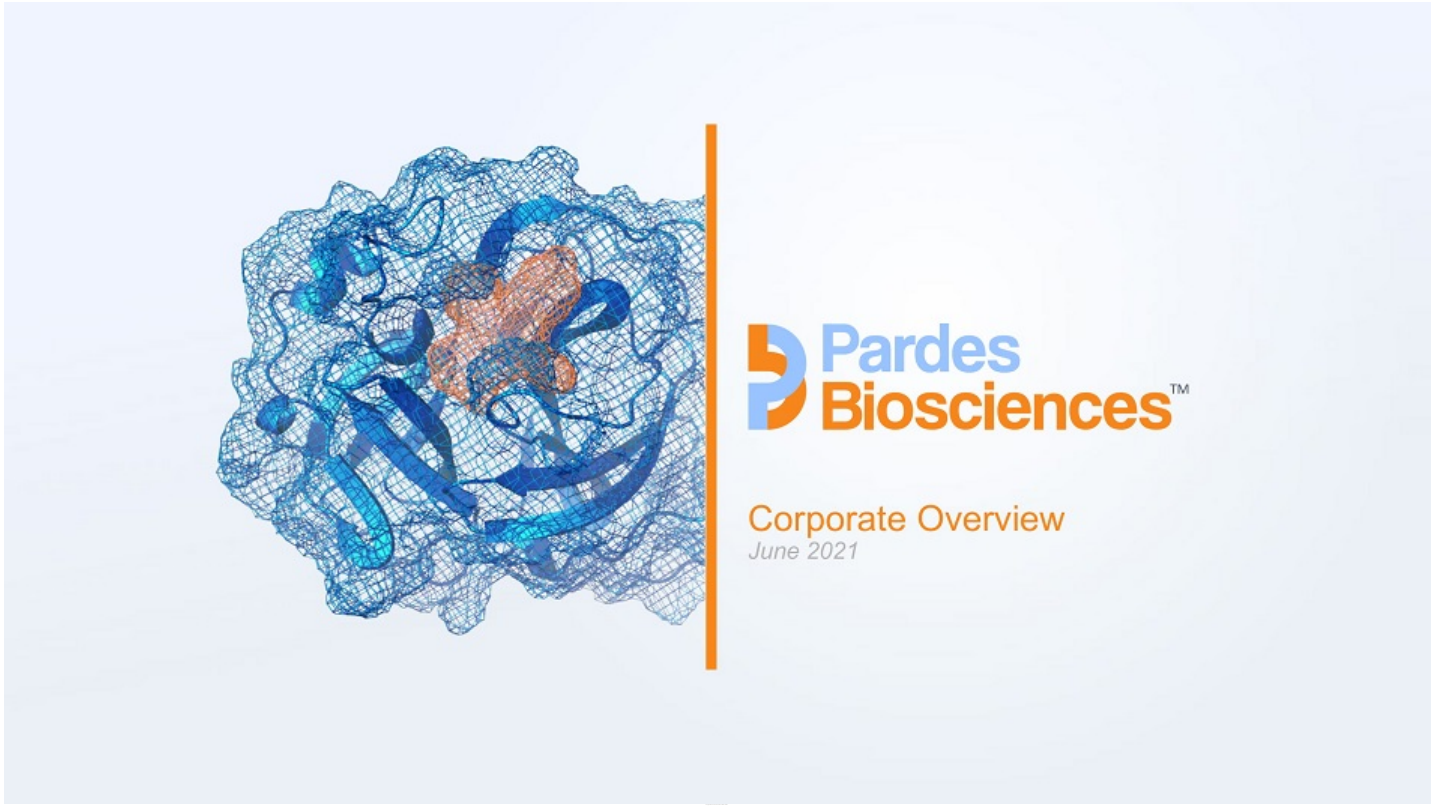
EX-99.2 10 ea143073ex99-2_fsdevelop2.htm INVESTOR PRESENTATION

**Exhibit 99.2**



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**Important Information About the Merger and Where to Find It**

A full description of the terms of the business combination will be provided in a registration statement on Form S-4 (the "Registration Statement") to be filed with the SEC by FS Development II that will include a prospectus with respect to the securities of the combined company upon the closing of the business combination, to be issued in connection with the business combination, and a proxy statement with respect to the stockholder meeting of FS Development II to vote on the business combination. FS Development II urges its investors, stockholders and other interested persons to read, when available, the preliminary proxy statement/prospectus as well as other documents filed with the SEC because these documents will contain important information about FS Development II, the Company and the business combination. After the Registration Statement is declared effective, the definitive proxy statement/prospectus to be included in the Registration Statement will be mailed to stockholders of FS Development II as of a record date to be established for voting on the proposed business combination. Once available, stockholders will also be able to obtain a copy of the Registration Statement, including the proxy statement/prospectus, and other documents filed with the SEC without charge, by directing a request to: FS Development Corp. II, Attn: Secretary, 900 Larkspur Landing Circle, Suite 150, Larkspur, California 94939. The preliminary and definitive proxy statement/prospectus to be included in the Registration Statement, once available, can also be obtained without charge, at the SEC's website at www.sec.gov.

**Participants in the Solicitation**

FS Development II and the Company and their respective directors and executive officers may be considered participants in the solicitation of proxies with respect to the proposed business combination described in this presentation under the rules of the SEC. Information about the directors and executive officers of FS Development II is set forth in FS Development II's final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act on February 18, 2021, and is available free of charge at the SEC's website at www.sec.gov or by directing a request to: FS Development Corp. II, Attn: Secretary, 900 Larkspur Landing Circle, Suite 150, Larkspur, California 94939. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of the FS Development II stockholders in connection with the proposed business combination will be set forth in the Registration Statement containing the proxy statement/prospectus for the proposed business combination when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

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# Transaction Overview

**Timing**

- Transaction closing expected as early as Q3 2021

**Pro Forma Cash**

| | $ mm |
|---|---|
| Pardes Existing Cash[1] | $42.2 |
| SPAC Cash in Trust [2] | $201.2 |
| PIPE | $75.0 |
| **Total PF Cash [3]** | **$318.4** |

**Summary**

| | Shares (mm) | $ mm |
|---|---|---|
| Pardes | 32.50 | $325.0 |
| SPAC | 25.76 | $257.6 |
| PIPE | 7.50 | $75.0 |
| **Post-Money** | **65.76** | **$657.6** |

(1) As of April 30, 2021.
(2) Assuming no redemptions from FSII shareholders.
(3) Excludes PIPE financing, M&A transaction and deferred IPO fees.

