### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 8-K

#### CURRENT REPORT Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 10, 2022

### **4D MOLECULAR THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-39782 (Commission File Number) 47-3506994 (IRS Employer Identification Number)

5858 Horton Street #455 Emeryville, California 94608 (Address of principal executive offices, including Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

 $\Box$  Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.  $\Box$ 

#### Item 7.01 Regulation FD Disclosure

On January 10, 2022, 4D Molecular Therapeutics, Inc. (the "Company") provided a corporate presentation relating to its research and development programs by posting a corporate presentation to the investor section of the Company's website at: https://ir.4dmoleculartherapeutics.com. The Company's corporate presentation is attached hereto as Exhibit 99.1.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the slides is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures. For important information about forward looking statements, see the slide titled "Legal Disclaimer" in Exhibit 99.1 attached hereto.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01 and in the presentation attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Corporate Presentation of 4D Molecular Therapeutics, Inc. dated January 10, 2022.

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

#### SIGNATURES

Pursuant to the requirements 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 hereunto duly authorized.

#### 4D MOLECULAR THERAPEUTICS, INC.

Date: January 11, 2022

By: /s/ August J. Moretti August J. Moretti Chief Financial Officer



## Harnessing the Power of Directed Evolution for Targeted Gene Therapies

Corporate Presentation | January 2022



### Legal Disclaimer

This Presentation contains forward looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Presentation, including statements regarding our clinical development plans, strategy, future operations, future financial position, prospects, plans, and objectives of management, are forward looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward looking statements, all forward looking statements, other the plans, intentions, or expectations disclosed in these forward looking statements, and you should not place undue reliance on these forward looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward looking statements. In addition, the forward looking statements included in this Presentation represent our views as of the date of this Presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward looking statements in the future, we specifically disclaim any obligation to do so. These forward looking statements is should not be relied upon as representing our views as of any date subsequent to the date of this Presentation.

This Presentation discusses our product candidates that are under preclinical study and in clinical trials, and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of our product candidates for the therapeutic use for which they are being studied.

This Presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

This Presentation shall not constitute an offer to sell or the solicitation of an offer to buy securities.

# We are Boldly Innovating to Unlock the Full Potential of Gene Therapy for Millions of Patients

| COMPANY                 | <b>Co-Founders</b><br>Kirn, MD & Schaffer, PhD | Emeryville                                      | Control Contro |  |  |  |  |
|-------------------------|--|---|--|--|--|--|--|
| PLATFORM                | <b>Directed Evolution</b>                      | ~I BILLION AAV<br>synthetic capsid<br>sequences | Targeted & Evolved<br>Vectors  |  |  |  |  |
| PIPELINE                | Vector Modularity                              | Lead Vectors & 3 The                            | rapeutic Areas   |  |  |  |  |
| CLINICAL<br>DEVELOPMENT |  | 5 Clinical Candidate                            | 25   |  |  |  |  |
| STRATEGY                | Fully Integrated Biopharmaceutical Company     |   |  |  |  |  |  |

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### Successes & Limitations of Conventional AAV

OPPORTUNITY FOR TARGETED GENE THERAPY VECTORS & PRODUCTS



#### **OPPORTUNITY:** UNLOCK THE FULL POTENTIAL OF GENE THERAPY BY HARNESSING THE POWER OF DIRECTED EVOLUTION

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## Platform Solution: Therapeutic Vector Evolution



### Platform Solution: ~I Billion Synthetic Capsid Sequences

**40 DISTINCT LIBRARIES** 



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## Platform Solution: Compete for Target Vector Profile Fitness THERAPEUTIC VECTOR EVOLUTION



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## Modular Approach to Therapeutic Area Pipeline PRODUCT DESIGN & ENGINEERING FOR ACCELERATED DEVELOPMENT



