-710 will be feasible.

Initially, we plan to focus on the approximately 15% of all people with CF who are not amenable to CFTR modulators as we believe these people have the highest unmet need. In people with CFTR variants that are amenable to modulators, many do not regain or cannot preserve lung function. Further, these chronic therapies require daily dosing for the person's lifetime. We therefore expect to eventually develop 4D-710 in this population, as a single agent and/or in combination with these CFTR modulators.

4DMT Differentiation: AAV Genetic Medicines for Cystic Fibrosis Lung Disease

A number of biotechnology companies have pursued genetic medicine solutions to treat cystic fibrosis. We believe these prior attempts to deliver AAV genetic medicine to the lungs of people with CF have failed due to an inability of conventional AAV vectors to penetrate through the lung mucus barrier and transduce lung cells efficiently. Further, we believe antibody neutralization of AAV likely also played a role in the lack of efficacy, as the mucosal immune system actively transports large quantities of antibodies into all mucus secretions, including on the lung mucosa.

While a number of companies are currently pursuing other genetic medicine solutions utilizing liposomes, herpesvirus, lentivirus, or conventional AAV vectors, these product candidates are in early stages of development. Moreover, they are not, to our knowledge, comprised of AAV vectors evolved in primates for aerosol delivery diffusely throughout the lung airways and alveoli. In addition, we believe these products were not designed for resistance to pre-existing antibodies to conventional AAVs, which is potentially a key requirement for successful delivery in the lung. As a result, to our knowledge, 4D-710 is the only AAV genetic medicine product candidate in development designed specifically with a vector selected for aerosol delivery in primates, including humans, and with resistance to antibodies in the human population.

We believe 4D-710 has the potential to be differentiated from approved agents, and those in clinical development to our knowledge, on the basis of four features:

1. Corrective mechanism-of-action: An aerosol dose of 4D-710 is designed to result in therapeutic levels of the CFTR protein directly within target cells lining the airway.
2. Long duration therapy: Unlike CFTR-targeted small molecules that require daily dosing for a person's entire life or liposomal and herpesvirus delivered genetic medicines that are being studied for dosing every few days to weeks, 4D-710 is designed for significantly less frequent dosing.
3. CFTR mutation-independent efficacy: Unlike CFTR-targeted small molecules that are only effective against specific mutations, 4D-710 is designed to be used in people with CF with any mutation, including in the approximately 15% of people whose disease is not amenable to standard medical therapy.
4. Resistance to AAV antibodies: Unlike conventional AAV vectors, which are sensitive to anti-AAV antibody inhibition, 4D-710 utilizes A101, a vector invented for resistance to human antibody inhibition.

Clinical Development: AEROW Phase 1/2 Clinical Trial

The AEROW Phase 1/2 clinical trial is a multicenter, open-label, dose-escalation and dose-expansion trial of 4D-710 in people with cystic fibrosis who are ineligible for CFTR modulator therapy or who have discontinued therapy due to adverse effects. The primary endpoint of the trial is safety and tolerability. Secondary endpoints include assessments of clinical activity including lung function, quality of life, and transgene delivery and CFTR expression as measured from bronchoscopic samples. The trial is being conducted within the Cystic Fibrosis Therapeutics Development Network, the largest CF clinical trials network in the world.

Interim Data from Phase 1 Stage of 4D-710 AEROW Clinical Trial in Cystic Fibrosis

In December 2025, we announced positive interim clinical data. The interim clinical data focused on safety, transgene expression, and clinical activity for 16 participants enrolled across four Phase 1 dose cohorts (2E15, 1E15, 5E14 and 2.5E14 vg).

The interim results, with best available data through December 1, 2025, included:

- Safety Data
  - No new pulmonary or other safety events occurred since previous update in higher-dose cohorts (1E15 and 2E15 vg) with up to 3.5 years of follow-up
  - In lower-dose cohorts (4 to 24 months of follow-up), 4D-710-related adverse events were generally mild, transient and resolved by 2 months, with no 4D-710-related severe adverse events
- Biopsy Data
  - In biopsies collected approximately 4 weeks post-dosing, consistent and dose-dependent CFTR transgene RNA levels at or above physiologically relevant levels in non-CF control samples across all dose levels
    - In 2.5E14 vg dose cohort, results met target expression profile
  - Durable CFTR transgene expression within or above target therapeutic range through at least 1 year across all dose levels as measured from optional paired biopsies collected at or beyond 1 year post-dosing

- In 2.5E14 vg dose cohort, consistent evidence of clinically meaningful activity detected in all endpoints, including $ppFEV_1$, $LCI_{2.5}$ and quality of life (CFQ-R-R) through 1 year
- Based on evaluation of safety, tissue expression and efficacy data, 2.5E14 vg was selected as the Phase 2 dose

The 4DMT Therapeutic Vector Evolution Platform: One Billion Synthetic Capsid Sequences for Targeted Genetic Medicines

Genetic medicines hold tremendous promise as a transformative therapeutic class. However, the majority of genetic medicines have encountered limitations such as inflammation and toxicity, high dose requirements, limited efficacy, and neutralization by pre-existing antibodies, due in part to their utilization of conventional AAV vectors that are naturally occurring and non-targeted. Through our Therapeutic Vector Evolution Platform, we apply the principles of directed evolution to invent targeted and evolved vectors for the delivery of genes to specific tissue types to treat diseases involving those same target tissue(s). Our product candidates are designed and engineered to utilize our targeted and evolved vectors to potentially address the limitations encountered with genetic medicines utilizing conventional AAV vectors.

The first step of directed evolution involves the generation of a diverse library of biological variants. Leveraging a wide range of molecular biology techniques, we have developed a collection of highly diverse and distinct libraries that are comprised of approximately one billion synthetic capsid sequences. We next define a Target Vector Profile that identifies the optimal vector features for the specific tissue type(s) and related set of diseases we seek to target, with the goal of overcoming limitations encountered by conventional AAVs. We then deploy TVE with our capsid libraries in NHPs and use competitive selection to identify targeted and evolved vectors from our libraries that demonstrate the strongest match to the Target Vector Profile. Subsequently, we characterize and evaluate a lead targeted and evolved vector for delivery and transgene expression through extensive studies in NHPs and human cell and organotypic tissue assays.

We believe our proprietary vectors will allow us to overcome known limitations of conventional AAV vectors, and to potentially address a broad range of diseases that affect both large and rare patient populations that cannot be addressed with conventional vectors.

Our proprietary Therapeutic Vector Evolution Platform is based on the principles of directed evolution. Directed evolution is a high-throughput platform approach that harnesses the power of evolution in order to create biologics with new and desirable characteristics.

Since our founding in 2013, we have developed and industrialized our Therapeutic Vector Evolution Platform to invent customized and evolved vectors for use in human therapeutic products. In addition, we have developed significant experience in performing TVE programs in NHPs. We have patent applications and issued patents covering hundreds of proprietary, unique AAV capsid vectors. We believe these proprietary customized vectors will give us significant competitive advantages to develop product candidates for a broad range of large market and rare disease patient populations, including those other genetic medicines cannot address.

Diverse Sub-Libraries of Synthetic Capsid Sequences

Each sub-library results from the application of a different genetic diversification methodology, such as variable loop mutagenesis, random peptide insertion, random point mutagenesis, DNA shuffling, and ancestral reconstruction, and is also defined by its starting material (AAV capsid gene sequences). We also apply bioinformatics, emerging technologies, experience and know-how resulting from previous discovery programs to continually improve and expand our libraries and improve our ability to invent customized and evolved vectors.

We believe the size and diversity of our proprietary synthetic capsid libraries represent a differentiating competitive advantage for us in the field of genetic medicines.

The Target Vector Profile Followed by Competitive Vector Selection

We employ a rigorous approach to inventing customized and evolved vectors based on what we consider an optimal vector and product profile, which we term the Target Vector Profile, for any disease or set of diseases affecting the same tissue(s). The Target Vector Profile includes any combination of the following: the target cell(s), the desired distribution of vector transduction within the target organ(s), the optimal route of administration for targeting the specific tissue(s), the optimal dose range, overall biodistribution, and resistance to human pooled antibodies.

We use our Therapeutic Vector Evolution Platform to select the "fittest" customized and evolved capsid that best matches our Target Vector Profile. We achieve this through serial rounds of "selection," or discovery, *in vivo* in primates with each round of selection funneling down to fewer and fewer remaining synthetic capsids from the original library. This funneling process is achieved by applying selective pressures—forcing competition—among all synthetic capsid variants in the library to achieve delivery to the target cells as defined in the Target Vector Profile. Each round is performed in a primate *in vivo*, sometimes in the presence of human antibodies.

We believe this deliberate approach to selection *in vivo* in primates and in human tissues should lead to identification of customized and evolved vectors with a higher likelihood of therapeutic benefit in humans.

Vector Invention Results to Date

We have completed unique vector selection programs or "selection processes" for specific proprietary synthetic capsids with specific Target Vector Profiles. Across our clinical development and discovery portfolio, we have utilized four different routes of administration: intravitreal, aerosol, intravenous, and intrathecal. We have completed discovery programs targeting a diverse array of tissue types including various retinal cell types, heart and skeletal muscle tissues, different lung cell types, liver, brain, dorsal root ganglia, and synovial joints, resulting in hundreds of unique and proprietary customized and evolved vectors.

Characterization of Novel Vector Variant "Hits" and "Leads"

Vector hits are typically characterized by three major criteria: manufacturability, human cell and human organotypic model transduction, and delivery to tissues in NHPs by the designated route of administration. Vector hits may also be evaluated for transduction in the presence of pooled human antibodies. In order to perform characterization studies, vectors are armed with marker transgene payloads such as enhanced green fluorescent protein ("EGFP"). A lead vector is selected after evaluation of these hits.

Competition

We are aware of several companies focused on developing genetic medicines in various indications as well as companies addressing methods for modifying genes and regulating gene expression. We may also face competition from large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions with genetic medicine and other therapeutic approaches.

We consider our most direct competitors in late-stage development with respect to 4D-150 for the treatment of retinal vascular diseases including wet AMD and DME to be late-stage AAV-based anti-VEGF genetic medicine programs including ABBV-RGX-314 from AbbVie Inc. and REGENXBIO Inc. (subretinal delivery in Phase 3 for wet AMD; suprachoroidal delivery initiating Phase 3 for diabetic retinopathy and in Phase 2 for wet AMD) and Ixo-Vec from Adverum Biotechnologies Inc., now a subsidiary of Eli Lilly and Company (intravitreal delivery in Phase 3 for wet AMD, previously discontinued in diabetic populations). We also face competition from late-stage sustained release VEGF receptor tyrosine kinase

inhibitor programs at EyePoint Inc. and Ocular Therapeutix Inc., anti-VEGF and IL-6 antibody biopolymer conjugate programs from Kodiak Sciences Inc, and Wnt signaling-pathway tri-specific antibody program from Merck & Company Inc. Currently marketed products include EYLEA (aflibercept) from Regeneron Pharmaceuticals Inc., which is the current standard of care, and a combination of antibody-based programs including, but not limited to, LUCENTIS, SUSVIMO, VABYSMO from Roche, and EYLEA HD from Regeneron Pharmaceuticals Inc.

We consider our most direct competitors with respect to 4D-175 for the treatment of geographic atrophy to be Apellis Pharmaceuticals Inc.'s C3 inhibitor SYFOVRE (approved by FDA in 2023) and Astellas Pharma Inc.'s C5 inhibitor IZERVAY (approved by FDA in 2023). We are also aware of other mid- to late-stage programs including but not limited to Annexon Biosciences, Inc.'s C1q inhibitor ANX007, Belite Bio, Inc's retinol binding protein 4 binder tinlarebant, Johnson & Johnson's AAV genetic medicine encoding CD59 JNJ-81201887, Regeneron Pharmaceuticals Inc.'s anti-C5 antibody pozelimab developed in combination with Alnylam Pharmaceuticals, Inc.'s RNAi therapeutic targeting C5 cemdisiran, Sanofi's AAV genetic medicine encoding C1s and Bb inhibitors SAR446597, and Stealth BioTherapeutics Inc.'s mitochondrial cardiolipin binder elamipretide.

We consider our most direct competitors with respect to 4D-710 for the treatment of CF lung disease to be Vertex Pharmaceuticals Incorporated, which has several approved CFTR modulators, as well as other companies in preclinical/early-clinical development of CF products, including Vertex Pharmaceuticals Incorporated, Sionna Therapeutics Inc., Krystal Biotech Inc., Arcturus Therapeutics Holdings Inc. and Recode Therapeutics, Inc.

Manufacturing

CMC Strategy

In order to fulfill our strategy to maximize the robustness and internal control of our manufacturing processes from discovery and process development through to clinical-grade current Good Manufacturing Practices ("cGMP") manufacturing, we have designed and are continually developing and scaling our in-house manufacturing platform for both GMP and non-GMP manufacturing. While many companies in the AAV genetic medicine field outsource their process development and manufacturing to other companies or academic manufacturing centers, in contrast, our manufacturing processes were developed internally using internal technology transfers from our own process development labs. Our current in-house manufacturing capabilities include GMP manufacturing (upstream, downstream and fill/finish), production capabilities for late-phase clinical trials, IND-enabling Good Laboratory Practice ("GLP") toxicology studies, and research candidate production. We also collaborate with contract development and manufacturing organizations ("CDMOs") to supplement our internal capacity, and expect to rely on CDMOs for potential commercial supply.

cGMP Capabilities

Our team has extensive experience with the manufacturing and analytical testing of numerous unique AAV capsids. Our team has internally manufactured over 300 unique AAV vectors, including both proprietary evolved 4DMT capsid variants and naturally occurring capsids. Our team has manufactured over 500 total lots of AAV vectors for research or clinical use. This total also includes multiple lots of product candidate material for GLP toxicology and biodistribution studies. We have in-house cGMP manufacturing capabilities for clinical trial material production. Our manufacturing team has completed and released 28 lots of clinical trial material for six product candidates in current or previous clinical development. Leveraging internal testing capabilities in addition to qualified contract testing laboratories, we fully test and release our GLP and GMP lots for use in toxicology and clinical trials, respectively. We have developed and qualified assays for characterization, in-process testing, and release and stability testing of our internally and externally manufactured proprietary AAV vectors.

Process Development Capabilities

We use robust, scalable and transferable manufacturing unit operations throughout both the vector characterization process and product development, which are both platform-specific and product-specific. The upstream manufacturing step involves triple plasmid transfections in an HEK293 mammalian production cell line. Downstream manufacturing steps for purification and concentration include multiple orthogonal column chromatography steps and tangential flow filtration. The downstream purification columns used in our process are from stable sources. Using internally developed manufacturing processes and testing, we characterize our novel capsids and payloads. In addition, leveraging internal expertise and capabilities, we package and test our novel vectors with payloads using internally developed manufacturing processes, including both adherent and suspension processes.

Manufacturing Facilities

Our manufacturing facilities are on site at company headquarters in Emeryville, California and include process development labs, an analytical development lab, QC lab, and a cGMP manufacturing facility. These process development facilities are designed for production of material for GLP toxicology and biodistribution studies. In addition, our cGMP facilities run at commercial scale (including adherent bioreactors and suspension stirred-tank reactors) and have provided materials for Phase 1 through Phase 3 clinical trial material.

Manufacturing Team

Our team of highly trained individuals is led by our Chief Technical Officer, Dr. Katy Barglow, and includes multiple Ph.D. scientists. Collectively, they have significant experience in viral vector manufacturing, chemistry-manufacturing-controls ("CMC"), regulatory affairs, analytical and process development, and quality assurance and controls. As of March 2026, our team had submitted 7 INDs, all of which have been granted clearance by the U.S. FDA, enabling our clinical candidates to advance to Phase 3 clinical development. Our team also has experience prior to 4DMT with manufacturing multiple viral vectors from preclinical studies through to multiple Phase 3 trials.

External Manufacturing

In addition to our in-house facilities, we have established a partnership with a leading global commercial CDMO for potential commercialization of 4D-150. We have successfully completed the tech transfer of produced and released Phase 3 batches using our intended commercial processes at this CDMO.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, manufacturing and process discoveries, and other know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. In particular, our patent strategy includes the filing of patent applications covering unique gene sequences selected through our TVE process. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

Our product and lead optimization candidates were discovered by us utilizing our proprietary technology. We have filed several non-provisional and provisional patent applications, all owned by us, relating to our product and lead optimization candidates in the United States and certain foreign countries and through the World Intellectual Property Organization that are directed to compositions of matter, dosing regimens, methods of treatment, medical uses, and formulations. We have also licensed several non-provisional patent applications, granted patents and international patent applications relating to our targeted and evolved vector, A101, which is used in 4D-710 and 4D-725, and to other AAV-based technologies.

As of February 14, 2026, our solely owned patent portfolio includes eighteen granted U.S. patents and one hundred and thirty-five granted foreign patents; each of these patents is expected to expire between May 2037 and April 2042, excluding any additional term from patent term adjustment or patent term extension if appropriate maintenance and other governmental fees are paid. Our solely owned patent portfolio also includes sixteen pending U.S. non-provisional applications and one hundred and sixty-nine pending foreign applications. We expect that United States and European patents, if issued from pending applications in our solely owned portfolio, would expire between May 2037 and September 2045, excluding any additional term from patent term adjustment or patent term extension if appropriate maintenance and other governmental fees are paid. Additional patent term for the presently issued or later issued U.S. patents may be awarded as a result of the patent term extension provision of the Hatch-Waxman Amendments of 1984. Similarly, in the European Union member countries, a supplementary protection certificate, if obtained, provides up to an additional five years of market exclusivity. Our solely owned patent portfolio also includes nine pending U.S. provisional patent applications.

In other jurisdictions (currently, Argentina, Australia, Bahrain, Brazil, Canada, Chile, China, Colombia, Costa Rica, Egypt, Hong Kong, India, Indonesia, Iran, Israel, Japan, Korea, Kuwait, Malaysia, Mexico, New Zealand, Oman, Peru, Philippines, Qatar, Russia, Saudi Arabia, Singapore, South Africa, Taiwan, Thailand, United Arab Emirates, Ukraine, and Vietnam), patents, if issued on pending applications in our solely owned patent portfolio, where applicable, relating to our product and lead optimization candidates, including composition of matter, dosing regimen, method of treatment, medical uses, and formulations are expected to expire between May 2037 and September 2045, if the appropriate maintenance, renewal, annuity, and other government fees are paid. These patents and patent applications (if applicable), depending on the national laws, may benefit from extension of patent term in individual countries if regulatory approval of any of our product candidates is obtained in those countries. For example, in Japan, the term of a patent may be extended by a maximum of five years in certain circumstances.

As of February 14, 2026, our in-licensed U.C. Berkeley patent portfolio, relating to our vector, A101, and other AAV-based technologies, includes five granted U.S. patents and twenty-one granted foreign patents; each of these patents is expected to expire between August 2027 and June 2038, excluding any additional term from patent term adjustment or patent term extension if appropriate maintenance and other governmental fees are paid. Our in-licensed U.C. Berkeley patent portfolio also includes one pending U.S. non-provisional patent application and ten pending foreign patent applications. We expect that United States and European patents, if issued from applications in our in-licensed U.C. Berkeley portfolio would expire between August 2027 and June 2038, excluding any additional term from patent term adjustment or patent term extension if appropriate maintenance and other governmental fees are paid.

As of February 14 2026, our in-licensed University of Pennsylvania patent portfolio includes two granted U.S. patents and ten granted foreign patents; each of these patents is expected to expire in September 2036, excluding any additional term from patent term adjustment or patent term extension if appropriate maintenance and other governmental fees are paid. Our in-licensed University of Pennsylvania patent portfolio also includes one pending U.S. non-provisional patent application and seven pending foreign patent applications. We expect that United States and European patents, if issued from applications in our in-licensed portfolio would expire in September 2036, excluding any additional term from patent term adjustment or patent term extension if appropriate maintenance and other governmental fees are paid.

In other jurisdictions (currently, for our in-licensed U.C. Berkeley patent portfolio, Australia, Brazil, Canada, China, Hong Kong, India, Japan, Korea and Mexico, and for our in-licensed University of Pennsylvania patent portfolio, Australia, Brazil, Canada, China, Israel, Japan, Korea and Hong Kong), patents, if issued on pending applications in our in-licensed patent portfolio, where applicable, relating to our product candidates, including composition of matter and various other patents, including dosage unit form, method-of-treatment and medical use patents are expected to expire between August 2027 and June 2038 for our in-licensed U.C. Berkeley patent portfolio, and expire in September 2036 for our in-licensed University of Pennsylvania patent portfolio, if the appropriate maintenance, renewal, annuity, and other government fees are paid. These patents and patent applications (if applicable), depending on the national laws, may benefit from extension of patent term in individual countries if regulatory approval of any of our

product or lead optimization candidates is obtained in those countries. For example, in Japan, the term of a patent may be extended by a maximum of five years in certain circumstances.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are effective for 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office ("USPTO") delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. The actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

We also protect our trade secrets and other proprietary technology and processes, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors or other contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have a material adverse impact on us.

Strategic Collaborations

Otsuka Pharmaceutical Co., Ltd.

On October 31, 2025, we entered into a Collaboration and License Agreement ("Otsuka Collaboration and License Agreement") with Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), pursuant to which we granted Otsuka exclusive rights to develop and commercialize 4D-150 for retinal vascular diseases, including wet AMD and DME, in Japan, China, Australia, and other Asia-Pacific ("APAC") markets. Otsuka has agreed to lead all regulatory and commercialization activities in its licensed territories. We agreed to continue to lead all Phase 3 clinical activities globally, including within the APAC region. Otsuka made an upfront cash payment of $85.0 million and has agreed to provide certain cost sharing for global development activities. In addition, we are eligible for up to $335.5 million in potential regulatory and commercial milestone payments and tiered double-digit royalties depending on net sales in Otsuka's licensed territories. We retain full development and commercialization rights for 4D-150 outside the APAC region, including the United States, Latin America, and Europe.

The Otsuka Collaboration and License Agreement remains in effect, unless earlier terminated, on a country-by-country basis, until the date that Otsuka is no longer developing or commercializing the licensed product in such country within the licensed territory. Each party has the right to terminate the Otsuka Collaboration and License Agreement for the other party's material breach of its obligations under the Otsuka Collaboration and License Agreement, subject to the right to cure such breach. Additionally, Otsuka may terminate the Otsuka Collaboration and License Agreement for convenience, on a country-by-country basis, upon sufficient prior written notice, or due to safety reasons or the failure of certain of our related clinical trials to achieve their primary endpoints. We may also terminate the Otsuka Collaboration and License Agreement upon notice if Otsuka challenges the patentability, enforceability, or validity of any

licensed patent, unless Otsuka withdraws the challenge within a specified period, or if Otsuka ceases all development activities and commercialization of all licensed products in Japan for an agreed upon period and does not resume such activities or commercialization within a specified notice period, unless such cessation is substantially attributable to specified circumstances. Upon termination, any license granted by us to Otsuka will terminate.

Cystic Fibrosis Foundation

In 2016, we received a grant from Cystic Fibrosis Foundation ("CFF") in the amount of $525,000 to support discovery and development of product candidates to treat cystic fibrosis. The grant was increased to $3.5 million in 2017 and was subsequently amended to allocate the $3.5 million to different milestones. In August 2023, the grant agreement was further amended, which modified the research plan, increased the aggregate milestone payments from $3.5 million to $6.3 million and extended the estimated project completion date. The grant provides for repayment to CFF upon the commercialization of any product developed under the grant. In August 2023, we executed an amendment to the CF Foundation agreement increasing the funding commitment under that agreement by $2.8 million to a total of $6.3 million, which covers anticipated spend for further development of our aerosolized lung epithelium gene delivery vectors. The repayment is capped at nine times the grant actually paid to us.

In April 2020, CFF made a $10.0 million investment in our Series C redeemable convertible preferred stock financing. In return for the investment, CFF received shares of our Series C redeemable convertible preferred stock, and we and CFF entered into a Funding Agreement (the Funding Agreement). Pursuant to the terms of the Funding Agreement, we agreed to use the proceeds of the CFF investment to support development of 4D-710, our product candidate for the treatment of cystic fibrosis, and to match CFF's support for the product candidate. As provided under the Funding Agreement, following acceptance by the FDA in October 2021 of our IND for 4D-710 ("Acceptance"), CFF made an additional $4.0 million investment (the "Subsequent Investment"), in exchange for 125,715 shares of our common stock. We have agreed to use the additional $4.0 million from the Subsequent Investment to support development of 4D-710 and to match CFF's support of the product candidate. Under the terms of the Funding Agreement, neither the $10.0 million investment in the Series C redeemable convertible preferred stock nor the $4.0 million of funding upon Acceptance are restricted as to withdrawal or usage.

In October 2025, CFF purchased 776,398 shares of our common stock for $7.5 million. We agreed to use the proceeds of this investment to support continued development of 4D-710. We also agreed with CFF to form a Joint Steering Committee, with senior clinical development and regulatory expertise to enhance strategic planning, guidance, and coordination of 4D-710's development. In addition, this agreement between CFF and us in October 2025 provides that CFF will invest an additional $3.6 million in exchange for shares of our common stock subject to achievement of specific clinical milestones and at our option. This agreement between us and CFF in October 2025 does not modify our prior agreements with CFF.

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 biological product candidates 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. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

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, and other federal, state, local and foreign statutes and regulations. 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 GLPs;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an Institutional Review Board ("IRB") or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy 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 current GMP 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 Good Clinical Practices ("GCP"); and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first 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(s) for clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must be allowed to proceed by the FDA before human clinical trials may begin. The IND automatically goes into effect within 30 days after receipt by the FDA, unless the FDA, within the 30-day time 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 proceed. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the submission of an IND to the FDA, under the National Institutes of Health ("NIH") Guidelines for Research Involving Recombinant DNA Molecules ("NIH Guidelines"), supervision of certain human gene transfer trials may also require 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 the public health or the environment, and such assessment may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, 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 clinical studies 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 or be combined:

- 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 labeling.

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 within the approved indication. These so-called Phase 4 studies, in addition to other post-marketing clinical trials, registry studies or comparable post-marketing commitments or requirements, may also be made a condition to approval of the BLA.

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

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. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, sponsors must develop methods for testing the identity, strength, quality, and

purity of the final product. 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.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, including results from 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 preclinical and clinical studies, 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 a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to FDA, and the sponsor of an approved BLA is also subject to an annual program fee. A waiver of user fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

In addition, the Pediatric Research Equity Act ("PREA"), requires a BLA sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original BLAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA 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 filing date. Priority review designation will direct overall attention and resources to the evaluation of applications for products that, if approved, would represent significant improvements in the safety or effectiveness in the treatment, diagnosis, or prevention of serious conditions. In both standard and priority reviews, the review process can be extended by three months for the FDA to review and respond to new information deemed a major amendment to the application. 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 also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions regarding approval.

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 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 GCP.

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 ("CRL"). An approval letter authorizes commercial marketing of the product

with specific prescribing information for specific indications. A CRL will generally 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 CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place a resubmitted BLA in condition for approval, including requests for additional clinical trials, or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS"), to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine 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 also require one or more Phase IV 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

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of drugs and biological products that meet certain criteria. Specifically, biological product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. For a fast track product candidate, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application. A fast track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing.

A product candidate 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 candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, 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 candidate, including involvement of senior managers.

In 2017, the FDA established the regenerative medicine advanced therapy ("RMAT") designation as part of its implementation of the 21st Century Cures Act. The RMAT designation program is intended to fulfill the 21st Century Cures Act requirement that the FDA facilitate an efficient development program for,

and expedite review of, any drug or biologic that meets the following criteria: (i) the drug or biologic qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the drug or biologic is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug or biologic has the potential to address unmet medical needs for such a disease or condition. Based on the FDA's current interpretation of Section 506(g) of the FDCA (as added by Section 3033 of the 21st Century Cures Act), certain human gene therapies and xenogeneic cell products may also meet the definition of a regenerative medicine therapy. RMAT designation provides all the benefits of breakthrough therapy designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of clinical trial sites, including through expansion of trials to additional sites.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product candidate with a fast track designation, RMAT 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 candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such 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). Under the accelerated approval program, the FDA may approve a BLA on the basis of either 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. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the 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. FDA may withdraw approval of a biologic or indication approved under accelerated approval on an expedited basis if, for example, the sponsor fails to conduct required post-marketing trials in a timely manner or if such trials fail to verify the predicted clinical benefit of the product.

Fast Track designation, priority review, accelerated approval, RMAT designation and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. Even if a product candidate 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.

We have obtained RMAT designation for 4D-150 for the treatment of neovascular (wet) AMD, and we plan to seek additional expedited designations for some or all of our product candidates in which there is a medically plausible basis for the use of these products.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the rare disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same approved use or indication within such rare disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs relating to the approved use or indication of patients with the rare disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same approved use or indication within the relevant rare disease or condition, or the same drug or biologic for any use or indication within 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 user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the disease or condition for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity within the relevant approved use or indication or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs relating to the approved use or indication of patients with the relevant rare disease or condition. We have obtained orphan drug designation for 4D-710 for the treatment of cystic fibrosis.

Rare Pediatric Disease Priority Review Voucher Program

In 2012, the U.S. Congress authorized the FDA to award priority review vouchers to Sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a “rare pediatric disease” may qualify for a voucher that can be redeemed to receive priority review of a subsequent marketing application for a different product. The Sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the Sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

For purposes of this program, a “rare pediatric disease” is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare diseases or conditions within the meaning of the Orphan Drug Act. Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2029. Consequently, unless Congress reauthorizes the program, the sponsor of the marketing application for a drug that receives Rare Pediatric Disease Designation will only be eligible to receive a voucher if the FDA grants the designation on or before September 30, 2029.

Post-Approval Requirements

Biologics 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. 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, annual program fees for any marketed products. 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 cGMP, 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 cGMP 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 cGMP 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 the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal 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 Exclusivity

The Affordable Care Act, signed into law in 2010, 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. 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, can be shown through analytical studies, animal studies, and a clinical study(ies). 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.

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 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.

Other Healthcare Laws

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, U.S. federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, and transparency laws and regulations with respect to payments and other transfers of value made to physicians and other healthcare professionals, as well as similar foreign laws in the jurisdictions outside the U.S. Violation of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement fines, additional reporting requirements and oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs, and imprisonment.

Data Privacy and Security Laws

Pharmaceutical companies may be subject to domestic and foreign privacy, security and data breach notification laws, which are rapidly evolving in many jurisdictions worldwide. In the United States, federal and state health information laws may govern the collection, use, disclosure and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. 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.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be reimbursed by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product, particularly for genetic medicine products where the Centers for Medicare & Medicaid Services ("CMS") and other third-party payors in the United States have not yet established a

uniform policy of coverage and reimbursement. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. 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 be limited, which may impact physician utilization.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their 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. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of us placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the "ACA") was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented 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; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, absent additional Congressional action. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on drug manufacturers' Medicaid drug rebate program liability, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

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 legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027, as well as the next set of 15 drugs that will be subject to price negotiations. HHS has issued and will continue to issue guidance implementing the IRA, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate that we commercialize. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug

price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. Some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for our investigational products that receive approval. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. Adoption of other new legislation or regulation at the federal, state, or foreign level could further limit reimbursement for pharmaceuticals, including our product candidates, if approved.

Employees and Human Capital

As of March 6, 2026, we had 196 full-time employees. Of these employees, 144 are engaged in research and development and 39 hold M.D. or Ph.D. degrees. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human resources objectives include, as applicable, identifying, recruiting, developing, managing, retaining, incentivizing and integrating our employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants, and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Facilities

We lease approximately 91,000 square feet of office, research and development, engineering, laboratory and warehouse space in Emeryville, California under lease agreements that expire between August 2026 and December 2030. We believe that our facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Corporate Information

We were formed on September 12, 2013 as a Delaware limited liability company under the name 4D Molecular Therapeutics, LLC. On March 11, 2015, 4D Molecular Therapeutics, Inc. was incorporated as a Delaware corporation. On March 20, 2015, 4D Molecular Therapeutics, LLC merged with 4D Molecular Therapeutics, Inc., with 4D Molecular Therapeutics, Inc. being the surviving entity. Our principal executive offices are located at 5858 Horton Street #455, Emeryville, California 94608, and our telephone number is (510) 505-2680.

Available Information

Our website address is www.4dmoleculartherapeutics.com. The information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. The U.S. Securities and Exchange Commission (“SEC”) maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) are also available free of charge on our investor relations website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this report, including our financial statements and the related notes and the section of this report "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. If any of the following risks actually occur, our business, reputation, financial condition, results of operations, revenue and future prospects could be seriously harmed. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. Unless otherwise indicated, references to our business being seriously harmed in these risk factors and elsewhere will include harm to our business, reputation, financial condition, results of operations, future prospects and stock price. If our business is seriously harmed, the market price of our common stock could decline, and you could lose part or all of your investment.

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

We are in the late stages of drug development for our lead program and have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with the potential to transform treatment paradigms and provide unprecedented benefits to patients. We commenced operations in September 2013, have no products approved for commercial sale and have not generated any product revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. If our product candidates are not successfully developed and approved, we may never generate any product revenue. To date, we have not completed any clinical trials (including any pivotal clinical trial), obtained marketing approval for any product candidates, manufactured commercial scale quantities of any of our product candidates or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company and stage of drug development make any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will be seriously harmed.

We have had recurring net losses, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred recurring net losses, including net losses of $140.1 million and $160.9 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $716.3 million.

We have devoted substantially all of our financial resources and efforts on research and development activities. We do not expect to generate revenue from product sales for several years, if at all. We continue to incur significant research and development and other expenses related to our ongoing operations. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our expenses may increase substantially if and as we:

- progress our current and any future product candidates through preclinical and clinical development;

- expand our manufacturing facilities and work with our contract manufacturers to scale up the manufacturing processes for our product candidates;
- continue our research and discovery activities;
- continue the development of our Therapeutic Vector Evolution platform;
- initiate and conduct additional preclinical, clinical or other studies for our product candidates;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;
- acquire or in-license product candidates, intellectual property and technologies;
- make milestone, royalty or other payments due under any current or future collaboration or license agreements;
- obtain, maintain, expand, protect and enforce our intellectual property portfolio;
- attract, hire and retain qualified personnel;
- experience any delays or encounter other issues related to our operations;
- meet the requirements and demands of being a public company;
- are adversely impacted by general economic conditions, such as rising inflation, tariffs and increased interest rates;
- defend against any product liability claims or other lawsuits related to our products; and
- experience delays in our preclinical studies and clinical trials, whether current or planned, due to pandemics or public health emergencies.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' deficit and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

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

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time consuming, expensive and uncertain process that takes years to complete. Our operations have required substantial amounts of cash since inception. To date, we have financed our operations primarily through the sale of equity securities and to a lesser extent from cash received pursuant to our collaboration and license agreements. We have initiated clinical trials, which are ongoing, and have additional product candidates in preclinical development that may enter clinical development. Developing our product candidates is expensive, and we expect to continue to spend substantial amounts as we fund our early-stage research projects, continue preclinical and clinical development of our product candidates and, in particular, advance our product candidates through clinical trials. Even if we are successful in developing our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial funding.

As of December 31, 2025, we had $514.0 million in cash and cash equivalents and marketable securities.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will allow us to fund our planned operations for at least one year from the date of the issuance of the financial statements included in this report.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise additional capital may be adversely impacted by global economic conditions affecting credit and financial markets (including due to increased interest rates and high inflation rates) and product supply chains. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or eliminate one or more of our development programs altogether; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to, or jointly own some aspects of, our product candidates or technologies that we would otherwise pursue on our own. We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and unless and until a product candidate is clinically tested, approved for commercialization and successfully marketed.

We will be required to seek additional funding in the future and currently intend to do so through collaborations, public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution, and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could seriously harm our business and cause the price of our common stock to decline.

Due to the significant resources required for the development of our product candidates, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on product candidates that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our product candidates, in particular our product candidates in IND-enabling studies and those in clinical trials, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product candidates may subsequently also prove to be less than optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the biopharmaceutical industry, particularly in retina and pulmonology, our business could be seriously harmed. As a result, we may fail to capitalize on viable

commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly, making it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside our control and may be difficult to predict, including:

- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or collaboration partners;
- the timing, cost, and level of investment in research, development and commercialization activities, which may change from time to time;
- the timing of receipt of approvals from regulatory authorities in the United States and internationally;
- the timing and status of enrollment and safety and efficacy readouts for our clinical trials;
- the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity of production, the cost of continuing to establish and scale up our manufacturing capabilities, and the terms of any agreements we enter into with third-party suppliers;
- the timing and amount of any option, milestone, royalty or other payments due under any current or future collaboration or license agreement;
- coverage and reimbursement policies with respect to our genetic medicine product candidates and potential future drugs that compete with our products, if approved;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the level of demand for our genetic medicine products, if approved, which may vary significantly over time;
- future accounting pronouncements or changes in our accounting policies; and
- the impact from general macroeconomic trends, such as higher inflation, tariffs and increased interest rates.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of financial analysts or investors for any period. If our revenue or operating results fall below or if operating expenses or other costs are higher than the expectations of analysts or investors or below or above, as the case may be, any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a

stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Risks Related to the Research, Discovery, Development and Commercialization of Our Product Candidates

All of our product candidates are based on a novel AAV genetic medicine technology with which there is limited regulatory and clinical experience to date, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. Further, the regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities.

All of our product candidates are based on genetic medicine technology, and our future success depends on the successful development of this novel therapeutic approach. We cannot assure you that any development problems we or other genetic medicine companies experience in the future related to genetic medicine technology will not cause significant delays or unanticipated costs in the development of our product candidates, or that such development problems can be solved. In addition, the clinical study requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities. Further, as we are developing novel treatments for diseases in which there is limited clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, EMA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, few genetic medicine products have been approved by the FDA or comparable foreign regulatory authorities, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the European Union ("EU") or other jurisdictions. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

Regulatory requirements governing genetic medicine products have evolved and may continue to change in the future. For example, the FDA has established the Office of Therapeutic Products within its Center for Biologics Evaluation and Research ("CBER") to consolidate the review of genetic medicine and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions.

The National Institutes of Health ("NIH") Guidelines for Research Involving Recombinant DNA Molecules ("NIH Guidelines") require supervision of human gene transfer trials, including 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. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

We are subject to significant regulatory oversight by the FDA, and, in addition, the applicable IBC and Institutional Review Board ("IRB"), of each institution at which we or our collaborators conduct clinical trials of our product candidates, or a central IRB if appropriate, need to review and approve the proposed clinical trial.

Similar requirements apply in the EU. The EMA has a Committee for Advanced Therapies ("CAT") that is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products, or ATMP(s). ATMPs include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for an ATMP candidate that is submitted to the EMA. In the EU, the development and evaluation of an ATMP must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions.

Changes in applicable regulatory guidelines may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions.

As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all and could seriously harm our business.

Adverse public perception or regulatory scrutiny of genetic medicine technology may negatively impact the developmental progress or commercial success of product candidates that we develop alone or with collaborators.

The developmental and commercial success of our current product candidates, or any that we develop alone or with collaborators in the future, will depend in part on public acceptance of the use of genetic medicine technology, including the use of AAVs, for the prevention or treatment of human diseases. Adverse public perception of gene therapies may negatively impact our ability to raise capital or enter into strategic agreements for the development of product candidates.

Genetic medicine remains a novel technology. The commercial success of our genetic medicine product candidates, if successfully developed and approved, may be adversely affected by claims that genetic medicine is unsafe, unethical or immoral. This may lead to unfavorable public perception and the inability of any of our product candidates to gain the acceptance of the public or the medical community. Unfavorable public perceptions may also adversely impact our or our collaborators' ability to enroll clinical trials for our product candidates. Moreover, success in commercializing any product candidates that receive regulatory approval will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of such product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

Publicity of any adverse events in, or unfavorable results of, preclinical studies or clinical trials for any current or future product candidates, or with respect to the studies or trials of our competitors or of academic researchers utilizing similar technologies, even if not ultimately attributable to our technology or product candidates, could negatively influence public opinion. Negative public perception about the use of AAV technology in human therapeutics, whether related to our technology or a competitor's technology, could result in increased governmental regulation, delays in the development and commercialization of product candidates or decreased demand for the resulting products, any of which may seriously harm our business.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

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

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Less common adverse effects may not become evident until investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval.

If any serious adverse events occur, clinical trials or commercial distribution of any product candidates or products we develop alone or with collaborators could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us or our collaborators to cease further development of, deny approval of, or require us to cease selling any product candidates or products for any or all targeted indications. If we or our collaborators elect, or are required, to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenue from them or other product candidates that we develop may be delayed or eliminated. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a Risk Evaluation and Mitigation Strategy (“REMS”), which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- the product may become less competitive;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have no products approved for commercial sale, and we have never generated any revenue from product sales, and we may never generate product revenue or be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. We do not anticipate generating any revenue from product sales until after we have successfully completed clinical development and received regulatory approval for the commercial sale of a product candidate, which will not occur for several years, if ever.

Our ability to generate revenue and achieve profitability depends significantly on many factors, including:

- successfully completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and any commercial demand for our product candidates;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- launching and successfully commercializing product candidates for which we obtain marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our product candidates are commercialized;
- obtaining adequate reimbursement for our product candidates or procedures using our product candidates from payors;
- the convenience and durability of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates, or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for any of our product candidates that may be approved;
- addressing any competing technological and market developments;
- the effects of any public health emergencies which may result in delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory agencies to perform studies in addition to

those that we currently anticipate, or if there are any delays in any of our or our collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable, and we will need to obtain additional funding through one or more equity or debt financings in order to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained 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 get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as large as we anticipate, the indication approved by regulatory authorities is narrower than we expect, the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines or the price and available third-party reimbursement are lower than anticipated, we may not generate significant revenue from sales of such product candidate, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our common stock, all or any of which may seriously harm our business.

We may encounter substantial delays in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be initiated, conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or a clinical trial application ("CTA") will result in the FDA or other regulatory authority, 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 delay, suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. In 2025, we initiated our wet AMD Phase 3 studies comparing a single dose of 4D-150 3E10 vg/eye to on-label aflibercept 2mg Q8 weeks. If we experience any delays in completing these trials, due to delays in enrollment or other factors, it could result in serious harm to our business. 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 agencies 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 contract research organizations ("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;
- refusal of the FDA to accept data from clinical trials in geographies outside the United States;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in identifying, recruiting, and enrolling patients who meet the requirements of our clinical trials;
- delays in obtaining required IRB approval or ethics committee opinion at each clinical trial site;

- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA or amendment, or equivalent foreign application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments on trials conducted by competitors for related technology that raise FDA or foreign regulatory authority concerns about risk to patients of the technology broadly; or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- 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 good clinical practice ("GCP") requirements or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance (including differing expectations across jurisdictions) that require amending or submitting new clinical protocols, expanding enrollment, modifying statistical assumptions (including non-inferiority margins), or submitting new or amended protocols, including for our Phase 3 trials of 4D-150;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a CDMO or by us, and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process;
- third parties being unwilling or unable to satisfy their contractual obligations to us; and
- adverse public perception or regulatory scrutiny of genetic medicine technology may negatively impact the developmental progress or commercial success of products that we develop alone or with collaborators.

Patient enrollment, a determinative factor in the timing of clinical trials, is affected by many factors including the severity and difficulty of diagnosing the disease under investigation, knowledge of the disease in the medical community and availability of effective diagnostic methods, size and distribution of the patient population and process for identifying subjects, access of patients to medical professionals experienced in their disease, our ability to effectively disseminate information about our clinical trials to the patient population and access of patients to such information, eligibility and exclusion criteria for the trial in

question, design of the trial protocol, availability, efficacy of, and our ability to compete with approved and standard of care therapies or other clinical trials for the disease or condition under investigation, perceived risks and benefits of the product candidate under trial or testing, availability of genetic testing for potential patients, efforts to facilitate timely enrollment in clinical trials, patient referral practices of physicians, ability to obtain and maintain subject consent, the risk that enrolled subjects will drop out before completion of the trial, the ability to monitor patients adequately during and after treatment, the time and financial commitments required of patients to enroll in our trials beyond the costs covered by the company, and the proximity and availability of and access to clinical trial sites for prospective patients. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required, or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates and could seriously harm our business.

The limited number of patients who have the diseases for which many of our product candidates are being studied may make it more difficult for us to enroll or complete clinical trials or may result in findings in our clinical trials that do not reach levels of statistical significance sufficient for marketing approval.

Many of the conditions for which we plan to evaluate our current product candidates in clinical trials are rare genetic diseases. Accordingly, there are limited patient pools from which to draw for clinical trials. In addition to the rarity of these diseases, the eligibility criteria of our clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their disease is either severe enough or not too advanced to include them in a trial. We or our collaborators may not be able to initiate or continue clinical trials on a timely basis or at all for any of our product candidates if we or our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in the trials as required by applicable regulations or as needed to provide appropriate statistical power for a given trial. Similarly, because many of the conditions we intend to treat are rare in nature, we plan to design and conduct clinical trials utilizing a small number of patients in order to evaluate the safety and therapeutic activity of our product candidates. Conducting trials in smaller subject populations increases the risk that any safety or efficacy issues observed in only a few patients could prevent such trials from reaching statistical significance or otherwise meeting their specified endpoints, which could require us to conduct additional clinical trials, or delay or prevent our product candidates from receiving regulatory approval, which would seriously harm our business.

Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized or if they will ever be successfully commercialized.

Aside from 4D-150, our product candidates are at an early stage of development. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- our competitors may develop platform technologies that render our Therapeutic Vector Evolution platform technology obsolete or less attractive;
- the product candidates and Therapeutic Vector Evolution platform technology that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights or may be covered by third-party patents or other intellectual property or exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate;
- delays in our clinical development plans due to public health emergencies; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we or our collaborators may be forced to abandon our development efforts for a product candidate or candidates, which would seriously harm our business. Failure of a product candidate may occur at any stage of preclinical or clinical development, and, because most of our product candidates and our Therapeutic Vector Evolution platform technology are in an early stage of development, there is a relatively higher risk of failure, and we may never succeed in developing marketable products or generating product revenue.

We may not be successful in our efforts to further develop our Therapeutic Vector Evolution platform technology and current product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Aside from 4D-150, each of our product candidates is in the early stages of development and will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all. Any clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates or if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

If any of our product candidates successfully complete clinical trials, we generally plan to seek regulatory approval to market our product candidates in the United States, the EU, and in additional foreign

countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate, which may impede our ability to secure approval and successfully launch our therapies. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would seriously harm our business. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, purity, potency, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. We may also rely on our collaborators or collaboration partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. We cannot be sure that our collaborators or collaboration partners will conduct these activities successfully or do so within the timeframe we desire. Even if we (or our collaborators or collaboration partners) are successful in obtaining approval in one jurisdiction, we cannot assure you that we will obtain approval in any other jurisdictions. Failure to obtain approval for our product candidates in multiple jurisdictions will seriously harm our business.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Any approval we may obtain could be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would seriously harm our business.

Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot assure you that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

Public health crises such as pandemics or similar outbreaks have affected and could continue to seriously and adversely affect our preclinical and clinical trials, business, financial condition and results of operations.

Public health crises, such as pandemics or similar outbreaks, could result in public health guidance measures, including in the locations of our offices, clinical trial sites, key vendors and partners. We expect that our clinical development program timelines could be negatively affected by such pandemics, any public health orders or measures implemented in response to such pandemics, or residual effects thereof, which could seriously harm our business.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations or policy changes could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all.

The ability of the FDA and foreign regulatory authorities to review and/or approve new products can be affected by a variety of factors, including government budget, personnel, and funding levels, statutory, regulatory, and policy changes, the FDA's and foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the

time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, 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, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

Separately, in response to the novel coronavirus pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or such other regulatory authorities to timely review and process our regulatory submissions, which could seriously harm our business.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization, which could seriously harm our business.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we or our collaborators must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Further, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our ongoing and planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business.

Further, even if such clinical trials are successfully completed, we cannot assure you that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of

our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans in the EU.

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

From time to time, we publicly disclose top-line or preliminary data from 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 related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary 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. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could seriously harm our business.

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 program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what we determine to be material information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line or interim data that we report differ from final results, or if others, including regulatory authorities, disagree with the

conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could seriously harm our business.

We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited, which could seriously harm our business.

One of our strategies is to identify and pursue preclinical and clinical development and commercialization of additional product candidates through our Therapeutic Vector Evolution platform technology. Our Therapeutic Vector Evolution platform technology may not produce a pipeline of viable product candidates, or our competitors may develop platform technologies that render our Therapeutic Vector Evolution platform technology obsolete or less attractive. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make them unmarketable or unlikely to receive marketing approval. Identifying, developing and obtaining regulatory approval and commercializing additional product candidates will require substantial funding and is prone to the risks of failure inherent in drug development. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited, which could seriously harm our business.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of the indications for which we have product candidates, including wet AMD, DME, GA and cystic fibrosis. Certain of our competitors have commercially approved products for the treatment of the diseases that we are pursuing or may pursue in the future, including Apellis Pharmaceuticals Inc., Astellas Pharma Inc., Regeneron Pharmaceuticals Inc., Roche and Vertex Pharmaceuticals Incorporated. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to our product candidates. Companies that we are aware are developing therapeutics in the retina and pulmonology disease areas include large companies with significant financial resources, such as AbbVie Inc, Astellas Pharma Inc., Eli Lilly and Company, Johnson & Johnson, Merck & Company Inc., Regeneron Pharmaceuticals Inc., Roche, Sanofi and Vertex Pharmaceuticals Incorporated, and biopharmaceutical companies such as Apellis Pharmaceuticals Inc., Arcturus Therapeutics Holdings Inc., EyePoint Inc., Kodiak Sciences Inc., Krystal Biotech Inc., Ocular Therapeutix Inc., Recode Therapeutics Inc., REGENXBIO Inc. and Sionna Therapeutics Inc. In addition to competition from other companies targeting retina and pulmonology, any products we may develop may also face competition from other types of therapies, such as gene-editing therapies and drug delivery devices.

Many of our current or potential competitors, either alone or with their strategic partners, 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 industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient

registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of retina and pulmonology indications, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing against competitors any product candidates we may develop.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, compliance, customer service, medical affairs and other support personnel;
- our inability to recruit and build a commercial infrastructure;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to

do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved and our business would be seriously harmed.

Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- sufficient third-party coverage or reimbursement;
- the extent to which physicians recommend our products to their patients;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by FDA, EMA or other regulatory agencies;
- product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength of marketing and distribution support; and
- the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable and our business could be seriously harmed.

Risks Related to Manufacturing

Gene therapies are novel, complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs, limit the supply of our products or otherwise seriously harm our business.

We currently manufacture and test clinical trial material for our products both internally at our cGMP facility, and externally at our partner CDMOs. Our product candidates require processing steps that are

more complex than those required for most chemical and protein pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the process works and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory, which could delay or prevent the initiation of clinical trials or receipt of regulatory approvals. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs.

In addition, FDA and other comparable foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other comparable foreign regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches which could be costly to us and otherwise seriously harm our business.

We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing process which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or the facilities with which we contract could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies, which could limit our access to additional attractive development programs. Problems in manufacturing processes or facilities also could restrict our ability to meet market demand for our products. Additionally, should our supply needs exceed our internal capabilities and supply agreements with other parties with whom we have manufacturing agreements be terminated for any reason, there are a limited number of manufacturers who would be suitable replacements, and it would take a significant amount of time to transition the manufacturing to an alternative manufacturing organization.

Delays in obtaining regulatory approval of our manufacturing process or disruptions in our manufacturing process may delay or disrupt our commercialization efforts.

Before we can begin to commercially manufacture our product candidates in third-party or our own facilities, we must obtain regulatory approval from the FDA to market our product using the manufacturing process and facility we proposed in our marketing application. In addition, we must successfully complete a pre-approval inspection of our manufacturing facility by the FDA before any of our product candidates can obtain marketing approval, if ever. In order to obtain approval of a BLA for our product candidates, we will need to ensure that all of our manufacturing processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any products that we may develop. Similar risks may exist in foreign jurisdictions.

Delays in developing our manufacturing capabilities or failure to achieve operating efficiencies from it may require us to devote additional resources and management time to manufacturing operations and may delay our product development timelines.

We have approximately 17,000 square feet of laboratory and manufacturing space at our headquarters in Emeryville, California, a large portion of which we plan to devote to manufacturing activities for our clinical trials under cGMP. We may face delays in the production of clinical supply at our manufacturing facility and cannot guarantee when our facility will be able to produce sufficient quantities of product candidates needed to support our planned clinical trials. Any delays in developing our internal manufacturing capabilities may disrupt or delay the supply of our product candidates if we have not maintained a sufficient back-up supply of such product candidates through third-party manufacturers. Moreover, changing manufacturing facilities during the clinical development process may also require that we or our collaborators conduct additional studies, make notifications to regulatory authorities, make additional filings to regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive. We will further need to comply with the FDA's and applicable foreign regulatory authorities' cGMP requirements for the production of product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements.

In order to develop internal manufacturing expertise, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, regulatory, facilities and information technology. We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing processes. If we experience unanticipated employee shortage or turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from developing these capabilities, which may negatively affect our product development timeline or result in difficulties in maintaining compliance with applicable regulatory requirements. Any such problems could result in the delay, prevention or impairment of clinical development and commercialization of our product candidates and would seriously harm our business.

We currently rely and expect to continue to rely on third parties to conduct product manufacturing for certain of our product candidates, and these third parties may not perform satisfactorily.

We currently rely, and expect to continue to rely, on third parties for the production of some of our planned clinical trial drugs and commercial drug materials and, therefore, we can control only certain aspects of their activities. The facilities used by our contract manufacturers to manufacture certain of our product candidates must be reviewed by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP or similar foreign requirements for manufacture of our products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to obtain and/or maintain regulatory approval for our products as manufactured at their manufacturing facilities. Further, our CDMOs may use different facilities to manufacture our product candidate(s), and we and our CDMOs will be required to meet certain regulatory conditions, such as establishing comparability between the product candidates manufactured at each facility. Our failure, or failure by our CDMOs, to demonstrate sufficient comparability between a product candidate manufactured at different facilities may cause a delay in using a manufacturing facility for production, extend our clinical trial timelines and adversely impact our regulatory approval process. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

In addition, we rely on additional third parties to manufacture plasmids used in the manufacture of our product candidates and to perform quality testing, and reliance on these third parties entails risks to which we would not be subject if we manufactured the plasmids ourselves, including:

- reduced control over certain aspects of manufacturing activities;
- termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future product candidates. Some of these events could be the basis for FDA or EU member state competent authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our research studies, preclinical, and clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage.

Some of the raw materials required in our manufacturing process, such as plasmids, are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could seriously harm our business.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could seriously harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Third-party suppliers could increase their prices or be unable to supply us with adequate raw materials, on a timely basis or at all, for a variety of reasons, including potential restrictions on trade or tariffs. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any interruption in supply of raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supplier in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would seriously harm our business.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, expensive, time consuming, and inherently unpredictable. If we are ultimately unable

to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

We and any collaborators are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We have not submitted for or obtained regulatory approval for any product candidate. We and any collaborators must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our or our collaborators' clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use of our products;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we or our collaborators may be unable to demonstrate to the FDA, or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, 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 or our collaborators' clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would seriously harm our business.

In addition, even if we or our collaborators were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose

significant limitations in the form of narrow indications, warnings, or a REMS. Regulatory authorities or other authorities responsible for pricing negotiations may not approve the price we or our collaborators intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

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

We may in the future seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, confirmatory studies to verify and describe the drug's clinical benefit. If such confirmatory studies fail to confirm the drug's clinical benefit, or if the sponsor fails to conduct required confirmatory studies in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, the Food and Drug Omnibus Reform Act of 2022 provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

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

Even if we or our collaborators obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct

of post-marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

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

We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products "off-label" for indications or uses for which they do not have approval, though we may share truthful and not misleading information that is otherwise consistent with our product's approved labeling. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval or label restrictions.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our manufacturing facility or our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. 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 be subject to enforcement action and we may not achieve or sustain profitability.

We have received orphan drug designation for 4D-710 for cystic fibrosis, and we may seek orphan drug designation for certain future product candidates. However, we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

We have received orphan drug designation in the United States for 4D-710 for the treatment of cystic fibrosis. Although we may seek orphan product designation for some or all of our other product candidates, we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. Orphan designation is granted by the European Commission ("EC") based on a scientific opinion of the EMA's Committee for Orphan Medicinal Products ("COMP"). A medicinal product may be designated as orphan if its sponsor can establish that (i) the product is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the medicinal product will be of significant benefit to those affected by the condition. The application for orphan designation must be submitted before the application for marketing authorization.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product receives the first FDA approval for the disease or condition for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same approved use or indication within such rare disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for a disease or condition broader than the orphan designated disease or condition and may be lost if the FDA later determines that the request for designation was materially defective. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees, fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirement for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan ("PIP"). The European exclusivity period can be reduced to six years, if, at the end of the fifth year a medicine no longer meets the criteria for orphan designation (i.e. the prevalence of the condition has increased above the orphan designation threshold or it is judged that the product is sufficiently profitable so as not to justify maintenance of market exclusivity).

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same uses or indications within the same rare disease or condition. Even after an orphan drug is approved, the FDA and foreign regulatory authorities can subsequently approve the same drug for the same approved

use or indication within the same rare disease or condition if the FDA or foreign regulatory authorities concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

We have received Regenerative Medicine Advanced Therapy ("RMAT") and PRIority MEdicine ("PRIME") designation for 4D-150 for the treatment of wet AMD and RMAT designation for 4D-150 for treatment of DME. We may seek RMAT and PRIME designations for certain future product candidates, however we may not be able to obtain such designations, and there is no guarantee that 4D-150 will experience a faster regulatory review or obtain regulatory approval.

The FDA has granted RMAT designation for 4D-150 for the treatment of neovascular (wet) age-related macular degeneration and diabetic macular edema, and may seek additional RMAT designations for 4D-150 or for our other product candidates. A biological product candidate is eligible for RMAT designation if: (1) it meets the definition of a regenerative medicine therapy, which the FDA defines as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) the candidate is intended to treat, modify, reverse, or cure a serious disease or condition; and (3) preliminary clinical evidence indicates that the candidate has the potential to address unmet medical needs for such disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review of BLAs. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or through reliance upon data obtained from a meaningful number of sites, including through expansion of clinical trials to a sufficient number of sites, as appropriate. RMAT-designated product candidates that receive accelerated approval may, as appropriate, be able to fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence (such as electronic health records), through the collection of larger confirmatory data sets, or via post-approval monitoring of patients treated with the therapy prior to approval.

RMAT designation is within the sole discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for RMAT designation, the FDA may disagree and instead determine not to make such designation. RMAT designation does not change the standards for product approval, and there is no assurance that such designation or eligibility for such designation will result in expedited review or approval, or that the approved indication will not be narrower than the indication covered by the RMAT designation.

In the EU, 4D-150 was accepted into the PRIME scheme by the EMA's Committee for Medicinal Products for Human Use ("CHMP") for the treatment of wet AMD. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which was launched by the EMA in 2016 and provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target an unmet medical need. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

Receipt of these designations does not increase the likelihood that FDA or EC will approve 4D-150 for any indication. In addition, the FDA or foreign competent authorities may rescind the designations if they believe that the designation is no longer supported by data from our clinical development program.

We have obtained a rare pediatric disease designation for 4D-710, however, there is no guarantee that FDA approval of 4D-710 will result in issuance of a priority review voucher.

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" that meets certain criteria may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

We have obtained a rare pediatric disease designation for 4D-710 for the treatment of cystic fibrosis, however, there is no guarantee that we will be able to obtain a priority review voucher, even if 4D-710 is approved by the FDA for this indication. For example, the FDA may determine that a BLA, even if ultimately approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- the product no longer meets the definition of a rare pediatric disease;
- the product contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in another marketing application;
- the application does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population;
- the application is approved for a different adult indication than the rare pediatric disease for which the product is designated

Moreover, Congress included a sunset provision in the statute authorizing the rare pediatric disease priority review voucher program. Under the current statutory sunset provisions, FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the product candidate, and that designation was granted by September 30, 2029, provided the relevant eligibility criteria are met.

If the product candidates that we or our collaborators may develop receive regulatory approval in the United States or another jurisdiction, they may never receive approval in other jurisdictions, which would limit market opportunities for such product candidates and seriously harm our business.