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EXECUTIVE SUMMARY

## Pardes Biosciences

- Pardes Biosciences was founded to help put an end to the COVID-19 pandemic and prevent the next one
- Leadership team with deep experience in antiviral drug development and commercialization
- Tunable reversible covalent warhead platform enables both novel designs and efficient intellectual property
- Lead program (PBI-0451): Oral coronavirus protease inhibitor with potential for treatment and prophylaxis
  - Discovered in < 9 months
  - Highly potent across multiple in-vitro models
  - Well tolerated to date in GLP tox studies
  - Anticipated FIH data 2H 2021; potential for Phase 2/3 registrational study start 1H 2022
  - Potential multibillion dollar global opportunity
- Additional early programs in pipeline

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# Experienced Executive 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

## Scientific Advisory Board

**Mike Varney, PhD**

**Robert Zamboni, PhD**

**Carol Brosgart, MD**

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# The "Old Normal" = Life with the "Common Cold"

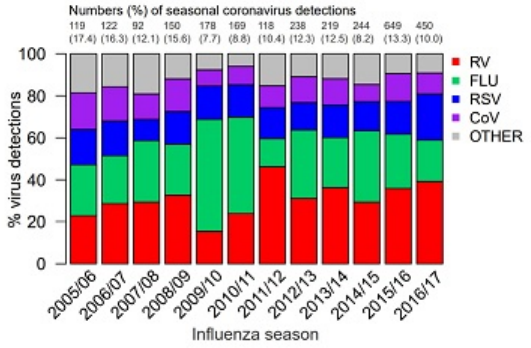
## That Which Didn't Kill You, Cost $$$

In 2001 the estimated direct economic burden (US alone) of symptomatic, non-influenza viral respiratory infections (VRIs) = **$17B/year**[1]

- Medical Services ($7.7B)
- Complications such as asthma ($4.8B)
- OTC Medications ($2.9B)
- Symptomatic Treatments ($400M)
- Antibiotics (> $1.1B)

Indirect costs (missed work, childcare, eldercare, etc.) increase economic burden further

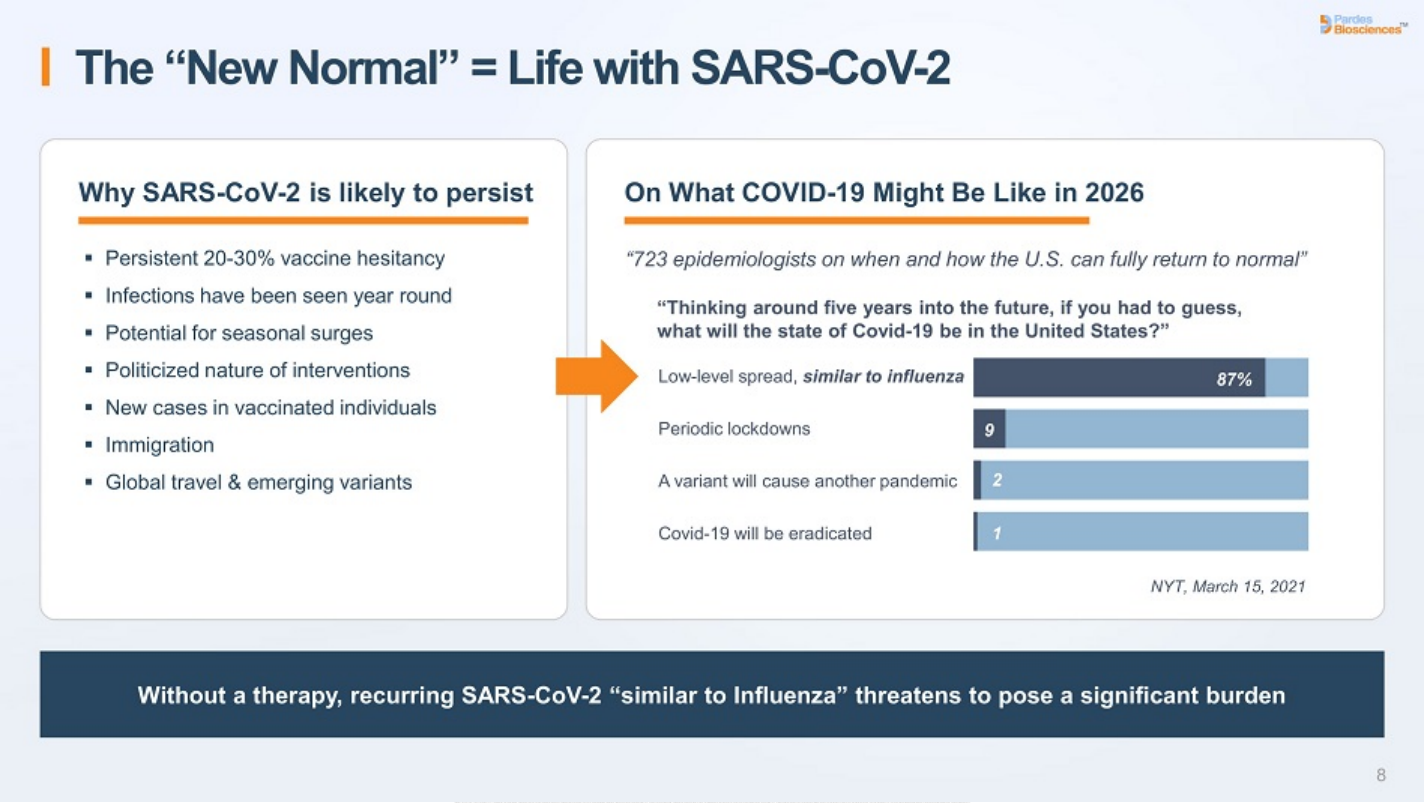
Increase in mortality is also seen: Adult hospitalized patients with non-influenza respiratory viruses detected found higher population-based incidence, significantly more ICU admissions, and higher in-house mortality (2017-2019, NYC)[2]

