# **Corporate Presentation**

J.P. Morgan Healthcare Conference

January 2022

NASDAQ: PRDS





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# **Pardes Biosciences Leadership Team**



**Uri Lopatin, MD** Chief Executive Officer & President

















Lee Arnold, PhD Chief Scientific Officer

















Brian Kearney, PharmD Chief Development Officer









Elizabeth Lacy, JD General Counsel













**Heidi Henson** Chief Financial Officer













**Sean Brusky Chief Commercial Officer** 









**Phil Tinmouth** Chief Business and Strategy Officer





## **Pardes Advisory Board Members**

Mike Varney, PhD (Roche)







Robert Zamboni, PhD O MERCK





Carol Brosgart, MD GILEAD



Brad Jenkins (Roche)











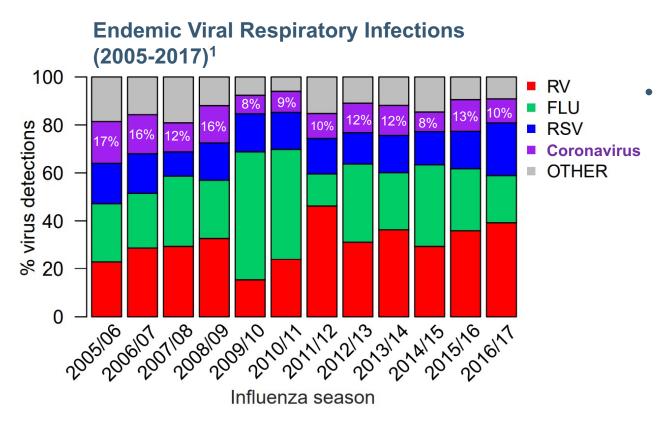
# **Executive Summary**

- Founded in Feb 2020 to discover and develop oral antivirals for SARS-CoV-2
- Chemistry initiated April 2020, lead candidate (PBI-0451) nominated Dec 2020, Phase 1 initiated Aug 2021
- PBI-0451 is an oral antiviral inhibitor of the coronaviral main protease (M<sup>Pro</sup>)
  - Preliminary Phase 1 data shows potential for an oral PBI-0451 regimen to achieve and maintain target blood concentrations as a standalone drug
  - Initiation of a Phase 2/3 program targeted for mid 2022
  - Manufacturing activities are underway to support the Phase 2/3 trial, and potential for follow-on commercialization
- We continue to apply our reversible covalent chemistry to advance both next-generation protease inhibitor molecules as well as earlier, discovery stage programs
- On December 27, 2021, we began trading as a public company under the Pardes Biosciences name (NASDAQ: PRDS)
- ~\$274M in gross proceeds from recently completed business combination



# The "Old Normal": Life with Endemic Viral Respiratory Infections (VRI)

# Before COVID-19, Viral Respiratory Infections already caused substantial economic impact and healthcare burden



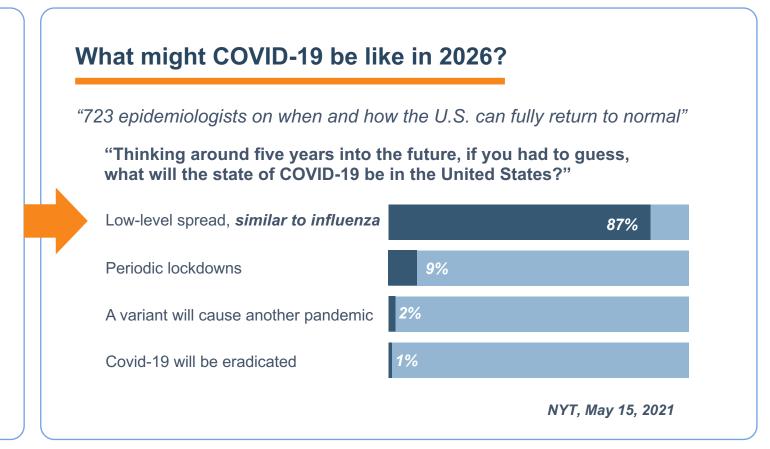
- In 2001, symptomatic non-influenza VRIs were estimated to cost ~\$40B/year (US)<sup>2</sup>
  - Direct medical costs ~\$17B / year
  - Indirect costs ~\$23B / year
    - ~20 million lost workdays
    - ~21 million lost school days