Approval of a product candidate in the United States by the FDA or by the requisite regulatory agencies in any other jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. The approval process varies among countries and may limit our or our collaborators' ability to develop, manufacture, promote and sell product candidates internationally. Failure to obtain marketing approval in international jurisdictions would prevent the product candidates from being marketed outside of the jurisdictions in which regulatory approvals have been received. In order to market and sell product candidates in the EU and many other jurisdictions, we and our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional preclinical studies or clinical trials both before and after approval. In many countries, any product candidate for human

use must be approved for reimbursement before it can be approved for sale in that country. In some cases, the intended price for such product is also subject to approval. Further, while regulatory approval of a product candidate in one country does not ensure approval in any other country, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we or our collaborators fail to comply with the regulatory requirements in international markets or to obtain all required marketing approvals, the target market for a particular potential product will be reduced, which would limit our ability to realize the full market potential for the product and seriously harm our business.

Enacted and future healthcare legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of and to commercialize our product candidates and may affect the prices we may set.

In the United States, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could, among other things, restrict our ability to profitably sell our product candidates and could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States and elsewhere, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative and regulatory initiatives. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any product candidates approved for sale. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business, results of operations and financial condition.

For example, in 2010, the Patient Protection and Affordable Care Act (the "ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and to obtain adequate prices for any product candidates approved for sale, are the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, revising the "average manufacturer price" definition, and extending rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; and
- establishment of a Center for Medicare & Medicaid Innovation ("CMMI") at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, U.S. Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of

limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on drug manufacturers' Medicaid drug rebate program liability for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

In 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). CMS has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027, as well as the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any other product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump administration's proposals will be implemented, the Trump administration's policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, the Trump administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although final regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient assistance programs. We also expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures and could seriously harm our business.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating

so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. Legally mandated price controls on payment amounts by third-party payors or other restrictions could seriously harm our business. 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 product candidates or put pressure on our product pricing. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. These reforms could reduce the ultimate demand for our product candidates or put pressure on our product pricing and could seriously harm our business.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage and payment criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or judicial action in the United States, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

The successful commercialization of any product candidates for which we obtain approval will depend in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage and adequate reimbursement. Failure to obtain or maintain

coverage and adequate reimbursement for our product candidates, if any and if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Our ability to successfully commercialize any products that we may develop also 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.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs (“VA”) hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. Increasingly, other 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. For genetic medicine and other 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. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be sufficient.

Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, EMA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our

inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could seriously harm our business.

Even if we obtain FDA approval for any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell any products effectively, if approved, or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize any product, if approved, in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In advance of any of our product candidates receiving regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time-consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses and our business would be seriously harmed.

Our business operations and current and future relationships 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 and seriously harm our business.

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. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. 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 U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil federal False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (as defined by statute), certain other non-physician practitioners (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants, and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government,

or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and

- similar healthcare laws in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

We may also be subject to additional federal laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof, and federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain of our advisory board arrangements with physicians, some of whom are compensated in the form of stock or stock options, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above 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, 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. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, 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.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials and chemicals. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products such as human tissue samples that may have the potential to transmit diseases. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.

The Animal Welfare Act ("AWA") is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane

handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

Risks Related to Our Reliance on Third Parties

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, CDMOs, clinical data management organizations, clinical data assessments and analysis organizations, medical institutions and clinical investigators, to conduct some aspects of our manufacturing, research, preclinical testing and clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities, but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and to post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Similar risks may exist in foreign jurisdictions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to manufacture, store and distribute drug supplies for our clinical trials. Any performance failure on the part of our manufacturers or distributors could delay clinical development, marketing approval or commercialization of any product candidates, producing additional losses and depriving us of potential product revenue.

We may depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We have sought, and may in the future seek, third-party collaborators for the research, development and commercialization of certain product candidates we may develop. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional, national and international pharmaceutical companies, biotechnology companies and academic institutions. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to

successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our product candidates we may develop, pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may decide not to pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, devices,

materials, know-how or intellectual property of the collaborator relating to our products and product candidates;

- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or our Therapeutic Vector Evolution platform technology; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate or delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue which could seriously harm our business.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

Our reliance on Chinese biotechnology companies may subject us to additional risks.

Certain Chinese biotechnology companies, CROs and contract development and manufacturing organizations may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could potentially impact services available for our research and development or our ability to secure the materials we need for our product candidates. For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from "biotechnology companies of concern", or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern". Congress has interpreted a "biotechnology company of concern" as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is

uncertain. If the Chinese or other foreign CROs and CDMOs we rely on become subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government (including designation as a "biotechnology company of concern" under the U.S. BIOSECURE Act), or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and China, it may have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible that some of our contractual counterparties could be impacted by the legislation described above. Such counterparties may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Such disruption could have adverse effects on the development of our product candidates.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Further, our licensed patents and applications include five granted patents (U.S. patent nos. 12,310,997, 12,180,254, 11,136,557, 11,634,691 and 10,988,519) and two pending patent applications (U.S. patent application nos. 18/184,184 and 18/924,426), that were made with government support, that may be subject, under certain circumstances, to march-in-rights under 35 U.S.C. 203, which is a right that allows the government, in certain limited circumstances, to force a party with a license to intellectual property funded, at least in part, by the government, to grant a license to such property to another entity. U.S. patent nos. 11,136,557 and 11,634,691 were made with the support of U.C. Berkeley and relate to our A101 vector of our 4D-710 and 4D-725 product candidates. U.S. patent nos. 10,988,519 and 12,180,254 were made with the support of University of Pennsylvania and relate to our short-form human complement factor H (sCFH) payload of our 4D-175 product candidate. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could seriously harm our business.

We and our licensors have applied, and we intend to continue applying, for patents covering aspects of our product candidates, proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of our current or future product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators or licensors will be successful in

protecting our product candidates, proprietary technologies and their uses by obtaining and defending patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office ("USPTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our licensors' patent applications for any patent application with an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Moreover, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, if issued, patents obtained by our collaborators or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products or product candidates, or limit the duration of the patent protection of our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our product candidates are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell, or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we or our licensors were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable products or will provide us with any competitive advantages;

- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could seriously harm our business.

Furthermore, our owned and in-licensed intellectual property rights may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could seriously harm our business.

The lives of our patents may not be sufficient to effectively protect our product candidates and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, are limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent's life can be extended based on certain delays caused by the USPTO and clinical development, this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we do not have sufficient patent life to protect our product candidates, proprietary technologies and their uses, our business would be seriously harmed.

If we do not obtain patent term extension for our product candidates, our business may be seriously harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of any of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration of the applicable product, and our business may be seriously harmed.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Our patent rights may be affected by developments or uncertainty in the U.S. or foreign patent statutes, patent case laws, USPTO rules and regulations or in the rules and regulations of foreign patent offices.

On September 16, 2011, the Leahy-Smith America Invents Act (“Leahy-Smith Act”) was signed into law. There remains many subsisting issued patents and some pending patent applications in the U.S. that were filed prior to its enactment and are therefore subject to the pre-Leahy-Smith Act U.S. patent laws and that may have relevance to our freedom-to-operate or ability to obtain patent issuances. The Leahy-Smith Act includes a number of significant changes to the U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. This could have a negative impact on some of our intellectual property and could increase uncertainties surrounding obtaining and enforcement or defense of our issued patents. In addition, Congress may pass patent reform legislation that is unfavorable to us. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Additionally, on June 1, 2023, the European Union Patent Package (EU Patent Package) regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European

Unified Patent Court (UPC) for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending all current and future patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Moreover, geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the U.S. and foreign government actions related to Russia's conflict with 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. For example, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the U.S. without consent or compensation. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other IP rights may not be effective or sufficient to prevent them from competing.

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the

intellectual property that we develop or license. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our business may be seriously harmed.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

Our agreements with employees and consultants provide that any inventions conceived by an individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all such individuals complete these agreements, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property may not be self-executing and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. We may also be subject to claims that former employees, consultants, or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could seriously harm our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to our management and other employees.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, 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.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

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

We rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. We have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees and consultants. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot

provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant or third party with authorized access. Our security measures may not prevent an employee, consultant, collaborator or third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product candidates that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Further, we may need to share our trade secrets and confidential know-how 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 actors in other countries, and those affiliated with or controlled by state actors.

Though our agreements with third parties typically restrict the ability of our employees, collaborators, licensors, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we have relied on, and in future expect to rely on third parties in the development, manufacture, and distribution of our product candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our product candidates may be dependent on our licensors.

We currently are reliant upon licenses of certain patent rights and proprietary technology from third parties that are important or necessary to the development of our technology, including technology related to our product candidates. For example, we rely on our exclusive license agreements with (i) U.C. Berkeley for certain rights with respect to the intellectual property covering certain compositions of matter and methods of use of certain AAV variants related to our 4D-710 and 4D-725 product candidates, and (ii) University of Pennsylvania for certain rights with respect to the intellectual property covering certain compositions of matter and methods of use of the short-form human complement factor H (sCFH) payload related to our 4D-175 product candidate. These and other licenses we may enter into in the future may not provide adequate rights to use such intellectual property and technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize our technology and product candidates in the

future. As a result, we may not be able to develop and commercialize our technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses.

Licenses to additional third-party technology that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, which could seriously harm our business.

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Our current licenses, and our future licenses, likely will impose various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from developing and commercializing our product candidates and proprietary technologies. Our business would be seriously harmed if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of royalty obligations we would be required to pay on the sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize any product candidates, we may be unable to achieve or maintain profitability.

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

Any trademarks we may register in the future or any current registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks

and trade names, to the extent any are registered, to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could seriously harm our business.

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

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

- others may be able to make genetic medicine products that are similar to our product candidates or utilize similar genetic medicine technology but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could seriously harm our business.

Our existing collaborations and any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Our existing collaborations, such as our collaboration with Otsuka Pharmaceutical Co., Ltd. and any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products,

availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators could independently develop, or develop with third parties, products and product candidates that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products and product candidates may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may adversely affect the price of our common stock and may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Reliance on third parties to conduct clinical trials, assist in research and development and to manufacture our product candidates, will at times require us to share trade secrets with them. We seek to protect our proprietary technology by in part entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may seriously harm our business.

We may fail to comply with any of our obligations under existing or future agreements pursuant to which we license or have otherwise acquired intellectual property rights or technology, which could result in the loss of rights or technology that are material to our business.

We are party to various agreements that we depend on to operate our business. Our rights to use currently licensed intellectual property, or intellectual property to be licensed in the future, are or will be subject to the continuation of and our compliance with the terms of these agreements. These agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations which could lead to disputes, including but not limited to those regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our proprietary technology and product candidates infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us or our counterparties, alone or jointly;
- the scope and duration of our payment obligations;
- rights upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

The resolution of any contractual interpretation dispute that may arise, if unfavorable to us, could seriously harm our business. Such resolution could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the third party's financial or other obligations under the relevant agreement.

If disputes over intellectual property rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under current or future license agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents or other proprietary rights of third parties.

Third parties may have or obtain patents or other proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products, if any, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, inter partes review proceedings and post-grant review proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

Furthermore, 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 and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may

be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent 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, which may negatively impact our ability to develop and market our product candidates.

As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates. As a result, we may be unaware of third-party patents that may be infringed by commercialization of our product candidates, and cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and/or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent our product candidates or any future products from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or proprietary technologies could subject us to

potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates or any future products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be time-consuming and a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. In addition, we cannot be certain that we could redesign our product candidates or proprietary technologies to avoid infringement, if necessary, or on a cost-effective basis. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates or any future products which could seriously harm our business. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court or administrative tribunal may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and may result in the revocation, cancellation, or amendment of any foreign patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on an affected product candidate. Such a loss of patent protection would seriously harm our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO, or equivalent actions brought in foreign jurisdictions, may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be seriously harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition,

the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace and seriously harm our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will depend in part on our ability to acquire, license or use these proprietary rights. We may be unable to acquire or 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 are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We have collaborated with a U.S. academic institution and may in the future collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

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 that program and our business could be seriously harmed.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we, our employees or consultants have wrongfully used or disclosed alleged confidential information or trade secrets of their former or concurrent employers or former or current clients.

As is common in the biotechnology and biopharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees or consultants, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer or former or current client. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could seriously harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management and other employees.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating 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, motivate and retain highly qualified managerial, scientific and medical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

We conduct our operations at our facilities in Emeryville, California, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region, and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity grants. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. In addition, our employees are employed at-will, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract, incentivize and retain quality personnel on acceptable terms, or at all, it could seriously harm our business.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As our development plans and strategies evolve, we must add a significant number of additional managerial, operational, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;

- managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties;
- expanding our operational, financial and management controls, reporting systems and procedures; and
- managing increasing operational and managerial complexity.

Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from factors such as increased inflation or closure of or liquidity issues at financial institutions or other macro factors such as a pandemic or geopolitical tensions could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;

- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Our information technology systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches and other disruptions.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, clinical trial data, proprietary business information and personal information of our employees and contractors (collectively, "Confidential Information"). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. Despite the implementation of security measures, our internal information technology systems and those of our collaborators, future CROs and other contractors and consultants may be vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, misconfigurations, "bugs" or other vulnerabilities, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, denial or degradation of service attacks, and sophisticated nation-state and nation-state supported actors.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We and our third party service providers and partners may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques, including artificial intelligence, that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Our third party service providers and partners are also subject to these heightened risks. The costs to us to investigate and mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. There can also be no assurance that our and our collaborators', future CROs' and other contractors' and

consultants' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers have experienced certain cyberattacks and security incidents from time to time. Although to our knowledge we have not experienced any significant system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our Confidential Information or other similar disruptions. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of clinical trial data or personal data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws.

Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also seriously harm our business. Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of Confidential Information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed. Any losses, costs or liabilities may not be covered by, or may exceed the coverage limits of, any applicable insurance policies.

Furthermore, federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. We may also be exposed to a risk of loss or litigation and potential liability, which could materially and adversely affect our business, results of operations or financial condition.

Business disruptions could seriously harm our business.

Our operations, and those of our CROs, CDMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our business.

All of our operations including our corporate headquarters are located in multiple facilities in Emeryville, California. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, earthquake and other natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business could be seriously harmed by such delays and interruption.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could seriously harm our business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively, "HIPAA"), imposes, among other things, certain standards on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA") requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have passed in other states, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the European Union General Data Protection Regulation (the "EU GDPR") and the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR") (the EU GDPR and UK GDPR together referred to as the "GDPR") impose strict requirements for processing the personal data of individuals within the European Economic Area ("EEA") and in the United Kingdom, respectively. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million / £17.5 million or 4% of the annual global revenue of the noncompliant undertaking, whichever is greater. Since we are subject to the supervision of relevant data protection

authorities under multiple legal regimes (including under both the EU GDPR and the UK GDPR), we could be fined under each of those regimes independently in respect of the same breach. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease or change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Additionally, the Securities and Exchange Commission (the "SEC") recently adopted a rule that enhances and standardizes disclosures regarding cybersecurity risk management and governance, as well as material cybersecurity incidents. Under this new rule, we will be required to make annual disclosures describing our processes for identifying and managing material cybersecurity risks, management's role in assessing and managing such risks and our board of directors' oversight of cybersecurity risks. We will also be required to disclose, in a Current Report on Form 8-K, the nature, scope and timing of any material cybersecurity incidents identified and the material impact or reasonably likely material impact on the company. We expect to face increased costs to comply with this new SEC cybersecurity rule, including increased costs for cybersecurity training and management.

As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and seriously harm our business.

Our business may be affected by the evolving regulatory framework for AI Technologies.

We use artificial intelligence ("AI"), machine learning, and automated decision-making technologies, (collectively, "AI Technologies") in our business. We expect that increased investment will be required in the future to continuously improve our use of AI Technologies. As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. There can be no assurance that the usage of or our investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability.

In particular, if the models underlying our AI Technologies are: incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate, biased or otherwise poor quality data, or on data to which we do not have sufficient rights or in relation to which we and/or the providers of such data have

not implemented sufficient legal compliance measures; used without sufficient oversight and governance to ensure their responsible use; and/or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats or material performance issues, the performance of our products, services and business, as well as our reputation, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party or civil claims.

We are in varying stages of development in relation to our products and internal business processes involving AI Technologies. The continuous development, maintenance and operation of our AI Technologies is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects or errors. For instance, the models underlying AI Technologies can experience decay (also known as "model drift") in which its performance and accuracy decreases over time without further human intervention to correct such decay.

We may not be successful in our ongoing development and maintenance of these technologies in the face of novel and evolving technical, reputational and market factors. Our efforts to develop proprietary AI models could increase our operating costs. Our ability to develop proprietary AI models may be limited by our access to processing infrastructure or training data, and we may be dependent on third-party providers for such resources.

The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of our AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations. Failure to appropriately respond to this evolving landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

It is possible that new laws and regulations will be adopted in the U.S. and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

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

Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards ("NOLs") and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOLs or other pre-change tax attributes if we undergo a future ownership change. We have experienced ownership changes in the past. We may also experience ownership changes as a result of any future shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation. We will be unable to use our NOLs or other tax attributes if we do not

attain profitability sufficient to offset our available NOLs or other tax attributes prior to their expiration, to the extent subject to expiration.

Changes in tax laws or regulations that are applied adversely to us or our customers may seriously harm our business.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile, which could result in substantial losses for investors.

Some of the factors that may cause the market price of our common stock to fluctuate include:

- results from, and any delays in, our clinical trials for our clinical-stage product candidates or any other future clinical development programs;
- the success of existing or new competitive products or technologies;
- commencement or termination of collaborations for our product candidates;
- failure or discontinuation of any of our product candidates;
- failure to develop our Therapeutic Vector Evolution platform technology;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- regulatory or legal developments in the United States and other countries, including sanctions imposed by either the U.S. or foreign governments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the commencement of litigation;
- the level of expenses related to any of the research programs or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- the impact of political instability, natural disasters, war and/or events of terrorism, such as the war between Ukraine and Russia, and the corresponding tensions created from such conflict

between Russia, the United States and countries in Europe as well as other countries such as China, and the ongoing war in the Middle East;

- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Further, the stock market in general has been highly volatile due to macroeconomic factors such as higher inflation and increased interest rates and political uncertainty in the United States. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Since the completion of our initial public offering in December 2020, the price of our common stock has been volatile, and we expect such volatility to continue. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of these analysts should drop research coverage of us or if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares of our common stock intend to sell shares, could reduce the market price of our common stock.

Further, shares issued upon the exercise of stock options outstanding under our equity incentive plans, or pursuant to future awards granted under those plans, will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (the “Securities Act”).

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We will seek additional capital through one or a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely

impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Additionally, as of December 31, 2025, there are pre-funded warrants outstanding to purchase 10,335,665 shares of common stock, which are exercisable at a nominal exercise price. If holders of these pre-funded warrants exercise these securities, existing shareholders will suffer dilution to their voting power and the Company may experience dilution in its earnings per share, as well as a negative impact on its share price.

Insiders have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers, holders of more than 5% of our outstanding stock and their respective affiliates beneficially own shares representing approximately 48% of our outstanding common stock as of December 31, 2025. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to public company compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would seriously harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the SEC require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations have and will likely continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. 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 our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 ("Section 404") and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not

be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend in part on CROs to provide timely and accurate notice of their costs to us.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our Company may deem advantageous. These provisions, among other things:

- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- provide that our directors may be removed only for cause;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- provide for a staggered board, which will result in only a few directors being up for re-election in each calendar year;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws;
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of our common stock to amend many of the provisions described above; and
- limit the liability of, and provide indemnification to, our directors and officers.

In addition, Section 203 of the General Corporation Law of the State of Delaware (“DGCL”) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our certificate of incorporation, bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, by the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. Nothing in our

amended and restated certificate of incorporation and amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could seriously harm our business. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Unfavorable conditions in the global economy caused by global political unrest or conflicts, including the ongoing conflict between Russia and Ukraine and in the Middle East, may exacerbate certain risks we face.

Political unrest, international conflict, terrorism or war, such as Russia's invasion of Ukraine and the armed conflict in the Middle East, and the global response to these conflicts, including the imposition of sanctions by the United States and other countries, could create or exacerbate risks facing our business. We have evaluated our operations and partner contracts, and we currently do not expect existing conflicts to directly have a significant effect on our financial condition or results of operations. However, if hostilities persist, escalate or expand, risks that we have identified in this Annual Report on Form 10-K may be materially increased. For example, if our supply arrangements or clinical operations are disrupted due to expanded sanctions or involvement of countries where we have operations or relationships, our business could be materially disrupted. Further, the use of cyberattacks could expand as part of the ongoing conflicts, which could adversely affect our ability to maintain or enhance our cyber security measures. These and other risks are described more fully in this "Risk Factors" section.

General Risk Factors

Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, such as disputes or employment claims made by our current or former employees. Any litigation, whether meritorious or not, could harm our reputation, increase our costs and may divert

management's attention, time and resources, which may in turn seriously harm our business. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could seriously harm our business.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Our employees, independent contractors, consultants, research or commercial partners or collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, research or commercial partners or other collaborators, including the foundations we work with, and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA, EMA and other comparable foreign

regulatory authorities; provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and third 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 be in compliance with such laws. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could seriously harm our business, including the imposition of significant fines or other sanctions.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could seriously harm our business.

Our business could be negatively impacted by corporate citizenship and ESG matters and/or our reporting of such matters.

Institutional, individual, and other investors, proxy advisory services, regulatory authorities, consumers and other stakeholders have increasingly focused on environmental, social and governance

("ESG") practices of companies. As we look to respond to evolving standards for identifying, measuring, and reporting ESG metrics, our efforts may result in a significant increase in costs and may nevertheless not meet investor or other stakeholder expectations and evolving standards or regulatory requirements, which may negatively impact our financial results, our reputation, our ability to attract or retain employees, our attractiveness as an investment or business partner, or expose us to government enforcement actions, private litigation, and actions by stockholders or stakeholders.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF"). This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- data integrity controls designed to protect our clinical data and our proprietary manufacturing and Chemistry, Manufacturing, and Controls ("CMC") data;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls, including annual penetration testing;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents for evaluating their materiality, and for ensuring their timely public disclosure when required; and
- a third-party risk management process for service providers and suppliers.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. However, a significant breach involving our clinical trial data or proprietary manufacturing processes could result in regulatory delays or the loss of competitive advantages.

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (the "Committee") oversight of cybersecurity and other information technology risks. The Committee oversees management's implementation of our cybersecurity risk management program.

The Committee receives quarterly reports from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The Committee members receive presentations on cybersecurity topics from our Senior Vice President, Information Technology & Facilities, internal security staff or external experts as part of the Committee's continuing education on topics that impact public companies.

Our management team, including our Sr. Director, Information Technology Operations and Security, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team's experience includes decades of security management in the Financial & Life Sciences industries.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment.

Item 2. Properties.

Our corporate headquarters are located in Emeryville, California, where we lease approximately 91,000 square feet of office, research and development, engineering, laboratory and warehouse space pursuant to lease agreements that expire between August 2026 and December 2030. We believe that our facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings.

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of its business. If applicable, the Company records a liability for such matters when it believes that it is both probable that a liability may have been incurred, and the amount of the liability can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "FDMT" since December 11, 2020. Prior to this date, there was no public market for our common stock.

Holders of Common Stock

As of March 16, 2026, there were approximately 11 holders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

Item 6. [Reserved]

Part II. Item 6 is no longer required pursuant to certain amendments to Regulation S-K that eliminated Item 301.

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 financial statements and the related notes included elsewhere in this Annual Report on Form 10-K (this "report"). This discussion and analysis and other parts of this report contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section titled "Risk Factors" and elsewhere in this report.

Overview

We are a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with potential to transform treatment paradigms and provide unprecedented benefits to patients. Our primary focus is advancing 4D-150 for wet age-related macular degeneration ("wet AMD") and diabetic macular edema ("DME") through late-stage studies and potential commercialization and advancing our other pipeline programs, 4D-175 for geographic atrophy, 4D-710 for CF lung disease, and 4D-725 for A1AT lung disease primarily through external funding including strategic partnerships. We believe we are well positioned to discover, develop, manufacture and if approved, commercialize targeted genetic medicines with the potential to transform the lives of patients suffering from debilitating diseases.

Our lead product candidate 4D-150 utilizes our proprietary R100 vector and a transgene encoding anti-VEGF biologics: aflibercept and an RNA interference (RNAi) approach targeting VEGF-C. The goal for our development and potential commercialization of 4D-150 is to transform the standard of care for large market retinal vascular diseases with a safe, in-office, and durable lifelong backbone therapy substantially reducing treatment burden and improving long-term vision outcomes. 4D-150 is initially being developed for the treatment of wet AMD and DME.

In March 2025, we initiated 4FRONT-1, our first Phase 3 trial of 4D-150 in wet AMD. Subsequently in February 2026, we announced enrollment completion within an approximately 11-month period, ahead of initial projections, with the clinical trial overenrolled and expected to exceed 500 patients randomized, reflecting strong interest from investigators and patients. We anticipate topline data with the 52-week primary endpoint in the first half of 2027.

Additionally, 4FRONT-2, our second Phase 3 trial of 4D-150 in wet AMD, was initiated in June 2025. 4FRONT-2 is a global clinical trial and is enrolling both treatment-naïve and recently diagnosed, treatment-experienced patients. We expect 52-week topline data for 4FRONT-2 in the second half of 2027.

In November 2025, we announced positive long-term interim results from the ongoing 4D-150 PRISM Phase 1/2 clinical trial in wet AMD. 4D-150 demonstrated consistent and durable benefit across all three patient cohorts as evidenced by maintenance of visual acuity, control of retinal anatomy and reduction of treatment burden at all time points with 1.5 to 2 years of follow-up. In addition, a consistent dose response was observed between 3E10 vg/eye, the selected Phase 3 dose, and the lower dose of 1E10 vg/eye. The Phase 3 dose achieved clinically meaningful reductions in treatment burden. No new cases of intraocular inflammation were reported during this follow-up period with up to approximately 3.5 years of follow-up.

In July 2025, we presented positive 60-week results from the 4D-150 SPECTRA clinical trial in DME where 4D-150 continued to be well tolerated with no intraocular inflammation observed at any timepoint or dose level. In addition, 4D-150 demonstrated durable and dose-dependent clinical activity with sustained gains in visual acuity and anatomic control between 3E10 vg/eye, the selected Phase 3 dose, and lower doses. The Phase 3 dose achieved clinically meaningful 78% reduction in treatment burden vs. projected on-label aflibercept 2mg Q8W. The FDA and EMA are aligned on a proposed single Phase 3 clinical trial being acceptable for possible future licensure for 4D-150 in DME.

In October 2025, we entered into a Collaboration and License Agreement with Otsuka Pharmaceutical Co., Ltd. (the “Otsuka Collaboration and License Agreement”), pursuant to which we granted Otsuka exclusive rights to develop and commercialize 4D-150 for retinal vascular diseases, including wet AMD and DME, in Japan, China, Australia, and other APAC markets. Otsuka has agreed to lead all regulatory and commercialization activities in its licensed territories. We have agreed to continue to lead all Phase 3 clinical activity globally, including within the APAC region. Otsuka made an upfront cash payment of $85 million and agreed to provide certain cost sharing for global development activities. In addition, we are eligible for up to $335.5 million in potential regulatory and commercial milestone payments and tiered double-digit royalties depending on net sales in Otsuka’s licensed territories. We retain full development and commercialization rights for 4D-150 outside the APAC region, including the United States, Latin America, and Europe.

Our other pipeline programs include 4D-710, which we believe is the first known genetic medicine to demonstrate successful delivery and durable expression of the cystic fibrosis transmembrane conductance regulator (“CFTR”) transgene in the lungs of people with cystic fibrosis ("CF") and is currently in Phase 2 development. We believe these results will translate into durable clinical improvements in people with CF, including improved lung function and quality of life. In October 2025, we announced a funding agreement with the Cystic Fibrosis Foundation ("CFF") to provide up to $11 million in additional funding, including $7.5 million in an initial tranche, which was completed in October 2025. The proceeds of this funding agreement enabled the start of the Phase 2 stage of the AEROW clinical trial, redosing, and Phase 3 readiness activities.

We have funded our operations primarily through the sale and issuance of equity securities and to a lesser extent from cash received pursuant to our collaboration and license agreements.

Our net losses were $140.1 million and $160.9 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $716.3 million. We do not expect positive cash flows from operations in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates, if approved.

We will require substantial additional funding to support our continuing operations and further the development of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which could include income from collaborations, strategic partnerships, or other strategic arrangements, for the foreseeable future. Adequate funding may not be available when needed or on terms acceptable to us, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from conflicts in the Middle East, the lingering impact of the COVID-19 pandemic, the war in Ukraine, rising interest rates, tariffs, inflation, government shutdowns and otherwise. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Restructuring and Other Charges

On July 2, 2025, we announced a workforce reduction of approximately 25% of current and planned roles, primarily in the areas supporting early-stage research and development and support functions following a strategic pipeline prioritization to focus on the development of 4D-150 and 4D-710. In connection with the workforce reduction, the Company recorded total expense of $3.2 million including severance, benefits and related termination costs during the year ended December 31, 2025. There are no future payments in connection with the workforce reduction.

Components of Results of Operations

Revenue

Our revenue to date has been generated through payments from our collaboration and license agreements, primarily from upfront and milestone payments and expense reimbursement. We have not generated any revenue from the sale of approved products and do not expect to do so for the foreseeable future.

In October 2025, we entered into the Otsuka Collaboration and License Agreement where we granted Otsuka exclusive rights to develop and commercialize 4D-150 for retinal vascular diseases, including wet AMD and DME, in Japan, China, Australia, and other Asia-Pacific markets. Otsuka made an upfront cash payment of $85 million which we recognized as revenue during the fourth quarter of 2025, and agreed to provide certain cost sharing for global development activities.

In August 2019, we amended our agreement with uniQure (the "Amended uniQure Agreement") and entered into a separate new collaboration and license agreement with uniQure (the "Second uniQure Agreement"). Neither party was required to pay monetary consideration in connection with the amendment or new agreement. We determined the incremental transaction price of the amendment and new agreement to be $5.1 million and recorded the amount as deferred revenue in August 2019. We began recognizing revenue related to uniQure in 2020 and recognized the remaining revenue under the agreement during the third quarter of 2023. We recognized immaterial revenue during the year ended December 31, 2023 related to this agreement. See Note 6, Research and Collaboration Agreements, to our financial statements included elsewhere in this report for further discussion regarding the accounting treatment of this agreement. The Amended uniQure Agreement and the Second uniQure Agreement were terminated by mutual agreement in November 2025. We did not incur any charges related to the termination of the uniQure Agreement.

Future collaboration and license revenue is highly dependent on the successful development and commercialization of products by our collaboration partners, which is uncertain, and revenue may fluctuate significantly from period to period. Additionally, we may never receive the consideration from our license agreements that is contemplated for option fees, development and sales-based milestone payments or royalties on sales of licensed products, given the contingent nature of these payments.

Operating Expenses

Research and Development

Our research and development expenses primarily consist of costs incurred for the discovery and preclinical and clinical development of our product candidates. These expenses include salaries and personnel-related costs, including stock-based compensation of our clinical, medical, chemistry, manufacturing and controls and scientific personnel performing research and development activities; laboratory supplies; research materials; fees paid to CROs to execute preclinical studies and clinical trials; fees paid to CDMOs to manufacture materials for preclinical studies and clinical trials; fees related to obtaining technology licenses; consulting costs; costs related to seeking regulatory approval of our product

candidates; and allocated facility-related costs, information technology costs, depreciation expense, and other overhead.

We expense all research and development costs in the periods in which they are incurred. We have entered into various agreements with CROs and CDMOs. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. Payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our balance sheet. The capitalized amounts are recognized as expense as the goods are delivered or the related services are performed.

We do not allocate our costs by product candidate, as a significant amount of research and development expenses includes internal costs, such as salary and other personnel-related expenses, laboratory supplies and allocated overhead, and external costs, such as fees paid to third parties to conduct research and development activities on our behalf, none of which are tracked by product candidate. In particular, with respect to internal costs, several of our departments support multiple product candidate research and development programs and, therefore, the costs cannot be allocated to a particular product candidate or development program.

At this time, we cannot reasonably estimate or know the nature, timing or estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. However, we expect our overall research and development expenses to increase in the near term primarily for 4D-150 Phase 3 trials in wet AMD and DME. The process of conducting the necessary clinical development to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. See the section titled “Risk Factors” for additional risks regarding regulatory development and approval.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expense for our personnel in executive, finance and accounting, legal, human resources, business development, and other administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, accounting and tax services, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

Other Income, Net

Our other income, net primarily consists of interest income earned on our cash equivalents and marketable securities and adjustments for the change in the fair value of our derivative liability which must be remeasured at each reporting date.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Revenue				
Collaboration and license revenue	$ 85,209	$ 37	$ 85,172	*
Operating Expenses:				
Research and development	195,696	141,299	54,397	38%
General and administrative	49,060	46,579	2,481	5%
Total operating expenses	244,756	187,878	56,878	30%
Loss from operations	(159,547)	(187,841)	28,294	(15)%
Other Income, Net	19,438	26,973	(7,535)	(28)%
Net loss	$ (140,109)	$ (160,868)	$ 20,759	(13)%

* not meaningful

Revenue

Revenue for the year ended December 31, 2025 increased by $85.2 million from the year ended December 31, 2024. The increase in revenue was primarily due to the upfront fees received from the Otsuka Collaboration and License Agreement in October 2025.

Research and Development Expenses

The following table provides a breakout of research and development expenses for the periods indicated (dollars in thousands):

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Research and development trials and consumables expenses	$ 100,220	$ 64,757	$ 35,463	55%
Payroll and personnel expenses	67,345	57,383	9,962	17%
Facilities and other research and development expenses	28,131	19,159	8,972	47%
Total research and development expenses	$ 195,696	$ 141,299	$ 54,397	38%

Research and development expenses for the year ended December 31, 2025 increased by $54.4 million, or 38%, from the year ended December 31, 2024. The increase was due to the following:

- a $35.5 million increase in research and development trials and consumables expenses mainly due to increased clinical trial activity for our product candidates, primarily 4D-150;
- a $10.0 million increase in payroll and personnel expenses primarily due to increased headcount of research and development personnel and one-time severance costs; and
- an $8.9 million increase in facilities and other research and development expenses primarily due to higher rent and increased clinical trial activity for our product candidates.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2025 increased by $2.5 million, or 5%, from the year ended December 31, 2024. The increase was primarily due to an increase in legal and consulting services.

Other Income, Net

Other income, net, decreased by $7.5 million, or 28%, from the year ended December 31, 2024 to the year ended December 31, 2025. The decrease was due to a reduction in invested balances from transfers out of investment accounts to fund operating expenses and lower market yields on our cash equivalents and marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $514.0 million. We have funded our operations primarily through the sale and issuance of our equity securities, including Follow-on Offerings and our “at-the-market” offering program, and to a lesser extent from cash received pursuant to our collaboration and license agreements. Our recent sources of liquidity include the following transactions:

Follow-on Offerings

In November 2025, we completed an underwritten offering (the "2025 Offering") in which 8,385,809 shares of our common stock were sold at an offering price of $10.51 per share, as well as pre-funded warrants to purchase 1,128,949 shares of our common stock at an offering price of $10.5099 per underlying share. The net proceeds from the 2025 Offering were approximately $93.3 million, after deducting the underwriting discounts and commissions and other offering expenses.

In February 2024, we completed the 2024 Offering in which 6,586,015 shares of our common stock were sold at an offering price of $29.50 per share, as well as pre-funded warrants to purchase 3,583,476 shares of our common stock at an offering price of $29.4999 per underlying share. The net proceeds from the 2024 Offering were $281.2 million, after deducting underwriting discounts and commissions and other offering expenses. We also granted the underwriters the option to purchase up to 1,525,423 additional shares of common stock in connection with the offering. In March 2024, the underwriters exercised their option and purchased 1,259,299 additional shares of common stock resulting in net proceeds of $34.9 million, after deducting underwriting discounts and commissions.

In May 2023, we completed the 2023 Offering in which 8,625,000 shares of our common stock were sold at an offering price of $16.00 per share. The net proceeds from the 2023 Offering were $129.2 million after deducting underwriting discounts and commissions and offering expenses.

At-the-Market Offering Program

In June 2024, we entered into a Sales Agreement (the “Leerink Sales Agreement”) with Leerink Partners LLC (“Leerink”) as sales agent to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $250.0 million pursuant to a Registration Statement on Form S-3 that we filed with the SEC in February 2024 as an “at-the-market” offering under the Securities Act. For the year ended December 31, 2025, 1,175,000 shares of the Company's common stock were sold pursuant to the Leerink Sales Agreement for net proceeds to the Company of $9.6 million, after deducting issuance costs.

In March 2022, we also entered into an Open Market Sales Agreement (the "Sales Agreement") with Jefferies LLC as sales agent to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $100.0 million pursuant to the S-3 Registration Statement as an "at-the-market" offering under the Securities Act (the "2022 ATM Offering Program"). On May 31, 2024, we terminated the Sales Agreement and the 2022 ATM Offering Program pursuant to the terms of the Sales Agreement. At termination, 1,684,550 shares of our common stock had been sold pursuant to the Sales Agreement for net proceeds to us of $34.4 million, after deducting issuance costs.

Collaboration and License Agreements

In October 2025, we entered into a Collaboration and License Agreement with Otsuka where we granted Otsuka exclusive rights to develop and commercialize 4D-150 for retinal vascular diseases, including wet AMD and DME, in Japan, China, Australia, and other Asia-Pacific markets. Otsuka made an upfront cash payment of $85 million and agreed to provide certain cost sharing for global development activities.

In July 2023, we entered into the License Agreement with AGT where we provided our 4D vector technology to AGT to deliver AGT's genetic payloads for the treatment of rare monogenic diseases. As partial consideration for the rights and licenses granted to AGT under the License Agreement, we received an upfront payment of $20.0 million.

Future Funding Requirements

We have experienced recurring net losses and had an accumulated deficit of $716.3 million at December 31, 2025. Our transition to profitability is dependent upon the successful development, approval and commercialization of our product candidates and those of our collaboration partners and achieving a level of revenue adequate to support our cost structure. We expect to continue to incur losses for the foreseeable future.

We expect that our overall research and development and general and administrative expenses will increase. As a result, we will need significant additional capital to fund our operations, which we may obtain through one or more equity offerings, debt financings or other third-party funding, the Otsuka Collaboration and License Agreement, and additional potential strategic alliances and licensing or collaboration arrangements.

Because of the numerous risks and uncertainties associated with the development and commercialization of gene therapy product candidates, we are unable to estimate the amount of increased capital we will need to raise to support our operations and the outlays and operating expenditures necessary to complete the development of our product candidates and build additional manufacturing capacity, and we may use our available capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the progress of our current and future product candidates through preclinical and clinical development;
- potential delays in our preclinical studies and clinical trials, whether current or planned;
- working with our contract manufacturers to scale up the manufacturing processes for our product candidates;
- continuing our research and discovery activities;
- continuing the development of our Therapeutic Vector Evolution platform;
- initiating and conducting additional preclinical, clinical or other studies for our product candidates;

- changing or adding additional contract manufacturers or suppliers;
- seeking regulatory approvals and marketing authorizations for our product candidates;
- establishing sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;
- acquiring or in-licensing product candidates, intellectual property and technologies;
- making milestone, royalty or other payments due under any current or future collaboration or license agreements;
- receiving milestone, royalty or other payments under any current or future collaboration or license agreements;
- obtaining, maintaining, expanding, protecting and enforcing our intellectual property portfolio;
- attracting, hiring and retaining qualified personnel;
- potential delays or other issues related to our operations;
- meeting the requirements and demands of being a public company;
- defending against any product liability claims or other lawsuits related to our products; and
- the lingering impact of the COVID-19 pandemic and adverse macroeconomic conditions such as, but not limited to, higher inflation and increased interest rates, each of which may exacerbate the magnitude of the factors discussed above.

We believe that our existing cash, cash equivalents and marketable securities will allow us to fund our planned operations for at least one year from the date of the issuance of the financial statements included in this report.

We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing sooner than currently projected, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. See the section titled “Risk Factors” for additional risks associated with our substantial capital requirements.

We have limited committed external sources of funds. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to complete the clinical development for the product candidates for treatment of wet AMD, DME, geographic atrophy, cystic fibrosis lung disease, alpha-1 antitrypsin deficiency lung disease or any other indication we may pursue. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter would result in fixed payment obligations and may involve agreements that include grants of security interests on our assets and restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, granting liens over our assets, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. Any debt financing or additional equity that we raise may contain terms that could adversely affect our common stockholders. Further, additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the war in Ukraine, conflicts in the Middle East, any expansion of these conflicts, rising interest rates and inflation, natural disasters and pandemics.

If we are unable to obtain additional funding, we expect to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or investment in manufacturing

capabilities, which could adversely affect our business. If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

Summary Statement of Cash Flows

The following is a summary of cash flows for the periods indicated below (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (109,082)	$ (134,585)
Net cash used in investing activities	(92,973)	(302,437)
Net cash provided by financing activities	112,960	337,250
Net decrease in cash and cash equivalents	$ (89,095)	$ (99,772)

Net Cash Used in Operating Activities

Net cash used in operating activities was $109.1 million for the year ended December 31, 2025. This was primarily due to the net loss of $140.1 million partially offset by a change of $24.8 million in noncash charges and by a net change of $6.2 million in our operating assets and liabilities. The noncash charges primarily consisted of stock-based compensation expense of $22.0 million, depreciation and amortization of $4.7 million and amortization of operating lease right-of-use assets of $2.9 million, partially offset by accretion of discount on marketable securities of $4.7 million and $0.1 million in change in fair value of derivative liability. The change in operating assets and liabilities was primarily due to an $8.1 million increase in accrued and other liabilities, a $6.8 million increase in accounts payable, offset by a $3.2 million decrease in operating lease liabilities, a $0.2 decrease in deferred revenue, a $0.4 million increase in prepaid expenses and other current assets and a $4.9 million increase in other assets.

Net cash used in operating activities was $134.6 million for the year ended December 31, 2024. This was primarily due to the net loss of $160.9 million partially offset by a change of $25.7 million in noncash charges and by a net change of $0.5 million in our operating assets and liabilities. The noncash charges primarily consisted of stock-based compensation expense of $26.1 million, depreciation and amortization of $4.7 million and amortization of operating lease right-of-use assets of $2.1 million, partially offset by accretion of discount on marketable securities of $7.2 million. The change in operating assets and liabilities was primarily due to a $6.5 million increase in accrued and other liabilities, a $0.9 million increase in accounts payable and $0.1 million increase in deferred revenue, offset by a $1.7 million decrease in operating lease liabilities, a $1.7 million increase in prepaid expenses and other current assets and a $3.6 million increase in other assets.

Net Cash Used in Investing Activities

Net cash used in investing activities was $93.0 million for the year ended December 31, 2025. This was due to purchases of marketable securities of $442.8 million and purchases of property and equipment of $0.5 million, offset by maturities of marketable securities of $350.4 million.

Net cash used in investing activities was $302.4 million for the year ended December 31, 2024. This was due to purchases of marketable securities of $467.6 million and purchases of property and equipment of $3.8 million, offset by maturities of marketable securities of $169.0 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $113.0 million for the year ended December 31, 2025. This was due to proceeds from the issuance of common stock upon underwritten offering, net of issuance costs, of $93.5 million, proceeds from the issuance of common stock from the ATM Offering Program of $9.7 million, proceeds from the issuance of common stock under a stock purchase agreement of $7.5 million, proceeds from the issuance of common stock from purchases from the Company's 2020 Employee Stock Purchase Plan ("ESPP") of $1.3 million, and proceeds from the issuance of common stock from the exercise of stock options and warrants of $1.0 million.

Net cash provided by financing activities was $337.3 million for the year ended December 31, 2024. This was due to proceeds from the issuance of common stock upon public offering, net of issuance costs, of $316.1 million, proceeds from the issuance of common stock from the 2022 ATM Offering Program of $15.3 million, proceeds from the issuance of common stock from the exercise of stock options and warrants of $4.6 million and proceeds from the issuance of common stock from purchases from the ESPP of $1.3 million.

Contractual Obligations, Commitments and Contingencies

Our commitments include obligations under vendor contracts to provide research services and other purchase commitments with our vendors. In the normal course of business, we enter into services agreements with contract research organizations, contract manufacturing organizations and other third parties. Generally, these agreements provide for termination upon notice, with specified amounts due upon termination based on the timing of termination and the terms of the agreement. The actual amounts and timing of payments under these agreements are uncertain and contingent upon the initiation and completion of the services to be provided. These amounts are not fixed and determinable.

As of December 31, 2025, our principal commitments consisted of obligations under our operating lease for our headquarters. Please see Note 8, Commitments and Contingencies, to our financial statements included elsewhere in this report.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenue and expenses during the reported periods. We evaluate these estimates and assumptions on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2, Summary of Significant Accounting Policies, to our financial statements included elsewhere in this report. We believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

Revenue Recognition

We determine revenue recognition for arrangements within the scope of Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASC 606") by performing the following five steps: (i) assessment whether a contract with a customer exists; (ii) determination of whether the promised goods or services are performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance

obligations based on estimated standalone selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

Our revenue is primarily derived through its license, research, development and commercialization agreements. The terms of these types of agreements may include (i) licenses to our technology, (ii) research and development services, and (iii) supplies of clinical and commercial materials. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in ASC 606. Significant judgment is required to determine whether the individual promised goods or services are distinct. Items are considered distinct if the customer can benefit from them on their own, or together with other readily available resources, and if they are separately identifiable from other items in the contract.

Payments to us under these arrangements typically include one or more of the following: nonrefundable upfront and license fees, cost-sharing and other forms of research funding, milestone and other contingent payments to us for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of any commercialized products.

We recognize as revenue sales-based royalties and milestone payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

Other variable amounts, such as cost-sharing and development and regulatory milestones, are included in the transaction price to the extent it is probable a significant reversal of cumulative revenue recognized will not occur when the associated uncertainties are resolved. We use the most likely or expected value amount methods as appropriate to estimate variable consideration.

At the end of each reporting period, we re-evaluate the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price.

We allocate the total transaction price to each performance obligation based on the estimated standalone selling prices. Variable consideration is allocated to the specific performance obligations if it is triggered by our performance or the outcomes from such performance, and if such allocation meets the allocation objective of recognizing revenue in amounts of consideration to which we expect to be entitled in exchange for transferring its promised goods or services to the customer.

We recognize revenue when, or as, the performance obligation is satisfied. Performance obligations recognized at a point in time, such as distinct licenses our intellectual property, are recognized when control transfers, including commencement of the license term. Performance obligations recognized over time, such as research and development services, are recognized using an appropriate measure of progress, such as total cost incurred.

We record accounts receivable when our right to consideration is unconditional, i.e. if and only passage of time is required before payment is due. Amounts collected or included in accounts receivable but not yet recognized in revenue are recorded as deferred revenues. Amounts recognized in revenue but not included in accounts receivable are recorded as contract assets.

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under the arrangement. Changes in these estimates can have a material effect on revenue recognized.

Accrued Clinical Research Organization Costs

We estimate our accrued clinical research organization costs as of each balance sheet date. This process involves reviewing contracts and purchase orders with service providers, identifying services that have been performed on our behalf and estimating the level of service performed, the expected remaining period of performance and the associated expenses incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Depending on the timing of payments to the service providers and the estimated expenses incurred, we may record net prepaid or accrued clinical research organization expenses relating to these costs.

Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with preclinical development and clinical studies; and
- other vendors related to process development and manufacturing of materials for use in preclinical development and clinical studies.

Our understanding of the status and timing of services performed relative to the actual status and timing may vary and may result in us reporting changes in estimates in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred.

Stock-Based Compensation Expense

We use a fair value-based method to account for all stock-based compensation arrangements with employees and nonemployees including stock options and stock awards. Our determination of the fair value of stock options on the date of grant utilizes the Black-Scholes option pricing model.

The fair value of the option granted is recognized on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. Prior to January 1, 2020, the stock-based compensation expense for nonemployees was subject to remeasurement until the related vesting conditions were met. Effective January 1, 2020, the measurement date for nonemployee awards is the date of grant without changes in the fair value of the award. We account for forfeitures as they occur for both employees and nonemployees.

Estimates of the fair value of equity awards as of the grant date using valuation models such as the Black-Scholes option pricing model are affected by assumptions with a number of complex variables.

Changes in the following assumptions can materially affect the estimate of fair value and ultimately how much stock-based compensation expense is recognized; and the resulting change in fair value, if any, is recognized in our statements of operations during the period the related services are rendered. These inputs are subjective and generally require significant analysis and judgment to develop:

- *Expected Term*—The expected term for employee stock options is calculated using the simplified method as we do not have sufficient historical information to provide a basis for estimate. The simplified method is based on the average of the vesting tranches and the contractual life of each grant.
- *Expected Volatility*—For all stock options granted to date, the expected volatility was estimated based on a study of publicly traded industry peer companies as we did not have sufficient trading history for our common stock. We selected the peer group based on similarities in industry, stage of development, size and financial leverage with our principal business operations. For each grant, we measured historical volatility over a period equivalent to the expected term.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues whose term is similar in duration to the expected term of the respective stock option.

- *Expected Dividend Yield*—We have not paid and do not currently anticipate paying any dividends on our common stock. Accordingly, we have estimated the dividend yield to be zero.

As of December 31, 2025, the unrecognized stock-based compensation expense related to stock options and RSUs was $34.2 million and is expected to be recognized as expense over a weighted-average period of approximately 1.7 years. The intrinsic value of all outstanding stock options as of December 31, 2025 was approximately $4.6 million, of which $1.0 million related to vested stock options and $3.6 million related to unvested stock options.

Income Taxes

We account for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the financial statement reporting and tax basis of our assets and liabilities. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses and research and development credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. A valuation allowance is provided against deferred tax assets unless it is more likely than not that they will be realized.

We account for uncertain tax positions by assessing all material positions taken in any assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. Our policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

NOLs and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies, to our financial statements included elsewhere in this report for information.

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

Interest Rate Sensitivity and Effects of Inflation

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $514.0 million, consisting of bank deposits, interest-bearing money market funds, and marketable securities, for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities of our cash equivalents and marketable securities, an immediate 10% change in interest rates would not have a material effect on the fair value of our cash equivalents or marketable securities.

We do not believe that inflation or interest rate changes have had a significant impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

4D Molecular Therapeutics, Inc.

Index to Financial Statements

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

None.

Item 9A. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures and Internal Control Over Financial Reporting

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 the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

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

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our evaluation, management has 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 our internal control over financial reporting because we are not an accelerated filer.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the fiscal quarter ended December 31, 2025, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

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

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting within 120 days after December 31, 2025 (the "Proxy Statement") and is incorporated in this Annual Report on Form 10-K by reference.

We have adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of our securities by directors, officers and employees that are designed to promote compliance with insider trading laws, rules and regulations and applicable Nasdaq listing standards, as well as procedures designed to further the foregoing purposes. See Exhibit 19.1 of our Annual Report on Form 10-K for the year ended December 31, 2024 for our insider trading policy.

Item 11. Executive Compensation.

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The financial statements schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(1) Financial Statements;

Reference is made to the financial statements included in Item 8 of Part II hereof.

(2) Financial Statement Schedules

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

(3) Exhibits

The exhibits required to be filed as part of this report are listed in the Exhibit List attached hereto and are incorporated herein by reference.

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation, as currently in effect.	8-K	12/15/20	3.1	
3.2	Amended and Restated Bylaws, as currently in effect.	8-K	10/02/25	3.1	
4.1	Description of Securities of the Registrant.				X
4.2	Form of Common Stock Certificate.	S-1/A	12/7/20	4.2	
4.3	Form of Pre-Funded Warrant issued in conjunction with February 2024 offering.	8-K	2/9/24	4.1	
4.4	Form of Pre-Funded Warrant issued in conjunction with November 2024 exchange.	10-Q	11/13/24	4.4	
4.5	Form of Pre-Funded Warrant issued in conjunction with December 2024 exchange.	8-K	12/11/24	4.1	
4.6	Form of Pre-Funded Warrant issued in conjunction with November 2025 Offering.	8-K	11/7/25	4.1	
4.7	Form of Pre-Funded Warrant issued in conjunction with January 2026 Exchange.	8-K	1/26/26	4.1	
10.1(a)#	2015 Equity Incentive Plan.	S-1	11/17/20	10.1(a)	
10.1(b)#	Form of Stock Option Agreement under 2015 Equity Incentive Plan.	S-1	11/17/20	10.1(b)	
10.2(a)#	2020 Incentive Award Plan.	S-8	12/15/20	99.2(a)	
10.2(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2020 Incentive Award Plan.	S-1/A	12/7/20	10.2(b)	
10.2(c)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2020 Incentive Award Plan.	S-1/A	12/7/20	10.2(c)	
10.2(d)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2020 Incentive Award Plan.	S-1/A	12/7/20	10.2(d)	
10.3#	2020 Employee Stock Purchase Plan.	S-8	12/15/20	99.3	
10.4†	Form of Indemnification Agreement for directors and officers.	S-1/A	12/7/20	10.4	
10.5†	Exclusive License and Bailment Agreement, dated December 19, 2013, between the Registrant and The Regents of the University of California.	S-1/A	12/7/20	10.8	
10.6†	Exclusive License and Bailment Agreement, dated December 19, 2013, between the Registrant and The Regents of the University of California.	S-1/A	12/7/20	10.9	
10.7#	Offer Letter, dated March 20, 2015 between David Kirn, M.D. and the Registrant.	S-1/A	12/7/20	10.10	
10.8#	Change in Control and Severance Agreement, dated September 22, 2021, by and between David Kirn and 4D Molecular Therapeutics, Inc.	8-K	9/24/21	10.1	
10.9#	Change in Control and Severance Agreement, dated September 22, 2021, by and between Fred Kamal and 4D Molecular Therapeutics, Inc.	10-Q	11/10/21	10.4	
10.10#	Restated Amended and Restated Non-Employee Director Compensation Policy.	10-Q	5/12/22	10.1	
10.11#	Offer Letter, dated September 4, 2023, between Uneek Mehra and the Registrant.	10-K	2/29/24	10.14	
10.12#	Change in Control and Severance Agreement, dated August 29, 2023, by and between Uneek Mehra and the Registrant.	10-K	2/29/24	10.15	

10.13#	Change in Control and Severance Agreement, dated September 22, 2021, by and between Scott Bizily and the Registrant.	10-K	2/29/24	10.16	
10.14#	Amended and Restated Change in Control and Severance Agreement, dated June 23, 2023 by and between Robert Kim and the Registrant.	10-K	2/29/24	10.17	
10.15#	2025 Employment Inducement Award Plan.	10-K	2/28/25	10.19	
10.16#	Amendment to 2025 Employment Inducement Award Plan.				X
10.17#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2025 Employment Inducement Award Plan.	10-K	2/28/25	10.20	
10.18#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2025 Employment Inducement Award Plan.	10-K	2/28/25	10.21	
10.19#	Offer Letter, dated May 24, 2024, between Ashoo Gupta and the Registrant.	10-Q	11/10/25	10.1	
10.20	Consulting Agreement, dated July 15, 2025, between Uneek Mehra and the Registrant.	10-Q	11/10/25	10.2	
10.21#	Offer Letter, dated November 3, 2025, between Kristian Humer and the Registrant.				X
10.22#	Change in Control and Severance Agreement, dated November 18, 2025, by and between Kristian Humer and the Registrant.				X
10.23	Transition Agreement with Fred Kamal, dated December 31, 2025, between Fred Kamal and the Registrant.				X
10.24†	Collaboration and License Agreement between the Registrant and Otsuka Pharmaceutical Co., Ltd. dated as of October 31, 2025.				X
19.1†	Insider Trading Compliance Policy, dated as of November 4, 2024.	10-K	2/28/25	19.1	
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included on the signature page of this Form 10-K).				X
31.1	Certification of the Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certifications of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97	Registrant's Policy for Recovery of Erroneously Awarded Compensation.	10-K	2/29/24	97	
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.				X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).				X

# Indicates management contract or compensatory plan.

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

* The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of 4D Molecular Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

4D Molecular Therapeutics, Inc.

Date: March 18, 2026

By: /s/ David Kirn

David Kirn, M.D.
President, Chief Executive Officer and Director
(Duly Authorized Officer and Principal Executive Officer)

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Kirn, M.D. and Kristian Humer, jointly and severally, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or their substitute or substitutes, 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.

Name	Title	Date
/s/ David Kirn **David Kirn, M.D.**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 18, 2026
/s/ Kristian Humer **Kristian Humer**	Chief Financial Officer *(Principal Financial Officer)*	March 18, 2026
/s/ Ashoo Gupta **Ashoo Gupta**	Vice President, Finance and Controller *(Principal Accounting Officer)*	March 18, 2026
/s/ John F. Milligan **John F. Milligan, Ph.D.**	Executive Chairman	March 18, 2026
/s/ Jacob Chacko **Jacob Chacko, M.D., MBA**	Director	March 18, 2026
/s/ Susannah Gray **Susannah Gray, MBA**	Director	March 18, 2026
/s/ Nancy Miller-Rich **Nancy Miller-Rich**	Director	March 18, 2026
/s/ Glenn Sblendorio **Glenn Sblendorio**	Director	March 18, 2026

/s/ Charles P. Theuer **Charles P. Theuer, M.D., Ph.D.**	Director	March 18, 2026
/s/ Shawn Cline Tomasello **Shawn Cline Tomasello, MBA**	Director	March 18, 2026

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of 4D Molecular Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of 4D Molecular Therapeutics, Inc. (the "Company") as of December 31, 2025 and 2024, and the related statements of operations, of comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including 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 the years then ended 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 of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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 Matters

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 (i) relates to accounts or disclosures that are material to the financial statements and (ii) 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.

Accrued Clinical Research Organization Costs

As described in Notes 2 and 5 to the financial statements, the Company recorded $10.3 million in accrued clinical and preclinical study costs as of December 31, 2025, a majority of which relates to accrued clinical research organization (CRO) costs. Accrued CRO costs include direct costs, as well as costs associated with patient visits and site activations. These costs are estimated by management based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted

costs. The estimated costs of research and development provided, but not yet invoiced by CROs, are included in accrued and other current liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, management will adjust the accrual accordingly. Estimating the accrued clinical research organization costs as of each balance sheet date requires the process of reviewing contracts and purchase orders with service providers, identifying services that have been performed on the Company's behalf and estimating the level of service performed, the expected remaining period of performance and the associated expenses incurred for the service when the Company has not yet been invoiced or notified of actual cost.

The principal considerations for our determination that performing procedures relating to accrued CRO costs is a critical audit matter are a high degree of auditor effort in performing procedures and evaluating audit evidence related to the Company's accrued CRO costs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included, among others (i) testing management's process for developing the estimated accrued CRO costs; (ii) testing the completeness and accuracy of the data used in developing the CRO accruals, including data related to patient visits and clinical site activations; and (iii) examining clinical vendor contracts to evaluate the completeness and accuracy of costs considered in the estimates.

/s/PricewaterhouseCoopers LLP
San Jose, California
March 18, 2026

We have served as the Company's auditor since 2016.