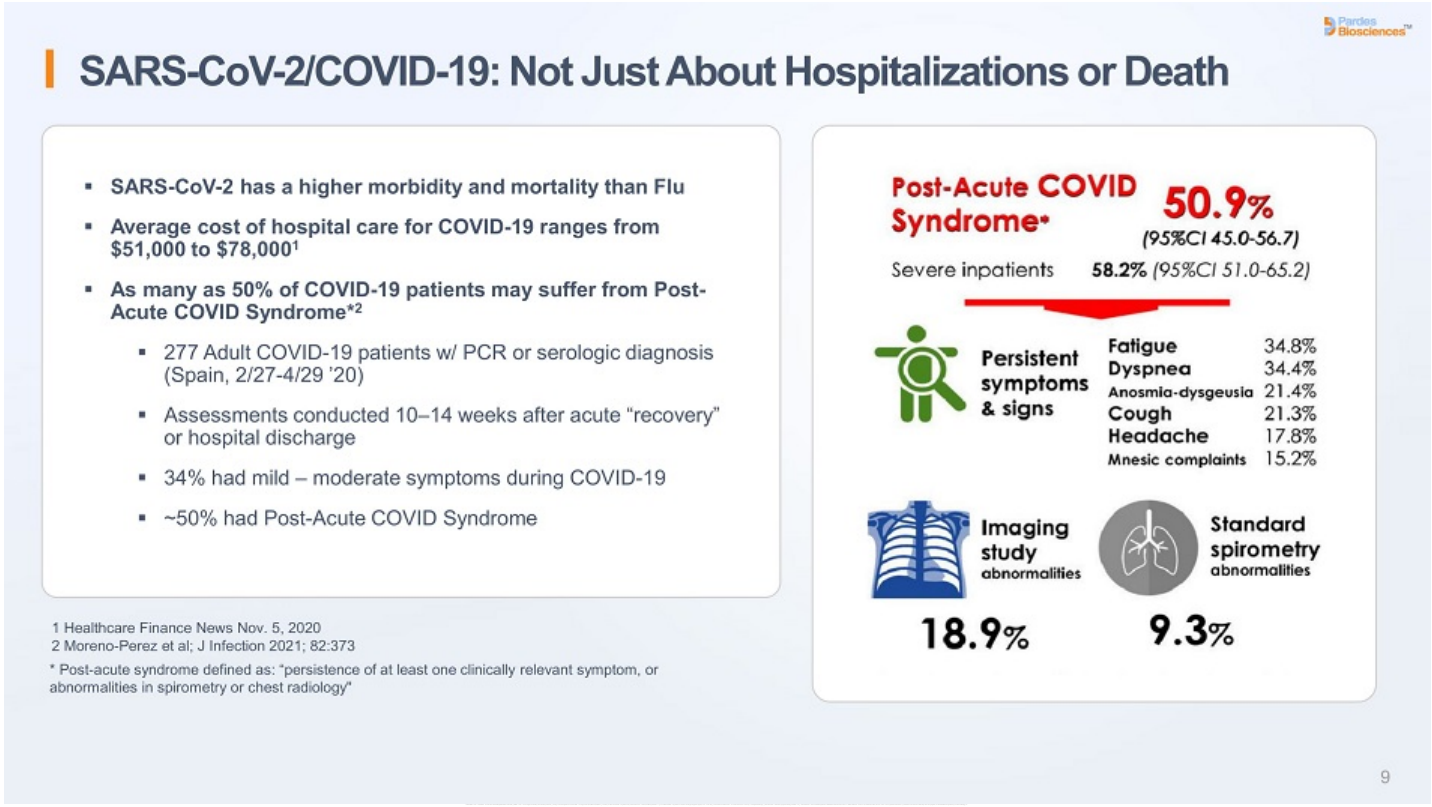


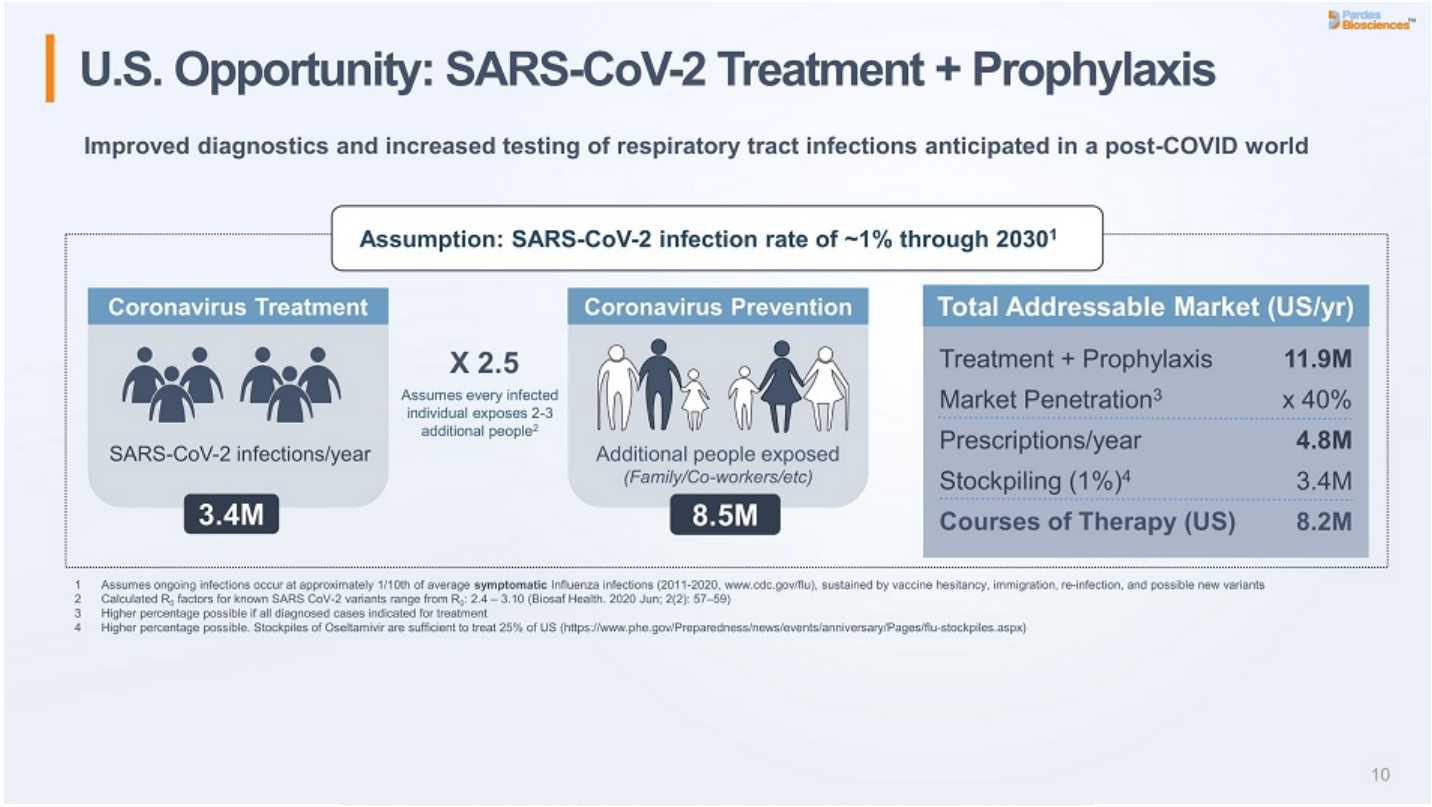

JID 2020:222 (1 July) • Nickbakhsh et al

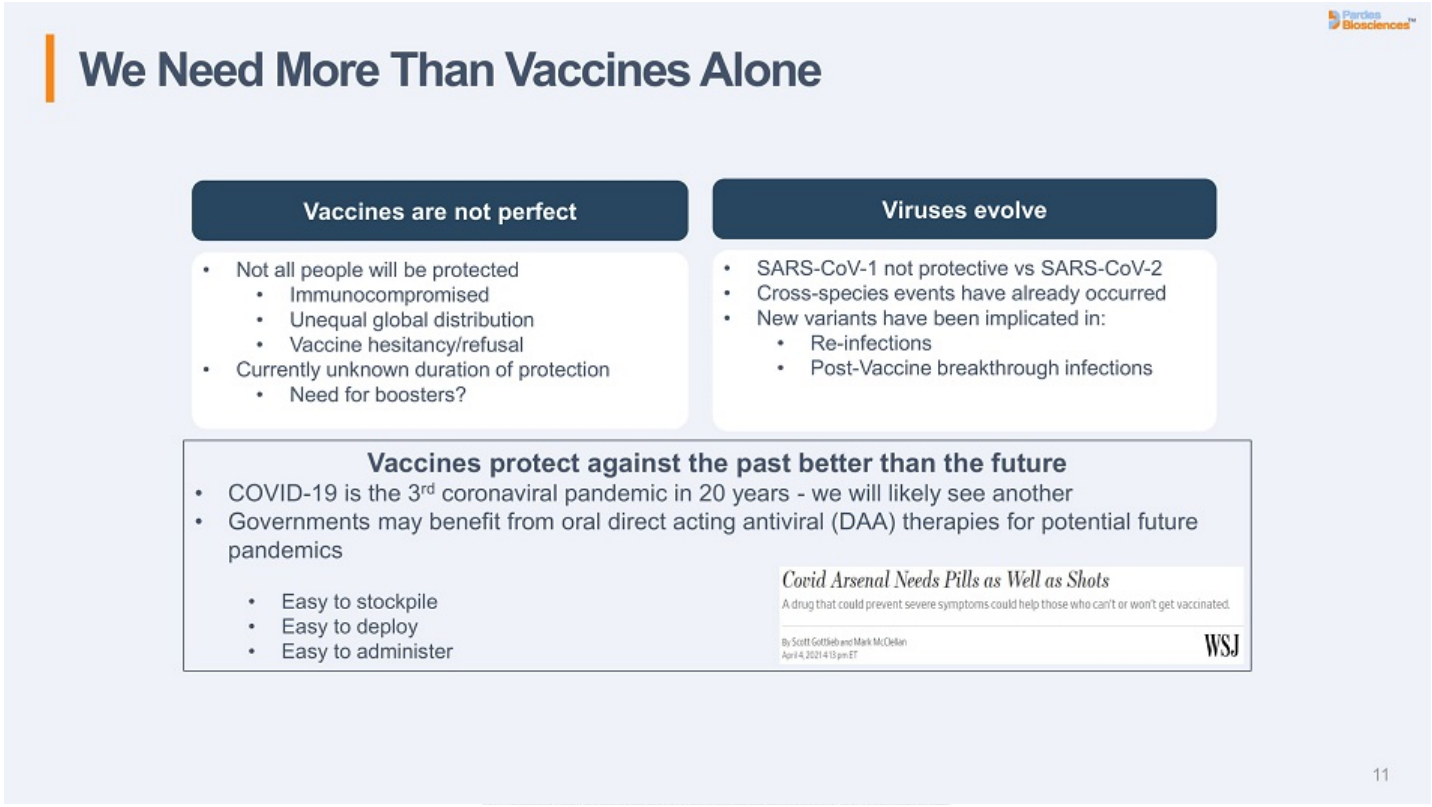
1 Arch Intern Med 2003;163:487-494
2 Influenza Other Respiratory Viruses. 2021;00:1–8.

7


Pardes Biosciences
The "New Normal" = Life with SARS-CoV-2
Why SARS-CoV-2 is likely to persist
Persistent 20-30% vaccine hesitancy
Infections have been seen year round
Potential for seasonal surges
Politicized nature of interventions
New cases in vaccinated individuals
Immigration
Global travel & emerging variants
On What COVID-19 Might Be Like in 2026
"723 epidemiologists on when and how the U.S. can fully return to normal"
"Thinking around five years into the future, if you had to guess, what will the state of Covid-19 be in the United States?"
Low-level spread, similar to influenza
87%
Periodic lockdowns
9
A variant will cause another pandemic
2
Covid-19 will be eradicated
1
NYT, March 15, 2021
Without a therapy, recurring SARS-CoV-2 "similar to Influenza" threatens to pose a significant burden
8


Pardes Biosciences™
SARS-CoV-2/COVID-19: Not Just About Hospitalizations or Death
SARS-CoV-2 has a higher morbidity and mortality than Flu
Average cost of hospital care for COVID-19 ranges from $51,000 to $78,000[1]
As many as 50% of COVID-19 patients may suffer from Post-Acute COVID Syndrome*[2]
277 Adult COVID-19 patients w/ PCR or serologic diagnosis (Spain, 2/27-4/29 '20)
Assessments conducted 10–14 weeks after acute "recovery" or hospital discharge
34% had mild – moderate symptoms during COVID-19
~50% had Post-Acute COVID Syndrome
1 Healthcare Finance News Nov. 5, 2020
2 Moreno-Perez et al; J Infection 2021; 82:373
* Post-acute syndrome defined as: "persistence of at least one clinically relevant symptom, or abnormalities in spirometry or chest radiology"
Post-Acute COVID Syndrome*
50.9%
(95%CI 45.0-56.7)
Severe inpatients
58.2% (95%CI 51.0-65.2)
Persistent symptoms & signs
Fatigue 34.8%
Dyspnea 34.4%
Anosmia-dysgeusia 21.4%
Cough 21.3%
Headache 17.8%
Mnesic complaints 15.2%
Imaging study abnormalities
18.9%
Standard spirometry abnormalities
9.3%
9


Pardes Biosciences