# The "New Normal": Living With a Potentially Endemic SARS-CoV-2

#### **SARS-CoV-2** is likely to persist

- Persistent vaccine hesitancy
- Infections have been seen year round
- Potential for seasonal surges
- Politicized nature of interventions
- Breakthrough cases
- Immigration & global travel
- Emerging variants
- Potential for zoonotic transfer



Without a therapy, recurring SARS-CoV-2 "similar to Influenza" threatens to pose a significant burden

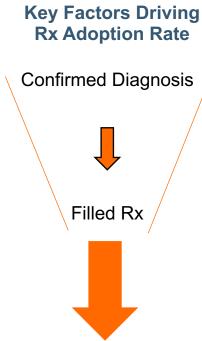


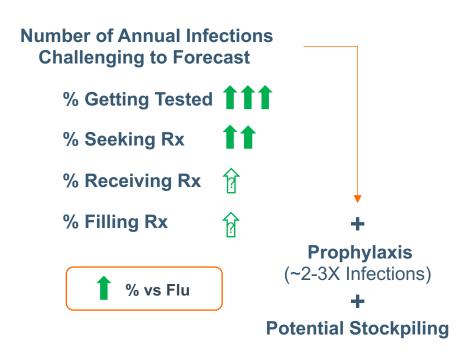
# Influenza Experience Informs Potential Adoption of Oral SARS-CoV-2 Antivirals

#### **Historical Influenza Oral Antiviral Adoption** (U.S. 2014 - 2020)

Potential SARS-CoV-2 Oral Antiviral Adoption (U.S. 2024+)







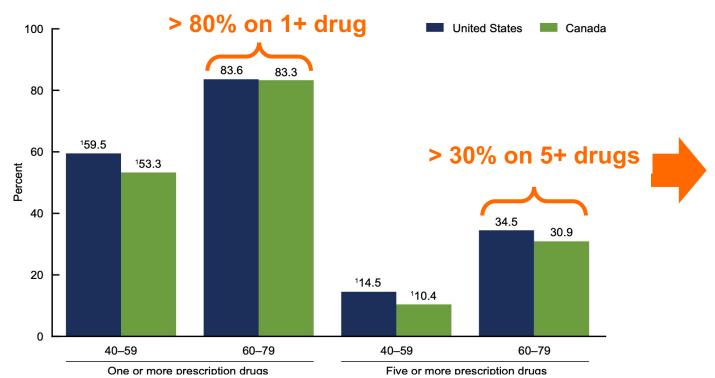
Effective antivirals for SARS-CoV-2 anticipated to have significant demand and adoption



# Patients Will Need Antivirals With Low Risk for Drug-Drug Interactions

#### Use of prescription drugs in the past 30 days among adults

United States (2015–2016) and Canada (2016–2017)<sup>i</sup>



<sup>1</sup>Significantly different from adults aged 60–79.

NOTE: Access data table for Figure 3 at: https://www.cdc.gov/nchs/data/databriefs/db347 tables-508.pdf#3

SOURCES: NCHS, National Health and Nutrition Examination Survey, 2015–2016, and Statistics Canada, Canadian Health Measures Survey, 2016–2017.

- ii livingfacts.org; Source: Pew Research center
- iii https://www.med.umich.edu/asp/pdf/outpatient\_quidelines/COVID-19-amb-treatment.pdf
- iv https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/
- v https://www.fda.gov/media/155050/download

22% of US Population is > 60yo

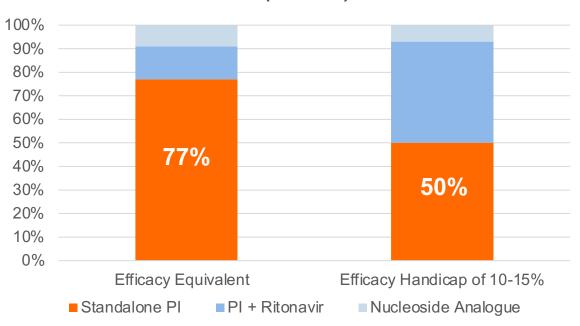
- Over 80% taking one or more prescription drugs<sup>i</sup>
- Over 30% taking five or more prescription drugs<sup>i</sup>
- Many of these are common medications which can be hard to pause – such as blood thinners, antipsychotics, antidepressants and antiarrythmia medications iii-v



i https://www.cdc.gov/nchs/data/databriefs/db347-h.pdf

# Efficacy + Drug-Drug Interactions = Key Drivers of Physician Prescribing

# Most Preferred Treatment Regimen (n = 106)



"All else being equal, I'd strongly prefer a regimen that did not require ritonavir boosting. In addition to the safety and liability considerations that come with potential drug-drug interactions, it would be harder to start a patient on therapy quickly until their other meds are stopped or adjusted. Time to initiation of treatment is critical with oral antivirals."