4D Molecular Therapeutics, Inc.
Balance Sheets
(In thousands, except share and per share amounts)

	As of December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 60,241	$ 149,336
Marketable securities	342,414	275,541
Prepaid expenses and other current assets	10,479	10,055
Total current assets	413,134	434,932
Marketable securities, long-term	111,379	80,583
Property and equipment, net	14,867	19,534
Operating lease right-of-use assets, net	18,143	21,074
Other assets	9,188	4,261
Total assets	$ 566,711	$ 560,384
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 11,159	$ 4,386
Accrued and other current liabilities	26,874	18,869
Deferred revenue	360	257
Operating lease liabilities, current portion	5,592	5,637
Total current liabilities	43,985	29,149
Deferred revenue, net of current portion	745	1,057
Derivative liability	358	410
Operating lease liabilities, long-term portion	15,821	18,969
Other liabilities	138	193
Total liabilities	61,047	49,778
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized at December 31, 2025 and 2024; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized at December 31, 2025 and 2024; 57,607,874 and 45,793,942 shares issued and outstanding at December 31, 2025 and 2024, respectively	6	5
Additional paid-in-capital	1,221,235	1,086,567
Accumulated other comprehensive gain	727	229
Accumulated deficit	(716,304)	(576,195)
Total stockholders' equity	505,664	510,606
Total liabilities and stockholders' equity	$ 566,711	$ 560,384

The accompanying notes are an integral part of these financial statements

4D Molecular Therapeutics, Inc.
Statements of Operations
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	**2024**
Revenue:		
Collaboration and license revenue	$ 85,209	$ 37
Operating expenses:		
Research and development (includes $1,322 and $1,005 for the years ended December 31, 2025 and 2024, respectively, attributable to related parties)	195,696	141,299
General and administrative	49,060	46,579
Total operating expenses	244,756	187,878
Loss from operations	(159,547)	(187,841)
Other income (expense):		
Interest income	19,475	27,050
Other expense, net	(37)	(77)
Total other income, net	19,438	26,973
Net loss	$ (140,109)	$ (160,868)
Net loss per share, basic and diluted	$ (2.42)	$ (2.98)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	57,930,180	53,943,741

The accompanying notes are an integral part of these financial statements

4D Molecular Therapeutics, Inc.
Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,	
	2025	2024
Net loss	$ (140,109)	$ (160,868)
Other comprehensive loss:		
Net unrealized gain on marketable securities	498	213
Total comprehensive loss	$ (139,611)	$ (160,655)

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

4D Molecular Therapeutics, Inc.
Statements of Stockholders' Equity
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2023	43,075,218	$ 4	$ 723,136	$ 16	$ (415,327)	$ 307,829
Issuance of common stock upon exercise of stock options and vesting of RSUs	427,036	—	4,580	—	—	4,580
Issuance of common stock upon public offering, net of issuance costs - February / March 2024 Public Offering Sale	7,845,314	1	316,148	—	—	316,149
Issuance of common stock upon ATM offering, net of issuance costs	585,938	—	15,263	—	—	15,263
Issuance of common stock - 2020 ESPP	170,436	—	1,258	—	—	1,258
Issuance of pre-funded warrant for common stock conversions	(6,310,000)	—	—	—	—	—
Stock-based compensation expense	—	—	26,116	—	—	26,116
Vesting of common stock warrants issued for services	—	—	66	—	—	66
Net unrealized gain on marketable securities	—	—	—	213	—	213
Net loss	—	—	—	—	(160,868)	(160,868)
Balances at December 31, 2024	45,793,942	$ 5	$ 1,086,567	$ 229	$ (576,195)	$ 510,606
Issuance of common stock upon exercise of stock options and vesting of RSUs	319,699	—	984	—	—	984
Issuance of common stock upon underwritten offering, net of issuance costs	8,385,809	1	93,339	—	—	93,340
Issuance of common stock upon ATM offering, net of issuance costs	1,175,000	—	9,576	—	—	9,576
Issuance of common stock - 2020 ESPP	467,762	—	1,253	—	—	1,253
Issuance of common stock - exercise of pre-funded warrants	178,280	—	—	—	—	—
Issuance of common stock - stock purchase agreement	776,398	—	7,500	—	—	7,500
Issuance of common stock - exercise of equity warrants	508,465	—	—	—	—	—
Issuance of common stock upon exercise of service warrants	2,519	—	—	—	—	—
Stock-based compensation expense	—	—	22,016	—	—	22,016
Net unrealized gain on marketable securities	—	—	—	498	—	498
Net loss	—	—	—	—	(140,109)	(140,109)
Balances at December 31, 2025	57,607,874	$ 6	$ 1,221,235	$ 727	$ (716,304)	$ 505,664

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

4D Molecular Therapeutics, Inc.
Statements of Cash Flows
(In thousands)

	Year ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (140,109)	$ (160,868)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	22,016	26,116
Vesting of common stock warrants in return for services	—	66
Change in fair value of derivative liability	(52)	41
Depreciation and amortization	4,694	4,653
Amortization of right-of-use assets	2,931	2,052
Net accretion of discount on marketable securities	(4,734)	(7,182)
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(424)	(1,699)
Other assets	(4,927)	(3,577)
Accounts payable	6,773	871
Accrued and other liabilities	8,152	6,524
Deferred revenue	(209)	69
Operating lease liabilities	(3,193)	(1,651)
Net cash used in operating activities	(109,082)	(134,585)
Cash flows from investing activities		
Purchases of marketable securities	(442,821)	(467,652)
Maturities of marketable securities	350,384	169,001
Acquisition of property and equipment	(536)	(3,786)
Net cash used in investing activities	(92,973)	(302,437)
Cash flows from financing activities		
Issuance of common stock upon exercise of stock options and vesting of RSUs	984	4,580
Issuance of common stock upon public offering, net of issuance costs	—	316,149
Issuance of common stock upon underwritten offering, net of issuance costs	93,540	—
Issuance of common stock under the ATM offering program, net of issuance costs	9,683	15,263
Issuance of common stock - 2020 ESPP	1,253	1,258
Issuance of common stock under stock purchase agreement	7,500	—
Net cash provided by financing activities	112,960	337,250
Net decrease in cash and cash equivalents	(89,095)	(99,772)
Cash and cash equivalents, beginning of period	149,336	249,108
Cash and cash equivalents, end of period	$ 60,241	$ 149,336
Supplemental disclosures of noncash investing and financing information		
Unpaid stock issuance costs in accrued and other liabilities	$ 307	$ —
Purchases of property and equipment in accounts payable and accrued and other liabilities	$ —	$ 509
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 11,587

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

1. The Company

4D Molecular Therapeutics, Inc. (the "Company") was formed as a limited liability company in September 2013 under the name 4D Molecular Therapeutics, LLC. The Company changed its name and converted into a corporation which was incorporated in the state of Delaware in March 2015. The Company is a late-stage biotechnology company advancing durable and disease-targeted therapeutics with potential to transform treatment paradigms and provide benefits to patients.

2024 Follow On Public Offering

In February 2024, the Company completed an underwritten public offering (the "2024 Offering") in which 6,586,015 shares of the Company's common stock were sold at an offering price of $29.50 per share, as well as pre-funded warrants to purchase 3,583,476 shares of the Company's common stock at an offering price of $29.4999 per underlying share pursuant to an effective Registration Statement on Form S-3. The net proceeds from the 2024 Offering were $281.2 million, after deducting underwriting discounts and commissions and other offering expenses. The Company also granted the underwriters the option to purchase up to 1,525,423 additional shares of common stock in connection with the offering. In March 2024, the underwriters exercised their option to purchase 1,259,299 additional shares of common stock resulting in net proceeds of $34.9 million, after deducting commissions.

2025 Offering

In November 2025, the Company completed an underwritten offering (the "2025 Offering") in which 8,385,809 shares of the Company's common stock were sold at an offering price of $10.51 per share, as well as pre-funded warrants to purchase 1,128,949 shares of the Company's common stock at an offering price of $10.5099 per underlying share pursuant to an effective Registration Statement on Form S-3. The net proceeds from the 2025 Offering were approximately $93.3 million, after deducting the underwriting discounts and commissions and other offering expenses.

Liquidity

The Company has incurred significant losses and negative cash flows from operations and had an accumulated deficit of $716.3 million as of December 31, 2025. The Company had cash, cash equivalents and marketable securities of $514.0 million as of December 31, 2025. The Company believes that its cash and cash equivalents and marketable securities as of December 31, 2025 are sufficient for the Company to fund planned operations for at least one year from the issuance date of these financial statements for the year ended December 31, 2025. The Company has historically financed its operations primarily through the sale of equity securities, and to a lesser extent, from cash received pursuant to its collaboration and license agreements. To date, none of the Company's product candidates have been approved for sale, and therefore, the Company has not generated any revenue from product sales. Management expects operating losses and negative cash flows from operations to continue for the foreseeable future. The Company plans to raise additional funding as required based on the status of its clinical trials and projected cash flows. There can be no assurance that, in the event the Company requires additional financing, such financing will be available on terms acceptable to the Company, if at all. Failure to generate sufficient cash flows from operations, raise additional capital and reduce discretionary spending should additional capital not become available could have a material adverse effect on the Company's ability to achieve its business objectives.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP").

Use of Estimates and Judgments

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses; and disclosure of contingent assets and liabilities as of the date of the financial statements. Such estimates include the determination of useful lives for property and equipment, the contract term, transaction price and costs of collaboration agreements, stock options and the derivative instrument and income tax uncertainties. Actual results could differ from those estimates.

Due to the war in Ukraine, conflicts in the Middle East, any expansion of these conflicts, rising interest rates, tariffs and inflation, natural disasters and health crises, such as pandemics, there has been uncertainty and disruption in the global economy and financial markets. The Company is not aware of any specific event or circumstance that would require an update to its estimates or judgments or a revision of the carrying value of its assets or liabilities as of December 31, 2025. While there was not a material impact to the Company's financial statements as of December 31, 2025, these estimates may change, as new events occur and additional information is obtained, as well as other factors that could result in material impacts to the financial statements in future reporting periods.

Segment Information

The Company manages its business as one segment which includes all activities related to the discovery, development, and commercialization of medicines for specific diseases. See Note 17, Segment Information, for financial information related to the Company's one segment.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, marketable securities and accounts receivable. The Company's cash is held at two financial institutions in the United States of America. The Company's cash equivalents are invested in money market funds. The Company also invests in U.S. Treasuries, U.S. government sponsored agencies, commercial paper, corporate bonds and certificates of deposit. The Company has not experienced any losses on its deposits of cash and cash equivalents. Such deposits may, at times, exceed federally insured limits.

The Company's partners in collaboration and license agreements who represent 10% or more of the Company's total revenue are as follows:

	Year Ended December 31,	
	2025	2024
Customer A	*	100%
Customer B	100%	-
Total	100%	100%

* Less than 10%

The Company did not have accounts receivable from its partners in collaboration and license agreements as of December 31, 2025 and 2024.

The Company's total revenues by geographic region, based on the location of the customer, are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
United States	$ 209	$ 37
Japan	85,000	—
Total revenue	$ 85,209	$ 37

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist of money market funds.

Marketable Securities

Marketable securities consist of certificates of deposit, commercial paper, corporate bonds, U.S. Treasuries and U.S. government sponsored agencies and are included in current and noncurrent assets. The Company classifies its marketable securities as available-for-sale and carries them at fair value on its balance sheet. Fair value is estimated using independent pricing sources based on quoted prices in active markets for similar securities. Unrealized gains and losses on the marketable securities are reported as a component of stockholders' equity in accumulated other comprehensive loss. The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the statements of operations. Realized gains and losses are included in interest income on the statements of operations.

The Company periodically evaluates its marketable securities to assess whether those with unrealized loss positions are other than temporarily impaired. The Company considers various factors in determining whether to recognize an impairment charge. If the Company determines that the decline in an investment's fair value is other-than-temporary, the difference is recognized as an impairment loss under other income (expense) in the statements of operations.

Acquisitions

The Company first determines whether a set of assets acquired constitute a business and should be accounted for as a business combination. If the assets acquired do not constitute a business, the Company accounts for the transaction as an asset acquisition where the cost of the acquisition is allocated to the assets acquired and liabilities based on their relative fair values. In-process research and development ("IPR&D") projects with no alternative future use are recorded as research and development expense upon acquisition, and contingent consideration obligations incurred in connection with an asset acquisition are recorded when it is probable that they will occur and they can be reasonably estimated. Business combinations are accounted for by means of the acquisition method of accounting. Under the acquisition method, assets acquired, including IPR&D projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill.

Other 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, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, suppliers for key raw materials, contract development and manufacturing organizations ("CDMOs") and contract research organizations ("CROs"), compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting.

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

Fair Value Measurements

The Company applies fair value accounting for all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-level fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

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

The Company accounts for transfers of financial instruments between levels of the fair value hierarchy on the date of the event or change in circumstance that caused the transfer.

Accounts Receivable—Allowance for Doubtful Accounts

The Company regularly reviews accounts receivable for collectability and establishes an allowance for probable credit losses and writes off uncollectible accounts as necessary. The Company has determined that no allowance was required at December 31, 2025 and 2024. The Company did not have any write-offs relating to uncollectible accounts receivable during the years ended December 31, 2025 and 2024.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation for acquired assets. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

Asset	Estimated Useful Life
Computer equipment and software	3 years
Office equipment	3 years
Furniture and fixtures	5 years
Laboratory equipment	5 years
Vehicles	5 years
Leasehold improvements	Shorter of useful life or lease term

Upon sale or retirement of assets, the costs and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected within operating expenses in the statements of operations. Maintenance and repairs are charged to expense as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted net cash flows, which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is typically measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets in the years ended December 31, 2025 and 2024.

Common Stock Warrants

The Company accounts for common stock warrants which meet the definition of a derivative as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement. Common stock warrants classified as liabilities are initially recorded at fair value and remeasured at fair value each balance sheet date with the offset adjustments recorded in other income (expense), net within the statements of operations. Common stock warrants classified as equity are initially measured at fair value on the grant date and are not subsequently remeasured.

Leases

The Company’s lease obligations relate primarily to leased office, laboratory and warehouse facilities under noncancelable operating leases.

At contract inception, the Company determines if an arrangement is or contains a lease. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. If determined to be or contain a lease, the lease is assessed for classification as either an operating or finance lease at the lease commencement date, defined as the date on which the leased asset is made available for use by the Company, based on the economic characteristics of the lease.

A right-of-use asset represents the economic benefit conveyed to the Company by the right to use the underlying asset over the lease term. A lease liability represents the obligation to make lease payments arising from the lease. Operating lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make payments arising from the lease. Operating right-of-use assets and liabilities are recognized at the commencement date of the lease and are measured at the present value of the fixed payments due over the expected lease term less the present value of any incentives, rebates, or abatements the Company expects to receive from the lessor. The Company records amortization of operating right-of-use assets and accretion of lease liabilities as a single lease cost on a straight-line basis over the lease term. No lease renewal options are recognized as part of the right-of-use assets and lease liabilities.

The Company's operating leases are presented in the balance sheet as operating lease right-of-use assets, classified as noncurrent assets, and operating lease liabilities, classified as current and noncurrent based on the discounted lease payments to be made within the proceeding twelve months.

As the implicit rate in the Company’s leases is not readily determinable, the Company uses its incremental borrowing rate to discount lease payments. The incremental borrowing rate represents an estimated rate of interest that the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date.

Revenue Recognition

The Company determines revenue recognition for arrangements within the scope of Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASC 606”) by performing the following five steps: (i) assessment whether a contract with a customer exists; (ii) determination of whether the promised goods or services are performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated standalone selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company’s revenue is primarily derived through its license, research, development and commercialization agreements. The terms of these types of agreements may include (i) licenses to the Company’s technology, (ii) research and development services, and (iii) supplies of clinical and commercial materials. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer, and is the unit of account in ASC 606. Significant judgment is required to determine whether the individual promised goods or services are distinct. Items are considered distinct if the customer can benefit from them on their own, or together with other readily available resources, and if they are separately identifiable from other items in the contract.

Payments to the Company under these arrangements typically include one or more of the following: nonrefundable upfront and license fees, cost-sharing and other forms of research funding, milestone and other contingent payments to the Company for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of any commercialized products.

The Company recognizes as revenue sales-based royalties and milestone payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

Other variable amounts, such as cost-sharing and development and regulatory milestones, are included in the transaction price to the extent it is probable a significant reversal of cumulative revenue recognized will not occur when the associated uncertainties are resolved. The Company uses the most likely or expected value amount methods as appropriate to estimate variable consideration.

At the end of each reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price.

The Company allocates the total transaction price to each performance obligation based on the estimated standalone selling prices. Variable consideration is allocated to the specific performance obligations if it is triggered by the Company's performance or the outcomes from such performance, and if such allocation meets the allocation objective of recognizing revenue in amounts of consideration to which the Company expects to be entitled in exchange for transferring its promised goods or services to the customer.

The Company recognizes revenue when, or as, the performance obligation is satisfied. Performance obligations recognized at a point in time, such as distinct licenses to the Company's intellectual property, are recognized when control transfers, including commencement of the license term. Performance obligations recognized over time, such as research and development services, are recognized using an appropriate measure of progress, such as total cost incurred.

The Company records accounts receivable when the Company's right to consideration is unconditional, i.e. if only passage of time is required before payment is due. Amounts collected or included in accounts receivable but not yet recognized in revenue are recorded as deferred revenues. Amounts recognized in revenue but not included in accounts receivable are recorded as contract assets.

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. Changes in these estimates can have a material effect on revenue recognized.

Research and Development Expenses

Costs related to research, design and development of programs are charged to research and development expense as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses including stock-based compensation, materials, laboratory supplies, outside services and allocated overhead, including rent, insurance, repairs and maintenance, depreciation and utilities. The Company expenses all research and development costs in the period in which they are incurred.

Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

Accrued Clinical Research Organization Cost

The Company has entered into various agreements with clinical research organizations (CROs). Accrued CRO costs include direct costs, as well as costs associated with patient visits and site activations. These costs are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced by CROs, are included in accrued and other current liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Estimating the accrued research organization costs as of each balance sheet date requires the process of reviewing contracts and purchase orders with service providers, identifying services that have been performed on the Company's behalf and estimating the level of service performed, the expected remaining period of performance and the associated expenses incurred for the service when the Company has not yet been invoiced or notified of actual cost. Payments made to CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses, other current assets or long-term other assets until the services are rendered.

Stock-Based Compensation

The Company accounts for stock-based compensation for stock options granted to employees, directors and nonemployees as measured at grant date, based on the fair value of the award. The Company measures the fair value of awards granted using the Black-Scholes option pricing model and recognizes the expense in the statements of operations over the requisite service period, generally four years, using the straight-line method. Forfeitures are accounted for as they occur. The Company's policy for issuing stock upon stock option exercise is to issue new common stock.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax basis of the Company's assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses and research and development credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. A valuation allowance is provided against deferred tax assets unless it is more likely than not that they will be realized.

The Company accounts for uncertain tax positions by assessing all material positions taken in any assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Embedded Derivative

Embedded derivatives that are required to be bifurcated from the underlying host instrument are accounted for and valued as a separate financial instrument. An embedded derivative exists in the award agreement with the Cystic Fibrosis Foundation ("CFF"). As described in Note 14, Derivative Liability, the embedded derivative has been bifurcated and is classified as a liability on the balance sheet and separately accounted for at its fair value. The derivative liability is subject to remeasurement to fair value each reporting period. Changes in the fair value of the derivative liability are recognized as a component of other income (expense), net within the statements of operations.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly related to the Company's in-process financings, until such financings are consummated. After consummation of the financing, these costs are recorded as a reduction of the proceeds received as a result of the offering. In the event that a planned offering does not occur or is significantly delayed, all related deferred offering costs will be expensed immediately within the Company's statements of operations.

Net Loss Per Share, Basic and Diluted

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by giving effect to all potentially dilutive common shares outstanding for the period. For purposes of this calculation, stock options to acquire shares of common stock, common stock warrants, and common stock expected to be issued under the ESPP, are considered potentially dilutive common shares, but have been excluded from the calculation of diluted net loss per share as their effect is antidilutive.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-09, *Improvements to Income Tax Disclosures.* The final guidance adds clarifications related to the presentation of rate reconciliation for public business entities and definitions of specific categories in rate reconciliation. These amendments are effective for public business entities for annual periods beginning after December 15, 2024. The Company adopted ASU No. 2023-09 for the 2025 calendar year prospectively. The adoption impacted disclosures only and did not impact the Company's statements of operations or balance sheets.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Topic 220) - Disaggregation of Income Statement Expenses*. ASU 2024-03 requires public business entities to disclose, on an annual and interim basis, disaggregated information about certain income statement expense line items in the notes to the financial statements. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026 (fiscal 2027) and interim periods within fiscal years beginning after December 15, 2027 (fiscal 2028). The ASU must be applied prospectively and may be applied retrospectively if elected. The Company is currently evaluating the effect of adopting this new accounting guidance.

3. Fair Value Measurements and Marketable Securities

The following tables represent the Company's fair value hierarchy for financial assets and financial liabilities measured at fair value on a recurring basis (in thousands):

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value as of December 31, 2025	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Assets							
Cash	$ 10,696	$ —	$ —	$ 10,696	$ 10,696	$ —	$ —
Level 1:							
Money market funds	39,570	—	—	39,570	39,570	—	—
Level 2:							
Certificates of deposit	35,986	37	—	36,023	—	36,023	—
Commercial paper	63,875	48	—	63,923	5,479	58,444	—
U.S. Treasuries	76,920	153	—	77,073	—	63,589	13,484
Corporate bonds	286,260	492	(3)	286,749	4,496	184,358	97,895
Subtotal	463,041	730	(3)	463,768	9,975	342,414	111,379
Total	$ 513,307	$ 730	$ (3)	$ 514,034	$ 60,241	$ 342,414	$ 111,379

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value as of December 31, 2024	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Assets							
Cash	$ 6,715	$ —	$ —	$ 6,715	$ 6,715	$ —	$ —
Level 1:							
Money market funds	142,621	—	—	142,621	142,621	—	—
Level 2:							
Certificates of deposit	47,592	55	—	47,647	—	47,647	—
Commercial paper	60,144	59	(1)	60,202	—	58,057	2,145
U.S. Treasuries	32,224	8	(122)	32,110	—	6,751	25,359
Corporate bonds	215,935	361	(131)	216,165	—	163,086	53,079
Subtotal	355,895	483	(254)	356,124	—	275,541	80,583
Total	$ 505,231	$ 483	$ (254)	$ 505,460	$ 149,336	$ 275,541	$ 80,583

There are no Level 3 assets and no Level 1 or 2 liabilities.

Level 3 Inputs

The fair value of the derivative liability is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using a present value analysis with multiple scenarios. In determining the fair value of the derivative liability, the inputs impacting fair value include the change of control payment to Cystic Fibrosis Foundation, the probability of a change of control event, the product status at time of a change of control event and the discount rate. See Note 14, Derivative Liability, for further discussion on the embedded derivative.

There were no transfers between Level 1, 2 and 3 for assets or liabilities during the periods presented.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 derivative liability (in thousands):

Balance as of December 31, 2023	$ 369
Change in fair value included in other income (expense), net	41
Balance as of December 31, 2024	410
Change in fair value included in other income (expense), net	(52)
Balance as of December 31, 2025	$ 358

All marketable securities held as of December 31, 2025 had contractual maturities of less than two years. There have been no material realized gains or losses on marketable securities for the periods presented.

Aggregate fair values of marketable securities with unrealized losses and gains were as follows (in thousands):

	As of December 31,	
	2025	2024
Aggregate fair value of marketable securities in a continuous loss position for less than twelve months	$ 15,449	$ 69,947
Aggregate fair value of marketable securities in a continuous loss position for more than twelve months	1,951	—
Aggregate fair value of marketable securities in unrealized gain position	446,368	286,177
Total marketable securities	$ 463,768	$ 356,124

The Company manages credit risk associated with its investment portfolio through its investment policy, which limits purchases to high-quality issuers and also limits the amount of its portfolio that can be invested in a single issuer. The Company did not record an allowance for credit losses or other impairment charges related to its marketable securities for any period presented. The Company has determined that (i) it does not have the intent to sell any of these investments, and (ii) it is not more likely than not that it will be required to sell any of these investments before recovery of the entire amortized cost basis. The Company further considered the maximum unrealized loss amounts both at the individual instrument level, $1 thousand, as well as in aggregate, $3 thousand, as of December 31, 2025, as immaterial. These unrealized losses were not attributed to credit risk and were associated with changes in market conditions. The Company periodically reviews its marketable securities for indications of credit losses. The Company anticipates that it will recover the entire amortized cost basis of such securities, and therefore, no credit loss existed as of December 31, 2025.

4. Property and Equipment, Net

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

	December 31,	
	2025	2024
Machinery and equipment	$ 14,538	$ 14,172
Leasehold improvements	18,467	17,763
Furniture and fixtures	1,086	1,104
Office equipment	324	256
Computer equipment and software	1,685	1,596
Transportation equipment	46	46
Construction in progress	—	1,182
Total property and equipment	36,146	36,119
Less: Accumulated depreciation and amortization	(21,279)	(16,585)
Property and equipment, net	$ 14,867	$ 19,534

All property and equipment are maintained in the United States. Depreciation expense was $5.2 million and $4.8 million for the years ended December 31, 2025 and 2024, respectively.

5. Accrued and Other Current Liabilities

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

	December 31,	
	2025	2024
Payroll and related expenses	$ 13,806	$ 8,106
Accrued clinical and preclinical study costs	10,273	7,977
Consulting and professional	2,666	2,672
Other accrued expenses	129	114
Total accrued and other current liabilities	$ 26,874	$ 18,869

6. Research and Collaboration Arrangements

Collaboration and license revenue for each period was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Otsuka Pharmaceutical Co., Ltd.	$ 85,000	$ —
Cystic Fibrosis Foundation	209	37
Total revenue	$ 85,209	$ 37

Deferred revenue is summarized as follows (in thousands):

	December 31,	
	2025	2024
Cystic Fibrosis Foundation	$ 1,105	$ 1,314

The total amount of revenue in each of the years ended December 31, 2025 and 2024, which was included in deferred revenue at January 1, 2025 and 2024, was immaterial.

uniQure

In January 2014, the Company and uniQure biopharma B.V. (“uniQure”) entered into a Collaboration and License Agreement (the “uniQure Agreement”) to collaborate on the discovery and non-clinical research activities related to the Company’s Therapeutic Vector Evolution platform in order to generate and validate vectors for gene delivery to treat diseases within the central nervous system and liver (together, the “uniQure Field”).

The uniQure Agreement provided uniQure with a research license as well as an exclusive development and commercialization license for each project variant selected for further development. The initial research term is three years with an option for uniQure to extend the research term one time for an additional year. Once the Company’s research plan has concluded, uniQure is solely responsible for the continued development, manufacturing and commercialization of the project variants as potential product candidates. In October 2016, uniQure exercised its option to extend the research term for an additional year to January 2018. The Company was also required to work exclusively with uniQure in the uniQure Field (the “uniQure Exclusivity Clause”).

Pursuant to the uniQure Agreement, the Company received upfront payments of $0.2 million, and was entitled to receive (i) contingent payments for the achievement of research and development milestones of up to $5.0 million for each licensed product selected under the arrangement, and (ii) royalties in the single digit range on future sales of the potential product candidates and sublicense consideration in the low teens to low thirties range on any future sublicensing arrangements. The Company also received

capped research and development service fees based on contractual full-time employee rates per year. In connection with the performance obligations under the uniQure Agreement, the founders of 4D Molecular Therapeutics, LLC received equity options to purchase an aggregate of 609,744 of uniQure ordinary shares that vested over the initial three-year term of the agreement.

The upfront payment of $0.2 million was recorded as deferred revenue and was recognized on a ratable basis over the estimated performance period of four years. Payments and reimbursements for research costs were recognized on an as-incurred basis. The options to purchase uniQure shares were deemed to be a noncash component of the arrangement consideration, as the vesting of options is linked to the uniQure Agreement and there is a requirement for the holders of the options to provide services under the agreement. The fair value of the uniQure options, which was estimated to be $10.6 million, was recognized ratably as revenue over the estimated performance period of four years and the associated compensation expense related to the stock options was recorded as research and development expense.

In August 2019, the Company and uniQure entered into an Amended and Restated Collaboration and License Agreement (the "Amended uniQure Agreement"), which amended and restated the uniQure Agreement, and a separate Collaboration and License Agreement (the "Second uniQure Agreement"). Under these agreements, the Company agreed to transfer incremental rights and services to uniQure in exchange for uniQure eliminating the uniQure Exclusivity Clause and transferring other rights back to the Company.

Under the Amended uniQure Agreement, uniQure continues to have an exclusive license to select AAV capsid variants (the "Selected Variants") in the uniQure Field. uniQure continues to be solely responsible, at its cost, to develop and commercialize the compounds and products containing the Selected Variants. The amended uniQure Agreement eliminated the uniQure Exclusivity Clause in the uniQure Agreement. Furthermore, the contingent payments that the Company was entitled to from uniQure for the achievement of research and development milestones of up to $5.0 million for each licensed product selected under the uniQure Agreement were eliminated and sublicense consideration on any future sublicensing arrangements was reduced from the low teens to low thirties percentages to mid-single digit to mid-twenties percentages.

Under the Second uniQure Agreement, the parties agreed to research and develop new AAV capsid variants (the "New Variants") that are not Selected Variants that affect certain targets selected by uniQure (the "uniQure Targets") in the uniQure Field. The Company is solely responsible, at its cost, for the research of the New Variants. The Company granted uniQure an exclusive license to a certain number of the New Variants (the "uniQure New Variants") that affect the uniQure Targets. uniQure is solely responsible, at its cost, to develop and commercialize the compounds and products containing the uniQure New Variants that affect the uniQure Targets (the "Licensed Products"). The Company retains all rights to New Variants in the uniQure Field that affect targets other than the uniQure Targets.

Under both the Amended uniQure Agreement and the Second uniQure Agreement, uniQure will be required to pay the Company royalties on worldwide annual net sales of Licensed Products at a mid-single digit percentage rate, subject to certain specified reductions. uniQure will also be required to pay the Company sublicensing consideration for sublicensing the Company's intellectual property rights licensed under the Amended uniQure Agreement or the Second uniQure Agreement to third parties at a rate between the mid-single digit to mid-twenties. The Company has reciprocal obligations, at the same percentage rates as uniQure, to pay uniQure royalties and sublicensing consideration for sublicensing certain intellectual property rights licensed under the Amended uniQure Agreement or the Second uniQure Agreement to third parties.

The Company concluded that the Amended uniQure Agreement and the Second uniQure Agreement should be accounted for as one combined contract that should be accounted for as a separate contract from the uniQure Agreement given that the incremental licensed intellectual property rights and research and development services are distinct from the rights and services previously transferred to uniQure under the uniQure Agreement and the transaction price increased by an amount that equals the standalone selling price of the incremental rights and services to be transferred to uniQure under the Amended uniQure Agreement and Second uniQure Agreement.

Neither party was required to pay monetary consideration in connection with the execution of the Amended uniQure Agreement or the Second uniQure Agreement or for subsequent performance by the parties under those agreements, notwithstanding the potential future royalty and sublicense consideration described above. The fair value of the non-monetary consideration given by uniQure to the Company, for the intellectual property right was $5.1 million. This intellectual property right was considered to be an in-process research and development asset with no alternative future use and, accordingly, was written off as acquired in-process research and development expense in the year ended December 31, 2019.

In accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers,* the incremental transaction price described in the paragraph above was recorded as deferred revenue given that the Company identified one single combined performance obligation, which includes the licenses to the New Variants, research services and participation in the joint steering committee (“JSC”). Revenue is being recognized using the input method based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligation. The Company completed its performance obligation during the third quarter of 2023 and the deferred revenue was recognized as revenue in the same period.

The Company determined the transaction price using the risk adjusted net present value analysis (“rNPV”) methodology to value the elimination of the uniQure exclusivity clause and other material rights received by the Company, including the potential royalties the Company would receive from uniQure. The rNPVs incorporate estimates and assumptions including the number of products the Company and uniQure would develop, the risk-adjusted probability of successfully developing a biopharmaceutical product, the probability that uniQure will develop a product, the research and development costs, the potential worldwide sales and associated commercialization costs, corporate tax rate, and discount rate.

During each of the years ended December 31, 2025 and 2024, the Company recognized revenue of zero under the Amended uniQure Agreement and the Second uniQure Agreement, respectively. As of December 31, 2025 and 2024, there was no deferred revenue relating to uniQure, and the aggregate amount of the transaction price allocated to the remaining performance obligation was zero. There were no amounts due from uniQure under the uniQure Agreement, Amended uniQure Agreement or Second uniQure Agreement as of December 31, 2025 and 2024. The Amended uniQure Agreement and the Second uniQure Agreement were terminated by mutual agreement in November 2025. The Company did not incur any charges related to the termination of the uniQure Agreement.

Cystic Fibrosis Foundation (“CFF”)

In September 2016, the Company entered into an award agreement for the Optimized Adeno-Associated Virus for Lung Epithelia Gene Delivery Development Program with CFF, a non-profit organization dedicated to finding a cure for cystic fibrosis, an inherited disorder that causes disease in the pulmonary airways leading to morbidity and mortality. Under this agreement, CFF contributes funding to help advance the Company’s cystic fibrosis research program. The September 2016 grant award agreement was incorporated into a new grant award agreement with CFF in September 2017 with the same objectives, which was subsequently amended in August 2018 and February 2021. In August 2023, the Company executed a third amendment to the agreement (the “August 2023 Amendment”), which modified the research plan, increased the aggregate milestone payments from $3.5 million to $6.3 million and extended the estimated project completion date. The aforementioned September 2017 agreement and three amendments are collectively referred to as the “CFF Agreement”. The August 2023 Amendment represents a contract modification to an existing contract under ASC Topic 606, given the amendment did

not include any additional goods or services, and the remaining research activities are not distinct from those previously provided. The August 2023 Amendment did not impact the transaction price, given the increased award amount relates to variable consideration for future milestones that are fully constrained. Accordingly, the contract modification did not result in a revenue adjustment. As of December 31, 2025 and 2024, the Company had achieved cumulative milestones totalling $1.8 million, under the CFF Agreement. The remaining award amount will be paid by CFF based on achievement of certain development milestones by the Company.

The Company expects to make payments to CFF equal to six times the actual award received by the Company in three installments within the first four years of the first commercial sale of a product developed under this agreement. The Company also has agreed to make future sales-based milestone payments to CFF of up to three times the actual award received upon achieving specified commercialization milestones with respect to the first of any product developed utilizing any compound covered under the CFF Agreement. The CFF Agreement also requires the Company to pay to CFF royalties of a mid-single digit percentage, up to six times the actual award received, on any amounts received by the Company from the sale, license or transfer to a third-party of rights in the technology developed as a result of this collaboration. Any such royalty payments shall be credited against the payments owed by the Company upon first commercial sale. In the event of a change of control of the Company, CFF will receive certain payments, depending on the timing of the change of control and the size of the transaction.

To date, the Company has not developed a commercial product in connection with the CFF Agreement, and it has not licensed, sold or otherwise transferred to another party the product developed under the CFF Agreement or the underlying technology.

If at any time prior to the first commercial sale of a product developed as a result of the CFF Agreement, the Company ceases to use commercially reasonable efforts to develop or commercialize any product under the CFF Agreement for a continuous period of 180 consecutive days and fails to present a reasonable plan to resume commercially reasonable efforts, the Company will grant to CFF an irrevocable, exclusive worldwide interruption license under all of the Company's interest in the research plan technology to exploit such product. Any third-party license granted by the Company shall be subject to such interruption license.

The Company identified one performance obligation within the CFF Agreement for research activities. The CFF Agreement does not include a significant financing component.

The Company concluded that the transaction price should not include the variable consideration related to future research milestones as they were considered to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal of cumulative revenue in the future. The Company re-evaluates the transaction price and estimated period of performance at each reporting period.

Revenue recognized during the year ended December 31, 2025 was $0.2 million, while revenue recognized during the year December 31, 2024 was immaterial. As of December 31, 2025 and 2024, deferred revenue relating to the CFF Agreement was $1.1 million and $1.3 million, respectively. There were no accounts receivable from CFF under the CFF Agreement as of December 31, 2025 and 2024. As of December 31, 2025 and 2024, the aggregate amount of the transaction price allocated to the remaining performance obligation was $1.1 million and $1.3 million, respectively. Based on current timelines, the deferred revenue is expected to be recognized as revenue over the next four years as the Company performs research services through the completion of IND-enabling studies.

The obligation to make payments to CFF upon a change of control meets the definition of an embedded derivative that is required to be bifurcated and separately accounted for as a derivative liability. See Note 14, Derivative Liability, for further discussion of the embedded derivative.

Otsuka Pharmaceutical Co., Ltd

On October 31, 2025, the Company entered into a Collaboration and License Agreement ("Otsuka Agreement") with Otsuka Pharmaceutical Co., Ltd. (“Otsuka”). Pursuant to the Otsuka Agreement, the Company granted Otsuka an exclusive royalty-bearing sublicensable license to its intellectual property to develop, manufacture and commercialize 4D-150, its lead product candidate for ophthalmological diseases, in Japan, Korea, China, Australia, and certain other Asia-Pacific markets ("Otsuka Territory"). The Company retains full development and commercialization rights for 4D-150 outside the Otsuka Territory, including the United States, Latin America, and Europe.

Otsuka will lead all regulatory and commercialization activities in the Otsuka Territory. The Company will lead all Phase 3 clinical activity globally, including within the Otsuka Territory. In aggregate, the Company is currently responsible for separate global phase 3 trials for wet age-related macular degeneration ("wet AMD") and diabetic macular edema (“DME”), local clinical trials in the Otsuka Territory as required by local regulatory authorities, and several other studies, including the related regulatory activities and long-term follow up studies. The Company and Otsuka will coordinate and review the development and other activities through a joint steering committee.

The Company also will manufacture and supply 4D-150 to Otsuka for clinical and commercial use at a supply price derived from the Company's manufacturing costs plus a margin.

The Company has received a nonrefundable upfront cash payment of $85.0 million and is eligible to receive quarterly clinical trial cost sharing and reimbursement amounts. In addition, the Company is eligible for up to $335.5 million in potential regulatory and commercial milestone payments and tiered double-digit royalties on net sales in the Otsuka Territory, and subject to royalty reductions under certain circumstances.

The Otsuka Agreement will remain in effect, unless earlier terminated, on a country-by-country basis, until the date that Otsuka is no longer developing or commercializing 4D-150 in such country within the Otsuka Territory. Otsuka may terminate the Otsuka Agreement for convenience, on a country-by-country basis, upon sufficient prior written notice as per the Otsuka Agreement, or due to safety reasons or the failure of certain of the Company’s related clinical trials to achieve their primary endpoints. The Company may terminate the Otsuka Agreement upon notice if Otsuka ceases all development activities and commercialization of 4D-150 in Japan for an agreed upon period as per the Otsuka Agreement and does not resume such activities or commercialization within a specified notice period. Upon termination, any license granted by the Company to Otsuka will terminate.

The Company concluded that Otsuka is a customer and that the arrangement represents a contract with a customer under the scope of ASC 606. The Company identified the following promised goods and services that represent performance obligations:

- the exclusive license to its intellectual property to develop, manufacture and commercialize 4D-150 in the Otsuka Territory,
- performance of separate global phase 3 trials for wet AMD and DME, local clinical trials in the Otsuka Territory as required by the local regulatory authorities, and several other studies, including the associated regulatory and joint steering committee activities. Separate performance obligations were identified for each individual trial or study.

The license was considered functional intellectual property as of the inception of the Otsuka Agreement and distinct from other promises under the contract, as Otsuka can benefit from the license on its own or together with other readily available resources. Each of the clinical trial and other study services were considered distinct as the customer can benefit from these services together with the license transferred at the inception of the Otsuka Agreement. The clinical trial and other study services will not modify or customize the initial intellectual property transferred at contract inception due to the late stage of development of the intellectual property.

The Company concluded manufacturing and supply of 4D-150 for clinical and commercial use does not represent a performance obligation, as these activities are at Otsuka's option. Product supply is priced at standalone selling prices, and therefore does not provide Otsuka with material rights.

To the extent Otsuka requests the Company to supply 4D-150, such supply will be considered a separate contract with the customer.

The initial transaction price includes the upfront cash payment and variable consideration for clinical trials and other studies performance obligations, some of which have started and others that have not yet started as of December 31, 2025. The upfront cash payment is $85 million and was received during the year ended December 31, 2025. The variable consideration in the form of the estimated cost sharing and reimbursement of approximately $40.0 million represents the amount allocated to unsatisfied or partially unsatisfied performance obligations, that have already started as of December 31, 2025, and was allocated entirely to the clinical trials and other studies performance obligations using the variable consideration allocation exception.

The regulatory milestone amounts are not currently probable and have not been included in the transaction price as the amounts are fully constrained. The sales-based commercial milestones and royalties relate to the granted intellectual property license and will be recognized when the related sales occur.

At the end of each reporting period, the Company will re-evaluate the estimated variable consideration and if necessary, adjust the transaction price.

To determine the standalone selling prices of each performance obligation, the Company used significant estimates and assumptions that include but are not limited to, expected market opportunity and pricing, expected future costs of clinical trials and other studies, and timelines and likelihood of success of clinical and regulatory activities. For the standalone selling price of the license, the Company used a discounted cash flow analysis of projected cash flows and potential revenues from the commercial sales of 4D-150 in the Otsuka Territory. To determine the standalone selling prices of the Company's obligations to conduct clinical trials and other studies, the expected cost plus margin approach was used.

Variable consideration to which the Company is entitled to is allocated directly to the associated performance obligations, as it is triggered by the Company's performance or represents specific outcomes from such performance, and the resulting allocation meets the allocation objective.

The upfront amount of $85.0 million was allocated entirely to the license performance obligation and was recognized at a point in time upon the transfer of control during the year ended December 31, 2025.

Revenue attributable to the remaining performance obligations to conduct clinical trials and other studies will be recognized over time as the underlying services are performed, over the period through the completion of program development activities. Progress is measured using an input method based on cumulative cost incurred relative to the total estimated cost of the performance obligation. Estimated progress and the underlying costs will be reviewed and adjusted as necessary at every reporting date. Revenue from clinical trials and other studies performance obligations was immaterial during the quarter and the year ended December 31, 2025.

The transaction price amount allocated to unsatisfied or partially unsatisfied performance obligations, which have started as of December 31, 2025 was approximately $40.0 million, expected to be recognized during 2026 through 2032 as clinical trials and other studies continue. Certain performance obligations have not started as of December 31, 2025 and the related amounts are not included above.

7. License Arrangements

Astellas Gene Therapies, Inc.

On July 5, 2023, the Company entered into a licensing agreement (the "Astellas License Agreement") with Astellas Gene Therapies, Inc. ("AGT"), pursuant to which the Company granted to AGT a license to utilize its intravitreal R100 vector ("4D Vector") to develop and commercialize licensed compounds and licensed products for one genetic target implicated in rare monogenic ophthalmic disease(s), with options to add up to two additional targets implicated in rare monogenic ophthalmic diseases after paying additional option exercise fees. Under the terms of the Astellas License Agreement, the Company has provided its 4D vector technology to AGT to deliver AGT's genetic payloads for the treatment of rare monogenic diseases. AGT will conduct all subsequent research, development, manufacturing, and commercialization activities. As partial consideration for the rights and licenses granted to AGT by the Company under this Astellas License Agreement, AGT paid the Company an upfront amount of $20.0 million, which was received in July 2023. The Company may receive potential future option fees and milestones of up to $942.5 million, including $42.5 million of potential future option fees, $90.0 million potential future development milestones, $120.0 million potential future regulatory milestones and $690.0 million potential future commercial sales milestones. In addition, the Company is entitled to receive mid-single digit to double-digit, sub-teen royalties on net sales of all licensed products.

Under the Astellas License Agreement, the Company's performance obligation is to grant and make available to AGT the Licensed IP and Licensed Know-How (each as defined in the Astellas License Agreement) with respect to the 4D Vector. In connection with the grant of the license, in July 2023, the Company delivered to AGT the Transferred Material (as defined in the Astellas License Agreement). This agreement was terminated by AGT in July 2025 for convenience. The Company did not incur any charges related to the termination of the Astellas License Agreement. As of December 31, 2025, there was no deferred revenue and no accounts receivable relating to the Astellas License Agreement.

Aevitas Therapeutics, Inc. and The Trustees of the University of Pennsylvania

On April 21, 2023, the Company entered into an agreement (the "Aevitas Agreement") with Aevitas Therapeutics, Inc. ("Aevitas"), pursuant to which the Company acquired all of Aevitas' worldwide rights to short-form human complement factor H (sCFH), which the Company plans to use for its 4D-175 product candidate research program. The asset purchase was accounted for as an asset acquisition. As consideration for the Aevitas Agreement, the Company shall pay Aevitas up to approximately $144.1 million in cash upon certain late-stage milestones being achieved, including $7.2 million for development milestones, $68.0 million for regulatory milestones and $68.9 million for sales milestones plus royalties in the low single digits range on sales of 4D-175. In addition, as part of the Aevitas Agreement, the Company was assigned a License Agreement for sCFH with the Trustees of the University of Pennsylvania, under which the Company shall pay the University of Pennsylvania up to approximately $41.6 million in cash upon certain late-stage milestones being achieved, including $1.9 million development, $21.5 million regulatory and $18.2 million sales milestones plus royalties in the low single digits range on sales of 4D-175. No upfront consideration was paid under the Aevitas Agreement.

As of December 31, 2025, the Company has not recorded a liability related to contingent consideration for future milestone and royalty payments to either Aevitas or the University of Pennsylvania, as the achievement of such milestones has not occurred and was not deemed probable and product sales have not commenced.

Regents of the University of California

The Company has exclusive, worldwide license agreements (the "UC Agreements") with the Regents of the University of California (the "UC Regents") relating to the use of certain patents and intellectual property surrounding its core technologies, including Therapeutic Vector Evolution. Pursuant to each of the UC Agreements executed prior to January 2019, the Company was obligated to pay a (i)

non-refundable license fee of $5,000 upon execution, (ii) a non-refundable license fee of $5,000 each year thereafter, until sales of a licensed product are made and royalties are paid to the UC Regents, (iii) reimbursement of domestic and foreign patent filing, prosecution and maintenance fees, and (iv) either $50,000 or issuance of a 3% equity interest in the Company upon the closing of the first qualified financing at the option of the UC Regents. The Company's first qualified financing occurred in 2015 and at the election of the UC Regents, the Company issued the UC Regents in January 2016 an amount of common stock equal to 6% of the equity interests in the Company pursuant to the applicable clause in each of the UC Agreements.

Pursuant to an agreement with the UC Regents executed in January 2019 the Company paid a non-refundable license fee of $50,000 to the UC Regents upon execution of the agreement. The Company is obligated to pay a non-refundable license fee of $5,000 on the one-year anniversary of the contract effective date and each year thereafter, until sales of a licensed product are made and royalties are paid to the UC Regents.

In addition, the Company is obligated to make certain contingent payments including (i) development milestones up to $3.1 million, (ii) low single digit royalties on the net sales of its developed products that consist of a minimum annual royalty of up to $0.1 million per year for the term of the agreement beginning in the first calendar year after the year in which net sales first occurred, and (iii) sublicense consideration in the mid-teens to the mid-twenties-range on any future sublicensing arrangements the Company may enter into with third-party licensees.

As of December 31, 2025, the Company has not recorded a liability related to contingent consideration for future milestone and royalty payments to UC Regents, as the achievement of such milestones has not occurred and was not deemed probable and product sales have not commenced.

8. Commitments and Contingencies

Operating Lease Commitments

5980 Horton Street Building Lease

In May 2015, the Company executed a lease agreement (the "5980 Horton Lease") for office and laboratory space in Emeryville, California. The 5980 Horton Lease, as amended, expires in August 2026. As of December 31, 2025, the right-of-use asset and lease liability related to the 5980 Horton Lease were $0.3 million and $0.4 million, respectively. As of December 31, 2024, the right-of-use asset and lease liability related to the 5980 Horton Lease were $0.8 million and $0.9 million, respectively.

5858 Horton Street Lease and Expansion

In October 2018, the Company executed a lease agreement (the "5858 Horton Lease") for office and laboratory facilities in Emeryville, California. The 5858 Horton Lease, as amended in 2019, 2021 and 2022, consists of approximately 40,802 square feet of space and has a lease term through December 31, 2029. In July 2024, the Company extended the term of the 5858 Horton Lease for a period of twelve months to December 31, 2030. In accordance with ASC Topic 842, *Leases*, the Company accounted for the extension as a modification and remeasured the lease liability based on the new lease term and an updated, estimated incremental borrowing rate of 10.75%. The modification resulted in an increase to the lease liability of $0.8 million and a corresponding increase to the carrying value of the right-of-use asset. No gain or loss was recognized upon the modification. As of December 31, 2025, the right-of-use asset and lease liability related to the 5858 Horton Lease was $8.8 million and $11.2 million, respectively. As of December 31, 2024, the right-of-use asset and lease liability related to the 5858 Horton Lease were $9.9 million and $12.6 million, respectively.

In July 2024, the Company also entered into a lease agreement for additional office and laboratory space in Emeryville, California (the "5858 Horton Expansion Lease"). The 5858 Horton Expansion Lease consists of approximately 32,038 square feet of space and commenced on September 1, 2024 and has a

lease term through December 31, 2030. As of December 31, 2025, the right-of-use asset and lease liability related to the 5858 Horton Expansion Lease were $7.8 million and $8.6 million, respectively. As of December 31, 2024, the right-of-use asset and lease liability related to the 5858 Horton Expansion Lease were $8.9 million and $9.6 million, respectively. The discount rate used to measure the lease liability was 11.02%.

Emeryville Warehouse Lease

In January 2024, the Company entered into a lease agreement for warehouse space in Emeryville, California (the "Warehouse Lease"). The Warehouse Lease commenced on August 1, 2024. The Warehouse Lease consists of approximately 7,800 square feet of warehouse space and has a lease term through December 31, 2029. As of December 31, 2025, the right-of-use asset and lease liability related to the Warehouse Lease were each $1.2 million. As of December 31, 2024, the right-of-use asset and lease liability related to the Warehouse Lease were each $1.5 million. The discount rate used to measure the lease liability related to the Warehouse Lease was 10.69%.

The following table summarizes the components of lease expense for the years ended December 31, 2025 and 2024, which are included in operating expenses in the Company's statements of operations (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease cost	$ 5,375	$ 3,696
Variable lease cost	2,764	1,829
Total	$ 8,139	$ 5,525

Variable lease payments include amounts relating to common area maintenance and are recognized in the statements of operations as incurred.

Cash paid for amounts included in the measurement of the Company's operating lease liabilities and presented within cash used in operating activities in the statements of cash flows was $5.6 million and $3.3 million for the years ended December 31, 2025 and 2024, respectively.

The following table summarizes supplemental information related to operating leases:

	Year Ended December 31,	
	2025	2024
Weighted-average remaining lease term (in years):	4.8	5.7
Weighted-average discount rate:	10.8%	10.7%

The following table summarizes the maturities of lease liabilities as of December 31, 2025 (in thousands):

2026	$ 5,601
2027	5,350
2028	5,510
2029	5,675
2030	5,455
Total future minimum lease payments	27,591
Less: Amount representing interest	(6,178)
Present value of future minimum lease payments	21,413
Less: Current portion of operating lease liabilities	(5,592)
Long-term portion of operating lease liabilities	$ 15,821

Indemnification Agreements

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions, such as with vendors and other parties. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently maintains directors' and officers' liability insurance that would generally enable it to recover a portion of any future amounts paid. The Company believes the estimated fair value of its indemnification agreements in excess of applicable insurance coverage is not material.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of its business. If applicable, the Company records a legal liability when it believes that it is both probable that a liability may have been incurred, and the amount of the liability can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. There are no material legal proceedings outstanding at December 31, 2025.

9. Income Taxes

The Company did not record any income tax expense during the years ended December 31, 2025 and 2024. The Company has a net operating loss and has provided a valuation allowance against net deferred tax assets due to uncertainties regarding the Company's ability to realize these assets. All losses before income taxes arose in the United States.

The Company adopted ASU No. 2023-09 for the 2025 calendar year prospectively. The effective tax rate of the Company's income tax expense (benefit) differs from the federal statutory rate pursuant to the disclosure requirements of ASU No. 2023-09 for the year ended December 31, 2025 as follows (in thousands):

	Year Ended December 31, 2025	
	Amount	Percent
US federal statutory income tax rate	$ (29,423)	21.0%
Research tax credit	(3,309)	2.4%
Change in valuation allowance	29,664	(21.2)%
Nondeductible items:		
Stock-based compensation	2,509	(1.8)%
Officer's compensation	363	(0.3)%
Permanent differences	196	(0.1)%
Provision for income taxes / Effective tax rate	$ —	0.0%

The effective tax rate of the Company's income tax expense (benefit) differs from the federal statutory rate for the year ended December 31, 2024 as follows:

	Year Ended December 31, 2024
Federal statutory income tax rate	21.0%
State tax rate	(7.6)%
Research tax credit	(4.8)%
Permanent differences	(0.1)%
Stock-based compensation	(0.5)%
Officer's compensation	(1.4)%
Valuation allowance	(6.6)%
Provision for income taxes	0.0%

The tax effects of temporary differences that give rise to significant components of the deferred taxes are as follows (in thousands):

	December 31,	
	2025	2024
Deferred Tax Assets		
Net operating loss carryforwards	$ 74,366	$ 72,385
Deferred revenue	232	254
Research tax credits	11,372	7,235
Stock-based compensation expense	6,777	5,336
Intangible asset basis	618	689
Operating lease liabilities	4,502	5,168
Capitalized research expenditures	62,343	40,345
Other	3,490	2,321
Total deferred tax assets	$ 163,700	$ 133,733
Deferred Tax Liabilities		
Operating lease right-of-use assets	$ (3,814)	$ (4,426)
Prepaid expenses	(1,331)	(1,223)
Total deferred tax liabilities	$ (5,145)	$ (5,649)
Less: valuation allowance	(158,555)	(128,084)
Total net deferred tax	$ —	$ —

The Company's valuation allowance increased by $30.5 million during the year ended December 31, 2025 and $10.6 million during the year ended December 31, 2024. The increase in the valuation allowance for each of the years ended December 31, 2025 and 2024 was primarily driven by net losses incurred, capitalized research expenditures, stock-based compensation expense and tax credits generated within the U.S.

The Company had federal net operating loss ("NOL") carryforwards of $307.6 million and $298.3 million as of December 31, 2025 and 2024, respectively, of which $9.5 million will begin to expire in 2037 and $298.1 million can be carried forward indefinitely. The Company had state NOL carryforwards of $142.3 million and $142.2 million as of December 31, 2025 and 2024, respectively. The state NOL carryforwards will begin to expire in 2036.

As of December 31, 2025 and 2024, the Company had federal research and development credit carryforwards of $9.9 million and $3.3 million, respectively, and California research and development credit carryforwards of $14.6 million and $12.5 million, respectively. The federal credit carryforwards begin to expire in 2044, and the California credits can be carried forward indefinitely.

Utilization of the NOL carryforwards and research credit carryforwards may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code Sections 382 and 383, and similar state provisions. Annual limitations may result in the expiration of the NOL and tax credit carryforwards before they are utilized. The Company has experienced ownership changes in the past. As a result of the ownership changes, approximately $21.1 million of the federal research and development credits are permanently limited and will expire unused for federal income tax purposes, and such amounts are excluded from the federal research and development credit carryforwards as of 2024. Subsequent ownership changes may result in additional limitations.

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

	Unrecognized Income Tax Benefits
Balance as of December 31, 2023	$ 11,902
Additions for current year tax positions	2,914
Reductions for tax positions of prior years	(7,738)
Balance as of December 31, 2024	7,078
Additions for current year tax positions	4,357
Reductions for tax positions of prior years	—
Balance as of December 31, 2025	$ 11,435

The unrecognized tax benefits would not impact the Company's effective tax rate if recognized. During the years ended December 31, 2025 and 2024, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits.

The Company files income tax returns in the U.S. federal and certain state tax jurisdictions. For jurisdictions in which tax filings have been filed, all tax years remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating losses or credits. The Company did not make any material federal and state tax payments during the years ended December 31, 2025 and 2024. The Company has no ongoing income tax examinations by tax authorities at this time.

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBB Act") was enacted, introducing amendments to U.S. tax laws with various effective dates from 2025 to 2027. The OBBB Act modified certain business deductions, including an immediate deduction for domestic research and development expenditures, and restoration of 100% bonus depreciation. The OBBB Act did not result in a material impact to the Company's income tax provision or effective tax rate.

10. Common Stock

As of December 31, 2025 and 2024, the Company's certificate of incorporation authorized the Company to issue 300,000,000 shares of common stock, at the par value of $0.0001 per share. The holder of each share of common stock is entitled to one vote per share.

Common stockholders are entitled to dividends if and when declared by the board of directors, subject to the prior rights of the preferred stockholders. As of December 31, 2025 and 2024, no dividends on common stock had been declared by the board of directors.

The Company has reserved common stock, on an as-converted basis, for future issuance as follows:

	December 31,	
	2025	2024
Issuance of common stock under the 2020 Equity Incentive Award Plan and 2025 Employment Inducement Award Plan	2,506,434	975,060
Issuance of common stock under the 2020 Employee Stock Purchase Plan	182,775	192,598
Exercise of stock options issued and outstanding and future vesting of restricted stock units	10,157,578	9,698,997
Exercise of common stock warrants	10,365,665	9,947,145
Total common stock reserved for future issuance	23,212,452	20,813,800

Funding Agreement with CFF — In April 2020, CFF made a $10.0 million investment in the Company's Series C redeemable convertible preferred stock financing. In return for the investment, CFF received shares of Series C redeemable convertible preferred stock, and the Company and CFF entered into a Funding Agreement (the "Funding Agreement"). Pursuant to the terms of the Funding Agreement, except in the event of a technical failure, the $10.0 million received from CFF will be used to advance the development program for 4D-710, the Company's lead product in cystic fibrosis, or any other therapeutic approved by the Program Advisory Group ("PAG") to alleviate pulmonary complications of cystic fibrosis (the "Funding Agreement Product").

CFF committed to provide an additional $4.0 million of funding upon acceptance of an IND application or its equivalent to allow for human testing of the Funding Agreement Product ("Acceptance").

In October 2021, the IND was cleared by the U.S. Food and Drug Administration and CFF made the additional investment of $4.0 million in cash for the issuance of 125,715 shares of the Company's common stock to CFF.

The Company was committed to providing an amount equal to the funding provided by CFF to be used solely to advance the Funding Agreement Product. As of December 31, 2025, the funding commitment has been fulfilled. Under the terms of the Funding Agreement, neither the $10.0 million investment in the Series C redeemable convertible preferred stock, which converted to common stock as of December 31, 2020, nor the $4.0 million of funding upon Acceptance are restricted as to withdrawal or usage.

CFF purchased 776,398 shares of the Company's common stock for $7.5 million in October 2025. The Company will use the proceeds of this investment to support continued development of 4D-710. The Company also agreed with CFF to form a Joint Steering Committee, with senior clinical development and regulatory expertise to enhance strategic planning, guidance, and coordination of 4D-710's development. This agreement between CFF and the Company in October 2025 also provides that CFF will invest an additional $3.6 million in exchange for shares of the Company's common stock subject to achievement of specific clinical milestones and at the option of the Company. This agreement between the Company and CFF in October 2025 does not modify the prior agreements with CFF.

Sales Agreement with Jefferies LLC ("Jefferies") — In March 2022, the Company entered into an Open Market Sales Agreement (the "Jefferies Sales Agreement") with Jefferies as sales agent to sell shares of the Company's common stock, from time to time, with aggregate gross sales proceeds of up to $100.0 million pursuant to the S-3 Registration Statement as an "at-the-market" ("ATM") offering under the Securities Act (the "2022 ATM Offering Program"). During the year ended December 31, 2024, 535,938 shares of the Company's common stock had been sold pursuant to the Jefferies Sales Agreement for net proceeds to the Company of $15.3 million, after deducting issuance costs. On May 31, 2024, the Company terminated the Jefferies Sales Agreement and the 2022 ATM Offering Program pursuant to the terms of the Jefferies Sales Agreement. As of the point of termination, 1,684,550 shares of the Company's common stock had been sold pursuant to the Jefferies Sales Agreement for net proceeds to the Company of $34.4 million, after deducting issuance costs.

Sales Agreement with Leerink Partners LLC ("Leerink") — In June 2024, the Company entered into a Sales Agreement (the "Leerink Sales Agreement") with Leerink as sales agent to sell shares of the Company's common stock, from time to time, with aggregate gross sales proceeds of up to $250.0 million pursuant to a Registration Statement on Form S-3 that the Company filed with the SEC in February 2024, and subsequently amended in February 2025, as an ATM offering under the Securities Act. For the year ended December 31, 2025, 1,175,000 shares of the Company's common stock were sold pursuant to the Leerink Sales Agreement for net proceeds to the Company of $9.6 million, after deducting issuance costs. For the year ended December 31, 2024, no shares had been sold pursuant to the Leerink Sales Agreement.

11. Stock-based Compensation

2025 Employment Inducement Award Plan

On February 3, 2025, the Company's board of directors adopted the 2025 Employment Inducement Plan (the "Inducement Plan") pursuant to which the Company reserved 500,000 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market. The Inducement Plan provides for the grant of stock options, restricted stock units, and other stock-based awards. As of December 31, 2025, there were 262,650 shares available for future grants under the Inducement Plan.

2020 Incentive Award Plan

In December 2020, the Company adopted the 2020 Incentive Award Plan ("2020 Plan"), which became effective on December 10, 2020. The 2020 Plan initially reserved 2,606,546 shares of common stock for the issuance of stock options, stock appreciation rights, restricted stock awards, restricted stock units, performance bonus awards, performance stock units, dividend equivalents or other stock or cash based award granted to employees, directors and consultants of the Company. The number of shares reserved for future issuance under the 2020 Plan will increase annually on the first day of each fiscal year beginning in 2021 and ending in 2030 by the lesser of (i) 5% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the Company's board of directors, provided, however, no more than 18,000,000 shares of the Company's common stock may be issued upon the exercise of incentive stock options. As a result of the operation of the automatic annual increase provision of the 2020 Plan, an additional 2,153,533 shares of common stock became available for issuance on February 29, 2024 and an additional 2,289,625 shares of common stock became available for issuance on February 28, 2025, under the 2020 Plan. All stock options are exercisable over a period not to exceed the contractual term of ten years from the date the stock options were issued. As of December 31, 2025, there were 2,243,784 shares available for grant under the 2020 Plan.