U.S. Opportunity: SARS-CoV-2 Treatment + Prophylaxis
Improved diagnostics and increased testing of respiratory tract infections anticipated in a post-COVID world
Assumption: SARS-CoV-2 infection rate of ~1% through 2030[1]
Coronavirus Treatment
SARS-CoV-2 infections/year
3.4M
X 2.5
Assumes every infected individual exposes 2-3 additional people[2]
Coronavirus Prevention
Additional people exposed
(Family/Co-workers/etc)
8.5M
Total Addressable Market (US/yr)
Treatment + Prophylaxis 11.9M
Market Penetration[3] x 40%
Prescriptions/year 4.8M
Stockpiling (1%)[4] 3.4M
Courses of Therapy (US) 8.2M
1 Assumes ongoing infections occur at approximately 1/10th of average symptomatic Influenza infections (2011-2020, www.cdc.gov/flu), sustained by vaccine hesitancy, immigration, re-infection, and possible new variants
2 Calculated $R_0$ factors for known SARS CoV-2 variants range from $R_0$: 2.4 – 3.10 (Biosaf Health. 2020 Jun; 2(2): 57–59)
3 Higher percentage possible if all diagnosed cases indicated for treatment
4 Higher percentage possible. Stockpiles of Oseltamivir are sufficient to treat 25% of US (https://www.phe.gov/Preparedness/news/events/anniversary/Pages/flu-stockpiles.aspx)
10


Perdeo Biosciences
We Need More Than Vaccines Alone
Vaccines are not perfect
• Not all people will be protected
• Immunocompromised
• Unequal global distribution
• Vaccine hesitancy/refusal
• Currently unknown duration of protection
• Need for boosters?
Viruses evolve
• SARS-CoV-1 not protective vs SARS-CoV-2
• Cross-species events have already occurred
• New variants have been implicated in:
• Re-infections
• Post-Vaccine breakthrough infections
Vaccines protect against the past better than the future
• COVID-19 is the 3rd coronaviral pandemic in 20 years - we will likely see another
• Governments may benefit from oral direct acting antiviral (DAA) therapies for potential future pandemics
• Easy to stockpile
• Easy to deploy
• Easy to administer
Covid Arsenal Needs Pills as Well as Shots
A drug that could prevent severe symptoms could help those who can't or won't get vaccinated.
By Scott Gottlieb and Mark McClellan
April 4, 2021 4:13 pm ET
WSJ
11