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## Pipeline: 5 Clinical-Stage Product Candidates THREE THERAPEUTIC AREAS, RARE & LARGE PATIENT POPULATIONS

| VECTOR<br>Delivery   | PRODUCT<br>CANDIDATE | INDICATION         | LEAD<br>OPTIMIZATION | IND-ENABLING | PHASE I / 2 | PHASE 3 | PRODUCT<br>RIGHTS |  |  |
|----------------------|----------------------|--------------------|----------------------|--------------|-------------|---------|-------------------|--|--|
| R100<br>Intravitreal | OPHTHALMOL           | .OGY               |                      |              |             |         |                   |  |  |
| ine and car          | 4D-125               | XLRP               |                      |              |             |         | @4DMT             |  |  |
|                      | 4D-110               | CHM                |                      |              |             |         | <b>4DMT</b>       |  |  |
|                      |                      | Wet AMD            |                      |              |             |         | <b>4DMT</b>       |  |  |
|                      | 40-150               | DME                |                      |              |             |         | <b>4DMT</b>       |  |  |
| C102                 | CARDIOLOGY           |                    |                      |              |             |         |                   |  |  |
|                      | 4D-310               | Fabry<br>Disease   |                      |              |             |         | <b>4DMT</b>       |  |  |
| AI0I<br>Aerosol      | PULMONOLOGY          |                    |                      |              |             |         |                   |  |  |
|                      | 4D-710               | Cystic<br>Fibrosis |                      |              |             |         | <b>\$4DMT</b>     |  |  |

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## CARDIOLOGY

Modular Vector: C102

4D-310: FABRY DISEASE



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## 4D-310 Product Design & C102 Target Vector Profile INVENTED FOR LOW DOSE IV DELIVERY TO TARGET ORGANS INCLUDING HEART & HIGH SERUM AGA



#### **PRODUCT DESIGN**

- Vector: CI02 .
- Transgene: GLA (encodes AGA enzyme) .
- Promoter: Ubiquitous



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## 4D-310 Competitive Advantages: Dual MOA Product Design designed for high stable aga expression in blood, heart & other target organs

|                                       |                                       | ERT                     | Г                  | <b>G</b> ene Therapy     |                       |                |  |  |
|---------------------------------------|---------------------------------------|-------------------------|--------------------|--------------------------|-----------------------|----------------|--|--|
| MOA                                   | Product Design                        | AGA Enzyme<br>Infusions | PEGylated<br>AGA   | Autologous<br>Stem Cells | AAV<br>Liver-directed | 4D-310         |  |  |
| AGA:<br>Systemic PK                   | Pharmacokinetics                      | Biweekly IV Dosing      | Biweekly IV Dasing | Single IV Dose           | Bingle IV Dose        | Bingle IV Dose |  |  |
|                                       | No chemotherapy/ bone marrow ablation | +                       | +                  | -                        | +                     | +              |  |  |
| AGA:<br>Production in<br>Target Cells | Heart, Kidney,<br>Blood Vessels       | -                       | -                  | -                        | _                     | +              |  |  |
| AGA:<br>Avoid<br>Anti-AGA Ab          | Intracellular production              | -                       | _                  | _                        | _                     | +              |  |  |

AGA, aspartylplucos ed virus: ERT. enzy idasa: AAV as

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## 4D-310 Study Design: Broad Enrollment Criteria

OPEN-LABEL, PHASE 1/2 TRIAL IN ADULTS WITH CLASSIC & LATE-ONSET FABRY DISEASE

#### STUDY DESIGN



#### ASSESSMENT SCHEDULE: BIOMARKERS

|   | Scree         | ning/Treat | ment F | eriod |    | Observation Period |    |     |     |    |            |     |     |     |              |
|---|---------------|------------|--------|-------|----|--------------------|----|-----|-----|----|------------|-----|-----|-----|--------------|
| Visit   | svi           | SV2        | D-I    | DI    | D2 | D4                 | D8 | DIS | W4* | W6 | <b>W</b> 8 | W12 | W26 | W38 | W52<br>or ET |
| Visit Window (days)   | Up to<br>-180 | -45 to -2  | -      | -     | -  | ±١                 | ±I | ±I  | ±3  | ±3 | ±3         | ±7  | ±7  | ±7  | ±7           |
| Fabry Blood Panel<br>(AGA, lysoGb3); central lab <sup>h</sup> |               | <b></b>    | •      |       |    |                    |    | •   | •   | •  | •          | •   | •   | •   | -            |

liomarker Assessment (Mayo Clinic)

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#### **KEY INCLUSION CRITERIA**