- Physician, Large group practice, Midwest



#### Standalone Protease Inhibitors Have Potential For a Substantial Market

2022

2023

2024+

Possible unmet market need

Insufficient supply of oral COVID-19 antivirals to meet projected global demand

Additional options needed for elderly, at risk populations on multiple other medicines

Multiple oral antiviral options with different mechanisms of action and resistance profiles

Diagnostics and Telemedicine Availability

- Telemedicine
- Point-of-care and at-home testing

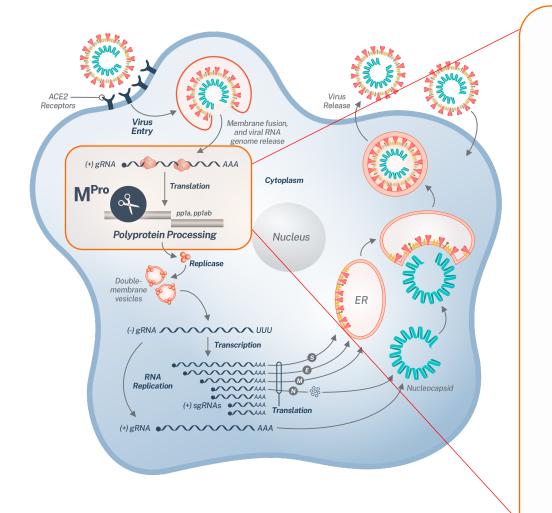
Potential anti-coronaviral market evolution\*

- PI + Ritonavir
- Monoclonal antibodies
- Nucleoside analogue

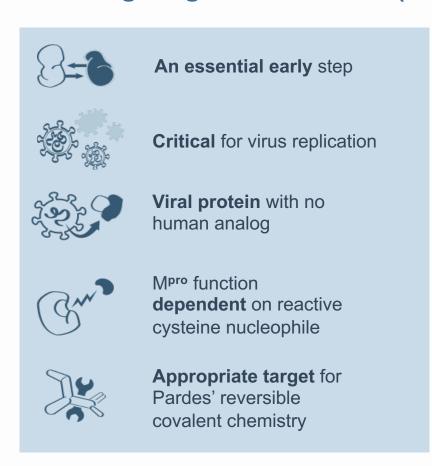
- Standalone Pl(s)<sup>1</sup>
- PI + Ritonavir
- Monoclonal antibodies<sup>2</sup>
- Nucleoside analogue / Polymerase inhibitors



# Viral Main Protease (Mpro): A Promising Pan-Coronavirus Target<sup>1-3</sup>



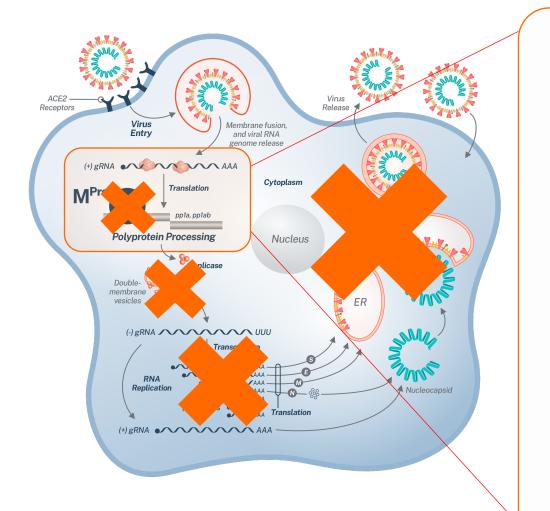
#### Rationale for Targeting Main Protease (Mpro)





- Bioorg Med Chem Lett. 2020 Sep 1; 30(17): 127377.
- 2. Science Translational Medicine 19 Aug 2020:Vol557.
- 3. biorxiv.org/content/10.1101/2020.09.12.293498v2.full.pdf.