Following the effectiveness of the 2020 Plan, the Company will not make any further grants under the 2015 Equity Incentive Plan (the "2015 Plan"). However, the 2015 Plan continues to govern the terms of stock options that remain outstanding under the 2015 Plan.

2015 Equity Incentive Plan

The 2015 Plan provided for grants of stock options, stock appreciation rights, restricted stock and restricted stock unit awards to employees, directors and consultants of the Company. As of December 31, 2025, stock options to purchase 1,346,450 shares of common stock were outstanding under the 2015 Plan. All stock options are exercisable over a period not to exceed the contractual term of ten years from the date the stock options were issued and are granted at prices not less than the estimated fair market value of the Company's common stock on the grant date as determined by the board of directors.

No additional grants will be made under the 2015 Plan, and all outstanding grants under the 2015 Plan that are repurchased, forfeited, expire or are cancelled are returned to the 2015 Plan and are not available for grant under the 2020 Plan.

Employee Stock Purchase Plan

In December 2020, the Company adopted the 2020 Employee Stock Purchase Plan (the "2020 ESPP"). Under the 2020 ESPP, 252,337 shares of the Company's common stock were initially reserved for employee purchases of the Company's common stock under terms and provisions established by the Company's board of directors and approved by the Company's stockholders. The number of shares reserved for future issuance under the 2020 ESPP will increase annually on the first day of each fiscal year beginning in 2021 and ending in 2030 by the lesser of (i) 1% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the Company's board of directors, provided, however, no more than 15,000,000 shares the Company's common stock may be issued under the 2020 ESPP. As a result of the operation of this annual increase provision of the 2020 ESPP, an additional 50,000 shares of common stock became available on February 29, 2024 and an additional 150,000 shares of common stock became available for issuance on February 28, 2025, under the 2020 ESPP.

Under the 2020 ESPP, the Company's employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The 2020 ESPP provides for a series of overlapping 24-month offering periods comprising four six-month purchase periods. The initial offering period under the 2020 ESPP is longer than 24 months, commencing February 15, 2021 and ending on May 14, 2023. Contributions under the 2020 ESPP are limited to a maximum of 15% of an employee's eligible compensation.

Restricted Stock Units

The Company has granted restricted stock unit ("RSU") awards under the 2020 Plan and the Inducement Plan that vest over a period of four years. The following table summarizes the RSU activity:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Unvested balance at December 31, 2024	361,997	$ 16.87	1.76	$ 2,016
Awarded	742,354	5.34		
Vested	(158,231)	12.45		
Canceled/Forfeited	(201,350)	10.03		
Unvested balance at December 31, 2025	744,770	$ 8.16	1.70	$ 5,586

Stock Options

The following table summarizes the stock options activity:

	Options Outstanding			
	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	9,337,000	$ 16.39	7.44	$ 342
Options granted	2,395,799	5.84		
Options exercised	(163,103)	6.03		
Options expired	(652,859)	16.77		
Options forfeited	(1,504,029)	12.19		
Outstanding at December 31, 2025	9,412,808	$ 14.53	6.12	$ 4,560
Shares exercisable, December 31, 2025	5,727,476	$ 16.90	4.91	$ 999
Shares vested and expected to vest, December 31, 2025	9,412,808	$ 14.53	6.12	$ 4,560

The following table is a summary of stock compensation expense for employees and nonemployees by function (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 11,831	$ 13,819
General and administrative	10,185	12,297
Total stock-based compensation expense	$ 22,016	$ 26,116

The total intrinsic value of stock options exercised was $0.7 million and $5.6 million for the years ended December 31, 2025 and 2024, respectively. During the years ended December 31, 2025 and 2024, the Company granted 2,384,549 and 1,821,891 stock options to employees with a weighted-average grant date fair value of $4.42 and $19.32 per share, respectively. During the years ended December 31, 2025 and 2024, the Company granted 11,250 and 12,000 stock options to nonemployees with a weighted-average grant date fair value of $2.04 and $18.55 per share, respectively. As of December 31, 2025, the

unrecognized stock-based compensation expense of unvested stock options and RSUs was $34.2 million and is expected to be recognized over a weighted-average period of 1.7 years.

There were no share-based liabilities paid during the years ended December 31, 2025 and 2024.

Stock-based compensation expense recorded for employees was $20.3 million and $24.4 million for the years ended December 31, 2025 and 2024, respectively. Stock-based compensation expense recorded for nonemployee consultants was $1.7 million for each of the years ended December 31, 2025 and 2024.

The Company estimates the fair value of employee and nonemployee stock options using the Black-Scholes option pricing model. The fair value of employee and nonemployee stock options is recognized on a straight-line basis over the requisite service period of the awards. The fair value of the Company's stock options was estimated using the following assumptions for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Expected term	5.9 - 6.1 years	5.9 - 6.1 years
Expected volatility	84.9% - 91.1%	85.8% - 88.1%
Risk-free interest rate	3.7% - 4.6%	3.9% - 4.4%
Expected dividend yield	—%	—%

Expected Term. The expected term for employee stock options is calculated using the simplified method as the Company does not have sufficient historical information to provide a basis for this estimate. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. The expected term for nonemployee stock options is the contractual term of the options.

Expected Volatility. The expected volatility is based on a mix of the Company's historical volatility and the historical volatility of comparable companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. For each grant, the Company measured historical volatility over a period equivalent to the expected term.

Risk-free Interest Rate. The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues whose term is similar in duration to the expected term of the respective stock option.

Expected Dividend Yield. The Company has not paid and does not anticipate paying any dividends on its common stock in the future. Accordingly, the Company has estimated the dividend yield to be zero percent.

12. Common Stock Warrants

In May 2018, the Company issued a warrant for 23,669 shares of the Company's common stock to a service provider with an exercise price of $3.19 per share. The fair value of the warrant was determined at the issuance date using the Black-Scholes option pricing model. The warrant was fully vested upon issuance and was exercised in May 2025 through a cashless exchange under the terms of the original agreement.

In December 2020, the Company issued a warrant for 30,000 shares of the Company's common stock to a service provider with an exercise price of $18.00 per share. This warrant vests over a period of four years and expires in 2027. The fair value of the warrant was determined at the issuance date using the Black-Scholes option pricing model.

The Company recognized no expense related to the above warrant shares during the year ended December 31, 2025. The Company recorded less than $0.1 million expense for the above warrants within operating expenses in the statements of operations during the year ended December 31, 2024.

In February 2024, the Company completed an underwritten public follow-on offering which included the sale of pre-funded warrants (the "Pre-funded Warrants") to purchase 3,583,476 shares of the Company's common stock at an offering price of $29.4999. The exercise price of each Pre-funded Warrant is $0.0001 per share, and each Pre-funded Warrant is exercisable from the date of issuance. The Pre-funded Warrants are classified as a component of stockholders' equity within additional paid-in-capital. The Company valued the Pre-funded Warrants at issuance and recorded net proceeds of $99.4 million, after deducting underwriters fees, during the year ended December 31, 2024 related to the sale of the Pre-funded Warrants. In February 2025, two holders of the Pre-funded Warrants gave notice of exercise to purchase an aggregate of 508,476 shares of the Company's common stock in a cashless exchange under the terms of the Pre-funded Warrants.

In November and December 2024, the Company entered into exchange agreements (the "Exchange Agreements") with each of Biotechnology Value Fund, L.P. and certain of its affiliates (collectively, "BVF") and RA Capital Healthcare Fund, L.P. ("RA Capital"), respectively. Pursuant to Exchange Agreements, BVF and RA Capital exchanged 5,775,000 and 535,000 shares, respectively, of the Company's common stock for pre-funded warrants to acquire the same respective number of shares of the Company's common stock. The pre-funded warrants have an exercise price of $0.0001 per underlying share of common stock, are exercisable at any time until they are fully exercised and will not expire until they are fully exercised. The Pre-funded Warrants are classified as a component of stockholders' equity within additional paid-in-capital. The number of shares of the Company's common stock issuable upon exercise of each pre-funded warrant is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting shares of the Company's common stock, as well as upon any distribution of assets, including cash, stock or other property, to the Company's stockholders. The fair value of the common stock exchanged approximated the fair value of the pre-funded warrants issued as of the transaction dates and no net proceeds were recorded in connection with the transactions. On December 22, 2025, BVF gave notice of exercise to purchase an aggregate of 178,280 shares of the Company's common stock in a cashless exchange under the terms of the pre-funded warrants.

In November 2025, the Company completed the 2025 Offering which included the sale of pre-funded warrants to purchase 1,128,949 shares of the Company's common stock at an offering price of $10.5099 per underlying share. The exercise price of each pre-funded warrant is $0.0001 per share, and each pre-funded warrant is exercisable from the date of issuance. The pre-funded warrants are classified as a component of stockholders' equity within additional paid-in-capital. The Company valued the pre-funded warrants at issuance and recorded net proceeds of $11.2 million, after deducting underwriters fees, during the year ended December 31, 2025.

13. Net Loss Per Share, Basic and Diluted

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Year Ended December 31,	
	2025	2024
Numerator		
Net loss	$ (140,109)	$ (160,868)
Denominator		
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	57,930,180	53,943,741
Net loss per share, basic and diluted	$ (2.42)	$ (2.98)

In February 2024, the Company issued and sold pre-funded warrants to purchase 3,583,476 shares of common stock at a nominal exercise price of $0.0001. In November and December 2024, the Company entered into Exchange Agreements with BVF and RA Capital to exchange 5,775,000 and 535,000 shares, respectively, of the Company's common stock for pre-funded warrants to acquire the same respective

number of shares of the Company's common stock. The pre-funded warrants have an exercise price of $0.0001 per underlying share of common stock. In November 2025, the Company issued and sold pre-funded warrants to purchase 1,128,949 shares of the Company's common stock. The pre-funded warrants have an exercise price of $0.0001 per underlying share of common stock (see Note 12, Common Stock Warrants). The shares of common stock into which the Pre-funded Warrants may be exercised are considered outstanding for the purposes of computing earnings per share, because the shares may be issued for little or no consideration, they are fully vested and the Pre-funded Warrants are immediately exercisable upon their issuance date.

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	December 31,	
	2025	2024
Options issued and outstanding	9,412,808	9,337,000
Restricted stock units subject to future vesting	744,770	361,997
2020 ESPP	364,443	774,897
Common stock warrants	30,000	53,669
Total	10,552,021	10,527,563

14. Derivative Liability

The Company identified an embedded derivative resulting from the change of control provision in the CFF Agreement. Embedded derivatives that are required to be bifurcated from the underlying host instrument are accounted for and valued as separate financial instruments. At the inception of the derivative in 2017, the Company recognized this derivative as a liability and revenue was reduced by the initial fair value of the derivative liability. The Company remeasures the derivative liability to fair value at each reporting period and records the change in fair value of the derivative liability as other income (expense), net. The Company uses a present value analysis with multiple scenarios, which incorporates assumptions and estimates to value the derivative instrument. The Company assesses these assumptions and estimates on a periodic basis as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the change of control payment to CFF (range of zero to $18.9 million at December 31, 2025 and 2024), the probability of a change of control event (range of 5.0% to 50.0% at December 31, 2025 and 2024), the probability of the product achieving development or commercial status at time of change of control (range of 4.8% to 17.2% at December 31, 2025 and 2024) and the discount rate (15% at December 31, 2025 and 2024). The Company determined the estimated fair value of this liability as of the inception date of the CFF Agreement and concluded that the amount was immaterial. The Company determined the fair value of this derivative liability was $0.4 million as of each of December 31, 2025 and 2024.

15. Related Party Transactions

In March 2024, the Company entered into a research and option agreement (the “Reignite Agreement”) with Reignite Therapeutics Inc. (“Reignite”), which was founded by David Kirn, M.D., Chief Executive Officer of the Company. Reignite has the expertise to develop high-capacity, helper-dependent adenovirus capsids which the Company plans to utilize as they expand their therapeutic capsid evolution platform. Reignite and the Company plan to collaborate on a one-to-two year program to develop these high capacity, helper-dependent adenovirus capsids. Under the Reignite Agreement, the Company shall have the final authority to amend and make updates to the plan and budget of the program. Further, the Company is responsible for the funding of the related research which includes the budgeted full-time employees and CRO costs, equipment costs not to exceed $60 thousand and all other costs, in total not to exceed $1.5 million in any year of the program. The Company will have an option to acquire up to three capsids resulting from the program. The Company shall pay to Reignite an option exercise fee of $1.0 million per selected capsid for which the Company has exercised its option. The maximum total amount payable is $3.0 million.

During the years ended December 31, 2025 and 2024, the Company paid Reignite $1.1 million and $0.8 million, respectively, for research and development expenses. As of December 31, 2025, the Company owes $0.2 million to Reignite for unpaid research and development expense. No option exercise fees were incurred during year ended December 31, 2025.

In 2024, an immediate family member of the Company's President and Chief Operating Officer was employed in the Company's Information Technology department. During the year ended December 31, 2025, the Company paid an immaterial amount of compensation and granted equity awards consisting of RSUs and stock options with an immaterial aggregate grant date fair value.

16. 401(k) Plan

In 2014, the Company adopted a 401(k) plan for all employees who have met certain eligibility requirements. The 401(k) plan allows employees to make pre-tax and post-tax contributions up to the maximum allowable amount set by the Internal Revenue Service. The Company made contributions to the 401(k) plan for all eligible participants and recorded contribution expenses of $2.2 million and $1.6 million for the years ended December 31, 2025 and 2024, respectively.

17. Segment Information

The Company operates in a single operating and reportable segment, which includes all activities related to discovery, development and commercialization of durable and disease-targeted therapeutics. The determination of a single business segment is consistent with the financial information regularly provided to the Company's chief operating decision maker (the "CODM") who manages the business activities on a consolidated basis. The Company's CODM is its Chief Executive Officer who assesses performance for the business and decides how to allocate resources based on net loss that also is reported on the statements of operations. In making this assessment, the CODM reviews and evaluates net loss to monitor budget versus actual results and to analyze cash flows for purposes of allocating resources and assessing financial performance.

In addition to the significant expense categories included within net loss presented in the Company's statements of operations, the following table provides disaggregated amounts that comprise research and development expenses (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development trials and consumables expenses	$ 100,220	$ 64,757
Payroll and personnel expenses	67,345	57,383
Facilities and other research and development expenses	28,131	19,159
Total research and development expenses	$ 195,696	$ 141,299

The measure of segment assets is reported on the balance sheets as total assets. As of December 31, 2025 and 2024, all of the Company's long-lived assets were located in the United States. The Company's revenues by geographic region, based on the location of the customer, is disclosed in Note 2, Summary of Significant Accounting Policies.

18. Restructuring and Other Charges

On July 2, 2025, the Company announced a workforce reduction of approximately 25% of current and planned roles in July 2025, primarily in the areas supporting early-stage research and development and support functions to implement a strategic pipeline prioritization to focus on the development of 4D-150 and 4D-710. The Company recorded $3.2 million for severance benefits and related termination costs included in research and development expenses in the Company's statements of operations for the year ended December 31, 2025. There are no future payments in connection with the workforce reduction.

19. Subsequent Events

On January 22, 2026, the Company entered into exchange agreements with RA Capital and BVF and its affiliates, pursuant to which RA Capital exchanged 4,850,000 shares of the Company's common stock for a pre-funded warrant to acquire 4,850,000 shares of the Company's common stock, and BVF exchanged 1,750,000 shares of the Company's common stock for a pre-funded warrant to acquire 1,750,000 shares of the Company's common stock. The pre-funded warrants have an exercise price of $0.0001 per underlying share of common stock, are exercisable at any time until they are fully exercised, and will not expire until they are fully exercised. The number of shares of the Company's common stock issuable upon exercise of the pre-funded warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company's shares of common stock, as well as upon any distribution of assets, including cash, stock or other property, to the Company's stockholders. The fair value of the common stock exchanged approximated the fair value of the pre-funded warrants issued as of the transaction dates and no net proceeds were recorded in connection with the transactions.

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2025, 4D Molecular Therapeutics, Inc. had one class of common stock registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation, our amended and restated bylaws, the forms of pre-funded warrants issued to holders and the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, each of which is incorporated herein by reference as an exhibit to the Annual Report on Form 10-K filed with the Securities and Exchange Commission, of which this Exhibit 4.1 is a part.

Authorized Capital Stock

Our authorized capital stock consists of 300,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share. Unless our board of directors determines otherwise, we will issue all shares of our capital stock in uncertificated form.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66 2/3% of the voting power of all of the then outstanding voting stock is required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, such as the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control or other corporate action. As of December 31, 2025, no shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

Warrants

Pre-Funded Warrants

As of March [16], 2026, pre-funded warrants to purchase up to [16,935,665] shares of our common stock were outstanding.

February 2024 Pre-Funded Warrants

On February 6, 2024, pursuant to an underwritten follow-on public offering, we sold shares of our common stock and pre-funded warrants to purchase up to 3,583,476 shares of our common stock (the "February 2024 Pre-Funded Warrants").

The February 2024 Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock and are exercisable from the date of issuance until exercised in full, subject to an ownership limitation. The exercise price of the February 2024 Pre-Funded Warrants and the number of shares of common stock issuable upon exercise of the February 2024 Pre-Funded Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our shares of common stock, as well as upon any distribution of assets, including cash, stock or other property, to our stockholders.

We issued the February 2024 Pre-Funded Warrants as individual warrant agreements to the purchasers. A holder of a February 2024 Pre-Funded Warrant agreement may exercise such February 2024 Pre-Funded Warrant, in whole or in part, with the notice of exercise form attached to the February 2024 Pre-Funded Warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price for the number of February 2024 Pre-Funded Warrants being exercised.

Under the terms of the February 2024 Pre-Funded Warrants, a holder will not be entitled to exercise any portion of a February 2024 Pre-Funded Warrant that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of common stock beneficially owned by such holder (together with its affiliates) to exceed 4.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise; or (ii) the combined voting power of our securities beneficially owned by such holder (together with its affiliates) to exceed 4.99% of the combined voting power of all of our securities outstanding immediately after giving effect to the exercise, as such percentage ownership is set forth in accordance with the terms of the February 2024 Pre-Funded Warrants.

The holders of the February 2024 Pre-Funded Warrants must pay the exercise price upon exercise of the February 2024 Pre-Funded Warrants, unless such holders are utilizing the cashless exercise provision of the February 2024 Pre-Funded Warrants. The February 2024 Pre-Funded Warrants may be exercised at such time by means of a "cashless exercise" in which, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise the net value of the February 2024 Pre-Funded Warrant in shares of common stock determined according to a formula set forth in the February 2024 Pre-Funded Warrants.

In the event of certain fundamental transactions (as described in the February 2024 Pre-Funded Warrants), a holder of February 2024 Pre-Funded Warrants will be entitled to receive, upon exercise of the February 2024 Pre-Funded Warrants, the kind and amount of securities, cash or other property that such holder would have received had they exercised the February 2024 Pre-Funded Warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the February 2024 Pre-Funded Warrants.

Exchange Pre-Funded Warrants

On November 8, 2024, we entered into an exchange agreement with Biotechnology Value Fund, L.P. and certain of its affiliates ("BVF"), pursuant to which BVF exchanged shares of our common stock for pre-funded warrants to acquire the same number of shares of our common stock. On December 6, 2024, we entered into an exchange agreement with RA Capital Healthcare Fund, L.P. ("RA Capital"), pursuant to which RA Capital exchanged shares of our common stock for a pre-funded warrant to acquire the same number of shares of our common stock. On January 22, 2026, we entered into exchange agreements with RA Capital and BVF, pursuant to which RA Capital and BVF exchanged shares of our common stock for a pre-funded warrant to acquire the same number of shares of our common stock (the pre-funded warrants issued to BVF and RA Capital together, the "Exchange Pre-Funded Warrants").

The Exchange Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock and are exercisable from the date of issuance until exercised in full, subject to an ownership limitation. The exercise price of the Exchange Pre-Funded Warrants and the number of shares of common stock issuable upon exercise of the Exchange Pre-Funded Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our shares of common stock, as well as upon any distribution of assets, including cash, stock or other property, to our stockholders.

We issued the Exchange Pre-Funded Warrants as individual warrant agreements to BVF and RA Capital respectively. The holders may exercise their Exchange Pre-Funded Warrants, in whole or in part, with the notice of exercise form attached to the Exchange Pre-Funded Warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price for the number of Exchange Pre-Funded Warrants being exercised.

Under the terms of the Exchange Pre-Funded Warrants, a holder will not be entitled to exercise any portion of an Exchange Pre-Funded Warrant that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of common stock beneficially owned by such holder (together with its affiliates) to exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise; or (ii) the combined voting power of our securities beneficially owned by such holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of our securities outstanding immediately after giving effect to the exercise, as such percentage ownership is set forth in accordance with the terms of the Exchange Pre-Funded Warrants.

The holders of Exchange Pre-Funded Warrants must pay the exercise price upon exercise of the Exchange Pre-Funded Warrants, unless such holders are utilizing the cashless exercise provision of the Exchange Pre-Funded Warrants. The Exchange Pre-Funded Warrants may be exercised at such time by means of a "cashless exercise" in which, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise the net value of the Exchange Pre-Funded Warrant in shares of common stock determined according to a formula set forth in the Exchange Pre-Funded Warrants.

In the event of certain fundamental transactions (as described in the Exchange Pre-Funded Warrants), the holders of Exchange Pre-Funded Warrants will be entitled to receive, upon exercise of the Exchange Pre-Funded Warrants, the kind and amount of securities, cash or other property that such holder would have received had they exercised the Exchange Pre-Funded Warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the Exchange Pre-Funded Warrants.

November 2025 Pre-Funded Warrants

On November 6, 2025, pursuant to an underwritten follow-on public offering, we sold shares of our common stock and pre-funded warrants to purchase up to 1,128,949 shares of our common stock (the "November 2025 Pre-Funded Warrants").

The November 2025 Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock and are exercisable from the date of issuance until exercised in full, subject to an ownership limitation. The exercise price of the November 2025 Pre-Funded Warrants and the number of shares of common stock issuable upon exercise of the November 2025 Pre-Funded Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our shares of common stock, as well as upon any distribution of assets, including cash, stock or other property, to our stockholders.

We issued the November 2025 Pre-Funded Warrants as individual warrant agreements to the purchasers. A holder of a November 2025 Pre-Funded Warrant agreement may exercise such November 2025 Pre-Funded Warrant, in whole or in part, with the notice of exercise form attached to the November 2025 Pre-Funded Warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price for the number of November 2025 Pre-Funded Warrants being exercised.

Under the terms of the November 2025 Pre-Funded Warrants, a holder will not be entitled to exercise any portion of a November 2025 Pre-Funded Warrant that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of common stock beneficially owned by such holder (together with its affiliates) to exceed 4.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise; or (ii) the combined voting power of our securities beneficially owned by such holder (together with its affiliates) to exceed 4.99% of the combined voting power of all of our securities outstanding immediately after giving effect to the exercise, as such percentage ownership is set forth in accordance with the terms of the November 2025 Pre-Funded Warrants.

The holders of the November 2025 Pre-Funded Warrants must pay the exercise price upon exercise of the November 2025 Pre-Funded Warrants, unless such holders are utilizing the cashless exercise provision of the November 2025 Pre-Funded Warrants. The November 2025 Pre-Funded Warrants may be exercised at such time by means of a "cashless exercise" in which, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise the net value of the November 2025 Pre-Funded Warrant in shares of common stock determined according to a formula set forth in the November 2025 Pre-Funded Warrants.

In the event of certain fundamental transactions (as described in the November 2025 Pre-Funded Warrants), a holder of November 2025 Pre-Funded Warrants will be entitled to receive, upon exercise of the November 2025 Pre-Funded Warrants, the kind and amount of securities, cash or other property that such holder would have received had they exercised the November 2025 Pre-Funded Warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the November 2025 Pre-Funded Warrants.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Amended and Restated Bylaws and Delaware Law

Certain provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock will make it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management.

Special Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called at any time by our board of directors, or our President or Chief Executive Officer, but such special meetings may not be called by our stockholders or any other person or persons.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws established advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of our board of directors.

Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and our amended and restated bylaws do not provide for the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors; Filling Vacancies

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of our common stock outstanding are able to elect all of our directors. Our amended and restated certificate of incorporation provides for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board of directors, may only be filled by a resolution of our board of directors unless our board of directors determines that such vacancies shall be filled by our stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or stockholders to us or to our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws (as either may be amended from time to time); or any action asserting a claim against us that is governed by the internal affairs doctrine. As a result, any action brought by any of our stockholders with regard to any of these matters will need to be filed in the Court of Chancery of the State of Delaware and cannot be filed in any other jurisdiction; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware (a "Foreign Action"), in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and amended and restated bylaws and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation and amended and restated bylaws contain the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Amendment of Charter Provisions

The amendment of any of the above provisions in our amended and restated certificate of incorporation, except for the provision making it possible for our board of directors to issue undesignated preferred stock, requires approval by a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Each of our amended and restated certificate of incorporation and amended and restated bylaws provides that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also obligate us to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our

directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damages.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol "FDMT."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219.

Exhibit 10.16

AMENDMENT TO
4D MOLECULAR THERAPEUTICS, INC.
2025 EMPLOYMENT INDUCEMENT AWARD PLAN

This amendment ("Amendment") to the 2025 Employment Inducement Award Plan (the "Inducement Plan") of 4D Molecular Therapeutics, Inc., a Delaware corporation (the "Company") is made pursuant to Section 11.4 of the Plan, effective as of January 23, 2026.

WITNESSETH THAT:

WHEREAS, the Company presently maintains the Inducement Plan for the benefit of its employees;

WHEREAS, pursuant to Section 11.4 of the Plan, the Board of Directors of the Company (the "Board") may amend, suspend, or terminate the Plan at any time;

WHEREAS, the Plan is exempt from Nasdaq rules requiring stockholder approval of "equity compensation plans" pursuant to the Nasdaq Rule 5635(c)(4) exemption for "employment inducement awards," and, accordingly, the Amendment shall not be submitted to the Company's stockholders for their approval; and

WHEREAS, the Board believes it is in the best interests of the Company to amend the Inducement Plan as set forth in this Amendment.

NOW THEREFORE, the Plan is hereby amended as follows:

1. Capitalized Terms. All capitalized terms used and not defined in this Amendment shall have the meanings given thereto in the Inducement Plan.

2. Amendment to the Plan. Section 5.1 of the Inducement Plan is hereby amended to the following:

   "Number of Shares. Subject to adjustment under Article IX and the terms of this Article V, Awards may be made under the Plan covering up to 1,500,000 Shares. Shares issued or delivered under the Plan may consist of authorized but unissued Shares, Shares purchased on the open market or treasury Shares."

3. Ratification and Confirmation. Except as specifically amended by this Amendment, the Inducement Plan is hereby ratified and confirmed in all respects and remains valid and in full force and effect.

4. Governing Law. To the extent not preempted by federal law, this Amendment shall be construed in accordance with and governed by the laws of the State of Delaware, without giving effect to conflicts or choice of law principles.

* * *

* * *

I hereby certify that the foregoing Plan was adopted by the Board of Directors of 4D Molecular Therapeutics, Inc. on January 23, 2026.

Executed on January 23, 2026.

/s/ Scott Bizily____
Corporate Secretary

Exhibit 10.21

November 3, 2025

Kristian Humer

Dear Kristian:

We are pleased to make you the following offer of employment. We believe you will play an important and meaningful role in our mission of developing genetic medicines for large market diseases.

Position. Your title will be **Chief Financial Officer**, reporting to David Kirn, with a start date of **November 17, 2025** (the date you actually commence employment, the "Start Date"). You agree to devote your full time and best efforts to the performance of your duties to 4D Molecular Therapeutics, Inc. (together with its successors, the "Company"). Your offer is contingent on the terms set forth in this letter and your commencement of employment on the Start Date.

Location of Role. Your home office will be your primary work location, although you understand that you will be required to be present at the Company's office, located at 5858 Horton Street, Emeryville, California, approximately ten business days per month, except to the extent you are required to travel for other business matters as reasonably requested by the Company.

Compensation. Your starting annual salary will be **$520,000**, pro-rated for any partial employment with the Company. You will be paid less applicable withholdings and deductions in accordance with the Company's normal payroll practices. Future adjustments in compensation, if any, will be made by the Company in its sole and absolute discretion.

In addition, you will receive a sign-on bonus in the amount of **$100,000**, less applicable withholdings and deductions. This will be paid to you in two equal installments. The first installment will be paid to you on the first pay date following your start date. The second installment will be paid to you the first pay date following your 12 month anniversary with 4DMT. In each case, payment will be subject to your continued employment through the applicable payment date. You and the Company acknowledge and agree that your signing bonus will not be deemed earned until the 12 month anniversary of the applicable date of payment.

Annual Bonus. You will be eligible to receive a discretionary annual performance bonus, with a target of **40%** of your annual salary, the amount of which is subject to approval by the Company's Board of Directors and based on actual bonus eligible wages earned and on the achievement of certain individual and corporate performance goals. Notwithstanding the foregoing, for your first

calendar year of employment, your bonus will be prorated based on your start date, and you will only be eligible to receive a bonus if you started employment at the Company no later than September 30th. The Company does not guarantee the payment of a bonus nor is there a guaranteed minimum or maximum amount payable. In order to be eligible for the discretionary bonus, you must be employed with the Company on the date the bonus is paid.

Equity Compensation. If you decide to join the Company, you will receive, subject to the approval of the Company's Board of Directors (or committee thereof), an option to purchase **480,000** shares of Common Stock in the Company at a price per share equal to the closing price per share of such Common Stock as reported by NASDAQ on the date of grant, which will be granted within the first three months of your employment (typically the second Tuesday of the month following the month of your first date of employment). Your stock option grant shall be subject to the terms and conditions of the Company's equity plan and an equity agreement, including vesting requirements which will be set forth in your equity agreement. No right to any equity is earned or accrued until such time that vesting occurs, nor does the option grant confer any right to continue vesting or employment.

Benefits. You will be eligible to receive employee benefits according to the terms of the applicable Company policy or benefit plan, as in effect or amended from time to time. The Company reserves the right to make changes to any of our benefits, programs or time-off policies as it deems necessary or appropriate in accordance with applicable laws.

Change in Control and Severance Agreement. You will be entitled to enter into the Company's standard applicable form of Change in Control and Severance Agreement, upon beginning your employment at the Company.

No conflicts. By signing below, you agree that there is no lawful reason to prevent you from accepting a position with the Company. We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed by the Company. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position with the Company, and you represent that such is the case. In addition, prior to your Start Date, we will require you to complete and and sign a form of Officer Questionnaire to enable us to evaluate potential conflicts of interest. You are prohibited from disclosing to the Company any confidential or proprietary information that you learned as a result of your prior employment. Please make sure that you do not use in your work or disclose to us any such confidential information.

Company Policies. As a Company employee, you will be expected to acknowledge and abide by the Company's rules and policies, including its Code of Conduct and Business Ethics, which may change from time to time in accordance with applicable laws.

Confidential Information/Nondisclosure/Nonsolicitation of Employees. As a condition of your employment with the Company, you are required to sign the Company's Confidential Information and Invention Assignment Agreement (CIIAA), a copy of which is attached.

At-Will Employment. Your employment is at will, which means that either you or the Company can terminate your employment with the Company at any time with or without notice and with or without cause and the Company can alter the terms and conditions of your employment, including your title, duties, rate of pay, benefits, and work location at any time with or without notice and with or without cause. Nothing in this letter or the CIIAA shall be construed to alter the at-will nature of your employment relationship with the Company.

Conditions of Employment. The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check. You are also required, as a condition of employment, to provide to the Company the required I-9 documentation evidencing your identity and eligibility for employment in the United States. This documentation must be provided to us on or before your first day of employment or your employment will be terminated.

Severability. Should any provision contained in this letter be held as invalid, illegal or unenforceable, such holding shall not affect the validity of the remainder of this letter, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth herein.

Acceptance of Offer. To accept the Company's offer of employment, please sign this letter in the space provided below via DocuSign. Also, please fill out the attached CIIAA via DocuSign.

Entire Agreement. This letter, along with the CIIAA, sets forth the terms of your employment with the Company and supersedes any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by you and the Company's Chief Executive Officer or Chief Legal Officer. You hereby acknolwedge that you have not relied on any agreements or representations, express or implied, that are not set forth expressly in this letter.

We look forward to your favorable reply and to working with you at 4D Molecular Therapeutics.

Sincerely,

/s/ Jelica Stulic
Jelica Stulic

VP, Human Resources

Date Signed: 11/3/2025

Agreed to and accepted:

/s/ Kristian Humer

Kristian Humer

Date Signed: 11/3/2025

Exhibit 10.22

4D MOLECULAR THERAPEUTICS, INC. CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Change in Control and Severance Agreement (the "***Agreement***") is made and entered into by and between Kristian F. Humer ("***Executive***") and 4D Molecular Therapeutics, Inc. (the "***Company***"), effective as of the latest date set forth by the signatures of the parties hereto below (the "***Effective Date***").

Background

A. The Board of Directors of the Company (the "***Board***") recognizes that the possibility of an acquisition of the Company or an involuntary termination can be a distraction to Executive and can cause Executive to consider alternative employment opportunities. The Board has determined that it is in the best interests of the Company and its stockholders to assure that the Company will have the continued dedication and objectivity of Executive, notwithstanding the possibility, threat or occurrence of such an event.

B. The Board believes that it is in the best interests of the Company and its stockholders to provide Executive with an incentive to continue Executive's employment and to motivate Executive to maximize the value of the Company upon a Change in Control (as defined below) for the benefit of its stockholders.

C. The Board believes that it is imperative to provide Executive with severance benefits upon certain terminations of Executive's service to the Company that enhance Executive's financial security and provide incentive and encouragement to Executive to remain with the Company notwithstanding the possibility of such an event.

D. Unless otherwise defined herein, capitalized terms used in this Agreement are defined in Section 9 below.

Agreement

The parties hereto agree as follows:

1. Term of Agreement. This Agreement shall become effective as of the Effective Date and terminate upon the date that all obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and Executive acknowledge that Executive's employment is and shall continue to be "at-will," as defined under applicable law. Except as provided in Section 5 below, if Executive's employment terminates for any reason, Executive shall not be entitled to any severance payments, benefits or compensation other than as provided in this Agreement.

3. Covered Termination Outside a Change in Control Period. If Executive experiences a Covered Termination outside a Change in Control Period, then, subject to (i) Executive delivering to the Company an executed general release of all claims against the Company and its affiliates in a form approved by the Company (a "***Release of Claims***") that becomes effective and irrevocable in accordance with Section 14(a)(v) below, or such shorter period of time specified by the Company, following such Covered Termination and (ii) Executive's continued compliance with Section 12 below, then in addition to any accrued but unpaid salary, benefits, vacation and expense reimbursements through the Termination Date payable in accordance with applicable law, the Company shall provide Executive with the following:

(a) Severance. The Company shall pay to Executive an amount in cash equal to nine (9) months of his/her base salary at the rate in effect immediately prior to the Termination Date. Such payment shall be made in a single lump sum, less applicable withholdings, on the first payroll date following the date the Release of Claims becomes effective and irrevocable in accordance with Section 14(a)(v) below.

(b) Target Bonus. Executive shall be entitled to receive an amount equal to a pro-rated portion (based on the number of days Executive was employed by the Company during the calendar year in which the Termination Date occurs) of Executive's target annual bonus assuming achievement of performance goals at one hundred percent (100%) of target at the rate in effect immediately prior to the Termination Date, payable in a cash lump sum, less applicable withholdings, on the first payroll date following the date the Release of Claims becomes effective and irrevocable becomes effective and irrevocable in accordance with Section 14(a)(v) below. Since it is impractical to predict organizational performance accurately, this Agreement assumes 100% goals achievement, regardless of actual performance trend for purposes of this subsection.

(c) Bonus Payments. Executive shall be entitled to receive any earned, but unpaid annual performance bonus for the fiscal year prior to the Termination Date. If and to the extent earned, such earned prior year annual bonus and/or pro-rated annual bonus shall be paid out at the same time annual bonuses are paid generally to other executives of the Company for the relevant year, less applicable withholdings and deductions, but in no event later than March 15th of the year immediately following that in which the Termination Date occurs.

(d) Continued Healthcare. If Executive timely elects to receive continued healthcare coverage pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("***COBRA***"), the Company shall directly pay, or reimburse Executive for, the Company's portion of the premium (at the same rates in effect on the Termination Date) for Executive and Executive's covered dependents through the earlier of (i) the nine (9) month anniversary of the Termination Date and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Notwithstanding the foregoing, (i) if any plan pursuant to which such benefits are provided is not, or ceases prior to the expiration of the period of continuation coverage to be, exempt from the application of Section 409A of the Internal Revenue Code of 1986, as amended, (the "***Code***") under Treasury Regulation Section 1.409A-1(a)(5), or (ii) the Company is otherwise unable to continue to cover Executive under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service Act), then, in either case, an amount equal to each

remaining Company subsidy shall thereafter be paid to Executive in substantially equal monthly installments. After the Company ceases to pay premiums pursuant to this Section 3(b), Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance with the provisions of COBRA. Executive shall notify the Company immediately if Executive becomes covered by a group health plan of a subsequent employer.

4. Covered Termination During a Change in Control Period. If Executive experiences a Covered Termination during a Change in Control Period, then, subject to (i) Executive delivering to the Company an executed Release of Claims that becomes effective and irrevocable in accordance with Section 14(a)(v) below, or such shorter period of time specified by the Company, following such Covered Termination and (ii) Executive's continued compliance with Section 12 below, then in addition to any accrued but unpaid salary, benefits, vacation and expense reimbursements through the Termination Date payable in accordance with applicable law, the Company shall provide Executive with the following:

(a) Severance. The Company shall pay to Executive an amount in cash equal to twelve (12) months of his/her base salary at the rate in effect immediately prior to the Termination Date. Such payment shall be made in a single lump sum, less applicable withholdings, on the first payroll date following the date the Release of Claims becomes effective and irrevocable in accordance with Section 14(a)(v) below.

(b) Target Bonus. Executive shall be entitled to receive an amount equal to the sum of (i) twelve (12) months plus (ii) a pro-rated portion (based on the number of days Executive was employed by the Company during the calendar year in which the Termination Date occurs) of Executive's target annual bonus assuming achievement of performance goals at one hundred percent (100%) of target at the rate in effect immediately prior to the Termination Date, payable in a cash lump sum, less applicable withholdings, on the first payroll date following the date the Release of Claims becomes effective and irrevocable becomes effective and irrevocable in accordance with Section 14(a)(v) below. Since it is impractical to predict organizational performance accurately, this Agreement assumes 100% goals achievement, regardless of actual performance trend for purposes of this subsection.

(c) Bonus Payments. Executive shall be entitled to receive any earned, but unpaid annual performance bonus for the fiscal year prior to the Termination Date. If and to the extent earned, such earned prior year annual bonus shall be paid out at the same time annual bonuses are paid generally to other executives of the Company for the relevant year, less applicable withholdings and deductions, but in no event later than March 15th of the year immediately following that in which the Termination Date occurs.

(d) Continued Healthcare. If Executive timely elects to receive continued healthcare coverage pursuant to the provisions of COBRA, the Company shall directly pay, or reimburse Executive for, the Company's portion of the premium (at the same rates in effect on the Termination Date) for Executive and Executive's covered dependents through the earlier of (i) the twelve (12) month anniversary of the Termination Date and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Notwithstanding the foregoing, (i) if any plan pursuant to which such benefits are provided

is not, or ceases prior to the expiration of the period of continuation coverage to be, exempt from the application of Section 409A of the Code under Treasury Regulation Section 1.409A-1(a)(5), or (ii) the Company is otherwise unable to continue to cover Executive under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service Act), then, in either case, an amount equal to each remaining Company subsidy shall thereafter be paid to Executive in substantially equal monthly installments. After the Company ceases to pay premiums pursuant to this Section 4(c), Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance with the provisions of COBRA. Executive shall notify the Company immediately if Executive becomes covered by a group health plan of a subsequent employer.

(e) Equity Awards. Each outstanding and unvested equity award (excluding any such awards that vest in whole or in part based on the attainment of performance-vesting conditions), including, without limitation, each restricted stock, stock option, restricted stock unit and stock appreciation right, held by Executive shall automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse with respect to one hundred percent (100%) of the shares subject thereto (excluding any such awards that vest in whole or in part based on the attainment of performance-vesting conditions, which shall be governed by the terms of the applicable award agreement), as of immediately prior to the Termination Date.

5. Certain Reductions. Notwithstanding anything herein to the contrary, the Company shall reduce Executive's severance benefits under this Agreement, in whole or in part, by any other severance benefits, pay in lieu of notice, or other similar benefits payable to Executive by the Company in connection with Executive's termination, including but not limited to payments or benefits pursuant to (a) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act, or (b) any other Company agreement, arrangement, policy or practice relating to Executive's termination of employment with the Company. The benefits provided under this Agreement are intended to satisfy, to the greatest extent possible, any and all statutory obligations that may arise out of Executive's termination of employment. Such reductions shall be applied on a retroactive basis, with severance benefits paid first in time being recharacterized as payments pursuant to the Company's statutory obligation.

6. Deemed Resignation. Upon termination of Executive's service for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its affiliates, and, at the Company's request, Executive shall execute such documents as are necessary or desirable to effectuate such resignations.

7. Other Terminations. If Executive's employment with the Company terminates for any reason other than due to a Covered Termination, then Executive shall not be entitled to any benefits hereunder other than accrued but unpaid salary, vacation and expense reimbursements through the Termination Date in accordance with applicable law and to elect any continued healthcare coverage as may be required under COBRA or similar state law.

8. Limitation on Payments. Notwithstanding anything in this Agreement to the contrary, if any payment or distribution Executive would receive pursuant to this Agreement or otherwise

("***Payment***") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then such Payment shall either be (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the largest payment, notwithstanding that all or some portion the Payment may be taxable under Section 4999 of the Code. The Company will select an adviser with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax, *provided*, that the adviser's determination shall be made based upon "substantial authority" within the meaning of Section 6662 of the Code to perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such adviser required to be made hereunder. The adviser shall provide its calculations to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company. Any good faith determinations of the adviser made hereunder shall be final, binding and conclusive upon the Company and Executive. Any reduction in payments or benefits pursuant to this Section 8 will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits payable to Executive.

9. Definitions. The following terms used in this Agreement shall have the following meanings:

(a) "***Cause***" means the occurrence of any of the following: (i) Executive's material failure to perform Executive's principal assigned duties or responsibilities as a service provider of the Company (other than a failure resulting from Executive's Disability (as defined in Section 22(e)(3) of the Code)); *provided*, that, the failure of Executive to achieve certain results, such as the Company's business plan, in and of itself, would not constitute "Cause"; (ii) Executive's engaging in any act of dishonesty, fraud or material misrepresentation relating to the business of the Company or its affiliates; (iii) Executive's violation of any federal or state law or regulation applicable to the business of the Company or its affiliates which results in or could reasonably be expected to result in harm or creates material risk to the Company, as determined by the Company;
(iv) Executive's breach of any confidentiality agreement or invention assignment agreement, or Executive's material breach of any other material contract between Executive and the Company (or any affiliate of the Company) or material violation of any of the written policies of the Company (or any affiliate of the Company); (v) Executive's being convicted of, or entering a plea of *nolo contendere* to, any felony or committing any act of moral turpitude; or (vi) Executive's commission of any act or involvement in any situation, or occurrence, which brings Executive into widespread public disrepute, contempt, scandal or ridicule, or which justifiably shocks, insults or offends a significant portion of the community, or Executive being subject to publicity for any such conduct or involvement in such conduct. The Company shall not terminate Executive for Cause pursuant to clause "(i)" above without first providing Executive with written notice of the acts or omissions constituting the grounds for such termination and if in the reasonable judgment of the Company such

failure may be cured within thirty (30) days, expiration of a reasonable cure period not to exceed thirty (30) days following the date of such notice.

(b) "***Change in Control***" has the meaning ascribed to such term under the Company's 2019 Equity Incentive Plan, as amended.

(c) "***Change in Control Period***" means the period of time (i) commencing on the date the Company enters into a definitive agreement that, if the transactions contemplated thereby were consummated, would result in a Change in Control and (ii) ending on the twelve (12) month anniversary of the closing of such Change in Control.

(d) "***Covered Termination***" means the termination of Executive's employment by the Company other than for Cause or by Executive for Good Reason, in each case that, to the extent necessary, constitutes a Separation from Service.

(e) "***Good Reason***" means the occurrence of any of the following events or conditions, without the Executive's express written consent (which consent may be denied, withheld or delayed for any reason):

(i) a requirement by the Company that Executive's principal place of employment relocate to a location more than twenty five (25) miles from Executive's then-present principal place of employment, except for required travel on the Company's business to an extent substantially consistent with travel requirements standard and customary in the industry;

(ii) a material diminution in Executive's duties, authority or responsibilities;

(iii) a material diminution in Executive's base salary; *provided* that in the absence of a Change in Control an across-the-board salary reduction similarly affecting all or substantially all similarly situated employees of the Company shall not constitute Good Reason; or

(iv)any material breach by the Company of this Agreement or any employment agreement or offer letter.

Executive must provide notice to the Company of the condition giving rise to "Good Reason" within ninety (90) days of the initial existence of such condition and the Company will have thirty (30) days following such notice to remedy such condition and Executive's resignation for Good Reason must occur within thirty (30) days following the expiration of such cure period if the Company did not remedy such condition. Executive's right to terminate Executive's employment for Good Reason will not be affected by Executive's incapacity due to physical or mental illness. Executive's continued employment will not constitute consent to, or a waiver of rights with respect to, any act or failure to act constituting Good Reason hereunder.

(f) "***Separation from Service***" means a "separation from service" with the Company within the meaning of Section 409A of the Code and the Department of Treasury regulations

and other guidance promulgated thereunder.

(g) "***Termination Date***" means the date on which Executive experiences a Covered Termination.

10. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "**Company**" shall include any successor to the Company's business or assets which executes and delivers the assumption agreement described in this Section 10(a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Executive's Successors. The terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

11. Notices. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including personal delivery by facsimile), delivery by email or the third day after mailing by first class mail, to the Company at its primary office location and to Executive at Executive's address as listed in the Company's books and records.

12. Confidentiality; Non-Disparagement.

(a) Confidentiality. Executive hereby expressly confirms Executive's continuing obligations to the Company pursuant to that certain confidentiality agreement by and between the Company and Executive (the "***Confidential Information Agreement***").

(b) Non-Disparagement. Executive agrees that Executive shall not disparage, criticize or defame the Company, its affiliates and their respective affiliates, directors, officers, agents, partners, stockholders or employees, either publicly or privately. Nothing in this Section 12(b) shall apply to any evidence or testimony required by any court, arbitrator or government agency.

(c) Whistleblower Protections and Trade Secrets. Notwithstanding anything to the contrary contained herein, nothing in this Agreement or the Confidentiality Agreement prohibits Executive from reporting possible violations of federal law or regulation to any United States governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including the right to receive an award for information provided to any such government agencies). Furthermore, in accordance with 18 U.S.C. § 1833, notwithstanding anything to the contrary in this Agreement: (i) Executive shall not be in breach of this Agreement, and shall not be held criminally or civilly liable under any federal or state trade secret law (A) for the disclosure of a trade secret that

is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (B) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (ii) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order.

13. Dispute Resolution. Unless otherwise prohibited by law or specified below, all disputes, claims and causes of action, in law or equity, arising from or relating to this Agreement or to Executive's employment or the termination thereof (each, a "***Claim***") shall be resolved solely and exclusively by final and binding arbitration held in Alameda County, California through JAMS under its Employment Arbitration Rules and Procedures, which are available at www.jamsadr.com/rules-employment-arbitration. The arbitrator shall: (a) provide adequate discovery for the resolution of the dispute; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. Except to the extent of filing fees Executive would incur were the matter to be litigated in court, the Company shall be responsible for the JAMS administrative fees and the arbitrator's fees and costs. The arbitrator shall award the prevailing party attorneys' fees and expert fees, if any. The parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; *provided*, *however*, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or the Confidential Information Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. Executive and the Company understand that by agreeing to arbitrate any claim pursuant to this Section 13, they will not have the right to have any claim decided by a jury or a court, but shall instead have any claim decided through arbitration. Executive and the Company waive any constitutional or other right to bring claims covered by this Agreement other than in their individual capacities. Except as may be prohibited by applicable law, the foregoing waiver includes the ability to assert claims as a plaintiff or class member in any purported class or representative proceeding. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration.

14. Miscellaneous Provisions.

(a) Section 409A.

(i) Separation from Service. Notwithstanding any provision to the contrary in this Agreement, no amount constituting deferred compensation subject to Section 409A of the Code shall be payable pursuant to Sections 3 or 4 above unless Executive's termination of employment constitutes a Separation from Service.

(ii) Specified Employee. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed at the time of his or her Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (A) the expiration of the six-month period measured from the date of Executive's Separation from Service or

(B) the date of Executive's death. Upon the first business day following the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 14(a)(ii) shall be paid in a lump sum to Executive, and any remaining payments due under this Agreement shall be paid as otherwise provided herein.

(iii)Expense Reimbursements. To the extent that any reimbursements payable pursuant to this Agreement are subject to the provisions of Section 409A of the Code, any such reimbursements payable to Executive pursuant to this Agreement shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(iv)Installments. For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment.

(v) Release. Notwithstanding anything to the contrary in this Agreement, to the extent that any payments due under this Agreement as a result of Executive's termination of employment are subject to Executive's execution and delivery of a Release of Claims, (A) the Company shall deliver the Release of Claims to Executive within ten business days following Executive's Termination Date, and the Company's failure to deliver a Release of Claims prior to the expiration of such ten business day period shall constitute a waiver of any requirement to execute a Release of Claims, (B) if Executive fails to execute the Release of Claims on or prior to the Release Expiration Date (as defined below) or timely revokes Executive's acceptance of the Release of Claims thereafter, Executive shall not be entitled to any payments or benefits otherwise conditioned on the Release of Claims, and (C) in any case where Executive's Termination Date and the Release Expiration Date fall in two separate taxable years, any payments required to be made to Executive that are conditioned on the Release of Claims and are treated as nonqualified deferred compensation for purposes of Section 409A of the Code shall be made in the later taxable year. For purposes hereof, "***Release Expiration Date***" shall mean (1) if Executive is under 40 years old as of the Termination Date, the date that is seven (7) days following the date upon which the Company timely delivers the Release of Claims to Executive, or such shorter time prescribed by the Company, and
(2) if Executive is 40 years or older as of the Termination Date, the date that is twenty one (21) days following the date upon which the Company timely delivers the Release of Claims to Executive, or, if Executive's termination of employment is "in connection with an exit incentive or other employment termination program" (as such phrase is defined in the Age Discrimination in

Employment Act of 1967), the date that is forty five (45) days following such delivery date. To the extent that any payments of nonqualified deferred compensation (within the meaning of Section 409A) due under this Agreement as a result of Executive's termination of employment are delayed pursuant to this Section 14(a)(v), such amounts shall be paid in a lump sum on the first payroll date following the date that Executive executes and does not revoke the Release of Claims (and the applicable revocation period has expired) or, in the case of any payments subject to Section 14(a)(v)(C), on the first payroll date to occur in the subsequent taxable year, if later.

(b) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local, or foreign withholding or other taxes or charges which the Company is required to withhold.

(c) Waiver. No provision of this Agreement shall be modified, waived or dis-charged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized member of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(d) Whole Agreement. This Agreement and the Confidential Information Agreement represent the entire understanding of the parties hereto with respect to the subject matter hereof and supersede all prior promises, arrangements and understandings regarding the same, whether written or unwritten, including, without limitation, any severance or change in control benefits in Executive's offer letter agreement, employment agreement and/or equity award agreement or previously approved by the Company.

(e) Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California without regard to its conflicts of law provisions.

(f) Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid or unenforceable provisions had never been contained herein.

(g) Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

(h) Executive Acknowledgement. Executive acknowledges that (i) Executive has consulted with or has had the opportunity to consult with independent counsel of Executive's own choice concerning this Agreement, and has been advised to do so by the Company, and (ii) that Executive has read and understands the Agreement, is fully aware of its legal effect, and has entered into it freely based on Executive's own judgment.

(*Signature page follows*)

The parties have executed this Agreement, in the case of the Company by its duly authorized officer, as of the dates set forth below.

4D MOLECULAR THERAPEUTICS, INC.

By: /s/ David Kirn, M.D.
David Kirn, M.D.
Chief Executive Officer

Date: 11/18/2025

EXECUTIVE

Kristian F. Humer

Date: 11/10/2025

Exhibit 10.23

TRANSITION AGREEMENT

This Transition Agreement (the "Agreement") by and between Fred Kamal, Ph.D. ("Executive") and 4D Molecular Therapeutics, Inc., a Delaware corporation (the "Company" and, together with Executive, the "Parties") is made effective as of the eighth day following the date Executive signs this Agreement (the "Effective Date") with reference to the following facts:

A. Executive currently serves as President and Chief Operating Officer of the Company; and

B. Effective as of December 31, 2025 (the "Transition Date"), Executive desires to voluntarily resign from his position with the Company as President and Chief Operating Officer on the terms and conditions set forth herein and, in connection with and following Executive's resignation, the Company wishes to secure the services of Executive, and Executive wishes to continue to serve as an employee of the Company in the role of Chief Technical Advisor of the Company on the terms and conditions set forth herein (the "Transition").

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth, the Parties agree as follows:

1. Transition Date. Effective as of the Transition Date, Executive shall voluntarily resign as President and Chief Operating Officer and from all other officer roles held by Executive with the Company. Executive acknowledges that Executive consents to the Transition, including the diminution in Executive's base salary and other compensation, duties, authority and responsibilities. Executive agrees that neither the Transition nor the effects of the Transition shall constitute Good Reason to terminate employment under the Change in Control and Severance Agreement, dated September 22, 2021, by and between Fred Kamal and 4D Molecular Therapeutics, Inc. (the "Severance Agreement"), and effective as of the Effective Date, neither the Company nor Executive shall have any further rights, interests or obligations under the Severance Agreement. Executive hereby agrees to execute such further document(s) as shall be determined by the Company as necessary or desirable to give effect to the termination of Executive's status as an officer of the Company.

2. Transition Period.

(a)*Transition Period; Duties*. Commencing on the date immediately following the Transition Date and ending on the date on which Executive's employment relationship with the Company is terminated (the "Transition Period"), Executive shall remain employed by the Company with the title of Chief Technical Advisor, reporting to the Chief Executive Officer, and shall (i) advise the Company on CMC and regulatory strategy with respect to 4D-150 and 4D-710, and (ii) assist with such other projects at the direction of the Chief Executive Officer (the "Services"). Unless Executive's employment relationship with the Company is earlier terminated, during the first six months of the Transition Period (i.e. from January 1, 2026 to June 30, 2026), Executive shall spend a minimum of two business days per week providing the Services, and thereafter one business day per week providing the Services. The Services to the Company shall be provided at such location(s) as are determined by the Company, consistent with Executive's role. During the Transition Period, Executive shall comply with all applicable policies and procedures of the Company, as in effect from time to time (including, without limitation, travel and entertainment expense policies, technology use, operating guidelines, confidentiality, background check and work authorization policies and procedures).

(b)*Salary and Benefits*. Unless Executive's employment relationship with the Company is earlier terminated, during the first six months of the Transition Period, Executive will be paid based on an annualized base salary of $221,904, and thereafter, based on an annualized base

salary of $110,952, in accordance with the Company's regular payroll procedures for part-time employees. All payments made to Executive during the Transition Period will be subject to required withholding taxes and authorized deductions. Executive understands and agrees that following the Transition Date, given Executive's part-time status, Executive will not be eligible to participate in or accrue benefits under any Company benefit plan requiring a higher minimum number of hours per week as a condition of such participation or accrual.

(c) *Annual Bonus*. Executive shall be paid Executive's annual bonus for calendar year ending December 31, 2025 based on the corporate bonus achievement multiplier determined the Company's Board of Directors or a committee thereof (the "Annual Bonus"), such payment to be made at the same time annual bonuses for the calendar year ending December 31, 2025 are paid to other employees. For the avoidance of doubt, except with respect to the Annual Bonus, Executive acknowledges that Executive is not eligible for, and will not be paid, any other bonus in respect of 2026 or future years.(d)Stock Options. Unless Executive's employment relationship with the Company is earlier terminated, during the first six months of the Transition Period, Executive will continue to vest in shares of common stock of the Company underlying the option awards set forth on Exhibit A attached hereto (the "Option Awards") in accordance with their terms. Effective as of the earlier of the six month anniversary of the Transition Date or the date Executive's employment relationship with the Company is terminated, any unvested portion of the Option Awards shall forfeit as of such date for no consideration. For the avoidance of doubt, Executive acknowledges that Executive is not eligible for, and will not receive, any other equity awards during the Transition Period, except at the sole discretion of the Company's Compensation Committee of the Board of Directors. Executive further acknowledges that any vested options that remain unexercised immediately following the expiration of the three (3)-month anniversary of Executive's cessation of Services shall thereupon terminate.(e)Expenses. During the Transition Period, Executive shall be entitled to reimbursement for business expenses in accordance with Company policies and applicable law, provided, that Executive shall not incur business expenses greater than $1,000 in the aggregate, without the prior written consent of the Chief Executive Officer.(f)Protection of Information. Executive reaffirms Executive's commitment to remain in compliance with the Confidential Information and Invention Assignment Agreement entered into between Executive and the Company as of August 6, 2018 (the "Confidentiality Agreement"), which shall survive the Transition Date and shall remain in full force and effect in accordance with its terms. Executive acknowledges that the payments set forth in this Section 2 are subject to Executive's compliance with the Confidentiality Agreement.

3. Termination of Transition Period; Full Payment. The employment relationship established in accordance with this Agreement may be terminated by the Company or Executive at any time and for any reason and with or without notice. Executive acknowledges that the payments herein shall constitute full and complete satisfaction of any and all amounts properly due and owing to Executive as a result of the Transition. Executive further acknowledges that, other than the Confidentiality Agreement and the award agreements evidencing Executive's Options Awards, this Agreement shall supersede each other agreement entered into between Executive and the Company regarding Executive's employment, including, without limitation, the Severance Agreement and any offer letter, employment agreement, severance and/or change in control agreement, and each such agreement (other than the Confidentiality Agreement and the award agreements evidencing Executive's Options Awards) shall be deemed terminated and of no further effect as of the Effective Date.

4. Stock Options Vesting Acceleration. Subject to Executive's continued compliance with Executive's obligations under this Agreement and the Confidentiality Agreement, in the event that a Change in Control (as defined in the Company's 2020 Incentive Award Plan) occurs prior to June 30, 2026 and Executive's employment relationship with the Company has not been terminated prior to such date, any unvested Option Awards will fully accelerate and will be fully vested effective as of the date of such Change in Control. Executive agrees that the benefits included in this Section 4 are not required under Executive's offer letter or the Company's normal policies or procedures

and are provided solely in connection with this Agreement. Executive acknowledges and agrees that the benefits referenced in this Section 4 constitute adequate and valuable consideration, in and of itself, for the promises contained in this Agreement.

5. Executive's Release of the Company. Executive understands that by agreeing to the release provided by this Section 5, Executive is agreeing not to sue, or otherwise file any claim against, the Company or any of its affiliates, directors, officers, employees, investors or other agents for any reason whatsoever based on anything that has occurred as of the date Executive signs this Agreement.