- Males  $\geq$  18 years of age
- Pathogenic GLA mutation
- Classic <u>OR</u> Late-onset FD with LVH
- ERT-On, ERT-Off OR ERT-naïve
- Anti-AGA Ab status positive **OR** negative

#### **KEY EXCLUSION CRITERIA**

- High titer anti-4D-310 NAb (>1:1,000)
- High titer anti-AGA NAb titer (>1:25,000)
- eGFR <45 mL/min/1.73m2
- LVEF <45% (Echo)</li>

#### PRIMARY ENDPOINT

Incidence & severity of adverse events

#### **KEY SECONDARY ENDPOINTS**

- Serum AGA Activity: change from baseline
- Cardiac Imaging & Functional: change from baseline

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### 4D-310 Baseline Patient Characteristics:

STUDY ENROLLED CLASSIC FABRY DISEASE PATIENTS WITH ANTI-AGA ANTIBODY POSITIVITY

|                                 | Patient I           | Patient 2          | Patient 3          |  |  |
|---------------------------------|---------------------|--------------------|--------------------|--|--|
| Age dosed with 4D-310           | 51 years            | 32 years           | 26 years           |  |  |
| Anti-AGA antibody titer         | l : 947             | I : 99,900         | I : I3,900         |  |  |
| Disease classification          | Classic             | Classic            | Classic            |  |  |
| Serum AGA activity (nmol/hr/mL) | 0.42                | 0.00               | 0.30               |  |  |
| ERT experience                  | Yes                 | Yes                | Yes                |  |  |
| ERT status                      | ERT-ON              | ERT-OFF            | ERT-ON             |  |  |
| Serum lyso-Gb3 (ng/mL)          | 6.28                | 101.00             | 8.78               |  |  |
| Mutation                        | c.1023A>C (p.E341D) | c.708G>T (p.W236C) | c.974G>A (p.G325D) |  |  |

Reference range: • Serum AGA activity: 4.44-27.42 nmol/hr/mL • Serum Lyso-Gb3: ≤ 1.0 ng/mL

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## 4D-310 Mean Serum AGA Activity: >20-Fold Mean Normal ANTI-AGA ANTIBODY POSITIVE LOW & MID TITERS: PATIENTS I & 3 AGA ACTIVITY OVER TIME



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## 4D-310 Mean Serum AGA Activity: Within Normal Range AGA ANTIBODY POSITIVE HIGHEST TITER: PATIENT 2 (HIGHEST TITER OF ALL ENROLLED & SCREENED)

### Mean Serum AGA Activity:

Serum lyso-Gb3:

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Patient 2: 5.7 nmol/hr/mL 



## Summary of Interim Data: 4D-310 Ph 1/2 Clinical Trial

- 4D-310 demonstrated a manageable safety profile & no DLTs
- Clinical activity observed in <u>all patients at all timepoints</u>:
  - Mean **AGA** enzyme activity:
    - Within, or significantly above, the normal range in all three patients
    - o Levels correlated with baseline anti-AGA antibody titers
  - Serum lyso-Gb3 substrate <u>decreased significantly</u> in patient with elevated pre-treatment lysoGb3 (entered study OFF-ERT)
  - Serum lyso-Gb3 substrate remained low following discontinuation of ERT in BOTH patients who entered study ON-ERT

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## OPHTHALMOLOGY

### Modular Vector: RI00

- 4D-125: XLRP
- 4D-150: wAMD/DME
- 4D-110: CHOROIDEREMIA



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## Ophthalmology: R100 Structure & Target Vector Profile INTRAVITREAL DELIVERY FOR RETINAL DISEASES



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### Ophthalmology: 4D-125 for XLRP



#### HIGH UNMET MEDICAL NEED

- Monogenic: X-linked (RPGR)
- Blinding: periphery to center
- NO FDA APPROVED THERAPY

#### DIFFERENTIATION

Intravitreal (IVT) Transduces Entire Retinal Surface IVT Routine & Safe All Stages

EPIDEMIOLOGY: US & EU-5
~24,000 prevalence

24,000 prevalence



#### **PRODUCT DESIGN**

- Vector: R100
- Transgene: RPGR
- Promoter: Photoreceptor-specific

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### STATUS:

Ongoing Phase 1/2 Clinical Trial Fast Track Designation **EXPECTED MILESTONE:** Ongoing Enrollment at 1E12 vg/eye

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## 4D-125 Study Design

OPEN-LABEL, PHASE 1/2 TRIAL IN ADULTS WITH XLRP

#### **STUDY DESIGN**



#### ASSESSMENT SCHEDULE



Biomarkers assessed by Independent Reading Center

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#### **KEY INCLUSION CRITERIA**

- Male ≥18 years of age
- Hemizygous RPGR mutation
- Clinical diagnosis of non-syndromic retinitis pigmentosa
- Measurable ellipsoid zone line (EZL) on macular SD-OCT
- Microperimetry:
  - >I nonzero point (dose-escalation) <u>OR</u>
  - $\circ \geq I dB$  mean retinal sensitivity (dose-expansion)

#### PRIMARY ENDPOINT

Incidence & severity of adverse events

#### **KEY SECONDARY ENDPOINTS**

- EZ Area (SD-OCT): Change from baseline over time vs contralateral non-injected control eye
- Microperimetry: Change from baseline in visual field sensitivity & # loci improving >7dB over 12 months vs contralateral non-injected control eye

## 4D-125 XLRP Biomarker Data: Preliminary Evidence of Activity BASELINE TO LAST VISIT; N=2 EVALUABLE & WITH AT LEAST 6 MONTHS FOLLOW-UP

|         |                               | Optical Coherence<br>[Ellipsoid Zone A | Tomography (OCT)<br>Area – % Change] | Micrope<br>[Mean Retinal S | erimetry<br>Sensitivity (dB)] | Microperimetry<br>[# of Loci with ≥ 7dB Improvement] |               |  |
|---------|-------------------------------|--|--------------------------------------|----------------------------|-------------------------------|--|---------------|--|
| Patient | Last Assessment               | Treated Eye                            | Untreated Eye                        | Treated Eye Untreated Eye  |                               | Treated Eye  | Untreated Eye |  |
| Cohort  | l (3×10 <sup>11</sup> vg/eye) |  |                                      |                            |                               |  |               |  |
| 1       | Month 12                      | -1.0%                                  | -2.1%                                | Not Evaluable              | Not Evaluable                 | Not Evaluable  | Not Evaluable |  |
| 2       | Month 12                      | Not Evaluable                          | -10.7%                               | -0.3                       | Not Evaluable                 | 0  | Not Evaluable |  |
| 3       | Month 9                       | -12.4%                                 | -16.2%                               | +1.65                      | +0.25                         | +6   | +1            |  |
| Cohort  | 2 (I×I0 <sup>12</sup> vg/eye) |  |                                      |                            |                               |  |               |  |
| 4       | Month 6                       | Not Evaluable                          | Not Evaluable                        | Not Evaluable              | Not Evaluable                 | Not Evaluable  | Not Evaluable |  |
| 5       | Month 6                       | -20.2%                                 | -28.7%                               | +0.90                      | +0.10*                        | +3   | 0*            |  |
| 6       | Month 9                       | Not Evaluable                          | -7%                                  | Not Evaluable              | Not Evaluable                 | Not Evaluable  | Not Evaluable |  |

\*Month 4 - Patient 5 unable to fixate in untreated eye at me

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### Summary of 4D-125 Interim Phase 1/2 Clinical Data

- 4D-125 well-tolerated with no dose-limiting toxicities, serious adverse events or chronic inflammation
- Evidence of clinical activity observed in the treated eye vs. the untreated eye in evaluable patients (2/2 pts) on three clinical activity endpoints
- Continuing enrolling patients at high dose (IE12 vg/eye) in expansion cohort, including less advanced patients
- Fast Track Designation received from FDA

## Ophthalmology: 4D-150 for Wet AMD & DME



#### HIGH UNMET MEDICAL NEED

- Frequent Injections
- Patient / Physician Adherence Issues
- Incomplete Responders

### DIFFERENTIATION

Intravitreal (IVT) Transduces Entire Retina Surface IVT Routine & Safe 4 Distinct Mechanisms-of-action



#### EPIDEMIOLOGY: US

- Wet AMD: ~200,000/yr incidence
- DME:~I.2M prevalence
- \$9.7 Billion 2019 global sales