# Viral Main Protease (Mpro): A Clinically Validated Target



#### Rationale for Targeting Main Protease (Mpro)



An essential early step



**Critical** for virus replication



Viral protein with no human analog



M<sup>pro</sup> function **dependent** on reactive cysteine nucleophile

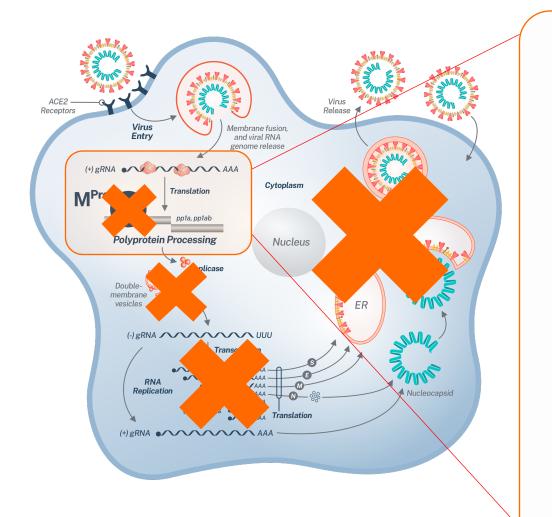


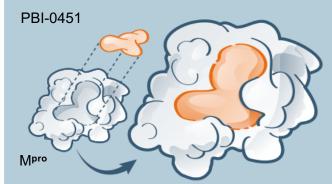
**Appropriate target** for Pardes' reversible covalent chemistry



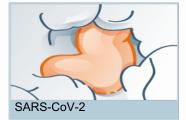
- Bioorg Med Chem Lett. 2020 Sep 1; 30(17): 127377.
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- 3. biorxiv.org/content/10.1101/2020.09.12.293498v2.full.pdf.

### The Main Protease Active Site is Similar Across Coronaviruses





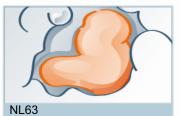
M<sup>pro</sup> inhibitors have potential to be effective against multiple endemic and pandemic coronaviruses<sup>1</sup>











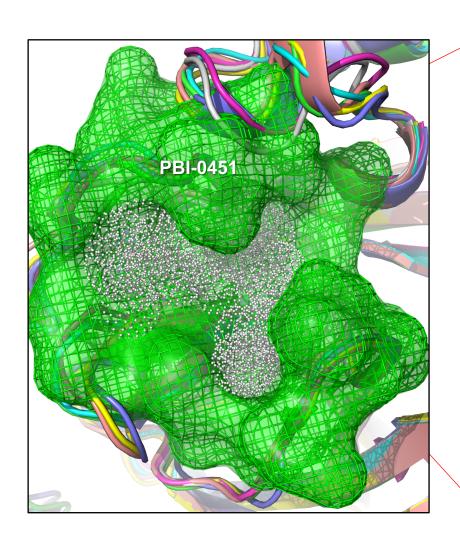


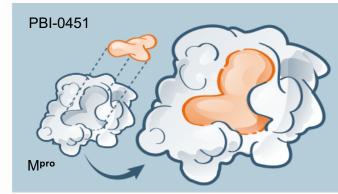
1. Including variants of concern (including Delta, Lambda, Mu etc)



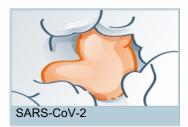
- Bioorg Med Chem Lett. 2020 Sep 1; 30(17): 127377.
- 2. Science Translational Medicine 19 Aug 2020:Vol557.
- 3. biorxiv.org/content/10.1101/2020.09.12.293498v2.full.pdf.

# Similarity of the Main Protease Active Site Across Coronaviruses





M<sup>pro</sup> inhibitors have potential to be effective against multiple endemic and pandemic coronaviruses<sup>1</sup>