(a)*Released Claims.* On behalf of Executive and Executive's heirs, assigns, executors, administrators, trusts, spouse and estate, Executive hereby releases and forever discharges the "Releasees" hereunder, consisting of the Company and its owners, affiliates, subsidiaries, predecessors, successors, assigns, agents, directors, officers, partners, employees, and insurers, and all persons acting by, through, under or in concert with them, or any of them, of and from any and all manner of action or actions, cause or causes of action, in law or in equity, suits, debts, liens, contracts, agreements, promises, liability, claims, demands, damages, loss, cost or expense, of any nature whatsoever, known or unknown, fixed or contingent (hereinafter called "Claims"), which Executive now has or may hereafter have against the Releasees, or any of them, by reason of any matter, cause, or thing whatsoever from the beginning of time to the date hereof, including, without limiting the generality of the foregoing, any Claims arising out of, based upon, or relating to Executive's hire, employment, remuneration or termination by the Releasees, or any of them, Claims arising under federal, state, or local laws relating to employment, Claims of any kind that may be brought in any court or administrative agency, including any Claims arising under Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. § 2000, et seq.; Americans with Disabilities Act, as amended, 42 U.S.C. § 12101 et seq.; the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 701 et seq.; the Age Discrimination in Employment Act, as amended, 29 U.S.C. § 621, et seq.; Civil Rights Act of 1866, and Civil Rights Act of 1991; 42 U.S.C. § 1981, et seq.; Equal Pay Act, as amended, 29 U.S.C. § 206(d); regulations of the Office of Federal Contract Compliance, 41 C.F.R. Section 60, et seq.; The Family and Medical Leave Act, as amended, 29 U.S.C. § 2601 et seq.; the Fair Labor Standards Act of 1938, as amended, 29 U.S.C. § 201 et seq.; the Executive Retirement Income Security Act, as amended, 29 U.S.C. § 1001 et seq.; the Worker Adjustment and Retraining Notification Act, as amended, 29 U.S.C. § 2101 et seq.; the California Equal Pay Law, as amended, Cal. Lab. Code §§ 1197.5(a),199.5; the Moore-Brown-Roberti Family Rights Act of 1991, as amended, Cal. Gov't Code §§12945.2, 19702.3; California Labor Code §§ 1101, 1102; the California WARN Act, California Labor Code §§ 1400 et. seq; California Labor Code §§ 1102.5(a),(b); Claims for wages under the California Labor Code; and any other federal, state or local laws of similar effect; the employment and civil rights laws of California; Claims for breach of implied or express contract; Claims arising in tort, including, without limitation, Claims of wrongful dismissal or discharge, discrimination, harassment, retaliation, fraud, misrepresentation, defamation, libel, slander, defamation, infliction of emotional distress, violation of public policy, and/or breach of the implied covenant of good faith and fair dealing; and Claims for damages or other remedies of any sort, including, without limitation, compensatory damages, punitive damages, injunctive relief and attorney's fees.

(b)*Unreleased Claims.* Notwithstanding the generality of the foregoing, Executive does not release the following claims:

(i) Claims under the California Fair Employment and Housing Act;

(ii) Claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law;

(iii) Claims for workers' compensation insurance benefits under the

terms of any worker's compensation insurance policy or fund of the Company;

(iv) Claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (COBRA);

(v) Claims to any benefit entitlements vested as the date of Executive's employment termination, pursuant to written terms of any Company employee benefit plan;

(vi) Claims for indemnification under any indemnification agreement with the Company, the Company's Bylaws or any applicable law; and

(vii) Executive's right to bring to the attention of the Equal Employment Opportunity Commission claims of discrimination; *provided*, *however*, that Executive does release Executive's right to secure any damages for alleged discriminatory treatment.

(c)*Acknowledgement.* In accordance with the Older Workers Benefit Protection Act of 1990, Executive has been advised of the following:

(i) Executive should consult with an attorney before signing this Agreement;

(ii) Executive has been given at least twenty-one (21) days to consider this Agreement (the "Consideration Period"); and

(iii) Executive has seven (7) days after signing this Agreement to revoke it. If Executive wishes to revoke this Agreement, Executive must deliver notice of Executive's revocation in writing, no later than 11:59 p.m. on the seventh (7th) day following Executive's execution of this Agreement to Scott Bizily, Chief Legal Officer, email: sbizily@4dmt.com. Executive understands that if he revokes this Agreement, it will be null and void in its entirety, and Executive will not be entitled to any payments or benefits provided in this Agreement that are not otherwise required by applicable law.

(d)EMPLOYEE ACKNOWLEDGES THAT EMPLOYEE HAS BEEN ADVISED OF AND IS FAMILIAR WITH THE PROVISIONS OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

BEING AWARE OF SAID CODE SECTION, EMPLOYEE HEREBY EXPRESSLY WAIVES ANY RIGHTS EMPLOYEE MAY HAVE THEREUNDER, AS WELL AS UNDER ANY OTHER STATUTES OR COMMON LAW PRINCIPLES OF SIMILAR EFFECT.

6. Non-Competition/Conflicts of Interest, Non-Disparagement, Non-Solicitation and Return of Company Property. Executive further agrees that:

(a)*Non-Competition/Conflicts of Interest*. During the Transition Period,

Executive will not, directly or indirectly, participate in or assist in any commercial business activity that competes in any way with any business then being conducted or planned by the Company or that otherwise which conflicts with his obligations hereunder or with the interest of the Company; provided that the parties expressly acknowledge that Executive may serve in the position set forth on **Exhibit B**. Prior to and during Executive's participation or assistance in any third party work in gene therapy and in conflicting indications, Executive shall promptly and fully disclose to the Company's Chief Legal Officer of such participation or assistance so that the Company may evaluate any potential conflicts of interest.

(b)*Non-Disparagement*. Executive agrees that Executive shall not disparage, criticize or defame the Company, its affiliates and their respective directors, officers, agents, partners, stockholders, employees, products, services, technology or business, either publicly or privately. The term "disparage" includes, without limitation, comments or statements to the press, to the Releasees' past or present employees or to any individual or entity with whom the Releasees have a business relationship (including, without limitation, any vendor, supplier, customer or distributor), or any public or private statement, that in each case is intended to, or can be reasonably expected to, damage the business, integrity, reputation or good will of any of the Releasees. Executive agrees that the obligations under this paragraph include (without limitation) refraining from publishing any critical or disparaging remark on any blog, online social network or any other website (including, but not limited to, www.glassdoor.com), whether or not such comments are made anonymously. Nothing in this Section 6(b), or this Agreement, shall prevent Executive from (a) testifying truthfully in response to a subpoena or other legal process; (b) discussing terms and conditions of Executive's employment with the Company, as permitted by the National Labor Relations Act and other applicable law, including but not limited to discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful; or (c) communicating directly with, cooperating with, or providing information to, any federal, state or local government regulator, including, but not limited to, the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, or the U.S. Department of Justice.

(c)*Non-Solicitation*. In addition to Executive's obligations under the Confidentiality Agreement, Executive shall not during the Transition Period, either on Executive's own account or jointly with or as a manager, agent, officer, employee, consultant, partner, joint venturer, owner or stockholder or otherwise on behalf of any other person, firm or corporation, directly or indirectly solicit or attempt to solicit away from the Company any of its officers or employees; *provided, however*, that a general advertisement to which an employee of the Company responds shall in no event be deemed to result in a breach of this Section 6(c).

(d)*Return of Company Property*. Executive warrants and represents that Executive has turned over to the Company no later than the end of the Transition Period or any earlier date requested by the Company in writing, all physical or personal property that are the property of the Company and that Executive had in Executive's possession, custody or control, including, without limitation, Executive's laptop computer, along with all other equipment and originals and copies of correspondence, drawings, manuals, letters, notes, notebooks, reports, programs, plans, proposals, financial documents, or any other documents concerning the Company's customers, business plans, marketing strategies, products, processes or business of any kind and/or which contain proprietary information or trade secrets which are in the possession or control of Executive or Executive's agents or representatives.

7. Executive Representations. Executive warrants and represents that (a) Executive has not filed or authorized the filing of any complaints, charges or lawsuits against the Company or any affiliate of the Company with any governmental agency or court, and that if, unbeknownst to Executive, such a complaint, charge or lawsuit has been filed on Executive's behalf, Executive will immediately cause it to be withdrawn and dismissed, (b) Executive has reported all hours worked as of the date of

this Agreement and has been paid all compensation, wages, bonuses, commissions, and/or benefits to which Executive may be entitled and no other compensation, wages, bonuses, commissions and/or benefits are due to Executive, except as provided in this Agreement, (c) Executive has no known workplace injuries or occupational diseases and has been provided and/or has not been denied any leave requested under the Family and Medical Leave Act or any similar state law,
(d) Executive is entering into this Agreement knowingly, voluntarily, and with full knowledge that it shall become a binding and enforceable contract affecting Executive's legal rights and has not been coerced, threatened, or intimidated into signing the Agreement; (e) Executive has a right to consult an attorney regarding this Agreement and have been provided with the opportunity to consult with an attorney during the Consideration Period under this Agreement; (f) in the event that Executive signs this Agreement prior to the end of the Consideration Period, Executive's decision to shorten the Consideration Period is knowing and voluntary and is not induced by the Company through fraud, misrepresentation, or a threat to withdraw or alter the offer prior to the expiration of the consideration period, or by offering more favorable terms for signing the Agreement prior to the expiration of the Consideration Period; (g) Executive has read this Agreement in its entirety and understand and accept the terms and conditions of the Agreement; (h) Executive understands that he may hereafter discover facts different from or in addition to those you now believe to be true and that the release herein shall remain in effect as a complete and general release, notwithstanding any such different or additional facts; (i) Executive understands that this Agreement includes the compromise of any disputed claims;
(j) the execution, delivery and performance of this Agreement by Executive does not and will not conflict with, breach, violate or cause a default under any agreement, contract or instrument to which Executive is a party or any judgment, order or decree to which Executive is subject, (k) Executive is and shall continue to be bound by and subject to the terms of the Company's Policy for Recovery of Erroneously Awarded Compensation effective as of October 2, 2023 (the "Policy") and compensation received by Executive may be subject to reduction, cancellation, forfeiture and/or recoupment to the extent necessary to comply with the Policy, notwithstanding any other agreement to the contrary, and (k) upon the execution and delivery of this Agreement by the Company and Executive, this Agreement will be a valid and binding obligation of Executive, enforceable in accordance with its terms.

8. No Assignment by Executive. Executive warrants and represents that no portion of any of the matters released herein, and no portion of any recovery or settlement to which Executive might be entitled, has been assigned or transferred to any other person, firm or corporation not a party to this Agreement, in any manner, including by way of subrogation or operation of law or otherwise. If any claim, action, demand or suit should be made or instituted against the Company or any other Releasee because of any actual assignment, subrogation or transfer by Executive, Executive agrees to indemnify and hold harmless the Company and all other Releasees against such claim, action, suit or demand, including necessary expenses of investigation, attorneys' fees and costs. In the event of Executive's death, this Agreement shall inure to the benefit of Executive and Executive's executors, administrators, heirs, distributees, devisees, and legatees. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only upon Executive's death by will or operation of law.

9. Governing Law. This Agreement shall be construed and enforced in accordance with, and the rights of the Parties shall be governed by, the laws of the State of California or, where applicable, United States federal law, in each case, without regard to any conflicts of laws provisions or those of any state other than California.

10. DISPUTE RESOLUTION. Unless otherwise prohibited by law or specified below, all disputes, claims and causes of action, in law or equity, arising from or relating to this Agreement or to Executive's employment or the termination thereof (each, a "***Claim***") shall be resolved solely and exclusively by final and binding arbitration held in Alameda County, California through JAMS under its Employment Arbitration Rules and Procedures, which are available at www.jamsadr.com/rules-employment-arbitration. The arbitrator shall: (a) provide adequate discovery

for the resolution of the dispute; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. Except to the extent of filing fees Executive would incur were the matter to be litigated in court, the Company shall be responsible for the JAMS administrative fees and the arbitrator's fees and costs. The arbitrator shall award the prevailing party attorneys' fees and expert fees, if any. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; *provided*, *however*, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or the Confidential Information Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. Executive and the Company understand that by agreeing to arbitrate any claim pursuant to this Section 10, they will not have the right to have any claim decided by a jury or a court, but shall instead have any claim decided through arbitration. Executive and the Company waive any constitutional or other right to bring claims covered by this Agreement other than in their individual capacities. Except as may be prohibited by applicable law, the foregoing waiver includes the ability to assert claims as a plaintiff or class member in any purported class or representative proceeding. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration. Further, this arbitration agreement shall not apply to: (a) claims for unemployment and workers' compensation benefits; (b) sexual harassment and sexual assault disputes arising under federal, state, local, or tribal law, unless Executive elects to arbitrate such disputes; (c) claims brought before the Equal Employment Opportunity Commission or similar state or local agency, if Executive is required to exhaust Executive's administrative remedies; provided, that any appeal from an award or denial of an award by any such agency or any further action upon receipt of a right-to-sue letter shall be arbitrated pursuant to the terms of this Agreement; and (d) any other claim, which by law cannot be subject to mandatory arbitration. Notwithstanding Section 9 above, the provisions of this Section 10 shall be governed by and enforceable pursuant to the Federal Arbitration Act, and, in all other respects, the arbitrator shall apply the substantive laws of the State of California, with the same statutes of limitation and available remedies that would apply if the claims were brought in a court of law of competent jurisdiction.

11. Miscellaneous. This Agreement, collectively with the Confidentiality Agreement and the award agreements governing the Option Awards, comprises the entire agreement between the Parties with regard to the subject matter hereof and supersedes, in their entirety, any other agreements between Executive and the Company with regard to the subject matter hereof. Executive acknowledges that there are no other agreements, written, oral or implied, and that Executive may not rely on any prior negotiations, discussions, representations or agreements. This Agreement may be modified only in writing, and such writing must be signed by all Parties and recited that it is intended to modify this Agreement. This Agreement may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one and the same agreement.

12. Company Assignment and Successors. The Company shall assign its rights and obligations under this Agreement to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise). This Agreement shall be binding upon and inure to the benefit of the Company and its successors, assigns, personnel and legal representatives.

13. Maintaining Confidential Information. Executive reaffirms Executive's obligations under the Confidentiality Agreement. For the avoidance of doubt, nothing in the Confidentiality Agreement or this Agreement will be construed to prohibit Executive from filing a charge with, reporting possible violations to, or participating or cooperating with any governmental agency or entity, including but not limited to the EEOC, the Department of Justice, the Securities and

Exchange Commission, Congress, or any agency Inspector General, or making other disclosures that are protected under the whistleblower, anti-discrimination, or anti-retaliation provisions of federal, state or local law or regulation. Executive does not need the prior authorization of the Company to make any such reports or disclosures, and Executive is not required to notify the Company that Executive has made such reports or disclosures. Furthermore, in accordance with 18 U.S.C. § 1833, notwithstanding anything to the contrary in the Confidentiality Agreement or this Agreement: (i) Executive shall not be in breach of the Confidentiality Agreement or this Agreement, and shall not be held criminally or civilly liable under any federal or state trade secret law (x) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (y) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (ii) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order.

14. Executive's Cooperation. Executive shall cooperate with the Company upon the Company's reasonable request, with respect to any internal investigation or administrative, regulatory or judicial proceeding involving matters within the scope of Executive's duties and responsibilities to the Company during Executive's employment with the Company (including, without limitation, Executive being available to the Company upon reasonable notice for interviews and factual investigations, appearing at the Company's reasonable request to give testimony without requiring service of a subpoena or other legal process, and turning over to the Company all relevant Company documents which are or may have come into Executive's possession during Executive's employment); *provided*, *however*, that any such request by the Company shall not be unduly burdensome or interfere with Executive's personal schedule or ability to engage in gainful employment.

15. Section 409A of the Code. This Agreement is intended, to the greatest extent permitted under law, to comply with the short-term deferral exemption and the separation pay exemption provided in Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and other interpretative guidance issued thereunder ("Section 409A") such that no benefits or payments under this Agreement are subject to Section 409A. Notwithstanding anything herein to the contrary, the timing of any payments under this Agreement shall be made consistent with such exemption. To the extent applicable, this Agreement shall be interpreted in accordance with Section 409A, including without limitation any such regulations or other guidance that may be issued after the Transition Date. Notwithstanding any provision of this Agreement to the contrary, in the event that the Company determines that any amounts payable hereunder may be subject to Section 409A, the Company may, to the extent permitted under Section 409A cooperate in good faith to adopt such amendments to this Agreement or adopt other appropriate policies and procedures, including amendments and policies with retroactive effect, that the Company determines are necessary or appropriate to avoid the imposition of taxes under Section 409A; *provided however*, that this paragraph shall not create an obligation on the part of the Company to adopt any such amendment, policy or procedure or take any such other action, nor shall the Company have any liability for failing to do so. To the extent that any reimbursements payable pursuant to this Agreement are subject to the provisions of Section 409A, such reimbursements shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, and Executive's right to reimbursement under this Agreement shall not be subject to liquidation or exchange for another benefit. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned have caused this Transition Agreement to be duly executed and delivered as of the date indicated next to their respective signatures below.

DATED: 12/31/2025 /s/ Fred Kamal

Fred Kamal, Ph.D.

DATED: 12/31/2025 **4D MOLECULAR THERAPEUTICS, INC.**

By: /s/ David Kirn
Name: David Kirn, MD
Title: Chief Executive Office

Certain confidential information contained in this document, marked by brackets and asterisk, has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K, because the Company treats such information as private or confidential and the omitted information is not material.

Exhibit 10.24

Confidential
Execution Version

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this "**Agreement**") is entered into as of October 31, 2025 (the "**Effective Date**") by and between **4D Molecular Therapeutics, Inc.**, a Delaware corporation with a place of business at 5858 Horton Street #455, Emeryville, CA 94608, USA ("**4DMT**") and **Otsuka Pharmaceutical Co., Ltd.**, a Japan corporation with its registered office at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan ("**Otsuka**"). 4DMT and Otsuka are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**".

BACKGROUND

WHEREAS, 4DMT is a clinical-stage, biopharmaceutical company researching and developing innovative and proprietary AAV-based gene therapies.

WHEREAS, Otsuka is a pharmaceutical and biotechnology company with expertise in the research, development, manufacture and commercialization of pharmaceutical products.

WHEREAS, the Parties hereby desire to establish a collaboration for the further development and commercialization of the Licensed Product in the Territory, in each case, in accordance with the terms and conditions set forth in this Agreement.

WHEREAS, under such collaboration, Otsuka shall have the exclusive development (subject to exceptions as set forth below) and commercialization rights in the Field in the Territory, as set forth in more detail in this Agreement.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set forth in this Article 1, whether used in the singular or plural form.

1.1 "**4D-150**" means 4DMT's proprietary gene therapy product that (a) is known as "4D-150," (b) consists of 4DMT's proprietary intravitreally deliverable AAV vector known as R100 (the "**Vector**") and a transgene cassette that expresses both aflibercept and a VEGF-C inhibitory RNAi, and (c) is described in IND number [*].

1.2 "**4DMT**" has the meaning set forth in the preamble to this Agreement.

1.3 "**4DMT Development Activities**" has the meaning set forth in Section 3.3.

1.4 "**4DMT Indemnitees**" has the meaning set forth in Section 11.2.

1.5 "**4DMT Local Clinical Trial**" means any Local Clinical Trial conducted by 4DMT as set forth in Section 3.2(b)(i).

1.6 "**4DMT Local Clinical Trial Plan**" has the meaning set forth in Section 3.2(b)(i).

1.7 "**4DMT Party**" means any of 4DMT, any of its Affiliates, any licensee of 4DMT or any of its Affiliates and any service provider of any of the foregoing acting on behalf of such Person.

1.8 "**4DMT Prosecuted Patents**" has the meaning set forth in Section 9.2(a)(i).

1.9 "**4DMT Regulatory Activities**" has the meaning set forth in Section 4.1(a).

1.10 "**AAV**" means adeno-associated virus.

1.11 "**Accounting Standards**" means the United States Generally Accepted Accounting Principles or International Financial Reporting Standards (IFRS), in each case, as consistently applied throughout the organization of a particular Person and its Affiliates.

1.12 "**Affiliate**" means, with respect to a Person (including a Party), any other Person controlling, controlled by or under common control with such first Person, at the time that the determination of affiliation is made and for as long as such control exists; *provided, however*, [*]. For the purposes of this definition, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means (a) direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such Applicable Laws; *provided*, *however*, that such ownership interest provides actual control over such Person), or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

1.13 "**Agreement**" has the meaning set forth in the preamble to this Agreement.

1.14 "**Alliance Manager**" has the meaning set forth in Section 2.6(a).

1.15 "**Allocated 4FRONT-1 Clinical Trial Cost**" has the meaning set forth in Section 8.2.

1.16 "**Allocated** [*] **Study Cost**" has the meaning set forth in Section 8.3(c).

1.17 "**Allocated Cross-Territory Clinical Trial Cost**" has the meaning set forth in Section 8.3(a).

1.18 "**Allocated** [*] **Study Cost**" has the meaning set forth in Section 8.3(c).

1.19 "**Allocated** [*] **Study Cost**" has the meaning set forth in Section 8.3(c).

1.20 "**AMD Indication**" means wet age-related macular degeneration.

1.21 "**Applicable Law**" means the applicable laws, rules and regulations, including any rules, regulations (including cGCP, cGLP and cGMP), guidelines or other requirements of

Governmental Authorities, including Regulatory Authorities, which may be in effect from time to time, including anti-corruption laws, data collection, processing, or transfer laws, rules or regulations, or any judgments or ordinances of any court or any subpoena of a competent court, in each case, having effect from time to time in applicable territory.

1.22"**Approved Label**" means, with respect to the Licensed Product and a jurisdiction: (a) the applicable Regulatory Authority-approved full prescribing information for the Licensed Product in such jurisdiction; and (b) the applicable Regulatory Authority-approved labels and any other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for the Licensed Product in such jurisdiction.

1.23"**Arising Product IP**" means (a) any and all Know-How that (i) is invented or otherwise generated (whether solely or jointly) by or on behalf of a Party or its Affiliates or licensees (including, sublicensees, and with respect to Otsuka, Sublicensees) in exercising rights or carrying out obligations under this Agreement, whether directly or via its agents or Contractors and (ii) relates to the Licensed Product, including its formulation, method of use or Manufacture, and (b) any and all right, title and interest in and to the intellectual property rights therein, including, for clarity, Patents Covering such Know-How described in the foregoing subclause (a).

1.24"**Asia and Oceania**" means the continent known as "Asia" together with the region known as "Oceania" and includes the countries that are listed in Schedule 1.24.

1.25"**Auditor**" has the meaning set forth in Section 8.13(c).

1.26"**Bankrupt Party**" has the meaning set forth in Section 13.6.

1.27"**Biosimilar Product**" means, on a country-by-country basis and with respect to the Licensed Product, a product (a) the approval, license, registration or authorization for marketing and sale of which in such country was obtained by means of a procedure that relies in whole or in part on the safety and efficacy data contained in an MAA for the Licensed Product submitted by or on behalf of an Otsuka Party or a 4DMT Party to the applicable Regulatory Authority in such country or any other country, to establish bioequivalence to the Licensed Product, (b) that is determined by the applicable Regulatory Authority in or for such country to be biosimilar to or interchangeable with the Licensed Product, as set forth at 42 U.S.C. § 262(k) (or foreign equivalent thereof), and (c) that is sold in such country by a Third Party that is not an Otsuka Party and that did not purchase such product in a chain of distribution that included any Otsuka Party.

1.28"**Business Day**" means a day other than (a) a Saturday or a Sunday, (b) a bank or other public holiday in Tokyo, Japan, or (c) a bank or other public holiday in Emeryville, California.

1.29"**Calendar Quarter**" means each period of three (3) consecutive calendar months, ending March 31, June 30, September 30, and December 31; *provided* that (a) the first Calendar Quarter of the Term shall extend from the Effective Date until December 31, 2025, and (b) the last Calendar Quarter of the Term shall end on the effective date of expiration or termination of this Agreement.

1.30"**Calendar Year**" means (a) for the first year of the Term, the period beginning on the Effective Date and ending on December 31, 2025, and (b) for each year of the Term thereafter, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on

December 31, except that the last year of the Term shall end on the effective date of expiration or termination of this Agreement.

1.31"**Change of Control**" means, with respect to a Person (including a Party), (a) the sale or disposition of all or substantially all of the assets of such Person or its direct or indirect controlling Affiliate to another Person, other than to an entity of which more than fifty percent (50%) of the voting capital stock are owned after such sale or disposition by shareholders of such Person or its direct or indirect controlling Affiliate (in either case, whether directly or indirectly through any parent entity) or (b) (i) the acquisition by another Person, alone or together with any of its Affiliates, other than an employee benefit plan (or related trust) sponsored or maintained by such Person or any of its Affiliates, of more than fifty percent (50%) of the outstanding shares of voting capital stock of such Person or its direct or indirect controlling Affiliate, or (ii) the acquisition, merger or consolidation of such Person or its direct or indirect controlling Affiliate with or into another Person, other than, in the case of subclause (i) or (ii), an acquisition or a merger or consolidation of such Person or its controlling Affiliate in which the holders of shares of voting capital stock of such Person or its controlling Affiliate, as the case may be, immediately prior to such acquisition, merger or consolidation will beneficially own, directly or indirectly, at least fifty percent (50%) of the shares of voting capital stock of the acquiring Person or the surviving corporation in such acquisition, merger or consolidation, as the case may be, immediately after such acquisition, merger or consolidation; and in each case ((a) or (b)), whether through a single transaction or a series of related transactions but excluding any and all *bona fide* financing transactions.

1.32"**Claim**" has the meaning set forth in Section 11.3.

1.33"**Clinical Sub-Committee**" has the meaning set forth in Section 2.7(c).

1.34"**Clinical Trial**" means any clinical testing of a Licensed Product in human subjects, including as applicable, Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or any clinical tests or studies that are intended to expand the product labeling for such Licensed Product and other post-marketing clinical studies of any Licensed Product. For clarity, a "Clinical Trial" shall include any long-term follow-up commitments for patients in such Clinical Trial that are required by any applicable Regulatory Authority, whether conducted under the same or a different protocol.

1.35"**Clinical Trial Failure**" has the meaning set forth in Section 13.2(e).

1.36"**CMC**" means chemistry, manufacturing and controls.

1.37"**CMO**" means a contract manufacturing organization.

1.38"**CNY**" means the Chinese yuan, the lawful currency of the PRC.

1.39"**Commercialization**" means the (a) marketing, promotion, detailing, sale and booking of sales, distribution, offer for sale, sampling, export for use, sale or distribution and import for use, sale or distribution of a product (including the Licensed Product in the Territory), or (b) performance of any activities affecting or contemplated by the Territory Commercialization Plan. Commercialization shall include, with respect to the Licensed Product, the activities relating to (i) marketing and promotion, (ii) market research matters, including revenue forecasting, market landscape/situational analyses, competitive intelligence, material testing, dashboard reporting, health economics/value proposition, branding and communications plans, and pricing strategy, (iii) field force matters, including field force training, field operations, performance metrics/reporting, field force sizing

and alignment, key customer development, and professional education (to the extent not performed by field representatives), including launch meetings, (iv) health services matters, and (v) market access and patient support services. "**Commercialize**" has a correlative meaning to Commercialization.

1.40"**Commercialization Sub-Committee**" has the meaning set forth in Section 5.4(b).

1.41"**Commercially Reasonable Efforts**" means, [*]

1.42"**Confidential Information**" means any and all confidential or proprietary information, data or know-how (including Know-How), whether technical or non-technical, oral or written, that is disclosed by or on behalf of one Party or its Affiliates ("**Disclosing Party**") to the other Party or its Affiliates ("**Receiving Party**") in accordance with or otherwise in connection with this Agreement. Confidential Information shall not include any information, data or know-how to the extent the Receiving Party can demonstrate through competent evidence that such information:

(a) was generally available to the public at the time of disclosure, or becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party or its Affiliates;

(b) was already known to the Receiving Party or its Affiliates, in each case, without any confidentiality restrictions, prior to its receipt from the Disclosing Party;

(c) is obtained by the Receiving Party at any time lawfully from a Third Party under circumstances permitting its use or disclosure (*i.e.*, such Third Party was not under any obligations of confidentiality or non-use with respect to such information and the Receiving Party is not subject to any obligations of confidentiality or non-use with respect to such information); or

(d) is developed independently by or on behalf of the Receiving Party or its Affiliates without use of, reference to or reliance upon any Confidential Information of the Disclosing Party.

The terms of this Agreement shall be considered Confidential Information of the Parties.

1.43"**Contractors**" means consultants, distributors, wholesalers, contract research organizations, CMOs and other subcontractors.

1.44"[*] **Study**" means the Clinical Trial that [*].

1.45"**Control**" means (as an adjective or as a verb including conjugations and variations such as "**Controls**" "**Controlled**" or "**Controlling**") (a) with respect to Patents, Know-How or other intellectual property rights, the possession by a Party of the ability to grant a license or sublicense of such Patents, Know-How or other intellectual property right, and (b) with respect to proprietary materials, including Regulatory Materials and Regulatory Approvals, the possession by a Party of the ability to supply such material to the other Party as provided herein, in each case of (a) and (b), (i) without violating the terms of any agreement or arrangement between such Party and any Third Party and (ii) solely with respect to Patents [*], Know-How or other intellectual property rights acquired or licensed from a Third Party after the Effective Date, without requiring any payments to a Third Party. In the event of a Change of Control of a Party, any Patents, Know-How or other intellectual property rights that are owned or controlled by such Party's New Affiliates as a result of such Change of Control will be deemed not to be Controlled by such Party or its Affiliates for purposes of this Agreement,

except to the extent used by such Party in connection with the performance of activities under this Agreement and falling within the first sentence of this definition. For clarity, with respect to any agreement that becomes an Upstream License pursuant to the process set forth in Section 7.8(c) and subject to the last sentence of Section 7.8(c), (A) the Patents, Know-How or other intellectual property rights licensed by 4DMT under such Upstream License shall be deemed Controlled by 4DMT and included in Licensed IP, and (B) Otsuka shall have the obligations specified in Section 7.8 including to be bound by the applicable terms and conditions of such Upstream License and to make the payments specified therein. For further clarity, [*].

1.46"**Cover**" means (as an adjective or as a verb including conjugations and variations such as "**Covered,**" "**Coverage**" or "**Covering**") that the Exploitation of a given compound, formulation, process or product would infringe a Valid Claim in the absence of a license under or ownership of the Patent rights to which such Valid Claim pertains (and for the purpose of determining such infringement, considering claims of pending patent applications as if they have already been issued). The determination of whether a compound, formulation, process or product is Covered by a particular Valid Claim shall be made on a country-by-country basis.

1.47"**Critical Reagents**" means reagents necessary for [*] (*e.g.*, [*]) and other materials necessary or reasonably useful for Exploitation of the Licensed Product in the Territory, but excluding [*].

1.48"**Cross-Territory Clinical Trial**" means a Phase 3 Clinical Trial that is required for Regulatory Approval of the Licensed Product in the United States for an Indication and includes clinical sites in [*], [*]or [*], with the goal of obtaining the Regulatory Approval for the Licensed Product in such Indication in such country (*i.e.*, [*], as applicable) [*]. For clarity, "Cross-Territory Clinical Trial" shall include the 4FRONT-2 Clinical Trial.

1.49"**Cross-Territory Clinical Trial Cost**" has the meaning set forth in Section 8.3(a).

1.50"**Development**" means to engage in research and development activities, including [*]. This includes [*], but excludes [*]. "**Develop**" has a correlative meaning.

1.51"**Disclosing Party**" has the meaning set forth in Section 1.42.

1.52"**DME Indication**" means diabetic macular edema.

1.53"**DMF**" means drug master file.

1.54"**Dollars**" means the United States dollar, and "**$**" shall be interpreted accordingly.

1.55"**Effective Date**" has the meaning set forth in the preamble to this Agreement.

1.56"**Executive Officer**" means (a) in the case of 4DMT, [*], and (b) in the case of Otsuka, [*].

1.57"**Existing CDA**" means the Mutual Confidential Disclosure Agreement by and between the Parties dated as of [*].

1.58"**Exploit**" means, to Develop, have Developed, register, use, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise exploit. "**Exploitation**" and "**Exploiting**" have a correlative meaning.

1.59"**FDA**" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.60"**FDCA**" means the United States Federal Food, Drug and Cosmetic Act, as amended.

1.61"**Field**" means all uses for the treatment or prevention of any ophthalmological diseases and conditions in humans.

1.62"**First Commercial Sale**" means, with respect to the Licensed Product and a country within the Territory, the first sale by an Otsuka Party to a Third Party of such Licensed Product in such country after all required Regulatory Approvals have been obtained in such country. For clarity, supply of the Licensed Product as samples or to patients for compassionate use, named patient use, Clinical Trials or other similar purposes shall not be considered a First Commercial Sale if no consideration is received for such supply.

1.63"**FTE**" means the equivalent of a full-time individual's work for a twelve (12)-month period (consisting of a total of [*] hours per year of dedicated effort). [*]. No person shall be treated as being more than one (1) FTE regardless of the number of hours worked.

1.64"**FTE Rate**" means an initial rate of [*] per hour, which rate shall apply through [*]. Thereafter, [*], the FTE Rate [*] shall be increased by [*], the first of which such increase shall take place on [*]. For clarity, from and including [*] and thereafter, in no event shall the FTE Rate [*] be lower than [*].

1.65"**Global Brand Elements**" has the meaning set forth in Section 7.4(d).

1.66"**Global Commercialization Plan**" has the meaning set forth in Section 5.4(a).

1.67"**Global Development Plan**" has the meaning set forth in Section 3.4.

1.68"**Global Medical Affairs Plan**" has the meaning set forth in Section 4.8(c)(i).

1.69"**Governmental Authority**" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.70"**ICMJE**" has the meaning set forth in Section 3.8.

1.71"**IND**" means (a) an Investigational New Drug Application as defined in the FDCA and applicable regulations promulgated thereunder by the FDA, or (b) in the European Union, a Clinical Trial Application (CTA), or (c) the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.72"**Indemnified Party**" has the meaning set forth in Section 11.3.

1.73"**Indemnifying Party**" has the meaning set forth in Section 11.3.

1.74"**Indication**" means the AMD Indication, the DME Indication and any New Indication.

1.75"**Infringement**" has the meaning set forth in Section 9.3(a).

1.76"**Initial Royalty Term**" has the meaning set forth in Section 8.8(d)(i).

1.77"**IP Sub-Committee**" has the meaning set forth in Section 2.7(b).

1.78"**JPY**" means the Japanese yen, the lawful currency of Japan.

1.79"**JSC**" has the meaning set forth in Section 2.1.

1.80"**Know-How**" means any proprietary and confidential data, results, and information of any type whatsoever, in any tangible or intangible form, including trade secrets, practices, techniques, methods, processes, inventions, discoveries, developments, specifications, formulations, formulae, software, algorithms, marketing reports, pricing and distribution costs, forecasts, strategies, plans, clinical and Nonclinical Study reports, technology, test data including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, stability data, studies and procedures, dosage regimens; in each case, whether or not patentable or copyrightable.

1.81"**Licensed IP**" means collectively, the Licensed Patents and Licensed Know-How.

1.82"**Licensed Know-How**" means any and all Know-How, whether patentable or not, that is (a) Controlled by 4DMT or its Affiliates as of the Effective Date or during the Term and (b) necessary or reasonably useful for the Exploitation of the Licensed Product in the Field. For clarity, Licensed Know-How includes 4DMT's and its Affiliates' ownership interest in any Know-How within the Arising Product IP, as specified in Section 9.1 (including joint ownership interest).

1.83"**Licensed Patents**" means all Patents that are (a) Controlled by 4DMT or 4DMT's Affiliates as of the Effective Date or during the Term and (b) necessary or reasonably useful for the Exploitation of the Licensed Product in the Field. Notwithstanding the foregoing, [*]. For clarity, [*]. For clarity, [*].

1.84"**Licensed Product**" means 4D-150, in any form or dosage strength.

1.85"**Licensed Product Trademark**" means any Trademark in the Territory that is Controlled by 4DMT or its Affiliates as of the Effective Date or during the Term and that corresponds to a Trademark that is or is intended to be used by or on behalf of 4DMT, its Affiliates or its licensees for the Exploitation of the Licensed Product in countries outside of the Territory, including any registrations thereof or any pending applications therefor. The Licensed Product Trademark also includes the local language variation, and a mutually agreed number of backup, alternative, or substitute Trademarks in each country in the Territory that the Parties agree via the IP Sub-Committee or otherwise to file, prosecute or maintain in such country for the Exploitation of the Licensed Product in such country.

1.86"**Local Clinical Trial**" means a Clinical Trial for the Licensed Product for an Indication that is conducted solely in one or more countries or jurisdictions within the Territory. For clarity, Local Clinical Trials do not include any Cross-Territory Clinical Trials.

1.87"**Local Clinical Trial Cost**" has the meaning set forth in Section 8.3(b).

1.88"**MAA**" means an application for Regulatory Approval to place a medical product on the market, including (a) a Biologics License Application, as defined under the United States Public Health Service Act, 42 U.S.C. §§ 201 et seq., as amended from time to time or (b) any foreign equivalent thereof (*e.g.*, New Drug Application submitted to the PMDA in Japan).

1.89"**Manufacture**" means, with respect to a Licensed Product and Related Materials, those operations required to manufacture, test, release, handle, package, store or dispose of such Licensed Product, including validation, qualification and audit of clinical and commercial manufacturing facilities, bulk production and fill/finish work, related quality assurance technical support activities, and support for the preparation of the chemistry, manufacturing and controls sections of any Regulatory Materials or Regulatory Approval, and including, in the case of a clinical or commercial supply of such Licensed Product, the synthesis, manufacturing, processing, formulating, packaging, labeling, holding, quality control testing and release of such Licensed Product. "**Manufacturing**" has a correlative meaning.

1.90"**Manufacturing Cost**" means, with respect to the Licensed Product and Related Materials Manufactured or supplied to Otsuka under the Supply Agreement(s), 4DMT's fully-burdened cost of Manufacturing and supplying such Licensed Product or such Related Materials as described in Schedule 1.90. For clarity, Manufacturing Cost does not include [*]. Manufacturing Cost shall be determined and allocated in accordance with the Accounting Standards.

1.91"**Manufacturing Technology Transfer**" has the meaning set forth in Section 6.4(a).

1.92"**Medical Affairs Activities**" means the activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, the Licensed Product in anticipation of or after its Regulatory Approval, including by way of example: [*]. For clarity, Medical Affairs Activities do not include [*].

1.93"**Medical Affairs Sub-Committee**" has the meaning set forth in Section 4.8(a).

1.94"**Net Sales**" means, for any period of determination, the gross amount invoiced for sales of the Licensed Product by an Otsuka Party to Third Parties in the Territory in that period, reduced by the following, in each case, without duplication and solely to the extent actually incurred or accrued in accordance with the Accounting Standards and not reimbursed to the Otsuka Party:

(a) [*];

(b) [*];

(c) [*];

(d) [*];

(e) [*]; and

(f) [*].

For the avoidance of doubt, Net Sales shall not include [*].

All of the foregoing elements of Net Sales calculations will be determined on an accrual basis in accordance with the Accounting Standards consistently applied in accordance with the accounting practices of the applicable Otsuka Party. In no event shall any particular amount identified above be deducted more than once in calculating Net Sales (*i.e.*, no "double counting" of deductions). [*].

1.95"**New Affiliate**" means a Third Party that becomes an Affiliate of either Party through merger, acquisition, consolidation or other similar transaction, including a Change of Control of such Party.

1.96"**New Indication**" means any indication in the Field, other than the AMD Indication and DME Indication, for which the Licensed Product is developed by or on behalf of 4DMT or its Affiliates or, by the JSC's mutual agreement (in accordance with Section 2.2(e) and subject to Section 2.5), by or on behalf of Otsuka or any other Otsuka Party. For clarity, a New Indication may include [*] and [*].

1.97"**New Priority Patent**" has the meaning set forth in Section 9.10.

1.98"[*]**Percentage**" has the meaning set forth in Section 8.8(e)(iii).

1.99"**NMPA**" means the National Medicine Products Administration of the PRC and any successor agency(ies) or authority having substantially the same function.

1.100"**Nonclinical Studies**" means all (a) preclinical studies (including toxicology and other animal studies) of the Licensed Product, and (b) studies with respect to the Manufacturing of the Licensed Product, including stability studies and studies focused on process improvements. For clarity, Nonclinical Studies do not include routine manufacturing and release of the Licensed Product or activities necessary for Manufacturing Technology Transfer.

1.101"**Other Recipients**" has the meaning set forth in Section 12.3(c).

1.102"**Otsuka**" has the meaning set forth in the preamble to this Agreement.

1.103"**Otsuka Development Activities**" has the meaning set forth in Section 3.3.

1.104"**Otsuka Indemnitees**" has the meaning set forth in Section 11.1.

1.105"**Otsuka Local Clinical Trial**" means any Local Clinical Trial conducted by Otsuka as set forth in Section 3.2(b)(ii).

1.106"**Otsuka Party**" means Otsuka, any of its Sublicensees and any of Otsuka's or its Sublicensees' Affiliates.

1.107"**Otsuka Prosecuted Patents**" has the meaning set forth in Section 9.2(b)(i).

1.108"**Otsuka Regulatory Activities**" has the meaning set forth in Section 4.1(a).

1.109"**Otsuka Technology**" means all Patents and Know-How Controlled by Otsuka or its Affiliates as of the effective date of termination of this Agreement (other than Arising Product IP) that are (a) incorporated into the Licensed Product or (b) utilized with respect to the Licensed Product (including the Manufacturing process therefor) in connection with Exploitation of the Licensed Product

in the Territory or the Manufacture of the Licensed Product outside the Territory for Exploitation in the Territory, in each case ((a) and (b)), as of the effective date of termination of this Agreement.

1.110"**Out-of-Pocket Expenses**" means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards consistently applied) by a Party (or its Affiliate) directly incurred in the conduct of any applicable activities under this Agreement, including [*]. With respect to [*], Out-of-Pocket Expenses shall be calculated based on [*]. For clarity, Out-of-Pocket Expenses shall not include: (a) [*]; or (b) [*].

1.111"**Party**" or "**Parties**" has the meaning set forth in the preamble to this Agreement.

1.112"**Patent**" means (a) a national, regional or international U.S. or foreign patent, patent application, utility model, design patent or design right or related application, including a priority application, (b) any additions, priority applications, divisionals, continuations, and continuations-in-part of any of the foregoing and (c) all patents issuing on any of the foregoing patent applications, together with all invention certificates, substitutions, reissues, reexaminations, registrations, supplementary protection certificates, confirmations, renewals and extensions of any of the foregoing subclauses (a), (b) or (c), and U.S. or foreign counterparts of any of the foregoing.

1.113"**Patent Challenge**" has the meaning set forth in Section 13.2(b).

1.114"**Payment Forms**" means one copy of each of the following documents which, at the time 4DMT provides such documents to Otsuka, must be currently effective (un-expired) and completed: [*]; [*]; and [*].

1.115"**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.116"**Pharmacovigilance Agreement**" has the meaning set forth in Section 4.6.

1.117"**Phase 1 Clinical Trial**" means any human clinical trial of a Licensed Product that would satisfy the requirements of 21 § CFR 312.21(a) or corresponding foreign regulations.

1.118"**Phase 2 Clinical Trial**" means any human clinical trial of a Licensed Product that would satisfy the requirements of 21 § CFR 312.21(b) or corresponding foreign regulations.

1.119"**Phase 3 Clinical Trial**" means any human clinical trial of a Licensed Product that would satisfy the requirements of 21 § CFR 312.21(c) or corresponding foreign regulations.

1.120"[*]" means [*].

1.121"**PRC**" means the People's Republic of China, including [*], but excluding [*].

1.122"**Pricing and Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product shall be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in the Territory.

1.123"**Promotional Materials**" has the meaning set forth in Section 7.4(c).

1.124"**Prosecution and Maintenance**" or "**Prosecute and Maintain**" means, with respect to a Patent, the preparation, filing, prosecution and maintenance (including payment of any patent annuity fees) of such Patent, as well as re-examinations, reissues, appeals, post grant reviews, inter partes reviews and requests for patent term adjustments and patent term extensions with respect to such Patent, together with the initiation or defense of interferences, oppositions and other similar proceedings with respect to the particular Patent, and any appeals therefrom, but, for clarity, shall not include any other enforcement actions taken with respect to a Patent pursuant to Section 9.3.

1.125"**Publication**" has the meaning set forth in Section 12.6.

1.126"**PV Sub-Committee**" has the meaning set forth in Section 4.7.

1.127"**Quality Agreement**" has the meaning set forth in Section 6.1.

1.128"**Receiving Party**" has the meaning set forth in Section 1.42.

1.129"**Regulatory Approval**" means, for a Licensed Product in a jurisdiction, any approval, license, registration or authorization necessary for the marketing and sale of such Licensed Product in such jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, but which shall exclude any Pricing and Reimbursement Approvals.

1.130"**Regulatory Authority**" means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting approvals for an IND, for the Manufacturing or marketing of the Licensed Product, Regulatory Approval or, to the extent required in such country or regulatory jurisdiction, Pricing and Reimbursement Approval of the Licensed Product in such country or regulatory jurisdiction, including [*], in each case, or its successor.

1.131"**Regulatory Correspondence**" has the meaning set forth in Section 1.133.

1.132"**Regulatory Exclusivity**" means, with respect to a particular country or regulatory jurisdiction, any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to the Licensed Product other than Patent rights, including pediatric exclusivity and orphan drug exclusivity.

1.133"**Regulatory Materials**" means (a) any filing, application or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including applications for Regulatory Approvals, INDs and MAAs or their equivalents in any jurisdiction ("**Regulatory Submissions**"), and (b) all material written correspondence or written communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority ("**Regulatory Correspondence**"), in each case, with respect to the Licensed Product.

1.134"**Regulatory Submissions**" has the meaning set forth in Section 1.133.

1.135"**Related Materials**" means [*].

1.136"**Remedial Action**" has the meaning set forth in Section 5.5.

1.137"**Representative**" has the meaning set forth in Section 12.1.

1.138"**Safety Issue**" means, [*].

1.139"**Securitization Transaction**" has the meaning set forth in Section 15.6(b).

1.140"[*] **Study**" means the Clinical Trial that [*].

1.141"[*]" means [*].

1.142"**[*]**" means [*].

1.143"**[*]Claim**" has the meaning set forth in Section 11.1.

1.144"**[*]**" has the meaning set forth in Section 9.4(a).

1.145"**[*] Study**" has the meaning set forth in Section 3.2(c).

1.146"**Sub-Committee**" has the meaning set forth in Section 2.7(a).

1.147"**Sublicensee**" means any Third Party that receives from Otsuka or its Affiliate, whether directly or indirectly (including through multiple tiers), a sublicense under the license granted by 4DMT to Otsuka under Section 7.1 or another right to Exploit the Licensed Product in the Field in the Territory. For clarity, a Contractor engaged by Otsuka or its Affiliate shall not be considered a Sublicensee under this Agreement provided that such Contractor (a) solely performs activities on behalf of Otsuka or its Affiliate or (b) (i) is a distributor or wholesaler and (ii) Otsuka and its Affiliates do not receive any royalty, share of revenue or profit or other payment based on Licensed Product sales made by such distributor or wholesaler.

1.148"**Supply Agreement**" has the meaning set forth in Section 6.1.

1.149"**Term**" has the meaning set forth in Section 13.1.

1.150"**Territory**" means Japan, PRC, [*], Australia, and [*]

1.151"**Territory Commercialization Plan**" has the meaning set forth in Section 5.3(a).

1.152"**Territory Development Plan**" has the meaning set forth in Section 3.3.

1.153"**Territory [*]**" has the meaning set forth in Section [*].

1.154"**Territory [*]**" has the meaning set forth in Section [*].

1.155"**Territory Medical Affairs Plan**" has the meaning set forth in Section 4.8(b).

1.156"**Third Party**" means a Person other than 4DMT, Otsuka and Affiliates of either of them.

1.157"**Third Party IP**" has the meaning set forth in Section 7.8(b).

1.158"**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

1.159"**Trademark Guidelines**" has the meaning set forth in Section 7.4(c).

1.160"**United States**" or "**U.S.**" means the United States of America (including all possessions and territories thereof).

1.161"**Upstream License**" means [*]

1.162"**Valid Claim**" means, [*].

1.163"**Vector**" has the meaning set forth in Section 1.1.

ARTICLE 2

GOVERNANCE

2.1 JSC Formation and Dissolution. No later than [*] ([*]) days after the Effective Date, 4DMT and Otsuka will form a joint steering committee (the "**JSC**"). The JSC shall exist during the Term unless dissolved earlier by mutual written agreement of the Parties, in which event, the JSC (a) shall be terminated and (b) shall have no further rights or obligations under this Agreement. If the JSC is so dissolved, the Alliance Managers shall continue to be the contact persons for the exchange of information under this Agreement and decisions of the JSC shall be decisions as between the Parties, subject to the same respective decision making rights and limitations set forth in Section 2.5, Section 2.9 and other terms and conditions of this Agreement.

2.2 JSC Responsibilities. The JSC will be responsible for the following activities, which shall only be decision-making activities if described below as "approving" or "deciding":

(a) coordinating and reviewing the Development, Commercialization, Manufacture (including any events or circumstances that may materially increase the Manufacturing Cost of the Licensed Product), and other Exploitation of the Licensed Product in the Field in the Territory under this Agreement;

(b) providing a forum for the discussion of the Parties' activities (including each Party's Development of the Licensed Product, as specified in Section 3.7) under this Agreement;

(c) (i) reviewing, discussing, and approving [*];

(d) reviewing and discussing the status and results of Nonclinical Studies (including, for clarity, CMC developments) with respect to the Licensed Product worldwide;

(e) reviewing, discussing and deciding [*];

(f) sharing information, reviewing and discussing material regulatory developments related to the Licensed Product worldwide, as specified in Section 4.1;

(g) sharing information, reviewing, discussing and approving the Territory Medical Affairs Plan and any updates and amendments thereto and reviewing and discussing the Global Medical Affairs Plan and any updates and amendments thereto, as specified in Section 4.8;

(h) reviewing and discussing[*];

(i) reviewing, discussing and approving [*][*]

(j) sharing and discussing the Global Commercialization Plan for the Licensed Product and sharing information, discussing and coordinating with respect to progress toward such Global Commercialization Plan;

(k) sharing information, discussing and coordinating with respect to Commercialization activities, including [*], as specified in Section 5.4 and Section 5.6; *provided* that, the foregoing does not require the sharing of any information the sharing of which would violate Applicable Law or information that is not required to be shared pursuant to Section 5.4 or Section 5.6;

(l) sharing information, discussing and coordinating with respect to the Manufacturing Technology Transfer;

(m) reviewing and discussing proposed Publications pursuant to Section 12.6;

(n) reviewing, discussing and serving as a forum for the sharing of information that is reasonably necessary or useful for the JSC to perform its responsibilities under this Section 2.2;

(o) attempting to resolve in the first instance all matters between the Parties that fall within the JSC's authority and are in dispute, including matters presented to it by any Sub-Committee pursuant to Section 2.7, in accordance with Section 2.5 and Article 14;

(p) establishing Sub-Committees as may be required for properly exchanging, reviewing and coordinating, information regarding the matters specified under this Section 2.2 and establishing any other Sub-Committees as it deems necessary to achieve the objectives and intent of this Agreement, as well as deciding whether to delegate, or withdraw any former delegation, responsibilities and decision-making authority that the JSC has under this Section 2.2 to any Sub-Committee; and

(q) perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement to the extent agreed in writing by the Parties.

2.3 Membership. The JSC will be composed of a total of [*] ([*]) (or another number to be mutually agreed upon by the Parties) representatives of each Party plus its respective Alliance Manager as a non-voting member, which will be appointed by each of 4DMT and Otsuka, respectively. Each individual appointed by a Party as a representative to the JSC will be an employee, officer or director of such Party with sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JSC's responsibilities, and will have knowledge and expertise in the Development or other Exploitation of similar products as the Licensed Product. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party's Alliance Manager. The JSC will be co-chaired by one (1) designated representative of each Party. Each co-chairperson will alternate being responsible for each meeting for (a) calling and conducting such meeting, (b) preparing and circulating

an agenda in advance of such meeting; *provided*, *however*, that the applicable co-chairperson will include any agenda items proposed by either Party on such agenda, (c) preparing draft minutes of such meeting that reflect the material decisions made and action items identified at such meeting, and (d) sending such draft meeting minutes to each member of the JSC for review and approval as soon as reasonably practicable after such meeting. The tasks under the foregoing subclauses (a) through (d) may be delegated to the Alliance Managers. Meeting minutes issued in accordance with the foregoing subclause (d) of this Section 2.3 will be deemed approved unless [*] ([*]) or more members of the JSC objects to the accuracy of such minutes within [*] ([*]) Business Days of receipt. The co-chairpersons will work cooperatively and in good faith to resolve any such objection promptly. Each JSC representative will be subject to confidentiality obligations no less stringent than those in Article 12. Each Party will be permitted to record audio or video of each meeting for reference purposes; *provided* that such Party shall promptly delete the recording following approval of the relevant meeting minutes.

2.4 Meetings; Reports. The JSC will hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than [*] ([*]) times per Calendar Year, unless otherwise agreed by the Parties. As soon as practicable prior to any meeting of the JSC, the applicable co-chairperson or Alliance Manager will prepare and circulate an agenda for such meeting. Either Party may call a special meeting of the JSC by providing reasonable prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the applicable co-chairpersons of the JSC and the Alliance Managers to provide the members of the JSC reasonably in advance of the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. The JSC shall meet by video conference unless its representatives mutually agree to meet in person. Other representatives of the Parties, their Affiliates, or Third Parties involved in the Exploitation of the Licensed Product may be invited by the members of the JSC to attend meetings as non-voting observers; *provided*, *however*, that such representatives are subject to confidentiality obligations no less stringent than those set forth in Article 12; and *provided*, *further*, that such other representatives shall be excluded from any portion of a meeting and from receipt of related materials or information upon the reasonable request of a Party or its co-chairperson. No action taken at a meeting will be effective unless at least one (1) representative of each Party (which representative is not such Party's Alliance Manager) is present or participating. Neither Party will unreasonably withhold attendance of at least one (1) representative of such Party at any meeting of the JSC for which reasonable advance notice was provided. Costs incurred by each Party in connection with its participation at any meetings of the JSC shall be borne solely by such Party.

2.5 Decision-Making. All decisions of the JSC and each Sub-Committee shall be made by unanimous vote, with each Party's representatives having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before any Sub-Committee established by the JSC, the representatives of the Parties on such Sub-Committee cannot reach a unanimous decision as to such matter within [*] ([*]) Business Days after a Party has requested resolution of such matter by such Sub-Committee, such matter shall be referred to the JSC for resolution. The JSC shall promptly meet and use good faith efforts to resolve such matter. If the JSC cannot resolve any matter within its decision-making authority within [*] ([*]) days after such matter has been referred to them, then, subject to Section 2.9:

(a) Otsuka shall have final decision making authority over any matter that relates [*]; and

(b) with respect to all other such matters within the decision-making authority of the JSC (including delegation of decision-making authority to Sub-Committees), [*].

For clarity, the JSC shall have no decision-making authority with respect to (x) the Development, Manufacture, Commercialization or other Exploitation of the Licensed Product outside the Field or outside the Territory, [*].

2.6 Alliance Managers.

(a) Appointment. Each Party will appoint a person to facilitate interactions between the Parties for all matters related to this Agreement (each, an "**Alliance Manager**"). The Alliance Managers will have the right to attend all meetings of the JSC and Sub-Committees thereof as non-voting participants, may bring to the attention of the JSC any matters or issues either Alliance Manager reasonably believes should be discussed, and will have such other responsibilities as the Parties may mutually agree in writing. Each Party may replace its Alliance Manager at any time by providing notice in writing to the other Party.

(b) Responsibility. The Alliance Managers will have the responsibility of creating and maintaining a constructive work environment within the JSC and between the Parties for all matters related to this Agreement. Without limiting the generality of the foregoing, each Alliance Manager will:

(i) provide a single point of communication within the Parties' respective organizations and between the Parties with respect to this Agreement;

(ii) coordinate cooperative efforts of the Parties with respect to this Agreement; and

(iii)take such other steps as may be required to ensure that meetings of the JSC occur as set forth in this Agreement, that procedures are followed with respect to such meetings (including working with the co-chairpersons with respect to the giving of proper notice, the preparation and circulation of agendas and the preparation and approval of minutes as described under Section 2.3) and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

2.7 Sub-Committees.

(a) The JSC may form and establish sub-committees or working groups as may be necessary or desirable to facilitate the work of the JSC or to support and inform the decision-making of the JSC (each such sub-committee, a "**Sub-Committee**").

(b) Within [*] ([*]) days after the Effective Date, the Parties shall, through the JSC, establish a Sub-Committee directed to Patents and other intellectual property related matters (the "**IP Sub-Committee**"). The IP Sub-Committee shall consist of at least [*] ([*]) (or such other number mutually agreed upon by the Parties) representatives from each of the Parties. From time to time, each Party may substitute one (1) or more of its representatives to the IP Sub-Committee by providing an advance written notice to the other Party. The IP Sub-Committee will hold meetings at such times as it elects to do so, by teleconference or videoconference (or in person if the Parties otherwise agree). The IP Sub-Committee shall be subject to the oversight of, and shall report to, the JSC [*]. For clarity, [*

]. In particular, the IP Sub-Committee shall serve as a forum to review and discuss (a) Third Party IP pursuant to Section 7.8(b), (b) disclosures of Arising Product IP made by a Party pursuant to Section 9.1(c), (c) the Prosecution and Maintenance, enforcement and defense of the Patents and Licensed Product Trademarks pursuant to Article 9, (d) [*], and (e) any other Patent or other intellectual property related matters between the Parties in connection with this Agreement.

(c) Within thirty ([*]) days after the Effective Date, the Parties shall, through the JSC, establish a Sub-Committee to coordinate, manage and support any Local Clinical Trials to be conducted by the Parties in the Territory (the "**Clinical Sub-Committee**").

(d) The JSC will form the PV Sub-Committee in accordance with Section 4.7, the Commercialization Sub-Committee in accordance with Section 5.4(b), and the Medical Affairs Sub-Committee in accordance with Section 4.8(a).

2.8 Good Faith. In conducting themselves on the JSC and the Sub-Committees, and in exercising the Parties' rights under this Article 2, all representatives of each Party shall consider diligently, reasonably and in good faith all input received from the other Party, and shall use reasonable efforts to reach consensus on all matters before the JSC or any Sub-Committee. In exercising any final decision-making authority granted to it under this Article 2, each Party shall act based on its good faith judgment.

2.9 Limitations on Decision-Making. Notwithstanding anything to the contrary set forth in this Agreement, neither the JSC nor a Party (in the exercise of a Party's final decision-making authority) may make a decision that (a) could reasonably be expected to require the other Party to take any action that such other Party reasonably believes would (i) require such other Party to violate any Applicable Law, the requirements of any Regulatory Authority, or any legally binding written agreement with any Third Party entered into by such other Party prior to the Effective Date or (ii) require such other Party to infringe or misappropriate any intellectual property rights of any Third Party, (b) could significantly increase costs of the other Party, unless agreed by such other Party, or (c) conflicts with, amends, interprets, modifies, or waives compliance under this Agreement, unless mutually agreed by the Parties.

ARTICLE 3

DEVELOPMENT

3.1 Nonclinical Studies. If a Regulatory Authority in the Territory requires one or more Nonclinical Study(ies) that are in addition to those Nonclinical Studies performed by 4DMT for the purpose of obtaining Regulatory Approval of the Licensed Product outside the Territory, Otsuka shall prepare and provide a study protocol with respect to such proposed Nonclinical Study to 4DMT for review and comment, and Otsuka shall [*]. For clarity, Otsuka shall not conduct any Nonclinical Studies unless set forth in the Territory Development Plan as approved by the JSC.

3.2 Clinical Trials.

(a) Clinical Trials in Global Development Plan. As between the Parties, 4DMT shall be solely responsible for conducting, and will conduct, (x) any and all Clinical Trials that are included in the initial Global Development Plan (attached hereto as Schedule 3.4) for purposes of the Regulatory Approval of the Licensed Product in the United States (including, for clarity, Cross-Territory Clinical Trials) for (i) the AMD Indication, (ii) the DME Indication, and (iii) at 4DMT's sole

discretion, a New Indication, (y) the 4DMT Local Clinical Trials, and (z) the [*] Study, the [*] Study, and the [*] Study. 4DMT shall be responsible for the costs of such Clinical Trials, *provided* that Otsuka shall make the payments set forth in Sections 8.2 and 8.3 with respect to the 4FRONT-1 Clinical Trial, Cross-Territory Clinical Trials, 4DMT Local Clinical Trials, the [*] Study, the [*] Study, and the [*] Study. For clarity, 4DMT is obligated pursuant to subsection (x) of this Section 3.2(a) to conduct a Cross-Territory Clinical Trial for the AMD Indication that includes clinical sites in [*] and [*], a Cross-Territory Clinical Trial for the DME Indication that includes clinical sites in [*] and [*], and a Cross-Territory Clinical Trial for, at 4DMT's sole discretion, any New Indication, that includes clinical sites in [*] and [*], in each case with the goal of obtaining the Regulatory Approval for the Licensed Product in such Indication in such country [*].

(b) Local Clinical Trials.