# COVID Arsenal: Why Viral Protease Inhibitors are Needed

| Attributes[1] | Vaccines | Antibodies | Polymerase Inhibitors | Protease Inhibitors |
|---|---|---|---|---|
| **Potential for oral formulation** | *No* | *No* | *Some** | ✓ |
| **Inhibition of multiple parts of viral lifecycle** | -- | *No* | *No* | ✓ |
| **High barrier to resistance** | *TBD* | *Not to date* | *Likely* | ✓ |
| **Potential for outpatient (home) use** | *No (Clinic only)* | *No (Clinic only)* | ✓ | ✓ |
| **Potential pre/post exposure prophylaxis** | *Pre – if enough lead time* | ✓ | ✓ | ✓ |
| **Low costs (manufacture, storage, distribution, delivery)** | *Variable* | *No* | ✓ | ✓ |
| **Potential pan-coronavirus inhibition** | *Unknown* | *Unknown* | *Likely* | ✓ |

1 Table reflects Pardes' assessment of current and potential treatments

*Remdesivir = IV

Protease inhibitors are beginning to enter the clinic this year

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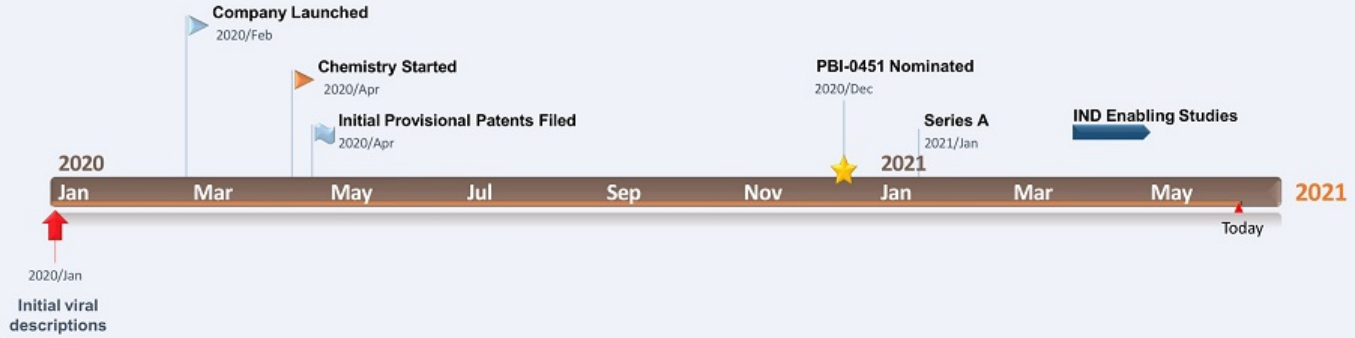
# Rapid Progress: Inception-to-date

## Concept → Development Candidate in <9 Months




## Clinical Urgency + Experienced Drug Hunters + Enabling Chemistry Platform = Speed

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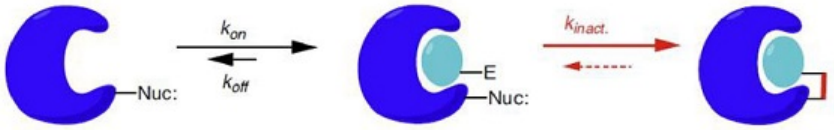
# Pardes' Platform: Tunable, Reversible Covalent Chemistry

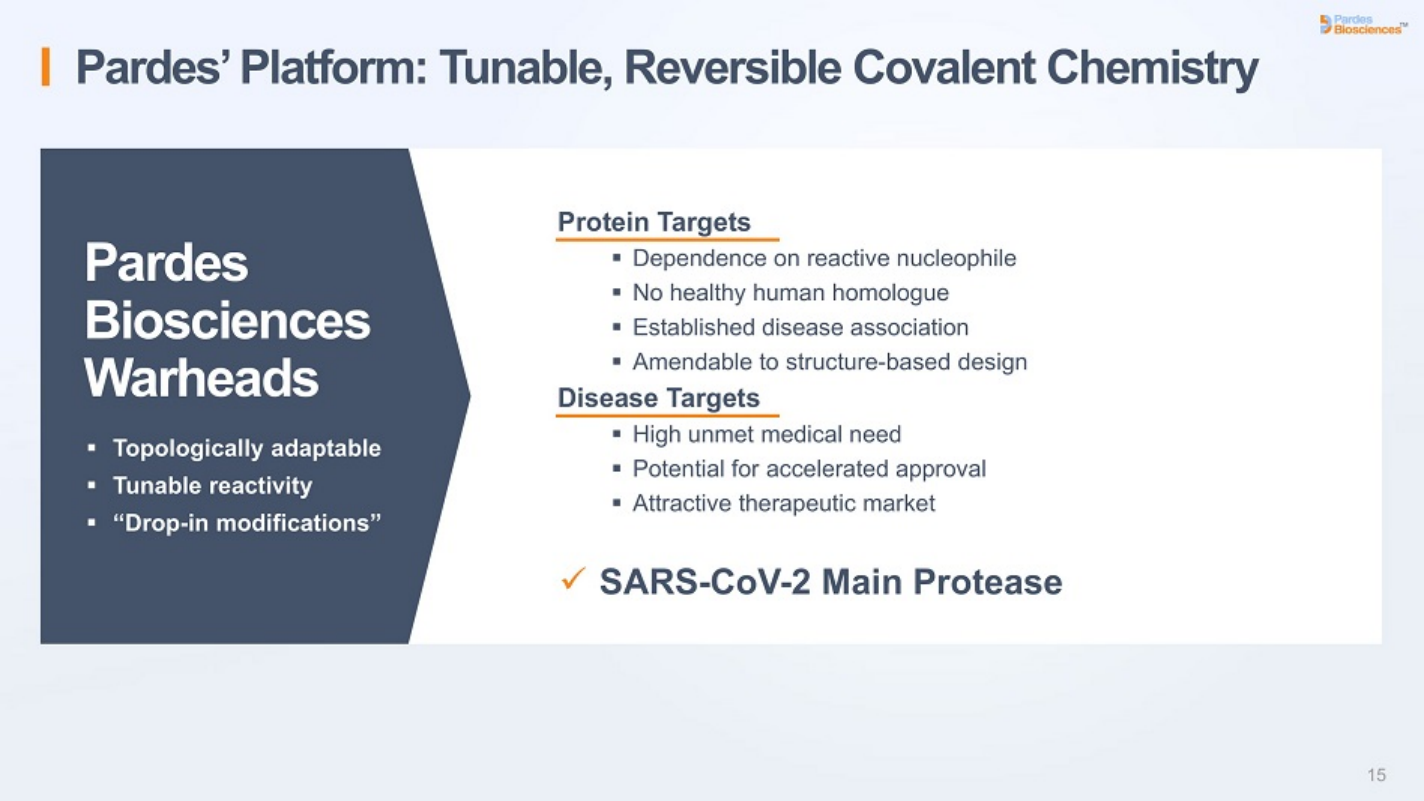
## Pardes Biosciences Warheads

- Topologically adaptable
- Tunable reactivity
- "Drop-in modifications"