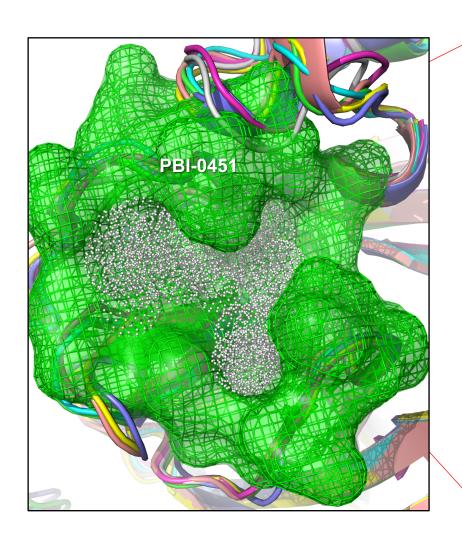




1. Including variants of concern (including Delta, Lambda, Mu etc)



# PBI-0451: Broad Activity Against Diverse Coronaviral Protease in-vitro



Coronavirus M <sup>pro</sup>	PBI-0451 Activity vs Protease* IC <sub>50</sub> (µM; Min,Max)	
SARS-CoV-2	0.02 - 0.03	
SARS-CoV	0.05 - 0.08	
MERS-CoV	0.41 - 0.62	
CoV-229E	0.12 - 0.17	
CoV-OC43	0.15 - 0.20	
CoV-HKU1	0.07 - 0.13	
CoV-NL63	0.24 - 0.38	

<sup>\*</sup> IC50 = 50% inhibitory concentration in In vitro activity; lower numbers = greater potency



# PBI-0451: Consistent Potent Activity in Cell-Based SARS-CoV-2 Assays (Including Delta Variant)

Cell line	Virus	Antiviral assay	EC <sub>90</sub> (nM, Avg±SD)	CC <sub>50</sub> (nM)
Induced Alveolar Type 2 Cells <sup>1</sup>	SARS-CoV-2 WA1 (MOI <sup>3</sup> 0.004)	SARS-CoV2 (PFU/ml)	106 (±90) N=4	>2,000
Induced Alveolar Type 2 Cells <sup>1</sup>	SARS-CoV-2 WA1 (MOI 0.004)	SARS-CoV2 (RNA copy/ml)	67 (±35) N=4	>2,000
A549-ACE2 cell line <sup>1</sup>	SARS-CoV-2_Nluc (MOI 0.025)	SARS CoV-2 (Nanoluciferase)	114 (±85)* N=6	>10,000
Vero E6 cell line (+efflux inhibitor) <sup>2</sup>	SARS-CoV2 (Delta, MOI 0.002)	Cytoprotective Effect	78 N=1	37,000
Vero E6 cell line (+efflux inhibitor) <sup>2</sup>	SARS-CoV2 (Delta, MOI 0.002)	Viral Yield Reduction	<32 N=1	37,000

<sup>1</sup> Vanderbilt University Medical Center

 $EC_{90}$  = 90% maximal effective concentration in cell-based assays; lower numbers = greater potency  $CC_{50}$  = Concentration to reduce cell viability by 50% in cell-based assays; Higher numbers = less cellular toxicity



<sup>2</sup> Utah State University

<sup>3</sup> MOI = Multiplicity of infection

# **Clinical Program Overview**





# Phase 1 First-in-Human Study of PBI-0451: Design and Objectives

## PBI-0451 FIH tolerability, safety and pharmacokinetics (PK) study of PBI-0451

- Objectives: Inform on dose and dosing regimen, as well as effect of food and select drug-drug interactions
- Design: Dose escalating tolerability, safety and PK in healthy subjects
  - Single and multiple (10 days) dose escalation: Ongoing\*
  - Food effect screening (representative FDA low-fat meal): Complete
  - Drug-drug interaction assessment: Partially complete
  - **Formulation:** Powder-in-bottle suspension → tablet transition

<sup>\*</sup>Study initiated in New Zealand in Aug 2021 coincident with delta variant outbreak that slowed initial study conduct due to quarantine. Currently anticipated to complete dosing in 1Q2022 assuming minimal delays attributable to factors such as COVID-19 outbreaks.



# **Phase 1: Preliminary Interim Data**

- Clinical safety observations (as of Jan 2, 2022)
  - Generally well-tolerated
  - No study drug interruptions or discontinuations
  - All adverse events reported by the Investigator as "mild", most considered unrelated or possibly related
  - No reported clinically significant abnormal laboratory or other safety data
- Single dose PK profile
  - Good oral bioavailability
  - Rapidly exceeds target plasma protein binding adjusted EC<sub>90</sub> value\* (374ng/mL)
  - Dose-proportional increase in concentrations over 10-fold dose range
- Preliminary single dose data support potential for a standalone oral regimen to achieve and maintain concentrations above target plasma protein binding-adjusted EC<sub>90</sub> value
  - Multiple dose PK profile with tablet formulation to inform on Phase 2/3 dose and dosing regimen selection



# **Phase 1 Program: Next Steps**

# Complete FIH study

- Multiple ascending doses (ongoing)<sup>†</sup>
- Drug-drug interaction (partially complete)<sup>†</sup>