(i) 4DMT Local Clinical Trials. If the Regulatory Authority in any country in the Territory (x) does not agree to accept for evaluation (whether during pre-filing consultation or otherwise) the filing dossier for the Licensed Product for an Indication and requires a or an additional Local Clinical Trial in such country, or (y) otherwise requires a Local Clinical Trial for any of the AMD Indication, the DME Indication or any New Indication, in both cases (x) and (y) in order to obtain Regulatory Approval for such Indication in such country, then 4DMT shall conduct such Local Clinical Trial regardless of the study design subject to the cost allocation set forth in Section 8.3. Notwithstanding the foregoing, in the event that (a) the 4FRONT-1 Clinical Trial or the Cross-Territory Clinical Trial for the AMD Indication does not achieve its primary endpoint as determined in 4DMT's reasonable discretion and (b) the relevant Local Clinical Trial for such Indication has not been initiated by or on behalf of 4DMT, 4DMT shall have no obligation to conduct such Local Clinical Trial. In the event that (1) the 4FRONT-1 Clinical Trial or the Cross-Territory Clinical Trial for the AMD Indication does not achieve its primary endpoint as determined in 4DMT's reasonable discretion and (2) the relevant 4DMT Local Clinical Trial has already been initiated, then 4DMT may cease the relevant 4DMT Local Clinical Trial only with Otsuka's prior written consent not to be unreasonably withheld. Prior to initiating any such 4DMT Local Clinical Trial conducted by 4DMT pursuant to this Section 3.2(b)(i), the Clinical Sub-Committee shall prepare and mutually agree to a "**4DMT Local Clinical Trial Plan**" consisting of (A) the relevant protocol, clinical and regulatory timelines (including anticipated IND filing date, date of first patient-in and last patient-out, anticipated filing date and approval date), identification of a proposed contract research organization, description of requested Otsuka operational support (if any) and (B) if Otsuka provides reimbursement with respect to such 4DMT Local Clinical Trial pursuant to Section 8.3, a budget therefor. Each 4DMT Local Clinical Trial Plan (including the study synopsis for the applicable 4DMT Local Clinical Trial) shall be subject to review and approval at the JSC. Subject to this Section 3.2(b)(i), 4DMT shall conduct a Local Clinical Trial for the AMD Indication in [*] in accordance with the terms and conditions of this Agreement.

(ii) Otsuka Local Clinical Trials. With respect to any other Local Clinical Trials in the Territory not otherwise described above in Section 3.2(b)(i), as between the Parties, Otsuka shall be solely responsible, at Otsuka's sole cost, for conducting such Local Clinical Trials in each of the AMD Indication, the DME Indication, and any New Indication, in each case, in accordance with the Territory Development Plan, if applicable, and as further described in this Article 3. Otsuka will be responsible, at Otsuka's sole cost, for conducting any such Otsuka Local Clinical Trials in each of the other Indications, in accordance with the Territory Development Plan, if applicable, and as further described in this Article 3. Prior to initiating any such Otsuka Local Clinical Trial conducted by Otsuka, Otsuka shall provide to 4DMT through the JSC a protocol therefor and Otsuka shall consider 4DMT's

comments in good faith and shall implement all such comments that 4DMT reasonably believes, if not implemented, would be reasonably likely to have a material adverse effect on (A) the Development of, Regulatory Approval for, or Commercialization of the Licensed Product outside the Territory or (B) 4DMT's retained rights under Section 7.2; *provided*, *however*, that, with respect to any Otsuka Local Clinical Trial that has already been initiated, Otsuka shall not be required to implement any such comments to the extent that implementation would conflict with or be prohibited by the requirements of the applicable Regulatory Authority or Applicable Law; *provided further* that Otsuka has considered and discussed with 4DMT in good faith possible mitigations of such potential material adverse effect. Upon Otsuka's reasonable request, 4DMT shall provide Otsuka reasonable, non-financial support for such Otsuka Local Clinical Trials *provided* that Otsuka shall reimburse 4DMT, in accordance with Section 8.5(a), for all Out-of-Pocket Expenses and internal FTE hours at the FTE Rate incurred by 4DMT in connection with providing such support.

(c) [*] Study. 4DMT will conduct, or continue conducting, a Clinical Trial to investigate [*] (the "**[*] Study**"). [*]. As soon as reasonably practicable after the Effective Date, 4DMT shall provide to Otsuka through the JSC a protocol [*] and budget therefor. 4DMT shall consider Otsuka's comments in good faith with respect to such protocol, and such budget shall be subject to mutual agreement of the Parties at the JSC. Costs for the [*] Study shall be allocated between the Parties as set forth in Section 8.3. 4DMT will provide to Otsuka the data from, and the formal clinical study report for, the [*] Study [*].

3.3 Territory Development Plan. As soon as reasonably practicable after the Effective Date, 4DMT shall submit to the JSC for discussion and approval by mutual agreement a written development plan, in the form of a presentation, that, at a minimum, sets forth (a) all material Development activities, including a reasonably detailed design of all 4DMT Local Clinical Trials (including the study synopsis but not including the protocol) (which, for clarity, as of the Effective Date consists of the Local Clinical Trial for the AMD Indication in [*]) and related material Development activities, if any, to be conducted by or on behalf of 4DMT, its Affiliates and Sublicensees pursuant to Section 3.2(b)(i) ("**4DMT Development Activities**") and (b) a reasonably detailed summary and anticipated timeline of all such activities (such plan, the "**Territory Development Plan**"). To the extent that Otsuka plans to conduct an Otsuka Local Clinical Trial or Nonclinical Study, Otsuka shall submit to the JSC for discussion and approval by mutual agreement an amendment to the Territory Development Plan, in the form of a presentation, that, at a minimum, sets forth (a) all material Development activities, including a reasonably detailed study design and study synopsis of the relevant Otsuka Local Clinical Trial (including the study synopsis but not including the protocol) or Nonclinical Study and related material Development activities, if any, to be conducted by or on behalf of Otsuka, its Affiliates and Sublicensees pursuant to Section 3.2(b)(ii) ("**Otsuka Development Activities**") and (b) a reasonably detailed summary and anticipated timeline of all such activities. For clarity, subject to Sections 2.5 and 3.2, Otsuka shall have final approval at the JSC over the protocol and synopsis of each Local Clinical Trial referenced in the Territory Development Plan. The Territory Development Plan shall, except as expressly agreed by 4DMT in writing and required by the applicable Regulatory Authority or to address specific operational requirements in the Territory, be focused on efficiently obtaining and maintaining Regulatory Approval of the Licensed Product in the Field in the Territory, while taking into consideration and mitigating any potential impact that 4DMT reasonably believes would be reasonably likely to be a material adverse effect on the Development, Regulatory Approval or Commercialization of the Licensed Product outside the Territory. From time to time during the Term, 4DMT and Otsuka may submit proposed updates or amendments to the Territory Development Plan to the JSC for review, discussion, and approval. Once approved by the JSC (subject to Section

2.5), the updated or amended Territory Development Plan shall become effective as of the date of such approval. For clarity, Otsuka and their respective Affiliates and Sublicensees shall not perform or have performed any Development activities other than Otsuka Development Activities that are set forth in a Territory Development Plan that has been approved by the JSC in accordance with Section 2.5.

3.4 Global Development Plan. Attached as Schedule 3.4 is a summary and anticipated timeline of 4DMT's Development activities for the global Development of the Licensed Product in the Field, including any Cross-Territory Clinical Trials (the "**Global Development Plan**"). 4DMT will keep the JSC reasonably informed of such activities (including any updates and amendments thereto). The Global Development Plan will include sufficient detail for the Parties through the JSC to develop a Territory Development Plan and for Otsuka to substantially conform its and its Affiliates' and Sublicensees' Development of the Licensed Product in the Field in the Territory to such Global Development Plan. Through the JSC at each meeting of the JSC, 4DMT will update Otsuka on 4DMT's progress against the Global Development Plan, in the form of a presentation, including providing material updates on the progress of each Clinical Trial and Nonclinical Studies (including material CMC developments) conducted by or on behalf of 4DMT (*e.g.*, enrollment status), a summary of all new Clinical Trials conducted, or planned to be conducted, by or on behalf of 4DMT, and a summary of all protocol amendments to any and all Clinical Trials conducted by or on behalf of 4DMT, in each case in connection with the Licensed Product. To the extent that 4DMT updates a Global Development Plan during the Term, Otsuka can update the Territory Development Plan and conform its Development activities to substantially conform to the updated Global Development Plan, subject to Section 3.5(a), at Otsuka's sole discretion.

3.5 Standards of Conduct; Development Diligence.

(a) Otsuka shall conduct all Otsuka Development Activities substantially in accordance with the Territory Development Plan, in a good scientific manner, and in compliance with Applicable Law.

(b) 4DMT shall conduct all 4DMT Development Activities substantially in accordance with the Territory Development Plan and Cross-Territory Clinical Trials substantially in accordance with the Global Development Plan, in a good scientific manner, and in compliance with Applicable Law.

(c) Otsuka shall use Commercially Reasonable Efforts, taking into account 4DMT's performance of its required Development activities pursuant to Sections 3.5(b) and 4.1(b), to Develop and obtain the Regulatory Approval for the Licensed Product [*]. Further, without limiting the foregoing, Otsuka shall use Commercially Reasonable Efforts to [*].

(d) 4DMT shall use diligent efforts to enroll, in the Cross-Territory Clinical Trial(s) for (x) the AMD Indication conducted by or on behalf of 4DMT, at least [*] ([*]) patients in [*], and (y) the DME Indication and any New Indication conducted by or on behalf of 4DMT, at least the number of patients that is agreed with each Regulatory Authority, or in the absence of such agreement, agreed by the Parties, in [*] and [*] such that no Local Clinical Trial needs to be performed in those countries to obtain Regulatory Approval for the Licensed Product for use in such Indications in such countries.

(e) Upon Otsuka's request, 4DMT shall promptly conduct additional data analyses required by any Regulatory Authority in the Territory in connection with patients in the Territory

enrolled in Cross-Territory Clinical Trials in accordance with Otsuka's reasonable instructions and Otsuka shall reimburse 4DMT for all Out-of-Pocket Expenses incurred by 4DMT in connection with conducting such analyses.

3.6 Data Exchange and Use. In addition to its adverse event and safety data reporting obligations pursuant to Section 4.6, each Party shall promptly provide the other Party with copies of all data and all supporting documentation (*e.g.*, protocols, CRFs, analysis plans) in the original language generated from (a) its and its Affiliates' and Sublicensees' Development of the Licensed Product under this Agreement, including, for clarity, Otsuka Development Activities (with respect to Otsuka) and (b) in the case of Otsuka, any investigator-initiated trial conducted in the Territory and supported by Otsuka or its Affiliate, to the extent such data and supporting documentation for such investigator-initiated trial is in Otsuka's or its Affiliate's possession and control, in each case ((a) and (b)), to the extent permissible under Applicable Law. Subject to Sections 8.2 and 8.3 and to the extent permissible under Applicable Law, Otsuka shall have the right to use and permit its Affiliates and Sublicensees to use such data provided by 4DMT for the purpose of obtaining and maintaining Regulatory Approval for, and Commercializing, the Licensed Product in the Field in the Territory. To the extent permissible under Applicable Law, 4DMT shall have the right to use and permit its Affiliates and licensees to use such data provided by Otsuka for the purpose of obtaining and maintaining Regulatory Approval for, and Commercializing, the Licensed Product outside the Territory.

3.7 Reporting. Each Party shall keep the other Party reasonably informed as to the progress and results of its, its Affiliates', and its Contractors', and with respect to Otsuka, its Sublicensees', Development of the Licensed Product, including, with respect to Otsuka, Otsuka Development Activities, and with respect to 4DMT, 4DMT Development Activities and all material Development activities under the Global Development Plan. Without limiting the foregoing, the status, progress and results of the Otsuka Development Activities and 4DMT Development Activities shall be discussed at meetings of the JSC. As soon as practicable before each regularly scheduled JSC meeting, each Party shall provide the JSC with a written report (which may be in the form of a presentation) summarizing its Development of the Licensed Product. In addition, each Party shall make available to the other Party such additional information about its Development of the Licensed Product in the Field as may be reasonably requested by the other Party through the JSC.

3.8 Clinical Trial Reporting. Each Party agrees that (a) each Clinical Trial that (i) is included in the Territory Development Plan or the Global Development Plan or is otherwise required to be conducted under this Agreement and (ii) is required to be posted pursuant to Applicable Law on ct.org, on clinicaltrials.gov or on any other similar registry shall be so posted, and (b) all results of such Clinical Trials that are necessary pursuant to Applicable Law or industry commitments accepted by such Party shall be posted on any registry with requirements consistent with the registration and publication guidelines of the International Committee of Medical Journal Editors ("**ICMJE**"), to the extent required. All data and information posted on clinicaltrials.gov or any other registry pursuant to this Section 3.8 shall be subject to prior review of the other Party for purposes of complying with Applicable Law, industry commitments and ICMJE requirements. If no comments are received within [*] ([*]) days after the other Party's receipt of the proposed disclosure, the requesting Party shall be free to make such disclosure on the applicable registry.

3.9 Development Records. Each Party shall maintain complete and accurate records (in the form of technical notebooks or electronic files where appropriate) of all Development activities conducted by it and its Affiliates and with respect to Otsuka and its Sublicensees. Such records shall

fully and properly reflect all work done and results achieved in the performance of such Development activities in sufficient detail and in good scientific manner appropriate for regulatory purposes. Each Party shall have the right to receive copies of such records maintained by the other Party, including in electronic format if maintained in such format, at reasonable times to the extent reasonably necessary to perform its obligations or exercise its rights under this Agreement.

3.10Contractors. Each Party and its Affiliates and Sublicensees may perform any Development activities under this Agreement through one (1) or more Contractors, *provided* that (a) such Party remains responsible and liable for the work allocated to, and payment to, such Contractors to the same extent it would if it had done such work itself, and (b), to the extent such Contractor is anticipated or reasonably likely to receive material Confidential Information of the other Party or to conceive of material intellectual property rights, (i) the Contractor undertakes in writing obligations of confidentiality and non-use regarding the other Party's Confidential Information that are at least as stringent as those undertaken by the Parties with respect to Confidential Information pursuant to Article 12 hereof, and (ii) the Contractor undertakes in writing to assign or exclusively license back to such Party (with the right to sublicense through multiple tiers) all intellectual property with respect to the Licensed Product developed in the course of performing any such work to such Party.

3.11Data Protection.

(a) In relation to each Clinical Trial conducted pursuant to or in furtherance of this Agreement by either Party, the Party conducting such Clinical Trial (including such Party's Affiliates and Contractors) will be responsible for providing all appropriate notices and obtaining all appropriate consents to permit the disclosure and transfer to, and the receipt, review and use by the other Party of data generated in the conduct of such Clinical Trial in connection with the other Party's Development, Commercialization and other Exploitation of the Licensed Products pursuant to and in accordance with the terms of this Agreement. The Party conducting such Clinical Trial will take all Commercially Reasonable Efforts necessary to furnish a notice in compliance with Applicable Law that provides for the transfer of data to the other Party and the uses by each Party as set out in this Agreement to each living study subject enrolled in such Clinical Trial and obtain the consent of such study subjects as may be required by and to the extent permitted by Applicable Law. Promptly, and as soon as practical after the Effective Date, the Parties will negotiate in good faith and enter into a data processing agreement related to the Licensed Products, the Clinical Trials, and associated data transfers contemplated under this Agreement which will define the Parties' responsibilities related to collection and other processing of personal information or data in order to comply with obligations under this Agreement and Applicable Law. Without limitation of the remainder of this Section 3.11, Otsuka shall not share, disclose, transfer or otherwise permit access, to any personal data disclosed or transferred to Otsuka by or on behalf of 4DMT under this Agreement, with or to any of its Affiliates or any Third Party unless and until the data processing agreement referenced in this Section 3.11(a) is signed by both Parties and is in full force and effect.

(b) Otsuka represents and warrants that Otsuka is not a "covered person" as defined in 28 CFR Part 202 (the "**Data Security Program**"). If at any time Otsuka meets such definition of a "covered person," Otsuka shall promptly cease, and cause its Affiliates and Sublicensees to cease, all access to, use of, and any other activities related to "bulk U.S. sensitive personal data" (as defined under the Data Security Program) obtained or otherwise made available by 4DMT and shall promptly notify 4DMT.

(c) Otsuka shall not, and shall cause its Affiliates and Sublicensees not to, share, disclose, transfer, or otherwise permit "access" (as defined under the Data Security Program) to "bulk U.S. sensitive personal data" (as defined under the Data Security Program) from or otherwise made available by 4DMT to or by any Person that meets the criteria of a "covered person" under the Data Security Program or otherwise provide access to such data to any "country of concern" (as defined under the Data Security Program) in violation of the Data Security Program. If Otsuka at any time determines that any such "covered person" or "country of concern" has obtained "access" (as defined by the Data Security Program) to such "bulk U.S. sensitive personal data" from or otherwise made available by 4DMT in violation of the Data Security Program, Otsuka shall promptly (i) terminate such "access" and (ii) notify 4DMT in writing.

ARTICLE 4

REGULATORY MATTERS; MEDICAL AFFAIRS ACTIVITIES

4.1 General.

(a) As between the Parties, (i) 4DMT shall be responsible, at 4DMT's sole cost (but subject to Section 3.2), for all regulatory activities relating to the 4FRONT-1 Clinical Trial, Cross-Territory Clinical Trials, the DMF (if any), all 4DMT Local Clinical Trials, the [*] Study, the [*] Study, and the [*] Study with respect to the Licensed Product in the Field in the Territory ("**4DMT Regulatory Activities**") and (ii) Otsuka shall be responsible, at Otsuka's sole cost, for all other regulatory activities with respect to the Licensed Product in the Field in the Territory, including (to the extent not related to conduct of the 4FRONT-1 Clinical Trial, Cross-Territory Clinical Trials, 4DMT Local Clinical Trials, the [*] Study, the [*] Study, or the [*] Study) the preparation of the filing dossiers for submission to the Regulatory Authorities in the Territory and other regulatory activities that are necessary for obtaining and maintaining Regulatory Approval of the Licensed Product in the Field in the Territory ("**Otsuka Regulatory Activities**"). All anticipated material Otsuka Regulatory Activities shall be set forth in the Territory Development Plan and Otsuka and its Affiliates and Sublicensees shall conduct and have conducted all such Otsuka Regulatory Activities in substantial conformity with the Territory Development Plan. Each Party shall keep the other Party informed through the JSC of all material regulatory activities related to the Licensed Product, including any decision by any Regulatory Authority regarding the Licensed Product.

(b) Except for any Regulatory Approvals for the 4FRONT-1 Clinical Trial, Cross-Territory Clinical Trials, 4DMT Local Clinical Trials, the [*] Study, the [*] Study, or the [*] Study (which, in each case, shall be held by or on behalf of 4DMT or its Affiliates or licensees), Otsuka (or any other Otsuka Party) shall apply for Regulatory Approvals of the Licensed Product in the Field in the Territory in its own name and shall be named as the holder of such Regulatory Approvals. Notwithstanding the foregoing, with respect to [*], to the extent required by Applicable Law or otherwise consistent with customary practice and necessary to avoid undue delay, 4DMT (or its designee) shall be the initial holder of any Regulatory Approval(s) for the Licensed Product and, to the extent permitted by Applicable Law, immediately upon Regulatory Approval of the Licensed Product in a given Indication in [*], 4DMT will transfer to Otsuka, and Otsuka will accept, ownership of such Regulatory Approval for such Indication; *provided* that, if such transfer of any such Regulatory Approval is permissible under Applicable Law prior to such time, Otsuka shall use Commercially Reasonable Efforts to accept transfer of ownership of each such Regulatory Approval as soon as permissible under Applicable Law. Otsuka shall reimburse 4DMT, in accordance with Section 8.5(a),

for all Out-of-Pocket Expenses incurred by 4DMT and all internal FTE hours at the FTE Rate incurred by 4DMT in connection with its role as the holder of such Regulatory Approvals. To the extent permitted by Applicable Law, Otsuka shall be responsible for and take the lead with respect to conducting any regulatory activities that are necessary for obtaining and maintaining Regulatory Approval of the Licensed Product in [*] consistent with Otsuka's conduct of Otsuka Regulatory Activities in other countries in the Territory; *provided*, for clarity, that 4DMT shall provide regulatory support to Otsuka with respect to regulatory activities in [*] consistent with 4DMT's support under this Agreement of Otsuka Regulatory Activities in other countries in the Territory, and Otsuka shall reimburse 4DMT, in accordance with Section 8.5(a), for all Out-of-Pocket Expenses incurred by 4DMT in connection therewith. Notwithstanding anything to the contrary herein, unless and until the ownership of any such Regulatory Approval for the Licensed Product for a given Indication is transferred to Otsuka, Otsuka shall have no right to Commercialize the Licensed Product in [*] for such Indication without 4DMT's prior written consent, which may be withheld in 4DMT's discretion.

4.2 Regulatory Materials.

(a) Within [*] ([*]) days of the Effective Date, 4DMT will provide to Otsuka copies of all material Regulatory Materials relating to the Licensed Product that have been submitted to or received from Regulatory Authorities in the Territory; *provided* that 4DMT shall have the right to redact sensitive Manufacturing and CMC information from such copies to the extent that such information is considered a trade secret by 4DMT. In connection with 4DMT Regulatory Activities, 4DMT shall provide Otsuka with drafts of all material Regulatory Materials relating to the Licensed Product to be submitted to any Regulatory Authority in the Territory at least [*] ([*]) Business Days in advance of the anticipated submission date (except for Regulatory Materials for safety reporting and responses to requests from any Regulatory Authority in the Territory, for which the review and comment period shall be sufficiently short to enable 4DMT to comply with timelines required by Applicable Law or such Regulatory Authority) to permit Otsuka to review and provide comments. Such Regulatory Materials shall be provided in the language in which such Regulatory Materials were or will be submitted. To the extent permissible and reasonably practicable, no such material Regulatory Material will be submitted to any Regulatory Authority in the Territory by 4DMT without 4DMT discussing with Otsuka any significant concerns that Otsuka raises in good faith within [*] ([*]) Business Days of Otsuka's receipt of the applicable draft thereof. If 4DMT (including any of its CMOs) wishes to control any CMC information for the Licensed Product under a DMF as part of the Regulatory Materials, 4DMT shall be responsible for preparing and submitting such DMF in the Territory. Otsuka shall be entitled to reference the DMF in Regulatory Materials, including in applications for Regulatory Approval and any MAA or equivalent submission for the Licensed Product in the Territory. 4DMT shall provide to Otsuka, at 4DMT's sole cost and expense, (i) the open part of the DMF, such as the sections containing general information, control of drug substance, container closure system, and stability, (ii) an eCTD containing data and information related to the Manufacture of the Licensed Product, and (iii) upon Otsuka's request, but subject to 4DMT's consent, not to be unreasonably withheld, conditioned or delayed, information in the closed part of the DMF which Otsuka reasonably believes is necessary for preparing Regulatory Materials for the Territory. To the extent that 4DMT does not use a DMF, 4DMT shall provide to Otsuka all CMC information which is necessary or reasonably useful for all regulatory activities for the Licensed Product in the Territory and in 4DMT's possession and Control.

(b) Upon Otsuka's reasonable request, 4DMT shall (i) provide Otsuka, in a timely manner and at no cost to Otsuka, electronic copies of material Regulatory Materials that (A) are

necessary or reasonably useful for Otsuka's performance of the Otsuka Regulatory Activities (including, for example, for Otsuka's filing of an IND for a Local Clinical Trial, all final study reports for the 4FRONT-1 Clinical Trial, each Cross-Territory Clinical Trial, each 4DMT Local Clinical Trial, the [*] Study, the [*] Study and the [*] Study in each case that has been completed, a Certificate of Pharmaceutical Product for the Licensed Product and any CMC information for the Licensed Product (except to the extent included in a DMF filed by 4DMT or any of its CMOs)) and (B) were submitted by 4DMT to the Regulatory Authority in the United States to obtain the Regulatory Approval for the Licensed Product in the Field in the United States, and a preliminary draft of each such submission in advance of filing and (ii) assist Otsuka in addressing any additional requirements requested by any Regulatory Authority in the Territory, including providing existing supplementary data or documentation; *provided* that (1) 4DMT shall not be required to generate any new raw data or perform any new Development activities in connection with providing such assistance, except as set forth in Section 3.2, and (2) Otsuka shall reimburse 4DMT, in accordance with Section 8.5(a), for all Out-of-Pocket Expenses incurred by 4DMT in connection with providing such assistance.

(c) Otsuka shall have the sole right to interact with Regulatory Authorities in the Territory in connection with the Licensed Product in the Field and prepare Regulatory Materials relating to the Licensed Product for submission to Regulatory Authorities in the Territory, except with respect to 4DMT Regulatory Activities. In connection with Regulatory Submissions by Otsuka in the Territory, Otsuka shall provide 4DMT on a timely basis with an initial draft of all material Regulatory Submissions in [*], [*] and [*] in a combination of local and English language portions and 4DMT shall have the opportunity to provide comments to Otsuka and Otsuka shall reasonably consider in good faith any timely comments received from 4DMT to the extent that doing so would not reasonably be expected to materially delay the applicable Regulatory Submission. In addition, Otsuka shall, at its own cost and expense, provide 4DMT on a timely basis with an English translation of the relevant portions of Regulatory Submissions for which Otsuka would like 4DMT to review and provide comment. 4DMT shall review any such portion and provide comments to Otsuka as soon as reasonably practicable, and Otsuka shall reasonably consider in good faith any timely comments received from 4DMT, in each case to the extent that doing so would not reasonably be expected to materially delay the applicable Regulatory Submission. In connection with all Regulatory Correspondence between Otsuka and any Regulatory Authority in the Territory, Otsuka shall provide 4DMT with a copy of all such material Regulatory Correspondence in the local language. In addition, Otsuka shall, at its own cost and expense, provide 4DMT with an English translation of all inquiries received from any Regulatory Authority in the Territory after submission of the relevant MAA in such country as soon as practicable after Otsuka's receipt of such inquiry. With respect to any such inquiries for which Otsuka reasonably believes 4DMT would be in the best position to prepare the initial draft written response, upon Otsuka's reasonable request, 4DMT shall prepare such draft written response and the Parties shall discuss the draft response. With respect to any other inquiries that Otsuka would like 4DMT to review and provide comment, Otsuka will prepare the draft written response in English and provide it to 4DMT. 4DMT shall review such draft response and provide comments to Otsuka as soon as reasonably practicable. Otsuka shall reasonably consider in good faith any comments received from 4DMT (whether 4DMT drafts such response or provides comments on such response) to the extent such comments are provided within the schedule agreed upon in advance by the Parties. Notwithstanding the foregoing, Otsuka shall not make any statement in any Regulatory Materials filed in the Territory that 4DMT identifies as inconsistent, or that Otsuka knows is inconsistent, with statements made in Regulatory Materials filed outside of the Territory without 4DMT's prior written consent, not to be unreasonably withheld to the extent such statement is required under Applicable Law. Otsuka shall reimburse 4DMT, in accordance with Section

8.5(a), for all Out-of-Pocket Expenses incurred by 4DMT in connection with providing assistance as described in this Section 4.2(c).

4.3 Regulatory Meetings.

(a) Each Party shall provide the other Party with advance notice for any meeting or discussion that it is planning to request with any Regulatory Authority in the Territory related to the Licensed Product in connection with 4DMT Regulatory Activities or Otsuka Regulatory Activities, as applicable, and shall notify the other Party in writing promptly after its receipt of written notice of any meeting or discussion with any Regulatory Authority in the Territory related to the Licensed Product. The Party providing such notice shall participate in such meeting or discussion, *provided* that the other Party receiving such notice or its designee shall have the right, but not the obligation, to attend and participate in such meeting or discussion to the extent permitted under Applicable Law, at such Party's sole cost. If such Party receiving such notice elects not to attend such meeting or discussion (or if such Party was not permitted under Applicable Law to participate in such meeting or discussion), the Party providing such notice shall, upon the other Party's request, provide the other Party with a written English summary of such meeting or discussion promptly after such meeting or discussion.

(b) In connection with Otsuka Regulatory Activities, if Otsuka requests, at a reasonable time in advance of such meeting, that 4DMT participate in any scheduled meeting with a Regulatory Authority in the Territory, 4DMT shall participate in such meeting, *provided* that Otsuka shall reimburse 4DMT, in accordance with Section 8.5(a), for all Out-of-Pocket Expenses incurred by 4DMT in connection with providing such participation unless such meeting primarily relates to CMC matters described in the DMF.

4.4 Right of Reference. Each Party hereby grants to the other Party the right of reference to all Regulatory Materials pertaining to the Licensed Product in the Field submitted by or on behalf of such Party or its Affiliates or Sublicensees. Subject to Section 3.2, Otsuka may use, and permit its Affiliates and Sublicensees to use, such right of reference to 4DMT's Regulatory Materials for the sole purpose of obtaining and maintaining Regulatory Approval of the Licensed Product in the Field in the Territory and satisfying other regulatory obligations required for the Commercialization of the Licensed Product in the Field in the Territory. 4DMT may use, and permit its Affiliates and licensees to use, such right of reference to Otsuka's Regulatory Materials in the Field for the sole purpose of obtaining and maintaining Regulatory Approval of the Licensed Product outside the Territory and satisfying other Commercialization-related regulatory obligations for the Licensed Product outside the Territory.

4.5 Regulatory Audits and Inspection. Each Party shall provide the other Party with notice of any inspection of such Party, its Affiliates, Sublicensees or Contractors by any Regulatory Authority relating to the Exploitation of the Licensed Product promptly after being notified of such an inspection by the Regulatory Authority and shall provide timely updates regarding the outcome of such inspections as well as such information as may be reasonably requested by the other Party. 4DMT shall have the right, but not the obligation, to be present at any such inspection of Otsuka, its Affiliates, Sublicensees or Contractors to the extent permitted by Applicable Law at its cost. 4DMT shall reasonably cooperate with Otsuka in connection with any inspection of Otsuka, its Affiliates, Sublicensees or Contractors by any Regulatory Authority relating to the Exploitation of the Licensed Product, including by cooperating in connection with the preparation of documents and on-site audits required for such inspection and the preparation of responses to the questions made by inspectors during such inspection at no cost to Otsuka. 4DMT will participate in any such inspection at Otsuka's reasonable request, and Otsuka will reimburse

the Out-of-Pocket Expenses and internal FTE hours at the FTE Rate incurred by 4DMT for such support. Solely to the extent required by Applicable Law: (i) Otsuka shall permit the Regulatory Authorities outside the Territory to conduct reasonable inspections of Otsuka, its Affiliates, Sublicensees or Contractors relating to any Licensed Product, and shall ensure that such Affiliates, and will use Commercially Reasonable Efforts to cause Sublicensees and Contractors, to permit such inspections; and (ii) 4DMT shall permit the Regulatory Authorities inside the Territory to conduct reasonable inspections of 4DMT, its Affiliates, sublicensees or Contractors relating to any Licensed Product, and shall ensure that such Affiliates, and will use Commercially Reasonable Efforts to cause sublicensees and Contractors to, permit such inspections.

4.6 Pharmacovigilance; Safety Information. Each Party will cooperate with the other Party, at no cost to the other Party, with regard to the reporting and handling of safety information involving the Licensed Product in accordance with and to the extent permitted by Applicable Law, regulatory requirements, and regulations on pharmacovigilance and clinical safety. Otsuka will be responsible for all processing of information with respect to the reporting and handling of safety information related to any adverse events for the Licensed Products in the Territory, except for any such adverse events related to the Cross-Territory Clinical Trial or any 4DMT Local Clinical Trial, and 4DMT will be responsible for all processing of information with respect to the reporting and handling of safety information related to any adverse events for the Licensed Products outside the Territory and any adverse events related to the Cross-Territory Clinical Trial and any 4DMT Local Clinical Trial, in each case, including any information regarding such adverse events that is received from a Third Party. Each Party will provide to the other Party in a timely manner the relevant safety information it receives (either directly or indirectly) related to the Licensed Product. At an appropriate time as agreed upon by the Parties following the Effective Date, but in any event prior to the earlier of the initiation of the first Clinical Trial conducted by Otsuka or the filing of the first MAA for the first Licensed Product in the Territory, the Parties will negotiate in good faith and enter into a separate agreement related to the Licensed Product, which will define the pharmacovigilance responsibilities of the Parties and include safety data exchange procedures governing the exchange of information affecting the class and products (*e.g.*, serious adverse events, emerging safety issues) to enable each Party to comply with all of its legal and regulatory obligations related to such Licensed Product (such agreement, the "**Pharmacovigilance Agreement**"). Prior to the execution of the Pharmacovigilance Agreement, each Party will have the right, upon reasonable notice to the other Party, to have up to three representatives conduct a baseline audit of such other Party's pharmacovigilance system, and the Parties will collaborate to reasonably resolve any findings or observations from such audit. 4DMT will own and maintain the global safety database for the Licensed Product at its sole cost and expense, provided that at Otsuka's reasonable request, 4DMT will run queries of such global safety database and will provide copies of the data contained in such global safety database to the extent necessary or reasonably useful to the Development and Commercialization of the Licensed Product in the Territory. As part of the negotiation of the Pharmacovigilance Agreement, the Parties will discuss and determine, either directly or through the PV Sub-Committee, which Party shall maintain and manage the pharmacovigilance system for the Licensed Product, taking into account that 4DMT will own and maintain the global safety database, and the Parties' determination of such matter will be set forth in the Pharmacovigilance Agreement. Subject to compliance with Applicable Law, each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement as the Parties may agree to modify it from time to time, and to cause its (sub)licensees to comply with such obligations. If there is a conflict between the terms and conditions of this Agreement and any terms and conditions of the Pharmacovigilance Agreement, then the terms and conditions of this Agreement will govern, unless the Parties expressly and specifically provide otherwise in the Pharmacovigilance Agreement.

4.7 Pharmacovigilance Sub-Committee. The JSC shall establish a joint pharmacovigilance subcommittee (the "**PV Sub-Committee**") at an appropriate time, but in any event prior to the earlier of (a) the First Commercial Sale of the first Licensed Product in the Territory, or (b) Otsuka's conduct of any Development activities related to the Licensed Product. In addition to any other matters that the JSC may delegate to the PV Sub-Committee, the PV Sub-Committee shall provide a forum for the Parties to discuss, share information, and escalate and attempt to resolve any safety issues regarding the Licensed Product, and any other pharmacovigilance matters, worldwide. The PV Sub-Committee will meet as often as necessary and mutually agreed to carry out such activities, and the terms of Section 2.7 will apply to the PV Sub-Committee.

4.8 Medical Affairs Activities.

(a) General. As between the Parties, (i) Otsuka shall be responsible for conducting Medical Affairs Activities for the Licensed Product in the Field in the Territory, at Otsuka's own cost and expense and (ii) 4DMT shall be responsible for conducting Medical Affairs Activities for the Licensed Product outside the Territory. Otsuka shall not conduct any Medical Affairs Activities prior to the JSC reviewing, discussing and approving the Territory Medical Affairs Plan and reviewing and discussing the Global Medical Affairs Plan pursuant to Section 2.2(g). The JSC shall establish a joint medical affairs subcommittee (the "**Medical Affairs Sub-Committee**") at an appropriate time, but in any event at least [*] ([*]) months before the anticipated date of the First Commercial Sale of the Licensed Product in the Field in the Territory. The Medical Affairs Sub-Committee may be dissolved at any time upon mutual written agreement of the Parties.

(b) Territory Medical Affairs Plan. Otsuka shall conduct all Medical Affairs Activities for the Licensed Product in the Field in the Territory pursuant to a written Medical Affairs Activities plan that sets forth the timeline and summaries of all material Medical Affairs Activities, including the criteria for any support of investigator-initiated trials of the Licensed Product, to be conducted by or on behalf of Otsuka for the Licensed Product in the Field in the Territory in presentation format (the "**Territory Medical Affairs Plan**"). No later than [*] ([*]) months before the anticipated date of the First Commercial Sale of the Licensed Product in the Field in the Territory, Otsuka shall, in consultation with 4DMT at the Medical Affairs Sub-Committee, prepare and submit the initial Territory Medical Affairs Plan for the Territory, which shall address [*], [*] and [*] and any material Medical Affairs Activities with key opinion leaders in the Territory, in presentation format to the JSC for review, discussion and approval. Thereafter, from time to time, but at least [*] solely to the extent that there have been any material changes to the Territory Medical Affairs Plan, including additional countries in the Territory to the extent material, Otsuka shall prepare updates or amendments to the Territory Medical Affairs Plan, in consultation with 4DMT at the Medical Affairs Sub-Committee, and shall submit the updates and amendments to the JSC for review, discussion and approval in presentation format before such updates and amendments become effective. Without limiting the foregoing, (i) Otsuka shall not provide any support to any investigator-initiated trial proposed to be conducted in any country in the Territory (A) for an indication other than the AMD Indication, the DME Indication or (B) for the AMD Indication, the DME Indication prior to Regulatory Approval in such country for such Indication, unless and until the Parties mutually agree at the Medical Affairs Sub-Committee to the support proposed to be provided in connection with such trial, and (ii) prior to providing any support to any other investigator-initiated trial proposed to be conducted in the Territory, Otsuka shall provide to 4DMT through the Medical Affairs Sub-Committee a protocol for such trial and a description of the support to be provided and Otsuka shall consider 4DMT's comments in good faith and shall implement all such comments that 4DMT reasonably believes, if not implemented, would be reasonably likely to

have a material adverse effect on (x) the Development of, Regulatory Approval for, or Commercialization of any Licensed Product outside the Territory or (y) 4DMT's retained rights under Section 7.2.

(c) Coordination of Medical Affairs Activities.

(i) No later than [*] ([*]) months before the anticipated date of the first commercial sale of the Licensed Product in the Field in the United States, 4DMT shall provide Otsuka with a reasonably detailed summary of its plans for global Medical Affairs Activities for the Licensed Product in the Field, including with respect to any Otsuka-sponsored Clinical Trial of the Licensed Product proposed to be conducted for the purposes set forth in clauses (a) through (f) (inclusive) of Section 1.92 (the "**Global Medical Affairs Plan**") and shall keep the Medical Affairs Sub-Committee and the JSC reasonably informed on such plans (including any updates and amendment thereto). The Global Medical Affairs Plan will include sufficient detail in order for Otsuka to substantially conform its Medical Affairs Activities for the Licensed Product in the Field in the Territory to the Global Medical Affairs Plan. 4DMT will keep Otsuka updated on progress with respect to and material changes to the Global Medical Affairs Plan through the Medical Affairs Sub-Committee and the JSC in presentation format. Except as expressly agreed by 4DMT in writing or to the extent required by the applicable Regulatory Authority or to address specific operational requirements in the Territory, the Territory Medical Affairs Plan and all Medical Affairs Activities for the Licensed Product in the Field in the Territory shall be in substantial conformance with the Global Medical Affairs Plan.

(ii) The Parties shall coordinate with respect to Medical Affairs Activities for the Licensed Product across their territories. If the Parties agree to jointly conduct any specific Medical Affairs Activities for the benefit of the Licensed Product in both Parties' territories, the Parties shall negotiate and agree on the details of such activities, including allocation of responsibilities, budget and cost sharing. Except to the extent required under Applicable Law and Otsuka discusses such requirement with 4DMT in advance of making such statement, Otsuka shall not make any statements in the course of Medical Affairs Activities for the Licensed Product that are inconsistent with factual statements made by 4DMT outside the Territory in connection with Medical Affairs Activities for the Licensed Product. Otsuka shall not conduct any Medical Affairs Activities for the Licensed Product outside the Field or Territory without 4DMT's express prior written consent.

(d) Medical Affairs Activities Reports. Otsuka shall keep 4DMT, through the Medical Affairs Sub-Committee, informed of its, its Affiliates' and its Sublicensees' material Medical Affairs Activities with respect to the Licensed Product. Without limiting the foregoing, (i) at each regularly scheduled JSC meeting, Otsuka shall provide the JSC with a reasonable report (which can be in the form of a presentation) summarizing the material Medical Affairs Activities performed by or on behalf of Otsuka Parties for the Licensed Product in the Field in the Territory, including interactions with key opinion leaders; and (ii) Otsuka shall make available to 4DMT such additional information about its material Medical Affairs Activities as may be reasonably requested by 4DMT from time to time. The Medical Affairs Sub-Committee, by mutual agreement, shall have the ability to determine the duration of Otsuka's obligation to provide such updates with respect to Medical Affairs Activities.

4.9 [*].

(a) In order to facilitate [*] no later than [*], 4DMT shall prepare [*]. 4DMT shall provide [*] to Otsuka for review and comment. Upon obtaining Otsuka's consent, 4DMT and Otsuka shall jointly conduct [*]. If [*], the Parties shall [*] and 4DMT shall [*], and shall promptly

provide [*] to Otsuka. In the event that [*] does not [*], and [*], 4DMT shall promptly prepare [*], and provide it to Otsuka for review and comment. Upon Otsuka's agreement, 4DMT shall establish [*], in each case at 4DMT's sole cost. In addition, with respect to any [*], 4DMT shall ensure that the [*] in [*]and the [*] in [*] include a statement indicating that [*]. [*].

(b) No later than [*], 4DMT and Otsuka shall jointly conduct a consultation with [*] to confirm whether [*] will agree that, if approved, Otsuka will be permitted to Commercialize Licensed Product in [*] . In the event that [*] requires the Licensed Product to be manufactured using [*], 4DMT shall promptly prepare [*], and provide it to Otsuka for review and comment. Upon Otsuka's agreement, 4DMT shall implement such agreed work plan at 4DMT's sole cost.

ARTICLE 5

COMMERCIALIZATION

5.1 General. As between the Parties, Otsuka shall be solely responsible for the Commercialization of the Licensed Product in the Field in the Territory, at Otsuka's own cost and expense, including developing and executing a commercial launch plan, product marketing and promotional efforts, market access and pricing strategies, negotiating with applicable Governmental Authorities regarding the price and reimbursement mechanisms, booking sales, product distribution, providing customer and product support (including handling medical queries), and performing other related functions, in each case subject to and in accordance with the terms and conditions of this Agreement. For clarity, Otsuka or another Otsuka Party shall book the sales of the Licensed Product in the Territory.

5.2 Commercialization Diligence; Standards of Conduct. Upon receiving the applicable Regulatory Approval for the Licensed Product in [*], [*] or [*], Otsuka shall, in each case, use Commercially Reasonable Efforts to Commercialize such Licensed Product in such country and to carry out the tasks specified under the Territory Commercialization Plan in a timely manner. Otsuka shall conduct, and shall cause its Affiliates and Sublicensees to conduct, all Commercialization activities in compliance with Applicable Law, applicable codes of conduct in the Territory, the terms and conditions of this Agreement and the Territory Commercialization Plan.

5.3 Territory Commercialization Plan; [*]; Conduct of Commercialization Activities.

(a) No later than [*] ([*]) months before the anticipated First Commercial Sale of the Licensed Product in the Field in the Territory, Otsuka shall provide to the JSC in presentation format a timeline reflecting [*]in [*], [*], [*] and other countries in the Territory, in each case, following receipt of the applicable Regulatory Approval (the "**[*]**"). No later than [*] ([*]) months before the anticipated First Commercial Sale of the Licensed Product in the Field in each of [*], [*] and [*], Otsuka shall provide to the JSC in presentation format a written Commercialization plan for such country that sets forth the timeline and details of all major Commercialization activities planned for the Licensed Product in the Field in such country in the Calendar Year that includes the anticipated date of the First Commercial Sale of a Licensed Product for use in the Field in such country (each such existing Commercialization plan and the [*], collectively, the "**Territory Commercialization Plan**") for review and discussion as and to the extent set forth in Sections 2.2 and 2.5. For clarity, Otsuka will provide [*] for the Licensed Product in the Field in [*], [*] and [*] only. Thereafter, Otsuka shall, [*] at a regularly scheduled JSC meeting, outline the then-current Territory Commercialization Plan to 4DMT in the form of a presentation, which shall summarize any updates, amendments, or changes

in such plans [*], including those in response to changes in the marketplace, relative success of the Licensed Product, and other relevant factors influencing such plan and activities, for review and discussion as and to the extent set forth in Sections 2.2 and 2.5. Without limiting the foregoing, 4DMT may, through the JSC, propose any updates and amendments to the Territory Commercialization Plan, which comments Otsuka shall reasonably consider in good faith. For clarity, subject to Section 2.5, Otsuka shall not be required to implement any such comments.

(b) All Commercialization of the Licensed Product in the Territory shall be conducted in accordance with Applicable Law, the terms and conditions of this Agreement, and the Territory Commercialization Plan, as amended from time to time by Otsuka in accordance with Sections 2.2 and 2.5, and, to the extent practicable given Applicable Law and local culture, language and market practice considerations, shall be consistent with the Global Brand Elements and 4DMT's key brand messages for the Licensed Product for use in the applicable Indication.

(c) Upon Otsuka's request, 4DMT shall provide Otsuka with samples of promotional materials (which samples, for clarity, may be provided in the Global Commercialization Plan, as further described in Section 5.4) used or to be used by or on behalf of 4DMT in connection with the Commercialization of the Licensed Product in the United States in order for Otsuka to prepare its own promotional materials to be used in connection with the Commercialization of the Licensed Product in [*] and other countries within the Territory. Otsuka shall ensure its promotional materials to be used by or on behalf of Otsuka (or any of Otsuka's Affiliates, Sublicensees or Contractors) in connection with the Commercialization of the Licensed Product in the Territory shall be substantially consistent with the Global Brand Elements and 4DMT's key brand messages for the Licensed Product in the United States, to the extent reasonably practicable given Applicable Law and local culture, language and market practice considerations. At 4DMT's request, Otsuka shall provide to 4DMT representative samples of such promotional materials sufficient to enable 4DMT to ensure such consistency. For the avoidance of doubt, Otsuka shall not be required to provide English translations of any such representative samples to 4DMT.

5.4 Coordination of Commercialization Activities.

(a) No later than [*] ([*]) months before the anticipated first commercial sale of the Licensed Product in the United States, 4DMT shall provide Otsuka with a reasonably detailed summary and anticipated timeline of its major Commercialization activities for the global Commercialization of the Licensed Product in the Field (the "**Global Commercialization Plan**") and will keep the JSC reasonably informed regarding such plans (including any updates and amendments thereto). The Global Commercialization Plan will include sufficient detail in connection therewith in order for Otsuka to conform the Commercialization of the Licensed Product in the Field in the Territory for an Indication to be consistent with the Global Brand Elements and 4DMT's key brand messages for the Licensed Product for such Indication in the United States, to the extent reasonably practicable given Applicable Law, and local culture, language and market practice considerations.

(b) The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of the Licensed Product in the Field across their territories. The JSC shall establish a joint commercialization subcommittee (the "**Commercialization Sub-Committee**") at an appropriate time, but in any event no later than [*] ([*]) months before the anticipated First Commercial Sale of the Licensed Product in the Field in [*]. The Commercialization Sub-Committee shall automatically dissolve on [*] unless otherwise agreed by the Parties. The Parties

may, through the Commercialization Sub-Committee and as otherwise mutually agreed by the Parties, coordinate such activities where appropriate and where permissible under Applicable Law, including scientific and medical communication, health economics, education and promotional messaging and materials. In principle, the Commercialization Sub-Committee shall serve as a forum for Otsuka to share information regarding its Commercialization activities in [*], [*], [*]and, in the case of [*], for[*], and for 4DMT to share information regarding its Commercialization activities in the United States. The Parties may mutually agree in writing, from time to time, to [*]. 4DMT may conduct activities associated with any conference or meeting in the Territory that is related to ophthalmological (including retinal) Indications and is expected to be attended by a majority of physicians or other healthcare providers from outside the Territory; *provided,* that it will offer Otsuka the ability to jointly manage such activities (and to the extent mutually agreed, share responsibilities and costs therefor). Otsuka (and its Affiliates, Sublicensees and Contractors) shall not make any statements in connection with the Commercialization of the Licensed Product in the Field in the Territory that Otsuka knows or would reasonably be expected to know to be inconsistent with factual statements about the Licensed Product. For clarity, Otsuka shall not conduct any Commercialization of the Licensed Product targeted outside the Field or Territory without 4DMT's express prior written consent. For clarity, the Commercialization Sub-Committee is intended to be a forum for review, discussion and coordination and the Commercialization Sub-Committee shall not have any decision-making authority with respect to any matter.

5.5 Recalls, Market Withdrawals or Corrective Actions. Each Party shall notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that the Licensed Product Commercialized under this Agreement is or may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (each, a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Otsuka shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory, including the decision to commence such Remedial Action and the control over such Remedial Action, *provided* that Otsuka shall provide advance notice to 4DMT and consider in good faith 4DMT's comments regarding such Remedial Action. As between the Parties, the cost and expenses of any Remedial Action in the Territory shall be borne solely by Otsuka; *provided, however*, that 4DMT shall bear, and will reimburse Otsuka for, all of the cost and expenses of any Remedial Action to the extent caused by 4DMT's material breach of the Supply Agreement(s), gross negligence or willful misconduct, whether directly or via its agents or Contractors. Otsuka shall, and shall ensure that its Affiliates, Sublicensees and Contractors will, maintain adequate records to permit the Parties to track and trace the distribution, sale and use of the Licensed Product in the Territory.

5.6 Commercialization Report. Otsuka shall update the JSC at each regularly scheduled JSC meeting in presentation format regarding the Commercialization activities with respect to the Licensed Product in [*], [*]and [*], as well as the sales performance in each country in the Territory. Each such update shall be in a form to be agreed by the Parties at the JSC and shall summarize Otsuka's, its Affiliates', its Sublicensees' and its Contractors' material Commercialization activities with respect to the Licensed Product in the Field in the Territory, including a list of the countries in the Territory in which Otsuka (a) has applied for Regulatory Approval for the Licensed Product in the Field, (b) has obtained Regulatory Approval for the Licensed Product in the Field, or (c) is planning to launch the Licensed Product in the Field. In addition, Otsuka shall make available to 4DMT such additional information about its Commercialization activities as may be reasonably requested by 4DMT from time

to time; *provided* that Otsuka shall have no obligation to provide any information, the sharing of which would violate Applicable Law.

5.7 Cross-Territorial Restrictions. Each Party hereby covenants and agrees that it shall not, and shall ensure that its Affiliates, Sublicensees (in the case of Otsuka) and Contractors shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold or otherwise Exploit any Licensed Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like (a) outside the Territory with respect to Otsuka or (b) in the Territory with respect to 4DMT, including in each case (a) or (b), to any Third Party that such Party knows (or reasonably should know after due inquiry) has previously exported or is likely to export the Licensed Product outside the Territory (with respect to Otsuka) or in the Territory (with respect to 4DMT). Neither Party shall engage, nor permit its Affiliates, Sublicensees (in the case of Otsuka) or Contractors to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of the Licensed Product located in any country or jurisdiction outside the Territory (with respect to Otsuka) or in the Territory (with respect to 4DMT), or solicit orders from any prospective purchaser located in any country or jurisdiction outside the Territory (with respect to Otsuka) or in the Territory (with respect to 4DMT). If a Party (or its Affiliates, Sublicensees (in the case of Otsuka) or Contractors) receive any order for the Licensed Product from a prospective purchaser located in a country or jurisdiction outside the Territory (with respect to Otsuka) or in the Territory (with respect to 4DMT), such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates, Sublicensees (in the case of Otsuka) or Contractors to, deliver or tender (or cause to be delivered or tendered) the Licensed Product to any Third Party for use in or distribution into any country or jurisdiction outside the Territory (with respect to Otsuka) or in the Territory (with respect to 4DMT), except as permitted under this Agreement including under Section 7.2. For the avoidance of doubt, (i) the mere fact that a website or other online resource maintained by Otsuka (or its Affiliates, Sublicensees or Contractors) and intended for users in the Territory is accessible by Persons located outside the Territory shall not, in and of itself, constitute a breach of this Section 5.7, provided that such website or online resource is not specifically targeted to Persons outside the Territory and (ii) the mere fact that a website or other online resource maintained by 4DMT (or its Affiliates, other licensees or Contractors) and intended for users outside the Territory is accessible by Persons located in the Territory shall not, in and of itself, constitute a breach of this Section 5.7, provided that such website or online resource is not specifically targeted to Persons in the Territory.

5.8 Contractors. Otsuka and its Affiliates and Sublicensees may perform any of its Commercialization activities relating to the Licensed Product in the Territory through one (1) or more Contractors, *provided* that (a) as between the Parties, Otsuka remains responsible and liable for the work allocated to, and payment to, such Contractors to the same extent it would if it had done such work itself, (b) with respect to any Contractor that is distributor or wholesaler or its involved in the transportation or storage of the Licensed Product, such Contractor is capable of complying with and does comply with the applicable shipping, storage and stability requirements for the Licensed Product, (c) the Contractor undertakes in writing obligations of confidentiality and non-use regarding the 4DMT's Confidential Information that are at least as stringent as those undertaken by Otsuka with respect to Confidential Information pursuant to Article 12 hereof and (d) the Contractor undertakes in writing to assign or exclusively license back to Otsuka (with the right to sublicense through multiple tiers) all intellectual property with respect to the Licensed Product developed in the course of performing any such work on behalf of Otsuka or its Affiliate or Sublicensee, but only to the extent necessary for Otsuka to comply with its obligations under this Agreement.

ARTICLE 6

MANUFACTURE AND SUPPLY

6.1 Manufacture by 4DMT; Supply Agreement. At Otsuka's request, the Parties shall enter into supply agreement(s) for the clinical and commercial Manufacture and supply of the Licensed Product and Related Materials, which agreement(s) shall include the terms set forth in this Section 6.1 and additional commercially reasonable terms customary for an agreement governing the clinical or commercial supply of a pharmaceutical product or ingredient, including terms related to order forecasting, payment and termination (each such agreement, a "**Supply Agreement**"). Upon Otsuka's request, the Parties will negotiate in good faith and enter into one or more quality technical agreements pertaining to clinical and commercial supply of Licensed Products to Otsuka (each, a "**Quality Agreement**") containing reasonable and customary terms and conditions regarding quality assurance, quality control, compliance with GMP, GDP and GCP (as applicable), specifications, change control procedures, and provisions relating to audits and inspections.

(a) Clinical and Commercial Supply Generally. Prior to completion of the Manufacturing Technology Transfer pursuant to Section 6.4, Otsuka shall purchase its requirements for the Licensed Product for Exploitation in the Territory from 4DMT in accordance with the Supply Agreement(s). For clarification, Otsuka has no obligation to purchase the Licensed Product for the Cross-Territory Clinical Trials but the costs of manufacturing the Licensed Product and Related Materials used in any Cross-Territory Clinical Trial shall be included in the costs of such trial.

(b) Clinical Supply. Pursuant to the relevant Supply Agreement and the relevant Quality Agreement for clinical supply, at Otsuka's request, 4DMT shall manufacture in accordance with cGMP, and supply to Otsuka, [*] for the Licensed Product, and other Related Materials for use in Otsuka Local Clinical Trials in the Territory, at the Manufacturing Cost plus a markup of [*] percent ([*]%). In case Otsuka requests supply of (i) above, 4DMT shall provide reasonable assistance to Otsuka in order for Otsuka to prepare the relevant labels and packaging. If Otsuka requests 4DMT to supply [*], 4DMT shall consider such request in good faith and if 4DMT in its discretion accepts such request, Otsuka will reimburse the Manufacturing Costs incurred by 4DMT for the supply of the [*] plus a markup of [*] percent ([*]%).

(c) Commercial Supply. Pursuant to the relevant Supply Agreement and the relevant Quality Agreement for commercial supply, 4DMT shall manufacture in accordance with cGMP, and supply to Otsuka, [*] to be (i) labeled and packaged by Otsuka and (ii) for Commercialization in the Territory, at the Manufacturing Cost plus a markup of [*] percent ([*]%). 4DMT shall provide reasonable assistance to Otsuka in order for Otsuka to prepare such labels and packaging. If [*], 4DMT shall consider [*], and if 4DMT accepts such request, Otsuka will [*] plus a markup of [*] percent ([*]%). No later than [*], 4DMT shall provide a good faith estimate of the Manufacturing Cost for the following year, which shall be the tentative Manufacturing Cost for such year. Within [*] ([*]) days after the end of each Calendar Year, 4DMT shall provide Otsuka with the actual Manufacturing Cost for the prior Calendar Year, together with reasonably detailed documentation supporting such determination. If the actual Manufacturing Cost in the prior Calendar Year was greater than the tentative Manufacturing Cost for such year, then Otsuka will pay the difference to 4DMT within [*] ([*]) days of such determination, and if the actual Manufacturing Cost in the prior Calendar Year was less than the tentative Manufacturing Cost for such year, then 4DMT will pay the difference to Otsuka within [*] ([*]) days of such determination.

(d) Supply Shortfall. In the event that 4DMT is unable to supply the full quantity of Licensed Product ordered by Otsuka pursuant to the Supply Agreement(s) due to a supply shortfall, 4DMT's and its CMOs' available supply of the Licensed Product shall be [*]. Such allocation shall be based on[*]; *provided*, *however*, that if the shortfall occurs less than [*] after the First Commercial Sale of the Licensed Product in the Territory, the allocation shall be based only on [*] following such First Commercial Sale of the Licensed Product in the Territory prior to the shortfall. In the event of any significant deviations, defects, or lot recalls relating to the Licensed Product supplied in accordance with the Supply Agreement(s), 4DMT will immediately notify Otsuka, with reasonably detailed explanations as to the circumstances giving rise to such deviations.

(e) Acceptance Testing. Upon Otsuka's request, 4DMT shall, either itself or through its Third Party service provider (at 4DMT's election): (i) conduct technology transfer for quality control tests for the Licensed Products, including the technology transfer of standard operation procedure for the quality control tests performed by or on behalf of 4DMT on the Licensed Product; and (ii) supply Otsuka with reagents necessary to conduct the quality control tests to the extent such reagents are not available commercially to Otsuka; and in each case ((i) and (ii)) Otsuka shall reimburse 4DMT for all costs (which, for clarity, shall include Out-of-Pocket Expenses and internal FTE hours at the FTE Rate) incurred by 4DMT in connection with any such technology transfer or supply.

(f) Additional Terms. 4DMT shall discuss with Otsuka in good faith Otsuka's requests for 4DMT to Manufacture and supply to Otsuka any dosage form or presentation of the Licensed Product requested by a Regulatory Authority in the Territory; *provided* that 4DMT shall have no obligation to Manufacture and supply Licensed Product in any such dosage form unless mutually agreed in a Supply Agreement. Otsuka shall use all Licensed Product and Related Materials supplied by 4DMT pursuant to the Supply Agreement(s) solely in Otsuka Local Clinical Trials or for Commercialization in the Territory. In the event that 4DMT becomes aware of events or circumstances that may materially increase the Manufacturing Cost of the Licensed Product, 4DMT shall promptly notify Otsuka and explain such circumstances to Otsuka in reasonable detail.

(g) Critical Reagents. If Otsuka requests 4DMT to supply Critical Reagents to Otsuka, (a) if such Critical Reagents are available through a Third Party supplier of 4DMT, 4DMT shall [*] or (b) to the extent such Critical Reagents are not available through a Third Party supplier [*], 4DMT shall [*]

6.2 Otsuka Audit Rights. Prior to the execution of the first Quality Agreement, Otsuka shall be entitled to conduct a quality assurance audit of 4DMT and its CMOs that Manufacture the Licensed Product to the extent permitted under 4DMT's agreements with such CMOs and subject to any conditions set forth in the agreements with such CMOs with respect to any inspection or audit (*e.g.*, an obligation to enter into a confidentiality agreement with the applicable CMO). In addition, if 4DMT elects to inspect or audit any facilities of its CMOs with respect to the Manufacture of Licensed Products for the Territory, 4DMT shall notify Otsuka of such inspection or audit and Otsuka shall have the right, but not the obligation, to have representatives participate in such inspection or audit or to accompany 4DMT and observe and review such inspection or audit at its cost. In addition, to the extent permitted under 4DMT's agreement with the applicable CMO and subject to any conditions set forth in such agreement with respect to any inspection or audit (*e.g.*, an obligation to enter into a confidentiality agreement with the applicable CMO), 4DMT shall provide Otsuka with copies of all reports of 4DMT's audits or inspections of such CMO relating to the Manufacture of the Licensed Products for the Territory. If Otsuka identifies the need to perform a "for cause" audit of such facilities to address quality

or compliance issues related to any Licensed Product Manufactured for the Territory (including to address any notice from a Governmental Authority in the Territory of noncompliance with Applicable Law), as well as in connection with the preparation of applications for Regulatory Approval for the Territory and in response to Regulatory Authority requirements in the Territory, then Otsuka shall notify 4DMT and if 4DMT agrees (such agreement not to be unreasonably withheld, conditioned or delayed) with Otsuka's determination that a "for cause" audit is needed, 4DMT will schedule and conduct such audit and Otsuka will have the right to participate as provided above. 4DMT will use Commercially Reasonable Efforts to secure from each CMO it enters into a contract with, or with which it renews a contract, after the Effective Date the right for Otsuka representatives to participate in any audit of such CMO and 4DMT will use Commercially Reasonable Efforts to cause each of its existing CMOs to permit Otsuka representatives to participate in any audit of such CMO. Otsuka shall reimburse 4DMT, in accordance with Section 8.5(a), for all costs (which, for clarity, shall include Out-of-Pocket Expenses and internal FTE hours at the FTE Rate) incurred by 4DMT in connection with any such audit of 4DMT or any of its CMOs.