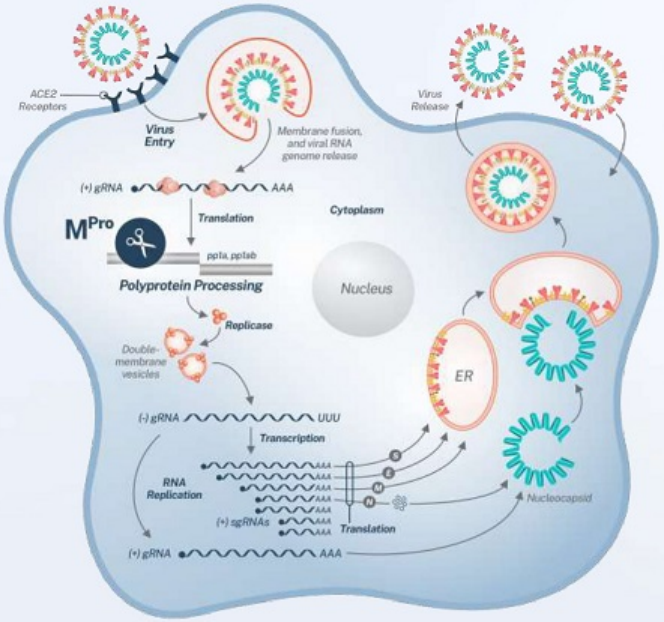



Nuc = Reactive nucleophile E = Electrophilic "trap"

14


Pardes Biosciences™
Pardes' Platform: Tunable, Reversible Covalent Chemistry
Pardes Biosciences Warheads
▪ Topologically adaptable
▪ Tunable reactivity
▪ "Drop-in modifications"
Protein Targets
▪ Dependence on reactive nucleophile
▪ No healthy human homologue
▪ Established disease association
▪ Amendable to structure-based design
Disease Targets
▪ High unmet medical need
▪ Potential for accelerated approval
▪ Attractive therapeutic market
✓ SARS-CoV-2 Main Protease
15

# Viral Main Protease ($M^{pro}$): A Promising Pan-Coronavirus Target[1-3]




- $M^{pro}$ activity required early in viral lifecycle
- No homologous human protease
- $M^{pro}$ is required for every known coronavirus
- $M^{pro}$ is highly conserved to date (unlike viral spike)

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

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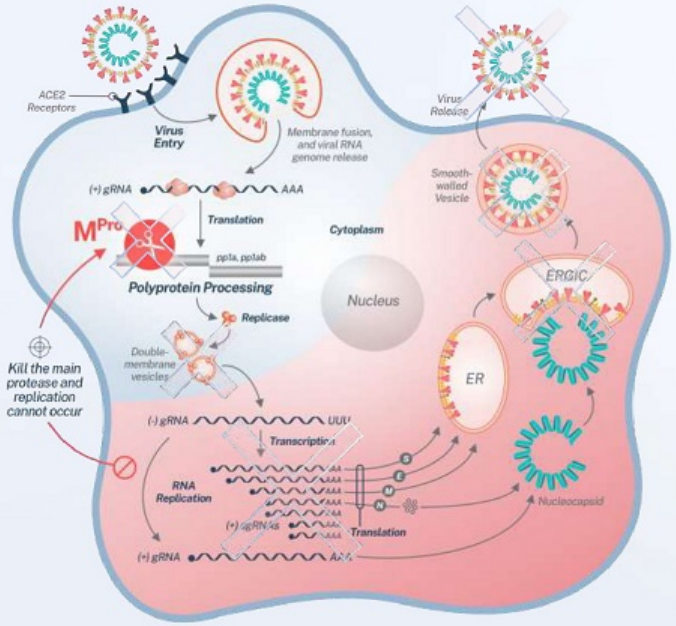
# Viral Main Protease ($M^{pro}$): A Promising Pan-Coronavirus Target




**Break the protease → Break the virus**

- $M^{pro}$ activity required early in viral lifecycle
- No homologous human protease
- $M^{pro}$ is required for every known coronavirus
- $M^{pro}$ is highly conserved to date (unlike viral spike)

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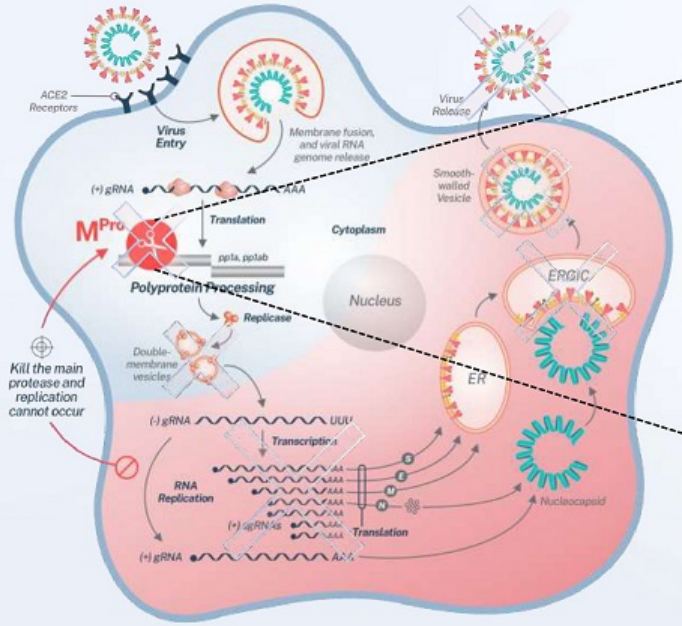
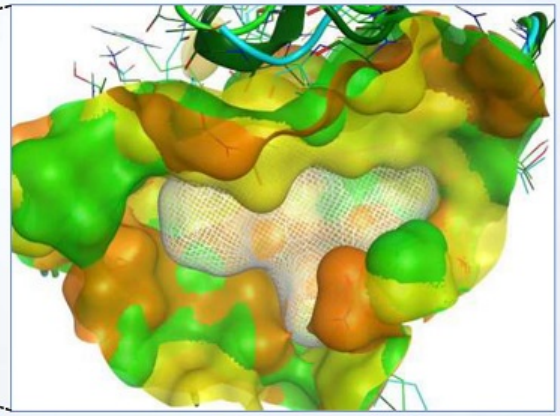
# The Viral Main Protease (Mpro) is a Cysteine Protease




## Highly Conserved Viral Cysteine Protease



(SARS-CoV-2, SARS, MERS, HKU1, OC43, NL63, 229E)*

*pathogenic coronavirus known to infect humans

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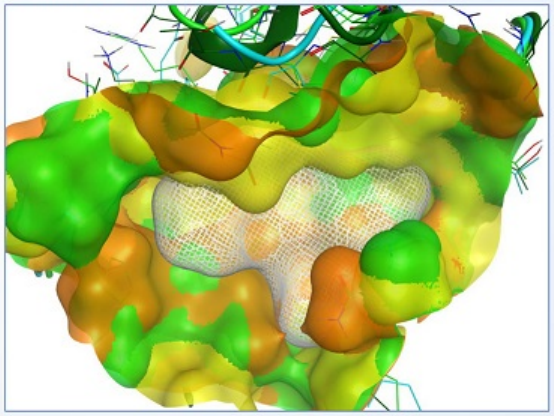
# Potent Inhibition of Coronaviral $M^{pro}$ in Biochemical Assays (*In Vitro*)

| Coronavirus $M^{pro}$ | PBI-0451 Activity vs Protease $IC_{50}$ (μM) |
|---|---|
| **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 – 0.2 |
| CoV-HKU1 | 0.07 - 0.13 |
| CoV-NL63 | 0.24 - 0.37 |

**Highly Conserved Viral Cysteine Protease**



(SARS-CoV-2, SARS, MERS, HKU1, OC43, NL63, 229E)

1. IC50 = Concentration at which 50% of maximal (inhibitory) effect is seen in a biochemical assay. Lower numbers = better (the lower the number, the more potent the compound).