#### PRODUCT DESIGN

- Vector: R100
- Transgene I: Aflibercept
- Transgene 2: VEGF-C RNAi
- Promoter: Ubiquitous

**STATUS:** Ongoing Phase 1/2 Clinical Trial **EXPECTED MILESTONE:** Ongoing Enrollment in Dose Escalation

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## Ophthalmology: 4D-150 Efficacy in NHP CNV Model



- 100% suppression of CNV,
- Including at lowest dose of IEII vg/eye
- Day 42 ocular assessments prior to laser:
  - o IEII vg / eye, no uveitis or retinal abnormalities
  - 3EII & IEI2 vg / eye, mild to moderate uveitis 0 in a minority of NHP; no retinal abnormalities
  - o Tapered 28-day steroid regimen

4D-150 Study Design PHASE 1/2 DOSE-ESCALATION FOLLOWED BY RANDOMIZED DOSE EXPANSION

#### **STUDY DESIGN**



#### **KEY INCLUSION CRITERIA**

- ≥ 50 years of age
- Diagnosed with CNV secondary to AMD
- Anti-VEGF treatment: minimum 6 injections last 12 mo
- Disease responsive to anti-VEGF treatment

#### **PRIMARY ENDPOINT**

Incidence and severity of adverse events

#### **KEY SECONDARY ENDPOINTS**

Rescue Aflibercept Injections: # over time vs pre-treatment .

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OSMC review

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### Ophthalmology: 4D-110 for Choroideremia



#### HIGH UNMET MEDICAL NEED

- Monogenic: X-linked (CHM)
- Blinding: periphery to center
- NO FDA APPROVED THERAPY

#### DIFFERENTIATION

Intravitreal (IVT) Transduces Entire Retinal Surface IVT Routine & Safe All Stages

# $\hat{\mathbf{c}}$

EPIDEMIOLOGY: US & EU-5
~13,000 prevalence

i o, o o prevalence



#### **PRODUCT DESIGN**

- Vector: R100
- Transgene: CHM
- Promoter: Ubiquitous

STATUS: Ongoing Phase 1/2 Clinical Trial EXPECTED MILESTONE: Ongoing Enrollment at 3E11 vg/eye

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### Key Takeaways for 4D-110 Clinical Data

TOLERABILITY @3ETI VG/EYE ASSOCIATED WITH CLINICAL ACTIVITY

- 3EII vg/eye dose (Cohort I):
  - Well-tolerated & no DLT or SAE
  - Clinical activity vs control eyes (FAF Area)
- IEI2 vg/eye dose (Cohort 2):
  - AE consistent with REPI transgene product over-expression (no association with inflammation)
- Dose expansion at 3EII vg/eye dose (n= 6 total)

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## PULMONOLOGY

Modular Vector: A101 • 4D-710: CYSTIC FIBROSIS



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## 4D-710 Product Design & A101 Target Vector Profile AEROSOL DELIVERY FOR LUNG DISEASES



## Pulmonology: 4D-710 Aerosol Delivery in NHP WIDESPREAD TRANSDUCTION IN NHP AIRWAYS & ALVEOLI



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## 4D-710 Study Design

OPEN-LABEL, PHASE 1/2 TRIAL

#### STUDY DESIGN



#### **KEY INCLUSION CRITERIA**

- ≥18 years of age
- Diagnosis of CF lung disease including:
  - o Bi-allelic mutations in the CFTR gene
  - CFTR modulator therapy:
    - Ineligible <u>OR</u>
    - Received modulator therapy but discontinued due to adverse effects or lack of efficacy

#### PRIMARY ENDPOINT

Incidence & severity of adverse events

#### **KEY SECONDARY ENDPOINTS**

Percent Predicted FEV<sub>1</sub>: change from baseline



## MILESTONES & FINANCIALS

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### **Expected Milestones & Cash Runway**



## CASH POSITION & RUNWAY GUIDANCE

### \$227M

Cash, cash equivalents and marketable securities as of the end of Q3 2021

\$111M

Net proceeds from October 2021 followon public offering

### \$338M proforma

Cash, cash equivalents & marketable securities expected to fund operations into 2H24

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## **THANK YOU**

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