# Additional anticipated Phase 1 studies

- US IND submitted December 2021 (currently under FDA review)
  - Definitive food effect (with tablets, in line with regulatory guidance for labelling)<sup>†</sup>
  - Drug-drug interactions (key/common concomitant medications, e.g., hormonal (oral) contraceptives, inducers of metabolism, CYP450 substrates)<sup>†</sup>
  - Mass Balance/ADME
  - Special Population PK: renal impairment or hepatic impairment

† High-risk Phase 2/3 study-enabling



# Phase 2/3 Program: Anticipated Study Timing, Designs and Objectives

- Geographically diverse Phase 2/3 initiation targeted for mid 2022, pending dose selection & regulatory interactions
- Studies anticipated to be in outpatients with mild-to-moderate COVID-19
  - Initial Phase 2/3 Treatment study in subjects with high-risk: COVID-related Hospitalizations/Death anticipated as primary endpoint<sup>1</sup>
  - Phase 3 Prophylaxis study linked to treatment study: Reduced transmission anticipated as primary endpoint<sup>1</sup>
  - Additional Treatment studies under consideration include<sup>1</sup>:
    - Evaluation in subjects with standard-risk
    - Evaluation(s) in key subpopulations
      - Immunocompromised
      - Study in individuals for whom ritonavir is contraindicated (comorbidities requiring concomitant medications)

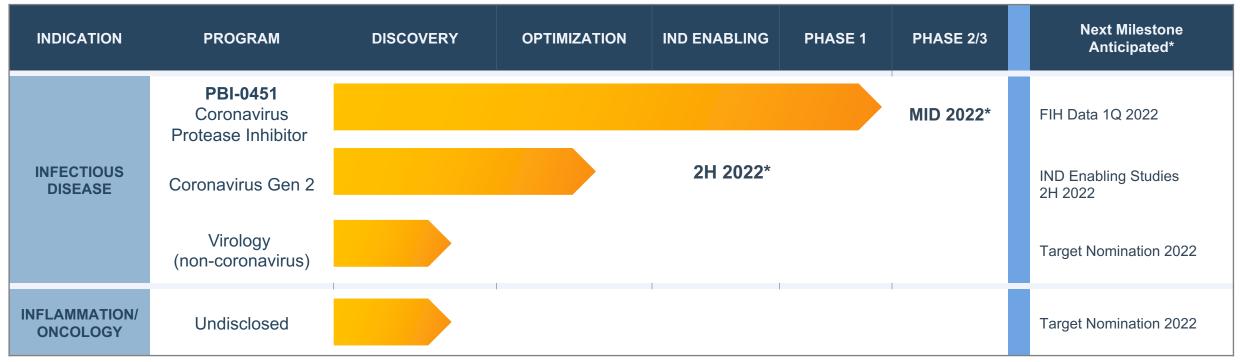


# **Intellectual Property and Manufacturing Overview**

- Pardes has multiple issued U.S. patents, including composition of matter for PBI-0451
  - Continuations of our patents have been filed with U.S. PTO
  - We continue to file IP on PBI-0451 polymorphs, process chemistry, formulations as well as compounds and technology related to our research programs and platform
- We have adequate capacity and capital to produce clinical trial material for our current clinical program projected needs
  - Initial Phase 2/3 supply has been manufactured with completion of the supply anticipated in 2Q 2022
- Current manufacturing process has potential for commercial scale
  - CDMO relationship established for potential commercial scale manufacture



# **Pardes Biosciences Pipeline**



\*Estimated initiation dates

All programs internally developed and wholly owned



# **Key Objectives and Anticipated Progress through 2022**

#### 2021

- ✓ Nominate development candidate and complete IND enabling studies
- ✓ Initiate Phase 1 study PBI-0451
- ✓ Initiated scale up of drug product for Ph 2/3
- ✓ Initiated 2<sup>nd</sup> Gen Program

#### 2022

- ☐ SARS-CoV-2 Oral Antivirals
  - ☐ Completion of PBI-0451 Phase 1
  - ☐ Initiate Phase 2/3 for PBI-0451
  - ☐ Initiate 2<sup>nd</sup> Gen IND enabling studies
- Advance Non-coronaviral Programs
- ☐ Corporate build out

~\$274M in gross proceeds from recently completed business combination

**NASDAQ: PRDS** 



# Thank you