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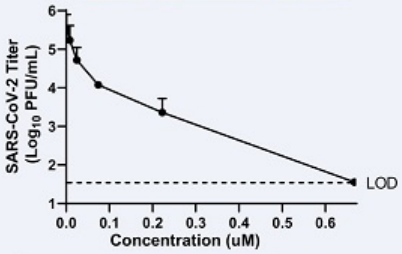
# Potent Inhibition of SARS-CoV-2 Replication in Cell-Based Assays

- ✓ Activity across **all coronaviruses** tested to date
  - Potent inhibition seen in both biochemical and cell-based assays against all coronaviruses tested
  - **Low nM $EC_{50}$** v. SARS-CoV-2-WA in A549-ACE2 lung cell line and ip-Alveolar type II (iAT2) lung cells
    - We are targeting exposures of > 10x our EC50s for our PK studies

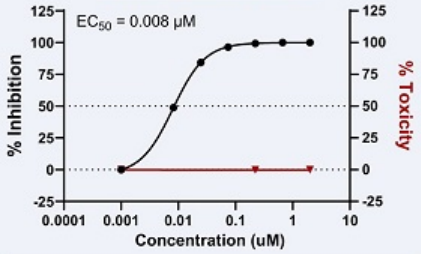
**Cell Culture Model:**
Human alveolar type II (iAT2) pneumocytes infected with SAR-CoV2 and treated with PBI-0451

Potency (Absolute Decline)




Multi log declines in viral shedding

Potency (% Max Effect)




50% of maximal effect seen at 8nM

VANDERBILT UNIVERSITY MEDICAL CENTER

Pruijssers, George, unpublished

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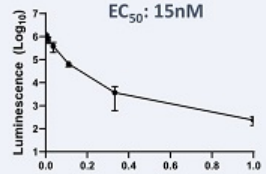
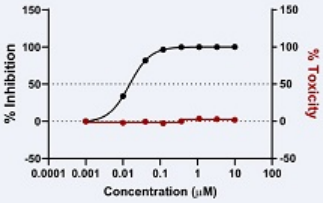
# PBI-0451 Potency Compares Favorably v Competition[1]

**Pardes Bio** | **Approved & in trials for COVID-19**

## PBI-0451[2]

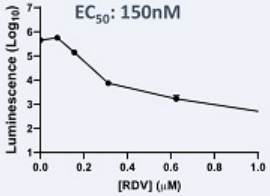
$EC_{50}$: 15nM

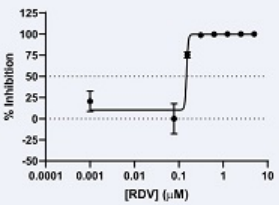



## Remdesivir[2,3]

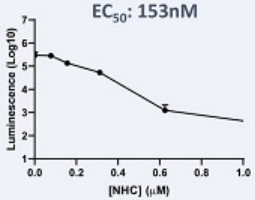
$EC_{50}$: 150nM

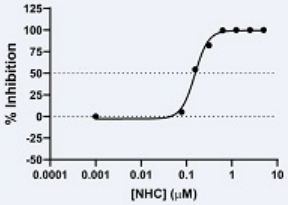



## NHC[2,3]

$EC_{50}$: 153nM

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*Pruijssers, George, unpublished*

1. Data shown from cross-study comparisons; studies run at different times in same lab, using same A549-cellular infection model and coronavirus reporter system
2. PBI-0451, Remdesivir and NHC (N4-hydroxycytidine, the active form of Molnupiravir) treatment of cells occurred post infection
3. Remdesivir purchased from MedChem Express; NHC, provided by Emory Inst of Drug Development

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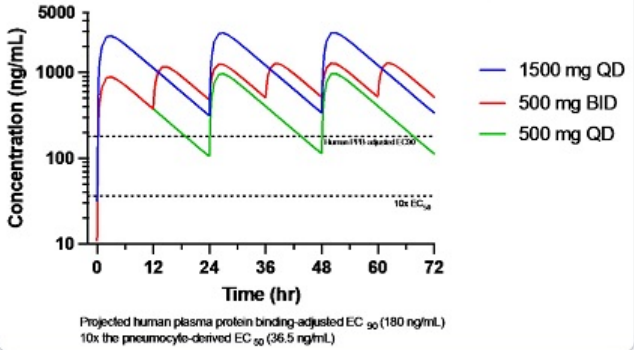
# PBI-0451: Potential for Favorable Pharmacokinetics

- ✓ Oral bioavailability observed across mice, rats, dogs and monkeys
- ✓ Similar plasma and lung exposure observed
- ✓ Allometric model suggests potential for BID or QD dosing interval

## Allometric Human PK Model:

- Allometric human PK modeling based on PK data from mice, rats, dogs and monkeys
- Long half-life projected (6.5 hr – 16hr)
- Potential to achieve target exposures at clinically acceptable doses and dosing frequencies

## Projected Human PK Profiles




Projected human plasma protein binding-adjusted $EC_{90}$ (180 ng/mL)
10x the pneumocyte-derived $EC_{50}$ (36.5 ng/mL)