6.3 Manufacture by Otsuka. Otsuka shall have the right (but not the obligation) at any time during the Term to request Manufacturing Technology Transfer as set forth in Section 6.4. Upon completion of such Manufacturing Technology Transfer as specified in Section 6.4(b), Otsuka shall be solely responsible for the Manufacture and clinical and commercial supply of the Licensed Product for Exploitation in the Field in the Territory; *provided* that, (a) Otsuka shall not obtain supply from any Third Party without 4DMT's prior written approval, not to be unreasonably withheld, conditioned or delayed, (b) Otsuka would be responsible for obtaining any Regulatory Approvals needed for performance of such Manufacturing and supply activities, and (c) following the completion of such Manufacturing Technology Transfer, (i) 4DMT shall have the right, during regular business hours and upon reasonable advance written notice, to conduct audits and inspections of Otsuka (and any permitted designee pursuant to Section 6.4(a)), in each case no more frequently than once every [*] ([*]) months (for clarity, with the first such audit permitted to be conducted any time following completion of such Manufacturing Technology Transfer) or more frequently "for cause," relating to testing, quality control, documentation, record keeping and other standard and general operating procedures used by Otsuka (or a permitted designee) in connection with the Manufacturing and supply of the Licensed Product in order to monitor Otsuka's (or the applicable permitted designee's) compliance with Applicable Law and obligations under this Agreement, and (ii) Otsuka shall be responsible for ensuring that, and shall, cause any permitted designee, to (A) cooperate in any such audits and inspections and (B) promptly take any reasonable actions requested by 4DMT to cure any deficiencies or non-compliance issues noted during any such audit or inspection; *provided* that if such obligations to cooperate and take actions to cure are inconsistent with the terms and conditions of the relevant agreement(s) between Otsuka and the applicable permitted designee, Otsuka shall use Commercially Reasonable Efforts to amend such agreements to require such cooperation and actions to cure. 4DMT shall reimburse Otsuka, in accordance with Section 8.5 *mutatis mutandis*, for all costs (which, for clarity, shall include Out-of-Pocket Expenses and internal FTE hours at the FTE Rate) incurred by Otsuka in connection with any such audit of Otsuka or any of its permitted designees.

6.4 Manufacturing Technology Transfer.

(a) Upon Otsuka's written request, the Parties shall coordinate and agree upon a Manufacturing technology transfer plan pursuant to which 4DMT will, at Otsuka's cost, transfer to Otsuka (or, subject to 4DMT's prior written approval, not to be unreasonably withheld, conditioned or delayed, to Otsuka's designee) the Licensed Know-How used in the then-current Manufacturing process

for the Licensed Product and will provide Otsuka with reasonable technical assistance in the use and understanding of such Licensed Know-How in the Manufacture of the Licensed Product in accordance with such process (the "**Manufacturing Technology Transfer**"), subject to Section 6.4(c). The Manufacturing Technology Transfer may include reasonable access to 4DMT's technical personnel involved in the Manufacture of the Licensed Product, and, upon Otsuka's request, an introduction to 4DMT's CMOs to facilitate the discussion and negotiation between Otsuka and such CMO regarding technology transfer or establishing a direct supply or licensing relationship. [*].

(b) The Manufacturing Technology Transfer shall be carried out in accordance with Applicable Law, including the requirements of any Regulatory Authority. The Manufacturing Technology Transfer shall be deemed to be completed following the successful completion by Otsuka or its designee (as applicable) of process performance qualification and Regulatory Approval of the Manufacturing facility for the Manufacture the Licensed Product, and upon completion of the Manufacturing Technology Transfer, Otsuka shall be solely responsible for the Manufacturing and supply of the Licensed Product for the Exploitation of the Licensed Product in the Territory.

(c) Otsuka shall reimburse 4DMT, in accordance with Section 8.5(a), for all costs (which, for clarity, shall include Out-of-Pocket Expenses and internal FTE hours at the FTE Rate including with respect to reference standards, assay development, validation, and plasmid and cell banking if required) incurred by 4DMT to provide such Manufacturing Technology Transfer.

6.5 Manufacturing Capacity. 4DMT shall use Commercially Reasonable Efforts to [*] for the Licensed Product in the Territory as set forth in the then-current forecasts provided by Otsuka pursuant to the Supply Agreement(s).

ARTICLE 7

LICENSES

7.1 License Grant to Otsuka. Subject to the terms and conditions of this Agreement, 4DMT hereby grants Otsuka a non-transferable (except as provided in Section 15.6), exclusive (even as to 4DMT but subject to 4DMT's retained rights set forth in Section 7.2), royalty-bearing, sublicensable through multiple tiers (solely as permitted in accordance with Section 7.3) license, under the Licensed IP, to Exploit the Licensed Product in the Field in the Territory during the Term and to Manufacture the Licensed Product outside the Territory solely for Exploitation in the Territory during the Term.

7.2 4DMT Retained Rights; License Grants to 4DMT.

(a) Without limiting the generality of Section 7.6, 4DMT shall retain any and all rights to the Licensed IP not expressly granted to Otsuka hereunder including the exclusive right to practice, license and otherwise Exploit the Licensed IP outside the scope of the license granted to Otsuka under Section 7.1. Notwithstanding the exclusive license granted to Otsuka pursuant to Section 7.1, 4DMT shall retain the right to perform the activities that 4DMT is responsible for, or otherwise has the rights to perform, under this Agreement (and may convey such retained rights to its Affiliates and Third Parties), including (i) to perform the 4FRONT-1 Clinical Trial, Cross-Territory Clinical Trials, 4DMT Local Clinical Trials, the [*] Study, the [*] Study, and the [*] Study, (ii) to Manufacture the Licensed Product in or outside the Territory for sale to Otsuka pursuant to Section 6.1, and (iii) to Develop and Manufacture the Licensed Product in the Territory solely for the purpose of Exploiting the Licensed Product outside of the Territory.

(b) Subject to the terms and conditions of this Agreement, Otsuka hereby grants 4DMT a non-transferable (except as provided in Section 15.6), non-exclusive, royalty-free, fully paid-up license, under the Arising Product IP Controlled by Otsuka, with the right to sublicense through multiple tiers (solely as set forth in this Section 7.2(b)), to (i) perform 4DMT's obligations under this Agreement or the Supply Agreement(s), and (ii) Develop and Manufacture the Licensed Product in the Territory solely for the purpose of Exploiting the Licensed Product outside of the Territory. The foregoing license grants are sublicensable through multiple tiers solely to (A) 4DMT's Affiliates, (B) 4DMT's and its Affiliates' licensees that have the right to Commercialize the Licensed Product in any country in the world outside the Territory and such Affiliates' and licensees' direct and indirect sublicensees that have the right to Commercialize the Licensed Product in any such country, and (C) service providers of 4DMT or any of the foregoing in (A) and (B) solely for the purpose of such service providers providing services to 4DMT or its Affiliates or its or their (sub)licensees in connection with the Licensed Products.

(c) Subject to the terms and conditions of this Agreement, and without limiting Section 7.2(b), Otsuka hereby grants 4DMT: (i) a non-exclusive, royalty-free, fully paid-up license, under any and all Arising Product IP, to Manufacture the Licensed Products outside of the Territory; and (ii) an exclusive (even as to Otsuka and its Affiliates), royalty-free, fully paid-up license, under any and all Arising Product IP to Exploit (other than to Manufacture) the Licensed Products outside the Territory. The foregoing license grants are sublicensable through multiple tiers solely to (A) 4DMT's Affiliates, (B) 4DMT's and its Affiliates' licensees that have the right to Commercialize the Licensed Product in any country in the world outside the Territory and such Affiliates' and licensees' direct and indirect sublicensees that have the right to Commercialize the Licensed Product in any such country, and (C) service providers of 4DMT or any of the foregoing in (A) and (B) solely for the purpose of such service providers providing services to 4DMT or its Affiliates or its or their (sub)licensees in connection with the Licensed Products.

7.3 Sublicensing by Otsuka.

(a) Scope of Permissible Sublicensing. Subject to Section 7.3(b), the licenses granted by 4DMT to Otsuka in Section 7.1 and Section 7.4 may be sublicensed to (i) Affiliates of Otsuka without 4DMT's consent (*provided* that a sublicense to an Affiliate of Otsuka shall immediately and automatically terminate if and when such Person ceases to be an Affiliate of Otsuka) or (ii) a Third Party upon receiving 4DMT's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, *provided* that, in each case of (i) and (ii), (A) Otsuka shall ensure that the terms of each sublicense are consistent with the terms of this Agreement and the Upstream Licenses, (B) 4DMT shall have no obligations to any such Affiliate or Sublicensee, (C) Otsuka shall be liable for any act or omission of any such Affiliate or Sublicensee that is a breach of any of Otsuka's obligations under this Agreement as though the same were a breach by Otsuka, and 4DMT shall have the right to proceed directly against Otsuka without any obligation to first proceed against such Affiliate or Sublicensee, and (D) each sublicense granted shall contain a requirement that such Affiliate or Sublicensee comply with all applicable provisions of this Agreement. For clarity, without limiting the generality of the foregoing, Contractors are not considered Sublicensees hereunder (subject to Section 1.147) and Otsuka and its Affiliates shall have the right to use such Contractors without 4DMT's prior written consent (except as set forth in Section 6.4 with respect to CMOs), but subject to Sections 3.10 or 5.8, as applicable.

(b) Sublicense Agreements. Otsuka shall provide 4DMT with a copy of any sublicense it enters into with a Third Party, within [*] ([*]) days after the execution thereof; *provided* that such copy may be subject to redaction as Otsuka reasonably believes appropriate to protect confidential business information, including financial provisions and other sensitive information as applicable, in each case, to the extent that the redacted provisions are not applicable to Otsuka's rights or obligations under this Agreement. For clarity, in the case of any Contractor, this Section 7.3(b) shall not apply but Otsuka shall comply with Sections 3.10 or 5.8, as applicable.

7.4 Grant of License to Licensed Product Trademark.

(a) Grant of License. Subject to the terms and conditions of this Agreement, 4DMT and its Affiliates hereby grant to Otsuka an exclusive (even as to 4DMT), royalty-free license, fully paid-up, sublicensable through multiple tiers (solely as permitted in accordance with Section 7.3) to use the Licensed Product Trademark solely for Commercializing the Licensed Product in the Field in the Territory.

(b) Covenants of Otsuka. Otsuka hereby agrees that, subject to Section 7.4(d), it shall use the Licensed Product Trademark solely for Commercializing the Licensed Product in the Field in the Territory, to the extent permitted under Applicable Law, and that any and all uses of the Licensed Product Trademark by Otsuka, and any goodwill arising from or associated therewith, shall inure solely to the benefit of 4DMT. Otsuka hereby agrees that nothing in this Agreement shall give Otsuka any right, title, or interest in the Licensed Product Trademark other than the rights granted in accordance with this Agreement including the use of the Licensed Product Trademark in accordance with this Agreement.

(c) Use of Licensed Product Trademark. Otsuka shall use the Licensed Product Trademark solely in the manner specified in this Agreement in connection with the Licensed Product in the Field in the Territory, and not for any other goods or services. Additionally, Otsuka shall not use the Licensed Product Trademark in a way that is reasonably likely to prejudice the distinctiveness of the Licensed Product Trademark or validity or the goodwill of 4DMT associated therewith and shall use reasonable efforts to use the Licensed Product Trademark with the trademark symbol "®" or "TM", where appropriate, but at least once per package or promotional document. 4DMT will develop guidelines in compliance with Applicable Law which are customary for therapeutic products similarly situated to the Licensed Product for the use of the Licensed Product Trademark in the Field in the Territory, including any restrictions as to color, size, font and placement of the Licensed Product Trademark and as to customary use with other marks including marks pertaining to medical congress booth displays (the "**Trademark Guidelines**"). Otsuka, shall, and shall require its Affiliates, Sublicensees or Contractors to, ensure that all products, product packaging, literature, brochures, signs, and advertising materials that bear, display, or include any reference to the Licensed Product Trademark in connection with promotion or Commercialization of the Licensed Product in the Field in the Territory (collectively, "**Promotional Materials**") shall be consistent with the Trademark Guidelines. Otsuka acknowledges and agrees that it shall be responsible for ensuring, and shall ensure, compliance of the Promotional Materials with Applicable Law. Otsuka will not without 4DMT's prior written approval (such approval not to be unreasonably withheld, conditioned or delayed) use the Licensed Product Trademark or distribute or otherwise use any samples or materials or other media bearing or displaying the Licensed Product Trademark inconsistent with the Trademark Guidelines.

(d) Global Brand Elements. As between the Parties, 4DMT will develop a global branding strategy for the Licensed Product and adopt key distinctive colors, logos, images, symbols, and Trademarks, including the Licensed Product Trademark, to be used in connection with the Commercialization of the Licensed Product throughout the world (such branding elements, collectively, the "**Global Brand Elements**"). The IP Sub-Committee will discuss and agree upon Global Brand Elements, including local language product names and back-up product Trademarks, for each country in the Territory; *provided* that Otsuka shall be responsible for conversion of product names and Trademarks into local languages. 4DMT shall own all rights in the Global Brand Elements and shall register and maintain the Global Brand Elements in each country in the Territory as agreed by the IP Sub-Committee (including local translations, Katakana and Chinese characters, taglines, slogans, trademarks and domain names), at 4DMT's own cost and expense; *provided* that 4DMT will register and maintain the product name Trademarks in each country in the Territory unless Otsuka provides written notice to 4DMT that Otsuka will not seek to Commercialize the Licensed Product in such country or will cease Commercializing the Licensed Product in such country, which notice Otsuka shall promptly provide to 4DMT upon making the decision to not seek to Commercialize the Licensed Product in such country or to cease Commercializing the Licensed Product in such country. Subject to the terms and conditions of this Agreement, 4DMT hereby grants to Otsuka an exclusive, royalty-free license, with the right to sublicense pursuant to Section 7.3 solely to use the then-current Global Brand Elements in Commercializing the Licensed Product in the Field in the Territory. Otsuka shall be required to Commercialize the Licensed Product in the Territory using the Global Brand Elements in a manner consistent with 4DMT's global branding strategy for the Licensed Product and the Trademark Guidelines, *provided* that, with respect to each country within the Territory, Otsuka shall not be required to use such Global Brand Elements in such manner in such country if such use (i) is impermissible under Applicable Law of such country or (ii) could reasonably be considered inappropriate (culturally, linguistically or otherwise) in such country.

7.5 Negative Covenant. Each Party covenants that it shall not, directly or indirectly, use or practice any of the other Party's intellectual property rights licensed to it under this Article 7 for any purposes other than those expressly granted to such Party under this Article 7. Without limiting the generality of the foregoing, Otsuka shall not (and shall ensure that its Affiliates and Sublicensees will not) Exploit any Licensed Product outside the Territory or outside the Field.

7.6 No Implied Licenses. Except as expressly set forth in this Agreement, neither Party grants to the other Party any license, express or implied, under its intellectual property rights.

7.7 Additional Covenants of Otsuka. Otsuka will not, will cause its Affiliates to not, and will contractually restrict its Sublicensees to not, directly or indirectly, (a) make, create, or develop any derivatives or modifications of the Licensed Product, or (b) Exploit the Licensed Product for any indication other than the AMD Indication, the DME Indication, or any New Indication that has been mutually agreed by the JSC and included in the Territory Development Plan in accordance with this Agreement, except in both cases ((a) and (b)) with the prior written consent of 4DMT.

7.8 Upstream Licenses.

(a) Generally. Otsuka acknowledges and agrees that 4DMT, during the Term, may obtain a license to certain Licensed IP from Third Parties pursuant to one or more Upstream Licenses, as further described in this Section 7.8 or Section 9.4. With respect to each agreement that is an Upstream License as of the Effective Date or that becomes an Upstream License pursuant to the process

set forth in Section 7.8(c) (excluding, for clarity, any such agreement that ceases to be an Upstream License pursuant to Section 7.8(c), from and after such time as such agreement ceases to be an Upstream License), Otsuka shall comply with the terms and conditions of such Upstream License and shall not take or fail to take any action that would cause 4DMT to be in breach of any such Upstream License. Without limiting the foregoing, upon 4DMT's request, Otsuka shall provide 4DMT, in a timely manner, all information necessary for 4DMT to comply with its obligations under any Upstream Licenses (excluding, for clarity, any such agreement that ceases to be an Upstream License pursuant to Section 7.8(c), from and after such time as such agreement ceases to be an Upstream License). 4DMT shall have the right to incorporate information received from Otsuka at the JSC or otherwise under this Agreement as needed to fulfill its reporting obligations under any Upstream Licenses, solely to the extent permissible by Applicable Law.

(b) Third Party IP. If during the Term either Party becomes aware of any Patent [*], Know-How or any other intellectual property right that is owned or controlled by a Third Party and is reasonably necessary or useful for the Development, Manufacture or Commercialization of the Licensed Product in the Field (such Patent, Know-How, or other intellectual property right, "**Third Party IP**"), then such Party shall, through the IP Sub-Committee, bring such matter to the attention of the other Party and the Parties shall, through the IP Sub-Committee, discuss whether it is advisable for the Parties to obtain a license under Third Party IP for the Licensed Product.

(c) Licenses to Third Party IP Obtained by 4DMT. As between the Parties: (i) 4DMT shall have the exclusive right (but not the obligation) to obtain a sublicensable license under such Third Party IP for the Exploitation (other than Manufacturing) of the Licensed Product with respect to countries outside the Territory; (ii) 4DMT shall have the first right (but not the obligation) to obtain a sublicensable license under such Third Party IP for the Exploitation of the Licensed Product solely with respect to one or more countries in the Territory; and (iii) 4DMT shall have the first right (but not the obligation) to obtain a sublicensable license under such Third Party IP for the Manufacture of the Licensed Product with respect to countries outside the Territory; *provided* that, with respect to any such license in (i), (ii) or (iii) obtained by 4DMT, 4DMT shall use Commercially Reasonable Efforts to negotiate terms with the applicable licensor that are not unreasonably less favorable to or more burdensome on Otsuka or the Territory than the corresponding terms that apply to 4DMT or outside the Territory. 4DMT shall notify Otsuka of its negotiation of any agreement to obtain such a license and, reasonably prior to execution, shall provide Otsuka with a draft of the relevant agreement, which may be redacted to protect confidential business information not relevant to Otsuka's rights or obligations under this Agreement if such agreement were to become an Upstream License, for Otsuka's review and comment; *provided* that 4DMT shall be under no obligation to incorporate any comments from Otsuka, but shall consider Otsuka's comments in good faith. If 4DMT obtains such a license, 4DMT shall provide Otsuka with notice and a copy of any such agreement within [*] ([*]) days following the execution of such agreement, which copy may be redacted to protect confidential business information not relevant to Otsuka's rights or obligations under this Agreement if such agreement were to become an Upstream License. Within [*] ([*]) days following Otsuka's receipt of such notice and copy, Otsuka shall elect, in its sole discretion, whether or not to be bound by the terms and conditions of such license agreement and provide 4DMT written notice of such decision. If Otsuka agrees to be bound by the terms and conditions of such license agreement: (i) such Third Party IP shall be deemed to be Controlled by 4DMT and constitute Licensed IP licensed to Otsuka pursuant to Section 7.1; (ii) such agreement shall constitute an Upstream License; (iii) Otsuka shall reimburse 4DMT for all payments arising under such Upstream License as a result of the activities of Otsuka or its Affiliates or Sublicensees under this Agreement, which payments shall be subject to the royalty offset provisions of

Section 8.8(e)(ii); and (iv) Otsuka shall comply with the terms and conditions of such agreement. If Otsuka does not agree to be bound by the terms and conditions of such license agreement (including by failing to provide notice to 4DMT within the applicable [*] ([*])-day period): (A) such Third Party IP shall not be Controlled by 4DMT or its Affiliates hereunder and shall not constitute Licensed IP licensed to Otsuka pursuant to Section 7.1, and Otsuka shall have no right to use or practice such Third Party IP in connection with the Licensed Product; (B) such agreement shall not be an Upstream License; and (C) Otsuka shall have no payment or other obligations with respect to such agreement. Notwithstanding anything to the contrary herein, if Otsuka decides that it is no longer willing to be bound by any terms and conditions of a given Upstream License (including any Upstream License existing as of the Effective Date), then (1) Otsuka shall so notify 4DMT in writing, (2) Otsuka shall no longer have a sublicense or any rights to the Patents, Know-How or other intellectual property rights licensed to 4DMT pursuant to such agreement, (3) such Patents, Know-How and other intellectual property rights shall be deemed to no longer be Controlled by 4DMT for the purposes of this Agreement, and (4) such agreement shall be deemed to no longer be an Upstream License. Notwithstanding anything to the contrary, Otsuka will not be bound to any terms or conditions of any Upstream License or any other license that includes a non-exclusive license grant to 4DMT or its Affiliates, unless: (x) it is set forth on Schedule 10.2(j); or (y) Otsuka agrees in writing pursuant to this Section 7.8 to be bound by its terms.

(d) Otsuka's Right to Obtain Licenses to Third Party IP. If 4DMT has not obtained a license to any Third Party IP with sublicense rights for the Territory with respect to Exploitation of the Licensed Product in the Territory, or outside the Territory with respect to Manufacturing the Licensed Product, by the date that is the later of (i) [*] ([*]) days after the Parties agree, through the IP Sub-Committee, to seek to obtain a license for such Third Party IP, or (ii) [*] ([*]) days after Otsuka has given written notice to the JSC of its desire for 4DMT to obtain such license, then unless the Parties otherwise agree after discussion at the IP Sub-Committee, Otsuka shall have the right to obtain, at its own cost and expense (which shall be subject to royalty offset provisions of Section 8.8(e)(ii) for Exploitation of the Licensed Product in the Territory), such a license under such Third Party IP for the Licensed Product.

7.9 [*]. If during the Term, [*], then [*]. If [*]. If, [*] then [*]. [*].

ARTICLE 8

FINANCIALS

8.1 Upfront Payment. In partial consideration of the licenses granted hereunder, Otsuka shall pay to 4DMT a one-time, non-refundable, non-creditable upfront payment of eighty-five million Dollars ($85,000,000) within [*] ([*]) Business Days after receipt of 4DMT's invoice for such amount and, subject to Section 8.10(b)(ii), Payment Forms for such payment received after the Effective Date. For clarity, in the event that 4DMT does not provide any such Payment Forms together with its invoice, Otsuka shall make such upfront payment to 4DMT in accordance with Section 8.10(b)(ii).

8.2 4FRONT-1 Payment. In accordance with Section 8.4, Otsuka shall reimburse 4DMT, on a Calendar Quarter basis, starting on the Calendar Quarter that starts on January 1, 2026, [*] percent ([*]%) of an amount equal to the sum of [*](the "**Allocated 4FRONT-1 Clinical Trial Cost**") capped at a total amount of [*]Dollars ($[*]).

8.3 Reimbursement for certain Clinical Trials.

(a) Cross-Territory Clinical Trial. Otsuka shall bear an amount equal to the sum of [*](the "**Cross-Territory Clinical Trial Cost**"), [*](such amount in the aggregate, the "**Allocated Cross-Territory Clinical Trial Cost**"). In accordance with Section 8.4, starting from the Calendar Quarter that starts on January 1, 2026 and ending during the Calendar Quarter during which the Cross-Territory Clinical Trial is completed (for clarity, through the end of the long-term follow-up commitments), Otsuka will reimburse 4DMT, on a Calendar Quarter basis, for [*]percent ([*]%) of the Cross-Territory Clinical Trial Cost; *provided, however*, that upon completion of such Cross-Territory Clinical Trial (excluding any long-term follow-up commitments), at such time as 4DMT has determined the final costs for such Cross-Territory Clinical Trial Cost (excluding any long-term follow-up commitments) and the number of patients enrolled in such Cross-Territory Clinical Trial within and outside [*], [*]and [*], (x) if the resulting actual Allocated Cross-Territory Clinical Trial Cost for such Cross-Territory Clinical Trial is greater than the total amount of reimbursement paid by Otsuka to 4DMT for such Cross-Territory Clinical Trial to date, then Otsuka shall reimburse the shortfall amount to 4DMT within [*] ([*]) days after receipt of the invoice therefor from 4DMT and (y) if the resulting actual Allocated Cross-Territory Clinical Trial Cost for such Cross-Territory Clinical Trial is less than the total amount of reimbursement paid by Otsuka to 4DMT for such Cross-Territory Clinical Trial to date, then 4DMT shall reimburse the excess amount to Otsuka within [*] ([*]) days after receipt of the invoice therefor from Otsuka. Upon completion of any long-term follow-up commitments for such Cross-Territory Clinical Trial, at such time as 4DMT has determined the final costs for such long-term follow-up commitments and the number of patients subject to such long-term follow-up commitments within and outside [*], [*]and [*], the foregoing clauses (x) and (y) will apply to Cross-Territory Clinical Trial Costs for such long-term follow-up commitments.

(b) 4DMT Local Clinical Trials. With respect to any 4DMT Local Clinical Trial that 4DMT conducts pursuant to Section 3.2(b)(i), (1) in the case of any such 4DMT Local Clinical Trial in [*] or [*] that is required by the relevant Regulatory Authority as a result of 4DMT's failure to enroll the number of patients agreed with such Regulatory Authority, or in the absence of such agreement, agreed by the Parties, in the Cross-Territory Clinical Trial for the same Indication, the conduct of such 4DMT Local Clinical Trial shall be at 4DMT's cost, and (2) in the case of any other such 4DMT Local Clinical Trial in the Territory, Otsuka shall bear an amount equal to the sum of [*](the "**Local Clinical Trial Cost**"), on a Calendar Quarter basis starting from the Calendar Quarter beginning January 1, 2026.

(c) [*] Study, the [*] Study, and the [*] Study. Otsuka shall bear an amount equal to [*] percent ([*]%) of the sum of [*]) (the "**Allocated** [*] **Study Cost**," the "**Allocated** [*] **Study Cost**," and the "**Allocated** [*] **Study Cost**," respectively), on a Calendar Quarter basis starting from the Calendar Quarter beginning January 1, 2026.

Any payment owed under this Section 8.3 shall be made in accordance with Section 8.4 within [*] ([*]) days of receipt of an invoice therefor from the relevant Party.

8.4 Quarterly Invoices and Quarterly Reports. Within [*] ([*]) days after the end of each Calendar Quarter, 4DMT shall send quarterly invoices to Otsuka for the Allocated 4FRONT-1 Clinical Trial Cost, the Local Clinical Trial Cost, the Allocated [*] Study Cost, the Allocated [*] Study Cost, the Allocated [*] Study Cost, and [*] percent ([*]%) of the Cross-Territory Clinical Trial Cost that was incurred during such Calendar Quarter and not previously reimbursed by Otsuka, together with

reasonable documentation thereof reasonably sufficient for Otsuka to verify all such amounts and including reasonable documentation for the actual costs in each relevant category (*e.g.*, contract research organization costs, clinical material costs and internal FTE costs), and Otsuka shall pay all undisputed amounts in each such invoice within [*] ([*]) days of receipt of such invoice; *provided* that Otsuka shall not be responsible for reimbursing any Local Clinical Trial Cost, Allocated [*] Study Cost, Allocated [*] Study Cost, or Allocated [*] Study Cost in excess of [*] percent ([*]%) of the applicable budget agreed at the JSC. If one or more Payment Forms previously provided has expired at the time of the applicable invoice, 4DMT shall provide such updated Payment Forms together with the invoice. In addition, no later than [*] ([*]) Business Days after the last Business Day of each Calendar Quarter, 4DMT shall provide Otsuka with a flash report showing the anticipated Allocated 4FRONT-1 Clinical Trial Cost, Allocated Cross-Territory Clinical Trial Cost, Local Clinical Trial Cost, Allocated [*] Study Cost, Allocated [*] Study Cost and Allocated [*] Study Cost for such Calendar Quarter. Such flash report shall present the information on a Calendar Quarterly basis in the format set forth in Schedule 8.4.

8.5 Reimbursement for 4DMT's Assistance.

(a) Unless otherwise expressly provided otherwise, Otsuka shall reimburse 4DMT for Out-of-Pocket Expenses incurred by 4DMT and internal FTE hours at the FTE Rate incurred by 4DMT in connection with performing any activities, or providing any assistance or support, requested by Otsuka (including pursuant to Sections 3.1, 3.2(b), 3.5(e), 4.1(b), 4.5, 6.1(e), 6.2, 6.4(c) and 9.9(c) (for which both Out-of-Pocket Expenses and internal FTE hours at the FTE Rate are reimbursable), and Sections 4.2(b), 4.2(c) and 4.3(b) (for which only Out-of-Pocket Expenses are reimbursable)); *provided* that (i) with respect to internal FTE costs, (A) there will be no charge for providing [*], and (B) for providing all other assistance there will be no charge for the [*] devoted by 4DMT to providing all such other assistance; and (ii) with respect to both internal FTE costs and Out-of-Pocket Expenses, Otsuka may not challenge such costs or expenses as unreasonable to the extent that (A) Otsuka had already approved a budget or fee estimate detailing such internal FTE costs or Out-of-Pocket Expenses and the resulting internal FTE costs or Out-of-Pocket expenses were less than or equal to such budget or fee estimate or (B) such internal FTE costs or Out-of-Pocket Expenses are reimbursable pursuant to Section 8.4 for a given Clinical Trial and the costs incurred for such Clinical Trial in the aggregate have not exceeded [*] percent ([*]%) of the mutually agreed budget for such Clinical Trial. 4DMT shall send quarterly invoices and, subject to Section 8.10(b)(ii), updated Payment Forms if previous Payment Forms are expired to Otsuka for such costs that have not previously been reimbursed by Otsuka, together with reasonable documentation thereof [*], and Otsuka shall pay each such invoice within [*] ([*]) days of receipt.

(b) 4DMT shall use reasonable efforts to not incur internal FTE costs and Out-of-Pocket Expenses that are excessive in light of the work performed and to closely monitor internal FTE costs and Out-of-Pocket Expenses and look for opportunities to reduce them without compromising quality or causing delay.

8.6 Regulatory Milestone Payments. In partial consideration for the licenses granted hereunder, Otsuka shall make the following one-time, non-refundable and non-creditable milestone payments to 4DMT on the first achievement of the regulatory milestone events as set forth in this Section 8.6.

(a) Otsuka shall notify 4DMT within [*] ([*]) Business Days after the achievement of each of the regulatory milestone events set forth in the table below and will pay the corresponding regulatory milestone payment within [*] ([*]) days of the receipt by Otsuka of 4DMT's invoice for such regulatory milestone payment and, subject to Section 8.10(b)(ii), updated Payment Forms if previous Payment Forms are expired (for clarity, in the event that 4DMT does not provide any such Payment Forms together with its invoice, Otsuka shall make such regulatory milestone payments to 4DMT in accordance with Section 8.10(b)(ii)):

Regulatory Milestone Event	***Regulatory Milestone Payment***
1.[*]	$[*]
2.[*]	$[*]
3.[*]	$[*]
4.[*]	$[*]

For clarity, if the [*]includes [*], then the corresponding regulatory milestone payments [*]shall be payable. By way of example only, if [*], then Otsuka shall pay regulatory milestone payments of [*] Dollars ($[*]) to 4DMT within [*] ([*]) days of the receipt by Otsuka of 4DMT's invoice for such regulatory milestone payment and, subject to Section 8.10(b)(ii), updated Payment Forms if previous Payment Forms are expired. For the avoidance of doubt, the aggregate amount of all payments made or required to be made by Otsuka to 4DMT pursuant to this Section 8.6(a) shall in no event exceed [*]Dollars ($[*]). For clarity, in the event that 4DMT does not provide any such Payment Forms together with its invoice, Otsuka shall make such regulatory milestone payments to 4DMT in accordance with Section 8.10(b)(ii).

(b) Upon [*] ([*]) [*] in [*] for a Licensed Product for [*]or [*] (or for [*]), Otsuka shall notify 4DMT of such [*] within [*] ([*]) Business Days after the achievement of such milestone event and will pay the corresponding regulatory milestone payment set forth in the table below within [*] ([*]) days of the receipt by Otsuka of 4DMT's invoice for such regulatory milestone payment and, subject to Section 8.10(b)(ii), updated Payment Forms if previous Payment Forms are expired (for clarity, in the event that 4DMT does not provide any such Payment Forms together with its invoice, Otsuka shall make such regulatory milestone payments to 4DMT in accordance with Section 8.10(b)(ii)):

[*]	***Regulatory Milestone Payments Based on [*]***		
	Less than [*]	***Greater than or equal to [*] and less than [*]***	***Greater than or equal to [*]***
[*]	$[*]	$[*]	$[*]
[*]	$[*]	$[*]	$[*]

For clarity, if [*] receives [*] in [*] after [*] receives [*] in [*] (or *vice versa*), the regulatory milestone payment for [*] shall be paid based on the [*] for the [*] and Otsuka will pay the regulatory milestone payment for [*] within [*] ([*]) days of the receipt by Otsuka of 4DMT's invoice for such regulatory milestone payment and, subject to Section 8.10(b)(ii), updated Payment Forms if previous Payment Forms are expired. For the avoidance of doubt, the aggregate amount of all payments made or required to be made by Otsuka to 4DMT pursuant to this Section 8.6(b) shall in no event exceed [*] Dollars ($[*]). For clarity, in the event that 4DMT does not provide any such Payment Forms together with its invoice, Otsuka shall make such regulatory milestone payments to 4DMT in accordance with Section 8.10(b)(ii).

(c) Upon [*] ([*]) [*] in [*] for [*] for [*], Otsuka shall notify 4DMT within [*] ([*]) Business Days after the achievement of such milestone event and will pay the corresponding regulatory milestone payment set forth in the table below within [*] ([*]) days of the receipt by Otsuka of 4DMT's invoice for such regulatory milestone payment and, subject to Section 8.10(b)(ii), updated Payment Forms if previous Payment Forms are expired (for clarity, in the event that 4DMT does not provide any such Payment Forms together with its invoice, Otsuka shall make such regulatory milestone payments to 4DMT in accordance with Section 8.10(b)(ii)):

[*]	***Regulatory Milestone Payments Based on [*]***		
	Less than [*]	***Greater than or equal to [*] and less than [*]***	***Greater than or equal to [*]***
[*]	$[*]	$[*]	$[*]
[*]	$[*]	$[*]	$[*]

For clarity, if [*] receives [*] in [*] after [*] receives [*] in [*] (or *vice versa*), the regulatory milestone payment for [*] shall be paid based on the [*] for the [*] and Otsuka will pay the regulatory milestone payment for [*] within [*] ([*]) days of the receipt by Otsuka of 4DMT's invoice for such regulatory milestone payment and, subject to Section 8.10(b)(ii), updated Payment Forms if previous Payment Forms are expired. For the avoidance of doubt, the aggregate amount of all payments made or required to be made by Otsuka to 4DMT pursuant to this Section 8.6(c) shall in no event exceed [*] Dollars ($[*]). For clarity, in the event that 4DMT does not provide any such Payment Forms together with its invoice, Otsuka shall make such regulatory milestone payments to 4DMT in accordance with Section 8.10(b)(ii).

(d) Each regulatory milestone payment set forth above shall be due and payable irrespective of whether the applicable development and regulatory milestone event is achieved by Otsuka or its Affiliate or Sublicensee.

8.7 Sales Milestone Payments.

(a) In partial consideration for the licenses granted hereunder, Otsuka shall pay to 4DMT the one-time, non-refundable and non-creditable sales milestone payments set forth in the table

below on the first occurrence of the corresponding sales milestone event. For the avoidance of doubt, the aggregate amount of all payments made or required to be made by Otsuka to 4DMT pursuant to this Section 8.7 shall in no event exceed [*]Dollars ($[*]).

Sales Milestone Event	***Sales Milestone Payment***
1. Aggregate Net Sales of all Licensed Product in the Territory in a particular Calendar Year exceed [*]	$[*]
2. Aggregate Net Sales of all Licensed Product in the Territory in a particular Calendar Year exceed [*]	$[*]
3. Aggregate Net Sales of all Licensed Product in the Territory in a particular Calendar Year exceed [*]	$[*]

(b) For clarity, the sales milestone payments are additive, such that if more than one sales milestone event is achieved in the same time period, then the corresponding sales milestone payments for all such achieved sales milestone events shall be payable.

(c) As part of the royalty report provided under Section 8.8(i), Otsuka shall provide written notice to 4DMT if any sales milestone event is achieved during the time period to which such royalty report pertains. Otsuka shall pay to 4DMT the corresponding sales milestone payments for such achieved sales milestone events concurrently with the delivery of such royalty report.

8.8 Royalties.

(a) Royalties for [*]. In partial consideration for the licenses granted hereunder, subject to the terms and conditions set forth in this Section 8.8, Otsuka shall pay to 4DMT non-refundable, non-creditable (but subject to Section 8.8(j)), tiered royalties on annual Net Sales of the Licensed Product in Japan in a Calendar Year, [*] r. [*]

Aggregate annual Net Sales [*] ***of the Licensed Product in*** [*]	[*]		
	Less than [*] ***(Tier 1)***	***Greater than or equal to*** [*] ***and less than*** [*] ***(Tier 2)***	***Greater than or equal to*** [*] ***(Tier 3)***
Less than or equal to [*]	[*]	[*]-[*]%	[*]%
Greater than [*]and less than or equal to [*]	[*]%	[*]-[*]%	[*]%
Greater than [*]and less than or equal to [*]	[*]%	[*]-[*]%	[*]%

Aggregate annual Net Sales [*] ***of the Licensed Product in*** [*]	[*]		
	Less than [*] ***(Tier 1)***	***Greater than or equal to*** [*] ***and less than*** [*] ***(Tier 2)***	***Greater than or equal to*** [*] ***(Tier 3)***
Greater than [*]	[*]%	[*]-[*]%	[*]%

Royalty rates for Tier 2 in the royalty table for [*] above shall be [*], *provided* that only the digits up to the first decimal place will be used (*i.e.*, the second decimal and the beyond will be truncated (and not rounded)):

Royalty rate in % = A% + ((B-A)% x (([*]– [*])**/(** [*]**)))**, where A is the applicable Tier 1 royalty rate and B is the applicable Tier 3 royalty rate.

(b) Royalties for [*]. In partial consideration for the licenses granted hereunder, subject to the terms and conditions set forth in this Section 8.8, Otsuka shall pay to 4DMT non-refundable, non-creditable (but subject to Section 8.8(j)), tiered royalties on annual Net Sales for the Licensed Product sold in [*] in a Calendar Year, [*]. For the avoidance of doubt, the royalty rates set forth in the table below apply to the portion of aggregate annual Net Sales of the Licensed Product in [*] in a Calendar Year that falls within each specified range.

Aggregate annual Net Sales [*] ***of the Licensed Product in*** [*]	[*]		
	Less than [*] (Tier 1)	***Greater than or equal to [*] and less than [*] (Tier 2)***	***Greater than or equal to [*] (Tier 3)***
Less than or equal to [*]	[*]%	[*]%	[*]%
Greater than [*]and less than or equal to [*]	[*]%	[*]%	[*]%
Greater than [*] and less than or equal to [*]	[*]%	[*]%	[*]%
Greater than [*]	[*]%	[*]%	[*]%

For clarity, until [*], the royalty tier in [*]shall be based upon the highest price listed on [*] of [*], of the Licensed Product in [*] at the time of its launch in [*]; *provided*, *however*, that if [*] offered by the applicable Regulatory Authority is unacceptable for Otsuka and Otsuka decides, in its sole discretion after being offered an [*] for the Licensed Product, to Commercialize the Licensed Product in [*] without [*], the royalty tier in [*] shall thereafter be based upon the Tier 1 royalty

rate set forth in the table above regardless of the selling price of the Licensed Product unless and until Otsuka Commercializes the Licensed Product in [*] with [*].

(c) Royalties for Other Countries within the Territory. In partial consideration for the licenses granted hereunder, subject to the terms and conditions set forth in this Section 8.8, Otsuka shall pay 4DMT non-refundable, non-creditable (but subject to Section 8.8(j)), royalties equal to [*] percent ([*]%) of the Net Sales for the Licensed Product sold in any country within the Territory other than [*] and [*].

(d) Royalty Term.

(i) Royalties under Section 8.8(a), Section 8.8(b) and Section 8.8(c) shall be payable, on a Licensed Product-by-Licensed Product and country-by-country basis, during the period of time beginning with First Commercial Sale of such Licensed Product in such country within the Territory and ending on the latest of (A) the date that is [*] ([*]) years after such First Commercial Sale, (B) the expiration of all Regulatory Exclusivity for such Licensed Product in such country within the Territory, or (C) the last to expire Valid Claim within the Licensed Patents that Covers the composition of matter of such Licensed Product (including any components thereof) or method of using such Licensed Product in such country within the Territory (any such period, the "**Initial Royalty Term**"). If at any time after the end of the Initial Royalty Term for a particular Licensed Product in a particular country in the Territory, there becomes (whether through issuance or filing of a Licensed Patent) a Valid Claim within the Licensed Patents that Covers the composition of matter of such Licensed Product (including any components thereof) or method of using such Licensed Product in such country within the Territory, then the Initial Royalty Term for such Licensed Product in such country shall restart and continue until there is no longer any such Valid Claim.

(ii) After the First Commercial Sale of a Licensed Product and during any period that is not within an Initial Royalty Term, royalties under Section 8.8(a), Section 8.8(b) and Section 8.8(c) shall be payable, on a Licensed Product-by-Licensed Product and country-by-country basis, on the Net Sales of such Licensed Product in such country within the Territory at the rate of [*] percent ([*]%) (notwithstanding the royalty rates set forth in Section 8.8(a), Section 8.8(b) and Section 8.8(c)), *provided* that, notwithstanding anything to the contrary provided herein, such [*] percent ([*]%) royalty rate shall not be subject to any further reductions or adjustments under this Agreement except as set forth in Section 8.8(j).

(e) Royalty Reductions.

(i) With respect to royalties payable during any period within the Initial Royalty Term only, if (A) the Licensed Product is generating Net Sales in a country in the Territory during the applicable Initial Royalty Term at a time when [*], and (B) there has been at least a [*] percent ([*]%) reduction of unit sales of the Licensed Product in such country within the Territory (relative to unit sales prior to [*]), calculated on a Calendar Quarter-by-Calendar Quarter basis, then the royalty rates applicable to Net Sales of such Licensed Product in such country with respect to such Calendar Quarter shall be reduced to [*]percent ([*]%) of the royalty rates set forth in Section 8.8(a), Section 8.8(b) and Section 8.8(c), but subject to Section 8.8(f), only during the Initial Royalty Term and for so long as [*] with at least such [*] percent ([*]%) reduction of unit sales of the Licensed Product. For the purposes of this Section 8.8, if [*] in the middle of a Calendar Quarter, the comparison of unit sales for determining whether the [*] percent ([*]%) reduction threshold has been met shall be made against the Calendar Quarter immediately preceding the Calendar Quarter during which [*].

(ii) With respect to royalties payable during any period within the Initial Royalty Term only, if (A) 4DMT or Otsuka becomes aware of a Third Party's Patent and where Otsuka reasonably determines, in the absence of a license to such Patent from such Third Party, such Patent would be necessarily infringed by the Exploitation of any Licensed Product, (B) Otsuka obtains a license to such Patent from such Third Party in a country in the Territory or from 4DMT pursuant to Section 7.8(c) and Section 7.8(d), and (C) under such license, Otsuka is obligated to make royalty payments to such Third Party directly or indirectly through 4DMT on account of the sale of such Licensed Product in such country in the Territory, then subject to Section 8.8(f), Otsuka shall be permitted to deduct from the royalty payments payable by Otsuka to 4DMT during any period within the Initial Royalty Term with respect to Net Sales of such Licensed Product in such country during any Calendar Quarter under this Agreement, an amount equal to [*] percent ([*]%) of all amounts paid by Otsuka to such Third Party during such Calendar Quarter, on account of sales of such Licensed Product in such country, including upfront payments, milestone payments, and royalties; *provided, however*, that such deduction shall only be applied against royalties owed to 4DMT for such Calendar Quarter and shall in no event reduce the royalties payable to 4DMT below the minimum amount specified in Section 8.8(f).

(iii)With respect to royalties payable under Section 8.8(a) during any period within the Initial Royalty Term only, if the Licensed Product is generating Net Sales in [*] during the applicable Initial Royalty Term at a time when the Licensed Product is subject to [*] and [*] (the "[*] **Percentage**") at one time, then, at the time [*], the applicable royalty rates set forth in Section 8.8(a) shall be reduced by ([*])% of the applicable original royalty rates set forth in Section 8.8(a). For example, if the royalty rates in Tier 3 apply and [*], the royalty rate of [*]%, [*]%, [*]% and [*]% in Tier 3 will be revised to [*]% ([*]% x (1- ([*])), [*]% ([*]% x (1- ([*])), [*]% ([*]% x (1- ([*]))), and [*]% ([*]% x (1- ([*]))), respectively.

(iv)Notwithstanding this Section 8.8(e), in no event will the royalties payable by Otsuka to 4DMT under this Agreement outside of any Initial Royalty Term be reduced. All reductions on royalties payable by Otsuka to 4DMT under this Agreement set forth in this Section 8.8(e) are subject to Section 8.8(f).

(f) Royalty Floor. Notwithstanding anything to the contrary provided in this Agreement, the reductions and deductions under Section 8.8(e), Section 8.8(g) and Section 8.8(h), individually or in combination, shall not reduce the royalties paid by Otsuka to 4DMT with respect to the Net Sales of the Licensed Product in any country within the Territory in any given Calendar Quarter to less than [*] ([*]%) of the royalty payment that would otherwise have been due under Section 8.8(a), Section 8.8(b) and Section 8.8(c), as applicable, with respect to such Net Sales without any reductions or deductions.

(g) Royalty Reduction [*]. In the event that [*], then upon [*], the royalty rate(s) applicable to Net Sales of the Licensed Product in such country set forth in Section 8.8(a), Section 8.8(b) or Section 8.8(c) (as applicable) shall be reduced by [*] percent ([*]%) [*]. For clarity, [*].

(h) Royalty Reduction [*]. In the event that [*], the royalty rate(s) applicable to Net Sales of the Licensed Product in such country [*] set forth in Section 8.8(a), Section 8.8(b) or Section 8.8(c) (as applicable) shall be reduced by [*] percent ([*]%) [*]. For clarity, [*].

(i) Royalty Payments and Reports. Starting from the date of First Commercial Sale of the Licensed Product in the Territory, within [*] ([*]) days after the end of each Calendar

Quarter, Otsuka shall provide to 4DMT a written statement (in English) setting forth the following information for the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product and country-by-country basis, and in the form attached hereto as Schedule 8.8(i): (a) the amount of gross sales of such Licensed Product in such country within the Territory, (b) an itemized calculation of Net Sales of such Licensed Product in such country within the Territory showing separately each type of deduction provided for in the definition of "Net Sales" hereunder, (c) an itemized calculation of all reductions and deductions (if any) that apply to such Licensed Product in such country pursuant to Section 8.8, (d) a calculation of the royalty payment due on such Net Sales in Dollars, including the exchange rate used in such calculation in accordance with Section 8.11, (e) withholding taxes, if any, required by Applicable Law to be deducted with respect to such royalties and (f) the aggregate annual Net Sales and whether any sales milestone event under Section 8.7 has been achieved. Otsuka shall pay to 4DMT the royalties owed with respect to Net Sales for each Calendar Quarter, if any, and, if any sales milestone event under Section 8.7 has been achieved during such Calendar Quarter, the corresponding sales milestone payments under Section 8.7 within [*] ([*]) days after receiving 4DMT's invoice therefor, issued after 4DMT's receipt of the written statement for such Calendar Quarter and, subject to Section 8.10(b)(ii), updated Payment Forms if previous Payment Forms are expired. If no royalties are due for any Calendar Quarter hereunder following the First Commercial Sale of the Licensed Product in a country within the Territory, Otsuka will so report. For clarity, in the event that 4DMT does not provide any such Payment Forms together with its invoice, Otsuka shall make such royalty payments to 4DMT in accordance with Section 8.10(b)(ii).

(j) Royalty Set-Off. Notwithstanding anything to the contrary in this Agreement, if [*], Otsuka may, at its option, set off, against any payment due to 4DMT under this Agreement, the amount of such [*]; *provided*, *however*, that in no event shall such set-off reduce the royalties paid by Otsuka to 4DMT with respect to the Net Sales of the Licensed Product in any country within the Territory in any given Calendar Quarter to less than [*] percent ([*]%) of the royalty payment that would otherwise have been due under Section 8.8(a), Section 8.8(b), Section 8.8(c) and Section 8.8(d)(ii), as applicable, with respect to such Net Sales without any reductions or deductions. For clarity, if the period during which Otsuka is entitled to such set-off falls outside of the Initial Royalty Term, the reduction shall continue to apply to royalties payable under Section 8.8(d) for the duration of such period, subject to the foregoing [*] percent ([*]%) royalty floor.

8.9 Interest. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of (a) per-annum rate of (i) prime (as reported in *The Wall Street Journal (U.S., Eastern Edition)*) plus [*] ([*]) basis points or (ii) [*] percent ([*]%) per month, whichever ((i) or (ii)) is greater, or (b) the maximum rate permitted under Applicable Law, in each case ((a) or (b)), calculated on the number of days such payment is delinquent.

8.10 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement, including applicable withholding taxes, VAT, stamp duty or other taxes required by Applicable Law.

(b) Tax Cooperation.

(i) The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made under this Agreement. To the extent Otsuka is obligated to deduct and withhold taxes on any payment to 4DMT, Otsuka shall deduct those taxes from the remittable payment, pay the taxes to the proper tax authority in a timely manner, and promptly send proof of payment to 4DMT. 4DMT shall provide Otsuka any tax forms including Payment Forms that may be reasonably necessary in order for Otsuka to not withhold tax or to withhold tax at a reduced rate under any applicable tax treaty. 4DMT shall use reasonable efforts to provide any such tax forms to Otsuka in advance of the due date. At the request of 4DMT, Otsuka shall provide reasonable assistance and cooperation to enable the recovery, to the extent permitted by Applicable Law, of withholding taxes or similar obligations resulting from payments made under this Agreement.

(ii) In the event that 4DMT does not provide any of the Payment Forms together with the applicable invoice, Otsuka shall make the applicable payment to 4DMT, deduct and withhold the required amount, and pay such withheld amount to the appropriate Governmental Authority. Otsuka shall promptly provide 4DMT with copies of receipts or other evidence reasonably required and sufficient to allow 4DMT to document such tax withholdings adequately for purposes of claiming foreign tax credits and similar benefits. Otsuka shall additionally cooperate with 4DMT in claiming a refund of any such taxes, including by filing a [*] on behalf of 4DMT and taking such other actions as 4DMT may reasonably request in connection therewith. The Parties shall cooperate reasonably in completing and filing documents required under the provisions of any applicable tax laws or under any other Applicable Law, in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment, and the Parties shall cooperate to minimize such taxes in accordance with Applicable Laws, including using reasonable efforts to access the benefits of any applicable treaties.

(c) Withholding Action. If, as a result of any action or inaction by Otsuka, including assignment or transfer of this Agreement, change in the residence of Otsuka for tax purposes, change in the entity making such payment, or failure on the part of Otsuka to comply with Applicable Law or filing or record retention requirements, the amount of any tax (including income tax, value added tax) that Otsuka is required to deduct or withhold from a payment made by Otsuka to 4DMT under this Agreement is increased, then the sum payable by Otsuka to 4DMT shall be increased to the extent necessary to ensure that 4DMT receives a sum equal to the sum that 4DMT would have received had no such action or inaction occurred.

8.11 Method of Payment; Foreign Exchange. All payments to be made by Otsuka to 4DMT under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to the bank account set forth in Schedule 8.11, which 4DMT may update from time to time by written notice. The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in other currencies shall be calculated based on average currency exchange rates across the Calendar Quarter for which remittance is made for royalties. The rate of exchange to be used in computing the amount of currency equivalent in Dollars shall be made using Otsuka's standard conversion method, based on the currency conversion rates issued by Mizuho bank and consistent with Otsuka's customary and usual conversion procedures used in preparing its publicly filed and audited financial statements and applied in accordance with its Accounting Standards on a consistent basis, provided that such procedures utilize a widely accepted source of published exchange rates. This Section 8.11 will apply *mutatis mutandis* to 4DMT for any payments owed to Otsuka by 4DMT

hereunder; *provided* that 4DMT may at its discretion replace the currency conversion rates issued by Mizuho bank with another widely accepted source of published exchange rates.

8.12Financial Records.

(a) Otsuka Record Keeping. Otsuka and its Affiliates will, and will cause their respective Sublicensees to, keep complete, true and accurate books and records in accordance with the Accounting Standards of the items underlying milestone and royalty payments under this Agreement (including the calculation of Net Sales and any royalty reductions or deductions). Otsuka and its Affiliates will, and will cause their respective Sublicensees to, keep such books and records for at least [*] ([*]) years following the Calendar Quarter to which they pertain.

(b) 4DMT Record Keeping. 4DMT and its Affiliates will, and will cause their respective licensees and sublicensees to, keep complete, true and accurate books and records in accordance with its accounting standards of the items underlying costs to be reimbursed by Otsuka under this Agreement. 4DMT and its Affiliates will keep such books and records for at least [*] ([*]) years following the Calendar Quarter to which they pertain.

8.13Audits.

(a) 4DMT will have the right no more than [*] per Calendar Year, at its own expense, to have an internationally-recognized independent, certified public accountant, selected by 4DMT and reasonably acceptable to Otsuka to review the books and records of Otsuka, its Affiliates and Sublicensees in the location(s) where such records are customarily maintained upon reasonable prior written notice (not less than [*] ([*]) days' prior written notice), during regular business hours, not interfering unreasonably with the audited Person's business activities and under commercially reasonable obligations of confidentiality and non-use, except to the extent disclosure is required by Applicable Law, for the sole purpose of verifying the basis and accuracy of milestone or royalty payments invoiced, owed or made under this Agreement and the content of any royalty report provided pursuant to Section 8.8(i), within the prior [*] ([*])-year period after receipt of such report. The records covering any specific period of time may be audited no more than once.

(b) Otsuka will have the right no more than [*] per Calendar Year, at its own expense, to have an internationally-recognized independent, certified public accountant, selected by Otsuka and reasonably acceptable to 4DMT, review any such books and records of 4DMT and its Affiliates (including those relating to FTE costs and Manufacturing Cost) in the location(s) where such records are customarily maintained upon reasonable prior written notice (not less than [*] ([*]) days' prior written notice), during regular business hours, not interfering unreasonably with the audited Person's business activities and under commercially reasonable obligations of confidentiality and non-use, except to the extent disclosure is required by Applicable Law, for the sole purpose of verifying the basis and accuracy of the reimbursable costs invoiced, owed or paid to 4DMT under this Agreement. The records covering any specific period of time may be audited no more than once.

(c) Audit Report. The report prepared by the applicable independent, certified public accountant (the "**Auditor**"), a copy of which will be sent or otherwise provided to each Party by such Auditor at the same time before such report is considered final, will be limited to a summary containing the conclusions of such Auditor regarding the audit and will specify that the amounts reported, invoiced or paid pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment, and the specific details regarding any discrepancies. The Auditor shall

not be permitted to include any extrapolation calculations in their calculation of amounts allegedly underpaid to the auditing Party. If such report reveals any underpayment, then the audited Party will remit to the auditing Party, within [*] ([*]) days after receipt of such report, (i) the amount of such underpayment and (ii) if such underpayment exceeds [*]percent ([*]%) of the total amount owed for the period then being audited, the actual costs incurred by the auditing Party in conducting such review. If such report shows any overpayment, then, as may be requested by the audited Party, the auditing Party will credit the overpaid amount against future payments owed to the auditing Party. The Parties mutually agree that all information subject to review under this Section 8.13(c) is Confidential Information of the audited Party and that the auditing Party will retain and cause the Auditor to retain all such information in confidence in accordance with confidentiality and non-use obligations no less stringent than those contained in Article 12.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership.

(a) Subject only to the rights expressly granted to Otsuka under this Agreement, 4DMT will retain all rights, title and interests in and to the Licensed Patents and Licensed Know-How. Each Party will retain all rights, title and interests in and to the Patents, Know-How and other intellectual property rights that are owned or otherwise controlled by such Party as of the Effective Date or that are generated or acquired by such Party outside the scope of this Agreement.

(b) Inventorship of any Arising Product IP shall be determined in accordance with the United States patent law. As between the Parties, ownership of Arising Product IP shall follow inventorship (*i.e.*, (i) each Party will solely own all Arising Product IP invented or otherwise generated (whether solely or jointly) solely by or on behalf of such Party or its Affiliates or Sublicensees, whether directly or via its or their respective Contractors, directors, officers, employees or other agents) in the course of conducting such Party's activities or exercising such Party's rights under this Agreement, and (ii) the Parties will jointly own all Arising Product IP invented or otherwise generated jointly by or on behalf of the Parties (or their respective Affiliates, independent contractors or Sublicensees or its or their respective directors, officers, employees or agents) in the course of performing activities or exercising rights under this Agreement. Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign and otherwise exploit any Arising Product IP jointly owned by the Parties (including any Patent claiming such jointly owned Arising Product IP), without a duty of accounting or seeking consent from the other Party.

(c) Disclosure Obligation. Each Party shall, through the IP Sub-Committee, disclose to the other Party all Arising Product IP invented or generated (whether solely or jointly) by or on behalf of such Party or its Affiliates or Sublicensees under this Agreement since the last meeting of the IP Sub-Committee, including any invention disclosures, or other similar documents, submitted to it or them by its or their respective employees, agents or independent contractors describing such Arising Product IP, and shall promptly respond to reasonable requests from the other Party for additional information relating to such Arising Product IP.

9.2 Prosecution and Maintenance of the Patents.

(a) 4DMT Prosecuted Patents.

(i) As between the Parties, 4DMT shall have the first right (but not an obligation) to Prosecute and Maintain all (A) Licensed Patents and (B) Patents within the Arising Product IP solely owned by 4DMT (including, for clarity, Patents within the 4DMT Arising Product IP) or jointly owned by the Parties (collectively, the "**4DMT Prosecuted Patents**") throughout the world; *provided* that, (x) in countries in the Territory that accept patent term extensions for multiple applicable patents, at Otsuka's request, 4DMT shall file patent term extensions for all 4DMT Prosecuted Patents in such country in the Territory, and (y) in countries in the Territory that accept a patent term extension for only one applicable patent, at Otsuka's request, the IP Sub-Committee shall discuss the filing of a patent term extension for one of the 4DMT Prosecuted Patents in such country in the Territory, but 4DMT shall have final decision-making authority with respect to whether such patent term extension will be filed. 4DMT shall be responsible for the cost and expenses of such Prosecution and Maintenance.

(ii) Through the IP Sub-Committee, 4DMT shall consult with Otsuka and keep Otsuka reasonably informed of the status of the Prosecution and Maintenance of the 4DMT Prosecuted Patents in the Territory and shall promptly provide Otsuka with all material correspondence received from any patent authority in the Territory in connection therewith. In addition, 4DMT shall, through the IP Sub-Committee, provide Otsuka with drafts of all proposed material filings and correspondence to any patent authority in the Territory with respect to the Prosecution and Maintenance of the 4DMT Prosecuted Patents for Otsuka's review and comment at least [*] ([*]) days prior to the submission of such proposed filings and correspondences. Through the IP Sub-Committee, 4DMT shall confer with Otsuka and consider in good faith Otsuka's comments prior to submitting such filings and correspondences in the Territory, *provided* that Otsuka shall provide such comments within [*] ([*]) days (or a shorter period reasonably designated by 4DMT if [*] ([*]) days is not practicable given the filing deadline) of receiving the draft filings and correspondences from 4DMT. Otsuka shall provide 4DMT all reasonable assistance and cooperation in the patent Prosecution and Maintenance efforts under this Section 9.2(a) at its own expense, including providing any necessary powers of attorney and executing any other required documents or instruments for such Prosecution and Maintenance.

(iii)If 4DMT intends to abandon or cease the Prosecution and Maintenance of any 4DMT Prosecuted Patent in the Territory, 4DMT shall provide prior written notice to Otsuka and the IP Sub-Committee of such intention (which notice shall be given at least [*] ([*]) days in advance of the next deadline to take any action in the relevant patent office necessary to maintain existing rights in any such 4DMT Prosecuted Patent). Upon Otsuka's written election provided no later than [*] ([*]) days after such notice from 4DMT, 4DMT shall permit Otsuka to assume the Prosecution and Maintenance of such 4DMT Prosecuted Patent in the Territory at its own expense and using patent counsel of its choosing.

(b) Otsuka Prosecuted Patents.

(i) As between the Parties, Otsuka shall have the first right (but not an obligation) to Prosecute and Maintain all Patents within the Arising Product IP solely owned by Otsuka (the "**Otsuka Prosecuted Patents**") throughout the world. Otsuka shall be responsible for the cost and expenses of such Prosecution and Maintenance.

(ii) Through the IP Sub-Committee, Otsuka shall consult with 4DMT and keep 4DMT reasonably informed of the status of the Prosecution and Maintenance of the Otsuka Prosecuted Patents and shall promptly provide 4DMT with all material correspondence received from any patent authority in connection therewith. In addition, Otsuka shall, through the IP Sub-Committee, promptly provide 4DMT with drafts of all proposed material filings and correspondence to any patent authority with respect to the Prosecution and Maintenance of the Otsuka Prosecuted Patents for 4DMT's review and comment prior to the submission of such proposed filings and correspondences. Through the IP Sub-Committee, Otsuka shall confer with 4DMT and consider in good faith 4DMT's comments prior to submitting such filings and correspondences, *provided* that 4DMT shall provide such comments within [*] ([*]) days (or a shorter period reasonably designated by Otsuka if [*] ([*]) days is not practicable given the filing deadline) of receiving the draft filings and correspondences from Otsuka. 4DMT shall provide Otsuka all reasonable assistance and cooperation in the patent Prosecution and Maintenance efforts under this Section 9.2(b) at its own expense, including providing any necessary powers of attorney and executing any other required documents or instruments for such Prosecution and Maintenance.

(iii)If Otsuka intends to abandon or cease the Prosecution and Maintenance of any Otsuka Prosecuted Patent, Otsuka shall provide prior written notice to 4DMT and the IP Sub-Committee of such intention (which notice shall be given at least [*] ([*]) days in advance of the next deadline to take any action in the relevant patent office necessary to maintain existing rights in any such Otsuka Prosecuted Patent). Upon 4DMT's written election provided no later than [*] ([*]) days after such notice from Otsuka, Otsuka shall permit 4DMT to assume the Prosecution and Maintenance of such Otsuka Prosecuted Patent at its own expense and using patent counsel of its choosing.

(c) Cooperation. Each Party will, and will cause its Affiliates and Sublicensees to, reasonably cooperate, with the other Party with respect to the preparation, filing, prosecution, extension and maintenance of the 4DMT Prosecuted Patents and Otsuka Prosecuted Patents pursuant to this Section 9.2, including with respect to obtaining Patent term restoration and Patent term extension with respect to such Patents in any country or jurisdiction where applicable. The Parties shall discuss matters related to the Prosecution and Maintenance of the Patents pursuant to this Section 9.2 through the IP Sub-Committee.

9.3 Patent Enforcement.

(a) Notice. Each Party shall promptly notify the other Party if it becomes aware of (i) any alleged or threatened infringement by a Third Party of any of the 4DMT Prosecuted Patents or Otsuka Prosecuted Patents in the Territory, which infringement adversely affects or is reasonably expected to adversely affect the Licensed Product in the Field in the Territory and (ii) any related declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the 4DMT Prosecuted Patents or Otsuka Prosecuted Patents in the Territory (collectively, "**Infringement**"). The IP Sub-Committee shall meet promptly to discuss such Infringement and strategies for responding to it.

(b) Enforcement Right. As between the Parties, (i) 4DMT shall have the first right (but not an obligation) to bring and control any legal action in connection with any Infringement (A) of any 4DMT Prosecuted Patent that claims or covers the formulation of the Licensed Product or the Vector or (B) for which there is alleged or threatened infringement of or that is likely to affect one or

more corresponding Patents outside the Territory, in each case ((A) or (B)), at its own expense as it reasonably determines appropriate, and (ii) Otsuka shall have the first right (but not an obligation) to bring and control any legal action in connection with any other Infringement in the Territory, at its own expense as it reasonably determines appropriate, in each case ((i) and (ii)), subject to discussion at the IP Sub-Committee with respect to alignment regarding global Patent enforcement strategy. If the Party with the first enforcement right under this Section 9.3(b) does not bring the applicable legal action within [*] ([*]) days after the notice provided pursuant to Section 9.3(a), then, with the consent of such Party (such consent not to be unreasonable withheld), the other Party shall have the right (but not an obligation) to bring and control any legal action in connection with such Infringement in the Territory at its own expense as it reasonably determines appropriate.

(c) Cooperation. At the request and expense of the Party bringing an action under Section 9.3(b) above, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action. In connection with any such enforcement action, the enforcing Party shall, through the IP Sub-Committee, keep the other Party reasonably informed on the status of such action, allow such other Party to review and provide comment in connection with all proceedings (which the Party bringing the action will reasonably consider), and shall not enter into any settlement admitting the invalidity or non-infringement of, or otherwise impairing the other Party's rights in the 4DMT Prosecuted Patents or Otsuka Prosecuted Patents without the prior written consent of the other Party. The non-enforcing Party shall be entitled to separate representation in such enforcement action by counsel of its own choice and at its own expense.

(d) Allocation of Recoveries. Any settlements, damages or monetary awards recovered by either Party from any enforcement action relating to a claim of Infringement under this Section 9.3 will, after reimbursing the Parties for their reasonable Out-of-Pocket Expenses in making such recovery, be allocated in the following order of priority: (i) first, the Party bringing suit or action shall be reimbursed for all costs and expenses (including reasonable attorneys' fees and costs) incurred in connection with such suit or action, (ii) then (A) if Otsuka is the enforcing Party, it shall pay [*] percent ([*]%) of such excess recoveries to 4DMT and (B) if 4DMT is the enforcing Party, it shall pay [*] percent ([*]%) of such excess recoveries to Otsuka.

(e) Other Enforcement Actions. As between the Parties, 4DMT shall have the sole and exclusive right to bring and control any legal action to enforce the 4DMT Prosecuted Patents against any infringement that is not an Infringement or is outside the Territory, in each case, at its own expense and as it reasonably determines appropriate, and shall have the right to retain all recoveries.

9.4 [*].

(a) The Parties [*] and [*] on [*], [*] and [*], respectively. [*] shall discuss [*], and giving due consideration to such discussions of [*], 4DMT shall act as the lead Party in taking actions to [*] in relation to the launch of the Licensed Product in the Territory, which actions shall include using diligent efforts to, as may be necessary, (i) [*], (ii) [*], (iii) (A) [*] and (B) [*], or (iv) [*]; *provided* that [*]. 4DMT shall keep Otsuka informed about such activities via [*] and shall provide [*] with copies of, and a reasonable opportunity to comment on, [*] with respect to (i) or (ii) prior to [*] and [*] prior to [*], which [*] may be [*]. 4DMT will consider timely comments with respect to the foregoing activities, [*], and [*], in good faith. If [*], then [*].

(b) If 4DMT obtains [*]: (i) 4DMT shall provide Otsuka with notice and a copy of any such [*] within [*] ([*]) days following [*]; (ii) [*]; (iii) [*]; (iv) [*]; and (v) [*].

(c) For clarity, [*] are (i) [*], as applicable, (ii) [*], and (iii) [*].

9.5 Infringement of Third Party Rights.

(a) Notice. Each Party shall notify the other Party of any allegations it receives in writing from a Third Party, or as soon as it otherwise becomes aware, that the Development, Manufacture or Commercialization of the Licensed Product in the Field in the Territory under this Agreement (or any such Development, Manufacture or Commercialization of the Licensed Product that is applicable to the Territory) infringes, misappropriates or otherwise violates (or is alleged to infringe, misappropriate or otherwise violate) the intellectual property rights (except for Trademarks, which are covered by Section 9.9) of such Third Party. Such notice shall be provided promptly, but in no event after more than [*] ([*]) days following receipt of such allegations. Such notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. The IP Sub-Committee shall promptly meet to consider the claim or assertion and the appropriate course of action and the Parties may, if appropriate, agree on and, without limiting Section 9.6, enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties.

(b) Defense Action. Otsuka shall be solely responsible for the defense of any such infringement claims brought against Otsuka [*], at Otsuka's own cost and expense; *provided*, *however*, that the provisions of Section 9.3 shall govern the right of Otsuka to assert a counterclaim of infringement of any Patents; and, *provided*, *further*, that Otsuka shall not agree to any settlement, consent to judgement or other voluntary final disposition in connection with such defense action without 4DMT's consent (not to be unreasonably withheld or delayed). Otsuka shall, through the IP Sub-Committee, keep 4DMT informed on the status of such defense action, and 4DMT shall have the right, but not the obligation, to participate and be separately represented in such defense action at its sole option and at its own expense. 4DMT shall also have the right to control the defense of any infringement claim brought against 4DMT, at 4DMT's own cost and expense.

9.6 Common Interest. All information exchanged between the Parties regarding the Prosecution and Maintenance, enforcement, defense, non-infringement or design around strategies, invalidation or reduction of scope of any Patent under this Article 9 will be deemed Confidential Information of the Disclosing Party. In addition, the Parties acknowledge and agree that the interests of the Parties with respect thereto are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning any Patents under this Article 9, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Article 9 is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

9.7 Patents Licensed from Third Parties. Each Party's rights under this Article 9 with respect to the Prosecution and Maintenance and enforcement and defense of any Licensed Patent that is licensed by 4DMT from a Third Party shall be subject to the rights of such Third Party under the relevant agreement with such Third Party.

9.8 Patent Marking. Otsuka shall mark the Licensed Product sold in the Territory in accordance with the applicable patent marking laws, and shall require all of its Affiliates and Sublicensees to do the same. To the extent permitted by Applicable Law and as appropriate or practical in commercial practice, Otsuka shall indicate on the product packaging and trade dress, advertisement and promotional materials that the Licensed Product is in-licensed from 4DMT, and shall display 4DMT's corporate name and logo on the product packaging and trade dress, advertisement and promotional materials in addition to Otsuka's own corporate name and logo.

9.9 Prosecution, Enforcement, and Defense of Licensed Product Trademark.

(a) 4DMT and its Affiliates will use Commercially Reasonable Efforts to prosecute and maintain the Licensed Product Trademark for the Licensed Product in the Territory, subject to reasonable consultation and cooperation with Otsuka. The prosecution strategy for the Licensed Product Trademark in the Territory, including the selection of filing countries, filing options and filing schedules, shall be determined by 4DMT in consultation with Otsuka. Otsuka shall have the right to participate in the prosecution strategy for the Licensed Product Trademark in the Territory, and 4DMT shall consider in good faith all input provided by Otsuka prior to making any material decisions regarding such prosecution strategy in the Territory.

(b) Through the IP Sub-Committee, each Party shall consult with such other Party in good faith, with respect to any material, substantive issue or any opposition, cancellation, invalidity or other proceeding that may be raised or asserted against any application or registration for any Licensed Product Trademark in the Territory prior to taking any material action in response thereto. 4DMT shall provide Otsuka, on at least an annual basis or upon Otsuka's reasonable request, with an up-to-date list of all applications and registrations for the Licensed Product Trademark in the Territory, including relevant filing and registration details. In addition, 4DMT shall promptly respond to Otsuka's reasonable inquiries regarding the prosecution and maintenance status of the Licensed Product Trademark in the Territory.

(c) Otsuka and 4DMT shall promptly notify each other (i) of any claim, threat, lawsuit, filing, or other notice or allegation of infringement of which they become aware regarding Otsuka's or its Affiliates' or Sublicensees' use of the Licensed Product Trademark in the Territory or (ii) if the Parties become aware of the existence of any Third Party use or applications to register in the Territory any mark or name that consists of or incorporates the Licensed Product Trademark, or any mark or name which is confusingly similar thereto. 4DMT and its Affiliates shall have the right, but not the obligation, to take any action or bring any infringement, unfair competition, or other claims or proceedings involving the Licensed Product Trademark. If requested by 4DMT, Otsuka shall cooperate with 4DMT in connection with any such action. All outside expenses incurred in connection with actions initiated by 4DMT shall be paid by 4DMT, and any monetary damages recovered by 4DMT in such action initiated by 4DMT, shall be the property of 4DMT. If 4DMT or its Affiliates elect not to initiate or pursue any action pursuant to this Section 9.9(c), Otsuka shall have the right, but not the obligation, to take such action or proceeding at its own expense and retain any and all proceeds therefrom. In such event, 4DMT shall provide Otsuka with all reasonable assistance and cooperation,

and Otsuka shall reimburse 4DMT, in accordance with Section 8.5(a), for 4DMT's internal FTE hours at the FTE Rate incurred in connection with providing such assistance and cooperation.

(d) 4DMT shall be responsible for the renewal of the Licensed Product Trademark at its own cost in the Territory.

9.10 Election of New Priority Patents as Licensed Patents. 4DMT will promptly disclose to Otsuka each new Patent application filed by or on behalf of 4DMT after the Effective Date that (a) is owned and Controlled by 4DMT or its Affiliates during the Term, (b) is necessary or reasonably useful for the Exploitation of the Licensed Product in the Field, (c) is not a Patent within the Arising Product IP, and (d) does not claim priority to any Patent that is then a Licensed Patent (such Patent, a "**New Priority Patent**"). At any time within [*] ([*]) months of such disclosure, Otsuka can, upon written notice to 4DMT, elect to designate such New Priority Patent as a Licensed Patent. Unless and until Otsuka makes such election prior to the end of such [*] ([*])-month period, Otsuka shall not have any license or other rights with respect to such New Priority Patent or any Patent that claims priority to it.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as of the Effective Date as follows:

(a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

(b) Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate actions on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) No Conflict. It is not a party to and shall not enter into any agreement that would prevent it from granting the rights or exclusivity granted or intended to be granted to the other Party under this Agreement or performing its obligations under this Agreement.

(d) No Debarment. Neither it nor any of its or its Affiliates' employees, agents or Contractors performing under this Agreement, or in the case of 4DMT, no employee, agent or Contractor engaged by 4DMT or its Affiliates in the development of any Licensed Product prior to the Effective Date, has ever been, or is currently: (i) debarred under 21 U.S.C. § 335a or its equivalents; (ii) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (iii) listed in the FDA's Clinical Investigators – Disqualification Proceedings Database, including for restrictions; or (iv) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) or its equivalents, but has not yet been

excluded, debarred, suspended, or otherwise declared ineligible. Each Party further covenants that if it becomes aware that it or any of its or its Affiliates' or sublicensees' employees, agents or Contractors performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, such Party shall immediately notify the other Party.

10.2Representations and Warranties by 4DMT. 4DMT hereby represents and warrants to Otsuka as of the Effective Date as follows:

(a) Title; Encumbrances. Except as set forth on Schedule 10.2(a): (i) 4DMT is the sole owner of all right, title and interest in, to and under the Licensed Patents and Licensed Know-How; and (ii) no Person, other than 4DMT, has any right to enforce any Licensed Patent or any right to enforce any Licensed Know-How. 4DMT has the right under the Licensed IP to grant the licenses to Otsuka as purported to be granted under Section 7.1 of this Agreement, and 4DMT has not granted, and will not grant during the Term, any license or other right under the Licensed IP that conflicts with the license granted to Otsuka under Section 7.1 of this Agreement. Without limiting the foregoing, 4DMT Controls all Patents listed on Schedule 10.2(h), and Controls all Know-How created, conceived or otherwise developed by [*] for or on behalf of 4DMT.

(b) Notice of Infringement or Misappropriation. Neither 4DMT nor any of its Affiliates has received, as of the Effective Date, any written communication from any Third Party (i) asserting or alleging that the practice or other use of the Licensed IP or any Exploitation of the Licensed Product or Licensed Product Trademark infringed or misappropriated, or would infringe or misappropriate, the intellectual property rights of a Third Party, or (ii) challenging the validity, enforceability, patentability, use or ownership of any of the Licensed IP; and in each case ((i) and (ii)), to 4DMT's knowledge, none of the foregoing has been threatened by a Third Party.

(c) No Proceedings. There are no pending, and to 4DMT's knowledge, there are no threatened actions, claims, demands, suits, or proceedings against 4DMT or any of its Affiliates or, to the knowledge of 4DMT, pending or threatened against any Third Party, in each case, involving the Licensed IP.

(d) Third Party Activities. To the knowledge of 4DMT, there are no activities by Third Parties that would constitute infringement or misappropriation of the Licensed IP.

(e) Information Provided. To the knowledge of 4DMT, the technical, scientific and financial information, including documents, delivered or made available by 4DMT to Otsuka prior to the Effective Date with respect to the Licensed Product (i) are true and accurate in all material respects and (ii) include (A) all material technical, scientific and financial information controlled by 4DMT regarding the Licensed Products and (B) all material safety or efficacy information related to the Licensed Products. For clarity, 4DMT makes no representation or warranty pursuant to this Section 10.2(e) with respect to intellectual property-related information.

(f) Compliance with Applicable Law. To the knowledge of 4DMT, 4DMT has not conducted any Development activities (including any preclinical studies or Clinical Trials) in material violation of any Applicable Law.

(g) Dealings with Regulatory Authorities. With respect to each submission to a Regulatory Authority regarding the Licensed Product, 4DMT has not knowingly made an untrue

statement of a material fact or fraudulent statement to such Regulatory Authority or knowingly failed to disclose a material fact required to be disclosed to such Regulatory Authority.

(h) Existing Licensed Patents. Schedule 10.2(h) contains a correct and complete list of all Licensed Patents existing as of the Effective Date. The Licensed Patents in the Territory have been filed and prosecuted in good faith and in accordance with Applicable Law and all applicable fees and other payments have been paid on or before the due date for payments. To the knowledge of 4DMT, all of the Licensed Patents that are issued in the Territory as of the Effective Date are valid and enforceable.

(i) Non-Infringement. [*], to the knowledge of 4DMT, the practice of the Licensed IP and the Licensed Product Trademarks for the Exploitation of the Licensed Product in the Field in the Territory and for the Manufacture of the Licensed Product in the United States for the sole purpose of Development and Commercialization of the Licensed Product in the Field in the Territory, in each case as the Licensed Product is manufactured in the United States as of the Effective Date and formulated, dosed and administered for the AMD Indication and the DME Indication as of the Effective Date under the current protocols for the 4FRONT-1 Clinical Trial, the 4FRONT-2 Clinical Trial and the SPECTRA Clinical Trial, respectively, does not infringe any issued valid Patent or infringe or misappropriate any trade secret of any Third Party; *provided* that 4DMT makes no representation or warranty in this Section 10.2(i) with respect to the practice of any intellectual property rights other than the Licensed IP and the Licensed Product Trademarks or the Exploitation of any product other than the Licensed Product.

(j) Upstream Licenses. Except as set forth in Schedule 10.2(j), as of the Effective Date, (i) 4DMT has not received any license from a Third Party that grants 4DMT rights to Exploit any Licensed Product in the Territory and Manufacture any Licensed Product outside the Territory for Exploitation in the Territory and would constitute an Upstream License; and (ii) there are no Upstream Licenses under which Otsuka will have an obligation to pay any royalty or other fee to any Third Party for the use of intellectual property rights in connection with the Exploitation of the Licensed Products in the Territory, the Manufacture of the Licensed Product outside the Territory for Commercialization in the Territory and the use of the Licensed Products Trademarks in the Territory as contemplated by this Agreement.

(k) [*].

(l) Data Transfer. 4DMT has received an informed consent or other authorization from each study subject enrolled prior to the Effective Date in a Clinical Trial of the Licensed Product conducted by or on behalf of 4DMT that permits 4DMT to disclose and transfer to Otsuka data collected from such subject for the purpose of Otsuka's Development of, including filing Regulatory Materials and seeking Regulatory Approval for, the Licensed Product for use in the Indications in the Territory, *provided* that Otsuka performs such Development in full compliance with its obligations under Section 3.11 and the data processing agreement entered into by the Parties pursuant to Section 3.11.

10.3 Other Covenants.

(a) Export Control. Neither Otsuka nor 4DMT nor any of their Affiliates (or any of their respective sublicensees, employees and Contractors), in connection with the exercise of its rights or performance of its obligations under this Agreement, shall knowingly cause the other Party to be in violation of any applicable United States or foreign export control laws and regulations.

(b) Licensed IP. Neither Otsuka nor any of its Affiliates (or any of their respective Sublicensees, employees and Contractors), shall engage in any activities that use the Licensed IP in a manner that is outside the scope of the license rights granted to it hereunder. Neither 4DMT nor any of its Affiliates (or any of their respective sublicensees, employees and Contractors), shall engage in any activities that use the Licensed IP in a manner that conflicts with the exclusive license granted to Otsuka hereunder.

(c) Compliance with Applicable Law. Each Party shall comply with Applicable Law in the course of performing its obligations or exercising its rights pursuant to this Agreement, including, as applicable, cGMP, GCP, and GLP standards, and anti-corruption laws. Anti-corruption laws include laws concerning bribery, money laundering, or corrupt practices or which in any manner prohibit the giving of anything of value to any official, agent, or employee of any government, political party, or public international organization, candidate for public office, health care professional, or to any officer, director, employee, or representative of any other organization specifically including the U.S. Foreign Corrupt Practices Act (and foreign equivalents), in each case, in connection with the activities conducted pursuant to this Agreement. Each Party shall take no action that would cause the other Party to be in violation of anti-corruption laws. Further, each Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of anti-corruption laws in connection with the performance of this Agreement.

10.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 10, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. OTSUKA ACKNOWLEDGES AND AGREES THAT THE LICENSED PRODUCT IS THE SUBJECT OF ONGOING RESEARCH AND DEVELOPMENT AND THAT 4DMT CANNOT ASSURE THE SAFETY, USEFULNESS OR SUCCESSFUL DEVELOPMENT OR COMMERCIALIZATION OF THE LICENSED PRODUCT.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification by 4DMT. 4DMT shall defend, indemnify, and hold each Otsuka, its Affiliates and each of their respective officers, directors, employees, and agents (the "**Otsuka Indemnitees**") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Otsuka Indemnitees, resulting from claims, suits, proceedings or causes of action brought by or on behalf of such Third Party against such Otsuka Indemnitee that arise from or are based on (a) a breach of any of 4DMT's representations, warranties and obligations under this Agreement, (b) the willful misconduct or negligent acts of 4DMT or any 4DMT Indemnitees, (c) [*], or (d) any violation of Applicable Law by 4DMT or any 4DMT Indemnitees in connection with this Agreement; excluding, in each case ((a), (b), (c) and (d)), any damages or other amounts to the extent Otsuka has an obligation to indemnify any 4DMT Indemnitee pursuant to Section 11.2.

11.2Indemnification by Otsuka. Otsuka shall defend, indemnify, and hold 4DMT, its Affiliates, licensees, and each of their respective officers, directors, employees, and agents, (the "**4DMT Indemnitees**") harmless from and against any and all damages or other amounts payable to a Third Party claimant (excluding Sublicensees of 4DMT), as well as any reasonable attorneys' fees and costs of litigation incurred by such 4DMT Indemnitees, resulting from any claims, suits, proceedings or causes of action brought by such Third Party against such 4DMT Indemnitee that arise from or are based on (a) the Exploitation of any Licensed Products by or on behalf of Otsuka or its Affiliates or Sublicensees, (b) a breach of any of Otsuka's representations, warranties and obligations under this Agreement, (c) the willful misconduct or negligent acts of Otsuka or any Otsuka Indemnitees, (d) any violation of Applicable Law by Otsuka or any Otsuka Indemnitees in connection with this Agreement, or (e) 4DMT or its designee's role as the holder of any Regulatory Approval (or application therefor) in [*]; excluding, in each case ((a), (b), (c), (d) and (e)), any damages or other amounts to the extent 4DMT has an obligation to indemnify any Otsuka Indemnitee pursuant to Section 11.1.

11.3Indemnification Procedures. The Party claiming indemnity under this Article 11 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought ("**Claim**"). The Indemnifying Party's obligation to defend, indemnify, and hold harmless pursuant to this Article 11 shall be reduced to the extent the Indemnified Party's delay in providing notification pursuant to the previous sentence results in actual prejudice to the Indemnifying Party. At its option, the Indemnifying Party may assume the defense of any Claim for which indemnity is being sought by giving written notice to the Indemnified Party within [*] ([*]) days after receipt of the notice of the Claim. The assumption of defense of the Claim shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Claim, nor shall it constitute waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. The Indemnified Party shall upon request of the Indemnifying Party provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided*, *however*, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not admit liability or settle any Claim without the prior written consent of the Indemnified Party, unless the settlement involves only the payment of money. The Indemnified Party shall not settle any such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnified Party reserves any right it may have under this Article 11 to obtain indemnification from the Indemnifying Party.

11.4Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, INDIRECT DAMAGES, OR LOST PROFITS, LOST REVENUE OR LOST GOODWILL (EXCEPT IN EACH CASE TO THE EXTENT THEY CONSTITUTE DIRECT DAMAGES), ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY TORT CLAIMS ARISING HEREUNDER, REGARDLESS OF ANY NOTICE OR AWARENESS OF THE POSSIBILITY OF SUCH DAMAGES**.** NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION

11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 11, (B) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12 OR BREACH OF SECTION 5.6, (C) DAMAGES AVAILABLE IN THE CASE OF A PARTY'S FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, OR (D) DAMAGES TO THE EXTENT THAT SUCH LIMITATION OR RESTRICTION WOULD BE INVALID BY APPLICABLE LAW.

11.5Insurance. Each Party shall procure and maintain insurance, including general and product liability insurance, with respect to its activities hereunder that is consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold in such Party's territory; *provided* that 4DMT shall have: (i) inclusive of its umbrella coverage, general liability limits of not less than $[*] per occurrence and $[*] in the aggregate; and (ii) product liability limits of not less than $[*] per occurrence and $[*] in the aggregate. 4DMT will extend additional insured status to Otsuka with respect to the general liability, product liability, and umbrella insurance policies held by 4DMT. Each Party shall provide the other Party with evidence of such insurance upon request. Notwithstanding the foregoing, Otsuka may self-insure in whole or in part the insurance requirements described above, provided Otsuka continues to be investment grade determined by reputable and accepted financial rating agencies. Such insurance shall not be construed to create a limit of each Party's liability with respect to its indemnification obligations under this Article 11.

ARTICLE 12

CONFIDENTIALITY

12.1Non-Use and Non-Disclosure. Except as otherwise expressly set forth herein, the Receiving Party shall keep the Confidential Information of the Disclosing Party confidential using at least the same degree of care with which the Receiving Party holds its own confidential information, but in no event less than a commercially reasonable degree of care, and shall not (a) disclose such Confidential Information to any Third Party without the prior written approval of the Disclosing Party, except, solely to the extent necessary to exercise its rights or perform its obligations under this Agreement, to its and its Affiliates, Sublicensees, and Third Party licensees (with respect to 4DMT) and its and their employees, officers, directors, contractors, consultants or agents who have a need to know such Confidential Information for the Receiving Party to exercise its rights or to perform its obligations under this Agreement (each, a "**Representative**"), *provided* that (i) each Representative, prior to such disclosure, shall be bound by an obligation of confidentiality, non-use and non-disclosure at least as restrictive as set forth in the provisions of this Article 12 and (ii) the Receiving Party shall remain responsible and liable for its Representatives' compliance with such obligations of confidentiality, non-use and non-disclosure (and any failure by any such Representative to comply with such obligations shall be deemed a breach of this Agreement by the Receiving Party), or (b) use such Confidential Information for any purpose other than to perform the Receiving Party's obligations or exercise the Receiving Party's rights under this Agreement. The Receiving Party will use diligent efforts to cause the foregoing Representatives to comply with the restrictions on use and disclosure of the Disclosing Party's Confidential Information set forth in this Section 12.1, and shall be responsible for ensuring that such Persons maintain the Disclosing Party's Confidential Information in accordance with this Article 12.

12.2Return of Confidential Information. Upon the expiration or termination of this Agreement, the Receiving Party shall return to the Disclosing Party (or, as directed by the Disclosing Party, destroy) all Confidential Information of the Disclosing Party that is in the Receiving Party's possession or control; *provided*, *however*, that one (1) copy of any Confidential Information of the Disclosing Party may be retained and stored in the Receiving Party's secured archives solely for the purpose of determining its obligations under this Agreement; *provided* that the non-disclosure and non-use obligation under this Article 12 shall continue to apply to any such retained Confidential Information as long as such information is retained by the Receiving Party. In addition, the Receiving Party shall not be required to return or destroy any Confidential Information of the Disclosing Party contained in any computer system back-up records of the Receiving Party to the extent made in the ordinary course of business; *provided* that such Confidential Information may not be accessed without the Disclosing Party's prior written consent or as required by Applicable Law, and that such Confidential Information remain subject to the non-disclosure and non-use obligation under this Article 12 as long as such information is so retained by the Receiving Party.

12.3Permitted Disclosure. In addition to the exceptions contained in Section 1.42 and without limiting permitted disclosure to Representatives under Section 12.1, the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent (and solely to the extent) that such disclosure is reasonably necessary in the following instances:

(a) to comply with Applicable Law (including any securities law or regulation or the rules of a securities exchange pursuant to Section 12.3(c) below) or the order of a court of competent jurisdiction; *provided* that, where legally permissible, the Receiving Party shall (i) provide a written notice of such disclosure reasonably in advance of such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (ii) fully cooperate with the Disclosing Party, if so requested by the Disclosing Party, in maintaining the confidentiality of such information by applying for a protective order or any similar legal instrument. In any event, the Receiving Party shall only disclose such Confidential Information to the extent required under Applicable Law and shall continue to treat such information as Confidential Information for all other purposes under this Agreement;

(b) (i) to prosecute or defend litigation as permitted under Article 9, (ii) to obtain or maintain Regulatory Approvals and other regulatory filings and communications as permitted under Article 4, (iii) to file or prosecute Patent applications under Article 9 and (iv) to enforce Patent rights under Article 9; and

(c) to *bona fid*e prospective or actual purchasers, acquirers, licensees, Sublicensees, permitted assignees or merger candidates or to *bona fide* existing or potential investment bankers, investors, lenders, or financing sources solely for the purpose of evaluating or carrying out an actual or potential sale, investment, loan, financing, merger, acquisition, collaboration or license ("**Other Recipients**"), *provided*, that such Other Recipients are bound by commercially reasonable written obligations of confidentiality and non-use.

12.4Disclosure of Agreement. Either Party may disclose the terms of this Agreement (a) to the extent required to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in the Territory, as well as any securities exchange operated by [*] ([*]); *provided* that, to the extent permitted under Applicable Law, such Party shall submit a confidential treatment request in connection with such disclosure and

shall submit with such confidential treatment request only such redacted form of this Agreement as may be mutually agreed in writing by the Parties; (b) to Other Recipients, so long as such Third Party has executed with such Party, and such Party has provided to the other Party, a copy of a confidentiality agreement (redacted for name of party, economic terms or other competitive information) with terms at least as protective with respect to Confidential Information as those contained herein, in a form reasonably acceptable to the other Party (which acceptance shall not be unreasonably withheld, conditioned or delayed); and (c) to any Sublicensee, collaborator or potential Sublicensee or collaborator of such Party; *provided* that such Sublicensee, collaborator or potential Sublicensee or collaborator agree in writing to be bound by obligations of confidentiality and non-use no less protective of the Disclosing Party than those set forth in this Article 12 (and the failure of such Sublicensee, collaborator or potential Sublicensee or collaborator to comply with the terms and conditions of this Agreement shall be considered a breach of this Agreement by the Party disclosing such information).

12.5Publicity; Use of Name and Logo. The Parties have agreed on a press release announcing this Agreement, to be issued by the Parties on such date and time as may be agreed by the Parties. Except to the extent expressly permitted under this Agreement or required by Applicable Law, each Party will not use the other Party's or its Affiliates' name or logo in any label, press release or product advertising, or for any other promotional purpose, without first obtaining the other Party's written consent.

12.6Publications. Except to the extent required by Applicable Law, Otsuka shall not publish any peer-reviewed manuscripts, or give other forms of public disclosure such as abstracts and presentations, relating to the Licensed IP or the Licensed Product, including the data and results of the Development of the Licensed Product (each, a "**Publication**"), in each case, without 4DMT's prior review and approval. If Otsuka intends to make a Publication, Otsuka shall, via the Alliance Managers, provide 4DMT with such proposed Publication at least [*] ([*]) days prior to the intended publication date. 4DMT shall have the right to review and comment on such proposed Publication, and Otsuka shall, in good faith, consider such comments made by 4DMT, in each case, through the JSC. If such proposed Publication contains any Confidential Information of 4DMT, then upon the 4DMT's request, Otsuka shall delete any such information identified by 4DMT. If the 4DMT wishes to request a delay in any such Publication in order to protect patentable information contained in such proposed Publication, Otsuka shall delay such Publication for a period of up to [*] ([*]) days to enable the 4DMT to file the relevant patent applications. Once a Publication has been approved by 4DMT, Otsuka may make subsequent Publications of the content of such previously approved Publication without further approval by 4DMT; *provided* that such subsequent Publication does not (i) include any new data, information or conclusions or (ii) present the approved content in a form or manner that materially alters the conclusion or subject matter therein. 4DMT will provide Otsuka with a courtesy copy of any Publication to be published by 4DMT as soon as reasonably practicable, but in no event later than [*] ([*]) days after the date on which such Publication is submitted for publication.

12.7Engaging Individuals. Without limiting any other provision of this Agreement, each Party hereby agrees that all Persons engaged to perform any activities under this Agreement shall be bound by confidentiality obligations at least as restrictive as the obligations of confidentiality and non-use set forth in this Article 12 prior to performing such activities.

12.8Prior Non-Disclosure Agreement. As of the Effective Date, this Agreement shall supersede any prior non-disclosure, secrecy or confidentiality agreement(s) between the Parties (or their Affiliates) dealing with the subject matter of this Agreement, including the Existing CDA. Any

confidential information disclosed under any such prior agreement and dealing with the subject of this Agreement shall be deemed disclosed under this Agreement.

12.9Duration of Obligation. The obligations of confidentiality and non-use set forth in this Article 12 shall survive the expiration or termination of this Agreement and shall remain in full force and effect for a period of [*] ([*]) years after such expiration or termination (except as set forth in Section 12.2).

ARTICLE 13

TERM AND TERMINATION

13.1Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall continue in full force and effect, on a country-by-country basis, until the date that Otsuka is no longer Developing or Commercializing the Licensed Product in such country within the Territory (the "**Term**").

13.2Termination Rights of each Party.

(a) Termination by Otsuka for Convenience.

(i) During the Term and prior to the first MAA filing for the Licensed Product in any country within the Territory, Otsuka shall have the right to terminate this Agreement in its entirety for convenience, on a country-by-country basis, upon at least [*] ([*]) days' prior written notice to 4DMT.

(ii) During the Term and after the first MAA filing for the Licensed Product in any country within the Territory, Otsuka shall have the right to terminate this Agreement in its entirety for convenience, on a country-by-country basis, upon at least [*] ([*]) days' prior written notice to 4DMT.

(b) Termination by 4DMT for Patent Challenge. 4DMT shall have the right to terminate this Agreement in its entirety upon written notice to Otsuka in the event that an Otsuka Party directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Licensed Patent or any New Priority Patent for which the [*] ([*])-month election period in Section 9.10 has not expired (except as a defense against a claim, action or proceeding asserted by 4DMT against such Otsuka Party) (each, a "**Patent Challenge**"); *provided* that 4DMT shall not have the right to terminate this Agreement under this Section 13.2(b):

(i) for any such Patent Challenge by Otsuka or an Affiliate of Otsuka if such Patent Challenge is dismissed or withdrawn within [*] ([*]) days after 4DMT's notice to Otsuka under this Section 13.2(b) and not thereafter continued; or

(ii) for any such Patent Challenge by any Sublicensee (A) if such Patent Challenge is dismissed or withdrawn within [*] ([*]) days after 4DMT's notice to Otsuka under this Section 13.2(b) and not thereafter continued, or (B) in case that the Patent Challenge is not dismissed or withdrawn in accordance with the foregoing subclause (A), if Otsuka terminates the sublicense with such Sublicensee within [*] ([*]) days upon Otsuka's receipt of a written request from 4DMT to terminate such sublicense.

(c) Termination by 4DMT for Abandonment. 4DMT shall have the right to terminate this Agreement in its entirety upon written notice to Otsuka in the event that Otsuka and its Affiliates and Sublicensees: (i) cease all Otsuka Development Activities and Commercialization of all Licensed Products in Japan for a consecutive period of [*] ([*]) months or longer; and (ii) do not resume material Otsuka Development Activities or Commercialization of a Licensed Product in [*]within [*] ([*]) days of such notice; *provided* that such [*] ([*]) month period will be suspended and 4DMT shall not have the right to terminate this Agreement, during any period: [*].

(d) Termination by Otsuka for Safety Issue. In the event of a Safety Issue with respect to the Licensed Product, Otsuka may terminate this Agreement, in its entirety, upon [*] ([*]) days' prior written notice to Otsuka, which notice shall provide reasonable supporting information detailing the Safety Issue.

(e) Termination by Otsuka for Clinical Trial Failure. In the event that the 4FRONT-1 Clinical Trial or the Cross-Territory Clinical Trial for the AMD Indication does not achieve its primary endpoint as determined at Otsuka's reasonable discretion after discussion with 4DMT (such event, a "**Clinical Trial Failure**"), Otsuka may, within [*] ([*]) days of disclosure by 4DMT to Otsuka of topline data from such Clinical Trial indicating such Clinical Trial Failure, terminate this Agreement, in its entirety, immediately upon written notice to 4DMT.

13.3Termination by Either Party for Material Breach. If either Party believes that the other Party is in material breach of this Agreement, then the non-breaching Party may deliver notice of such breach to the other Party. The breaching Party shall have [*] ([*]) days (with respect to a payment breach) or [*] ([*]) days (with respect to a non-payment breach) from the receipt of the notice to cure such breach. If the breaching Party fails to cure such breach within such [*] ([*])- or [*] ([*])-day cure period, as applicable, then the non-breaching Party may terminate this Agreement in its entirety upon written notice to the other Party; *provided* that if the allegedly breaching Party disputes in good faith the existence or materiality of the alleged breach, and provides written notice to the other Party of such dispute within the relevant cure period, pursuant to Section 14.1, the other Party will not have the right to terminate this Agreement in accordance with this Section 13.3 unless and until the relevant dispute has been resolved pursuant to Article 14. During the pending dispute, the applicable cure period will be tolled, all the terms of this Agreement will remain in effect, and each Party shall continue to perform its obligations under this Agreement.

13.4Effects of Termination of the Agreement. Upon any termination of this Agreement, the following provisions of this Section 13.4 shall apply.

(a) Termination of Rights. All licenses and other rights granted by 4DMT to Otsuka under the Licensed IP and Licensed Product Trademarks shall terminate and all sublicenses thereunder granted by Otsuka shall automatically terminate. The license granted by Otsuka to 4DMT pursuant to Section 7.2(b) shall terminate and all sublicenses thereunder granted by 4DMT shall automatically terminate. For clarity, the license granted by Otsuka to 4DMT pursuant to Section 7.2(c) (and all sublicenses thereunder granted by 4DMT) shall survive.

(b) Reversion License. Effective upon the effective date of such termination, and subject to the assignments to 4DMT pursuant to Sections 13.4(c) and 13.4(e), (i) Otsuka hereby grants to 4DMT an exclusive, worldwide, royalty-free, fully paid-up perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Arising Product IP, to Develop, Manufacture, Commercialize and otherwise Exploit Licensed Products and (ii) solely to the extent this

Agreement is terminated by Otsuka under Section 13.2(a) or by 4DMT under Sections 13.2(b), 13.2(c), or 13.3, Otsuka hereby grants to 4DMT an exclusive, worldwide, royalty-bearing (as and to the extent provided below) perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Otsuka Technology (other than the Arising Product IP), to Exploit the Licensed Product in the Field in the Territory and to Manufacture the Licensed Product outside the Territory for Exploitation in the Territory. With respect to the license grant described in the foregoing clause (ii), 4DMT and Otsuka shall negotiate in good faith a commercially reasonable royalty rate and royalty term applicable to such license and from and after the effective date of this Agreement, 4DMT shall pay Otsuka royalties on sales by 4DMT or its Affiliates or licensees of Licensed Products on such terms. If the Parties are unable to agree on the royalty rate and royalty term for the license grant described in the foregoing clause (ii) within [*] ([*]) days after the effective date of such termination, then either Party may refer the royalty rate or royalty term matters for resolution by baseball arbitration in accordance with the procedures set forth in Schedule 13.4(b). The terms of Section 8.8(i) will apply to the payment and reporting of any royalties described in this Section 13.4(b), *mutatis mutandis*.

(c) Trademarks. Upon 4DMT's request, Otsuka shall (and shall cause its Affiliates and Sublicensees to) transfer and assign to 4DMT any and all Trademarks in the Territory that is Controlled by Otsuka or its Affiliates and sublicensees as of the effective date of such termination that are used by or on behalf of Otsuka or its Affiliates or Sublicensees for the Exploitation of the Licensed Product in the Territory, including any registrations thereof or any pending applications therefor, but excluding corporate name or logos of Otsuka or its Affiliates or Sublicensees.

(d) Regulatory Materials. Upon 4DMT's request, Otsuka shall (and shall cause its Affiliates and Sublicensees to), as instructed by 4DMT, either (i) to the extent permitted by Applicable Law, promptly transfer and assign to 4DMT or its designee all Regulatory Materials and Regulatory Approvals for the Licensed Product that are held by Otsuka or its Affiliate or Sublicensees; or (ii) continue to hold any such Regulatory Materials and Regulatory Approvals for the sole benefit of 4DMT or its designee (in which case, Otsuka shall appoint 4DMT or its designee as the exclusive distributor (with the right to subcontract and appoint subdistributors) under such Regulatory Materials and Regulatory Approvals for the Licensed Product in the Territory, and also as its agent to interact with the applicable Regulatory Authority in the Territory with respect to such Regulatory Materials and Regulatory Approvals) in the Territory, until such time 4DMT or its designee files its own Regulatory Materials and obtains its own Regulatory Approvals for the Licensed Product in the Territory but for no longer than a period of [*] ([*]) years from the effective date of termination of this Agreement; or (iii) terminate or withdraw any such Regulatory Materials and Regulatory Approvals in the Territory. Upon 4DMT's request, Otsuka shall provide 4DMT with reasonable assistance and cooperation regarding any inquiries and correspondence with Regulatory Authorities relating to the Licensed Product in the Territory.

(e) Data. Upon 4DMT's request, Otsuka shall (and shall cause its Affiliates and Sublicensees to) promptly transfer and assign to 4DMT, at no cost to 4DMT (except where the Agreement is terminated by Otsuka for 4DMT's uncured material breach pursuant to Section 13.3), (i) all data and other Know-How generated (whether solely or jointly) by or on behalf of Otsuka or its Affiliates or Sublicensees from the Development of the Licensed Product in the Territory, including all Otsuka Local Clinical Trials conducted by or on behalf of Otsuka, its Affiliates and Sublicensees hereunder, (ii) all data generated under any investigator-initiated trial for the Licensed Product in the Territory, to the extent such data is in Otsuka's possession and control, and (iii) all pharmacovigilance data (including all adverse event databases) relating to the Licensed Product in the Territory.

(f) Inventory. 4DMT shall have the right (but not the obligation) to purchase from Otsuka any or all of the inventory of the Licensed Product held by Otsuka or its Affiliates or Sublicensees as of the effective date of the applicable termination at a price equal to the price paid by Otsuka for such inventory, *provided* that such inventory complies with applicable specifications, has been Manufactured, handled and stored in compliance with Applicable Law (including cGMP). Otsuka shall have the right to sell off any remaining inventory not purchased by 4DMT for a period of [*] ([*]) days following the effective date of termination of this Agreement provided that Otsuka pays royalties on such sales in accordance with Section 8.8.

(g) Transition Assistance. Upon 4DMT's request and subject to Section 13.4(i), Otsuka shall (and shall ensure that its Affiliates and Sublicensees shall) reasonably cooperate with 4DMT, at 4DMT's request, to facilitate orderly transition of the Development, Manufacture, Commercialization and other Exploitation of the Licensed Product in the Field in the Territory to 4DMT, including (i) assigning or amending as appropriate, upon request of 4DMT, any agreements or arrangements with Third Party vendors (including distributors), solely to the extent such agreements or arrangements are assignable, to Develop, Manufacture, Commercialize and otherwise Exploit the Licensed Product in the Territory or, to the extent any such Third Party agreement or arrangement is not assignable to 4DMT, reasonably cooperating with 4DMT to arrange to continue to provide such services that are provided by Third Parties in the Territory for a reasonable time after termination but for no longer than [*] ([*]) years, at 4DMT's cost; and (ii) to the extent that Otsuka or its Affiliate or Sublicensee is performing any activities described in the foregoing subclause (i) in the Territory, reasonably cooperating with 4DMT to transfer such activities to 4DMT with respect to the Territory or its designee, and continuing to perform such activities on 4DMT's behalf in the Territory for a reasonable time after termination, but for no longer than [*] ([*]) years or until such transfer is completed (whichever is sooner), including continuing to Manufacture and supply Licensed Products to 4DMT at cost plus [*]percent ([*]%), where such cost is calculated applying the definition of Manufacturing Costs *mutatis mutandis*.

(h) Ongoing Local Clinical Trials. If, at the time of the applicable termination, any Otsuka Local Clinical Trials for the Licensed Product are being conducted, then, at 4DMT's sole election on a Otsuka Local Clinical Trial-by-Otsuka Local Clinical Trial basis: (i) Otsuka shall (and shall cause Otsuka Affiliates and Sublicensees to) fully cooperate with 4DMT to transfer the conduct of all such Local Clinical Trials to 4DMT, and 4DMT shall assume any and all liability and costs for such Otsuka Local Clinical Trials after the effective date of such termination, *provided* that Otsuka shall continue to bear all costs and expenses incurred in connection with the conduct of such Otsuka Local Clinical Trials until the earlier of the completion of the transfer to 4DMT of such Otsuka Local Clinical Trial or [*] ([*]) days after the effective date of such termination, whichever is earlier; or (ii) Otsuka shall (and shall ensure that its Affiliates and Sublicensees shall) at its own cost and expense, orderly wind down in compliance with Applicable Law (including any obligations for long-term follow-up of Clinical Trial participants) the conduct of any such Otsuka Local Clinical Trial that is not assumed by 4DMT under the foregoing subclause (i).

(i) Transition Cost. If (i) this Agreement is terminated by Otsuka under Section 13.3, then 4DMT shall reimburse Otsuka for the reasonable and documented internal and external costs incurred by Otsuka transferring the Regulatory Materials, data and Otsuka Local Clinical Trials to 4DMT and providing transition assistance to 4DMT under this Section 13.4, *provided*, for clarity, that costs for transition assistance relating to Manufacturing as described in clause (ii) of Section 13.4(g)

shall be covered exclusively by Manufacturing cost plus [*]percent ([*]%) as described in such clause (ii); or (ii) otherwise, Otsuka shall bear such costs.

13.5Other Remedies. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

13.6Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by 4DMT and Otsuka are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party (such Party, the "**Bankrupt Party**") under the U.S. Bankruptcy Code, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under the foregoing subclause (a), following the rejection of this Agreement by the Bankrupt Party upon written request therefor by the other Party.

13.7Survival. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement or which by their very nature are intended to survive termination, including Articles 1, 11, 12, 14 and 15, and Sections 3.11, 7.2, 7.5, 7.6, 7.7, 8.1 through 8.11 (inclusive, to the extent applicable and with respect to any amounts due prior to such expiration or termination), 8.12 through 8.13 (inclusive, for the time periods set forth therein), 9.1, 10.4, 13.4, 13.6 and this Section 13.7. All provisions not surviving in accordance with the foregoing shall terminate upon expiration or termination of this Agreement and be of no further force and effect.

ARTICLE 14

DISPUTE RESOLUTION

14.1Disputes. If the Parties are unable to resolve any dispute arising out of or in connection with this Agreement, either Party may, by written notice to the other Party, have such dispute referred to the Executive Officers (or their designees) of each of the Parties for attempted resolution by good faith negotiations within [*] ([*]) days after such notice is first received. In such event, the Parties shall cause their Executive Officers (or their designees) to meet and be available to attempt to resolve such dispute. If the Parties are unable to resolve any dispute under this Section 14.1, such remaining dispute shall be resolved pursuant to Section 14.2(a), *provided* that any matter that is specified in Section 2.5 to be resolved by the JSC with either Party's exercise of its final decision making authority,

shall be resolved via such Party's exercise of its final decision making authority in accordance with Section 2.5, not Section 14.2.

14.2Binding Arbitration.

(a) If the Parties fail to resolve the dispute through escalation to the Executive Officers under Section 14.1, and a Party desires to pursue resolution of the dispute, the dispute shall be submitted by either Party for resolution in arbitration administered by the International Chamber of Commerce ("**ICC**") pursuant to ICC's arbitration rules and procedures then in effect.

(b) The arbitration shall be conducted by a panel of three (3) arbitrators experienced in the pharmaceutical business. Within [*] ([*]) days after initiation of arbitration, each Party shall select one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third arbitrator (who shall be the chairperson of the arbitration panel) within [*] ([*]) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by ICC. If, however, the aggregate award sought by the Parties is less than [*] Dollars ($[*]) and equitable relief is not sought, the arbitration shall be conducted by a single arbitrator agreed by the Parties (or appointed by ICC if the Parties cannot agree).

(c) The seat and location of the arbitration shall be New York City, New York, United States, and the language of the proceedings shall be English. The arbitral tribunal shall determine the dispute by applying the provisions of this Agreement and, notwithstanding Section 15.1 with respect to applicable substantive law, any arbitration conducted pursuant to this Agreement shall be governed by the Federal Arbitration Act (9 U.S.C. §§ 1-16). The Parties agree that any award or decision made by the arbitral tribunal shall be final and binding upon them and may be enforced in the same manner as a judgment or order of a court of competent jurisdiction.

(d) By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue, at the request of a Party, a pre-arbitral injunction, pre-arbitral attachment or other order to avoid irreparable harm, maintain the status quo, preserve the subject matter of the dispute, or aid the arbitration proceedings and the enforcement of any award. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal shall have full authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect.

(e) The existence and content of the arbitral proceedings and any ruling or awards shall be kept confidential by the Parties and members of the arbitral tribunal except (i) to the extent that disclosure may be required of a Party by Applicable Law (including to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in the Territory) to fulfill a legal duty, protect or pursue a legal right, or enforce or challenge an award in bona fide legal proceedings before a state court or other judicial authority, (ii) with the consent of all Parties, (iii) where needed for the preparation or presentation of a claim or defense in the arbitration, (iv) where such information is already in the public domain other than a result of a breach of this clause, or (v) by order of the arbitral tribunal upon application of a Party.

(f) Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the administrator and the arbitrator.

(g) Notwithstanding anything in this Section 14.2, in the event of a dispute with respect to (i) the validity, scope, enforceability or ownership of any Patent or other intellectual property rights or (ii) compliance by a Party with any Applicable Law governing antitrust, anti-monopoly or competition law or regulation, and such dispute (either (i) or (ii)) is not resolved in accordance with Section 14.1, then such dispute shall not be submitted to an arbitration proceeding in accordance with this Section 14.2, and instead, the Parties shall resolve such dispute by litigation in a court of competent jurisdiction in any country in which such rights apply.

14.3Pending Dispute. During a pending dispute, where this Agreement has not yet been terminated, each Party shall continue to perform in good faith its obligations under this Agreement.

ARTICLE 15

MISCELLANEOUS

15.1Governing Law. This Agreement shall be governed in all respects by the laws of the State of New York, USA exclusively, without regard to any conflict of law rule that would result in the application of the laws of any jurisdiction other than the State of New York, USA. The application of the U.N. Convention on Contracts for the International Sale of Goods is excluded.

15.2Entire Agreement; Amendment. This Agreement, including the Pharmacovigilance Agreement, the Supply Agreement(s), the Quality Agreement(s) and Schedules attached hereto, set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings between the Parties with respect to the subject matter hereof, whether written or oral, including the Existing CDA, *provided* that all "Confidential Information" disclosed or received by 4DMT or Otsuka thereunder shall be deemed "Confidential Information" disclosed or received by such Party under this Agreement and shall be subject to the terms and conditions of this Agreement, as if such information had been disclosed hereunder. In the event of any inconsistency between (a) the terms of this Agreement, on the one hand, and (b) the terms of the Pharmacovigilance Agreement, the Supply Agreement(s), the Quality Agreement(s) or Schedules to this Agreement, on the other hand, the terms of this Agreement shall prevail. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as specifically set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.3Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party that are not avoidable, potentially including requisition by any Governmental Authority, the effect of any statute, ordinance or governmental order or regulation, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, failure of public utilities, common carriers or supplies, lockouts or other labor disturbances, fire,

earthquakes, storm, floods, pandemics or other acts of God (*provided* that such failure or delay could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances and resume performance of its obligations hereunder.

15.4Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall make specific reference to this Agreement and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.4, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable overnight delivery service, (b) on the day of sending by email (with documented confirmation of receipt from the recipient Party), if followed by mailing by first class certified or registered mail, postage prepaid, return receipt requested or sent by a reputable overnight delivery service or (c) [*] ([*]) days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested. This Section 15.4 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to 4DMT:

4D Molecular Therapeutics, Inc.
5858 Horton Street #455
Emeryville, CA 94608
U.S.A.
Attn: Scott Bizily, Chief Legal Officer
Email: [*]

With a copy (which will not constitute notice for purposes of this Agreement) to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
U.S.A.
Attn: Marya A. Postner
Email: [*]

If to Otsuka:

Otsuka Pharmaceutical Co., Ltd.
Shinagawa Grand Central Tower 2-16-4 Konan
Tokyo 108-8242
Japan
Attn: Director, Global Business Development
Email: [*]

With a copy (which will not constitute notice for purposes of this Agreement) to:

Otsuka Pharmaceutical Co., Ltd.
Shinagawa Grand Central Tower 2-16-4 Konan
Tokyo 108-8242
Japan
Attn: Director, Legal Affairs Department
Email: [*]

15.5No Strict Construction; Headings. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

15.6Assignment.

(a) Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party; *provided* that either Party may assign or transfer this Agreement without the other Party's prior written consent (but with written notice to the other Party promptly following such assignment or transfer) to an Affiliate or to a successor to all or substantially all of the business or assets of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets, reorganization, consolidation, royalty factoring or other similar transaction or series of transactions, so long as the assigning Party is not relieved of any obligation accrued hereunder prior to such assignment. Any permitted successor or assignee of rights or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights or obligations (and in any event, any Party assigning this Agreement to an Affiliate shall remain bound by the terms and conditions hereof). Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.6 shall be null, void and of no legal effect.

(b) Notwithstanding anything to the contrary in Section 15.6(a) or elsewhere in this Agreement, 4DMT may assign to a Third Party its right to receive all or any portion of the milestone payments, sales milestone payments or royalty payments owed under Article 8 (such assignment, a "**Securitization Transaction**") after notifying Otsuka. Further, in connection with a contemplated Securitization Transaction, 4DMT may disclose to such Third Party the existence and the terms of this Agreement, without the prior written consent of Otsuka, to the extent reasonably necessary to enable such Third Party to evaluate the Securitization Transaction opportunity (*provided* that (i) such Third Party is not a company whose business is primarily focused on the research, development and commercialization of pharmaceutical or biotechnology products and (ii) such disclosure is subject to applicable provisions of Article 12). As part of any consummated Securitization Transaction, 4DMT may assign to such Third Party 4DMT's rights to receive royalty reports, to conduct audits under Section 8.13 and to enforce the payment obligations so assigned.

15.7Further Actions. Each Party agrees to execute, acknowledge and deliver (or cause to be executed, acknowledged and delivered) such further instruments, and to do (or cause to be done) all such other acts, as may be necessary or appropriate or as the other Party may reasonably request in order to carry out the purposes and intent of this Agreement.

15.8Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Schedules mean the particular Articles, Sections or Schedules to this Agreement and references to this Agreement include all Schedules hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (b) the word "day" or "year" means a calendar day or year unless otherwise specified; (c) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Schedules); (e) the word "or" shall be construed as the inclusive meaning identified with the phrase "and/or;" (f) provisions that require that a Party or the Parties hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter or otherwise and that consents not be unreasonably withheld, delayed or conditioned; (g) words of any gender include the other gender; (h) words using the singular or plural number also include the plural or singular number, respectively; and (i) the word "will" shall be construed to have the same meaning and effect as the word "shall" wherever context requires. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

15.9Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the original intent of the Parties when entering into this Agreement may be realized.

15.10No Waiver. Any failure or delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time. No waiver shall be effective unless it has been given in writing and signed by any authorized representative of the Party giving such waiver.

15.11Affiliates. Except to the extent expressly stated otherwise in this Agreement, each Party may perform, at such Party's exclusive option, its obligations hereunder itself or through one or more Affiliates. Neither Party shall permit any of its Affiliates or permitted Third Party contractors to commit any act (including any act of omission) which such Party is prohibited hereunder from committing directly. The Party so acting through its Affiliate(s) shall remain liable for the due fulfilment of its obligations by, and for any breach, act or omission of, such Affiliate(s).

15.12Relationship of Parties; No Third Party Beneficiaries. Nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided therein. There are no express or implied Third Party

beneficiaries hereunder (except for 4DMT Indemnitees and Otsuka Indemnitees for purposes of Article 11).

15.13Injunctive Relief. Notwithstanding anything to the contrary in this Agreement, each Party hereby acknowledges and agrees that in the event of the other Party's actual or threatened breach of any provision of this Agreement relating to Confidential Information or intellectual property rights (including, Article 9 and Article 12), the non-breaching Party may suffer an irreparable injury such that no remedy at law would adequately protect or appropriately compensate the non-breaching Party for such injury. Accordingly, each Party agrees that the non-breaching Party shall have the right to enforce this Agreement and any of such provisions by injunction, specific performance or other equitable relief in any relevant jurisdiction, without bond and without prejudice to any other rights and remedies that the non-breaching Party may have for a breach of this Agreement.

15.14Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered shall be deemed to be original signatures, shall be valid and binding upon the Parties, and, upon delivery, shall constitute due execution of this Agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement by their respective duly authorized representatives as of the Effective Date.

4D MOLECULAR THERAPEUTICS, INC.

By:/s/ David Kirn, MD

Name: David Kirn, MD

Title: Chief Executive Officer

[*Signature Page to Collaboration and License Agreement*]

OTSUKA PHARMACEUTICAL CO., LTD.

By:/s/ Makoto Inoue
Name: Makoto Inoue
Title: President and Representative Director

By:/s/ Takeshi Watanabe, PhD, MBA
Name: Takeshi Watanabe, PhD, MBA
Title: Senior Vice President & Operating Officer, Global BD Head, Global BD

[*Signature Page to Collaboration and License Agreement*]

Schedule 1.24 – Asia and Oceania

[*]

Schedule 1.90 – Manufacturing Cost

[*]

Schedule 3.4 – Global Development Plan

[*]

Schedule 8.4 – Form for:
Allocated 4FRONT-1 Clinical Trial Cost and the Allocated Cross-Territory Clinical Trial Cost

[*]

Schedule 8.8(i) – Form for:
Royalty Reports

[*]

Schedule 8.11 – Payment Information

[*]

Schedule 10.2(a) – Title; Encumbrances

[*]

Schedule 10.2(h) – Existing Licensed Patents

[*]

Schedule 10.2(j) – Upstream Licenses

[*]

Schedule 13.4(b) – Baseball Arbitration

[*]

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-263925, 333-267013, 333-273845, and 333-276872) and Form S-8 (Nos. 333-251370, 333-254701, 333-263908, 333-270566, 333-277547, 333-285456, and 333-287089) of 4D Molecular Therapeutics, Inc. of our report dated March 18, 2026 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 18, 2026

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) AND
15d-14(a) UNDER THE EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Kirn, certify that:

1. I have reviewed this Annual Report on Form 10-K of 4D Molecular Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 18, 2026

By: /s/ David Kirn
David Kirn
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND
15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kristian Humer, certify that:

1. I have reviewed this Annual Report on Form 10-K of 4D Molecular Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 18, 2026

By: /s/ Kristian Humer
Kristian Humer
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K (the "Annual Report") of 4D Molecular Therapeutics, Inc. (the "Company") for the year ended December 31, 2025, David Kirn, as President and Chief Executive Officer of the Company, and Kristian Humer, as Chief Financial Officer of the Company, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

a) the Company's Annual Report for the year ended December 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

b) the information contained in such Annual Report fairly presents, in all material respects, the financial condition and results of operations of 4D Molecular Therapeutics, Inc.

Dated: March 18, 2026

By: /s/ David Kirn
David Kirn
President and Chief Executive Officer
(Principal Executive Officer)

Dated: March 18, 2026

By: /s/ Kristian Humer
Kristian Humer
Chief Financial Officer
(Principal Financial Officer)