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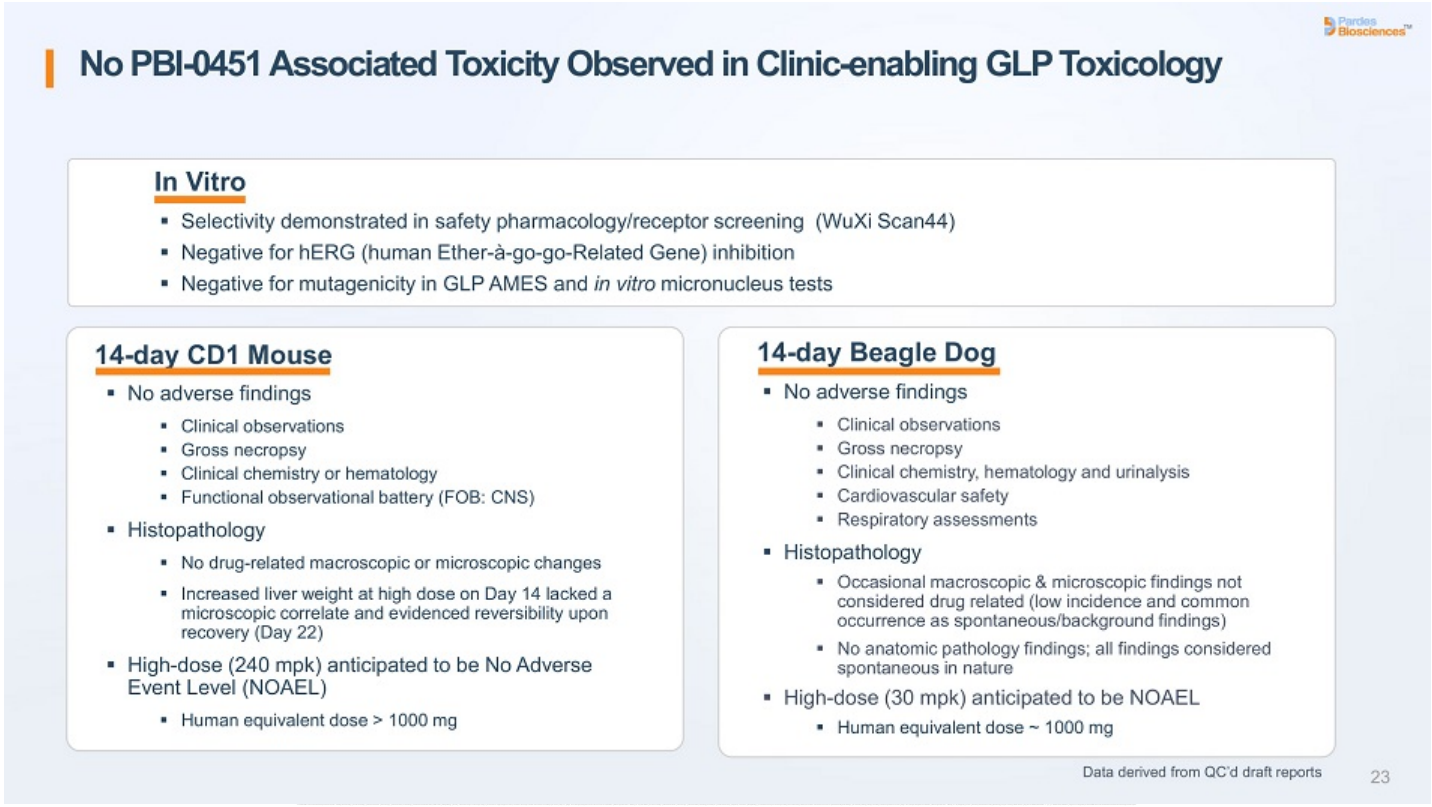
Pardes Biosciences™
No PBI-0451 Associated Toxicity Observed in Clinic-enabling GLP Toxicology
In Vitro
Selectivity demonstrated in safety pharmacology/receptor screening (WuXi Scan44)
Negative for hERG (human Ether-à-go-go-Related Gene) inhibition
Negative for mutagenicity in GLP AMES and in vitro micronucleus tests
14-day CD1 Mouse
No adverse findings
Clinical observations
Gross necropsy
Clinical chemistry or hematology
Functional observational battery (FOB: CNS)
Histopathology
No drug-related macroscopic or microscopic changes
Increased liver weight at high dose on Day 14 lacked a microscopic correlate and evidenced reversibility upon recovery (Day 22)
High-dose (240 mpk) anticipated to be No Adverse Event Level (NOAEL)
Human equivalent dose > 1000 mg
14-day Beagle Dog
No adverse findings
Clinical observations
Gross necropsy
Clinical chemistry, hematology and urinalysis
Cardiovascular safety
Respiratory assessments
Histopathology
Occasional macroscopic & microscopic findings not considered drug related (low incidence and common occurrence as spontaneous/background findings)
No anatomic pathology findings; all findings considered spontaneous in nature
High-dose (30 mpk) anticipated to be NOAEL
Human equivalent dose ~ 1000 mg
Data derived from QC'd draft reports
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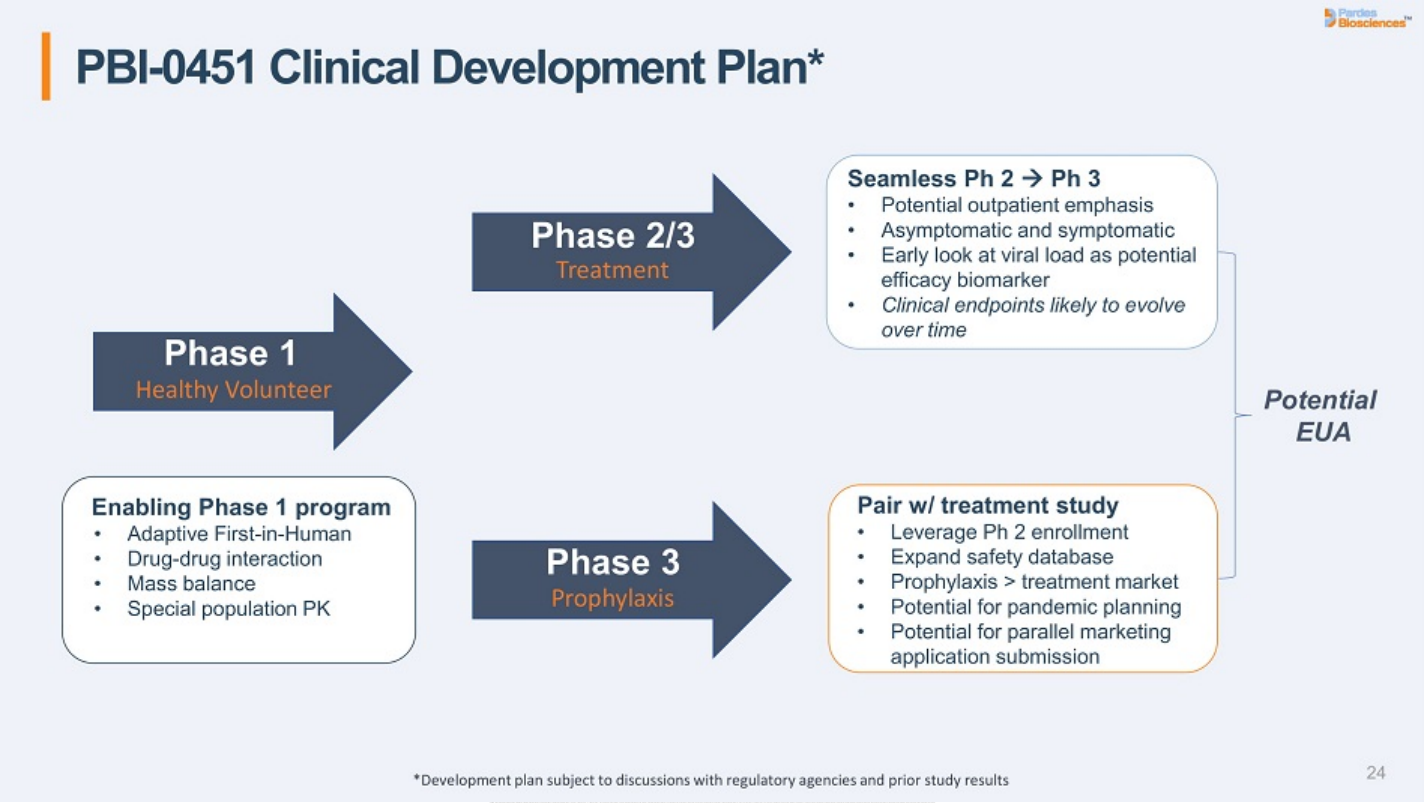
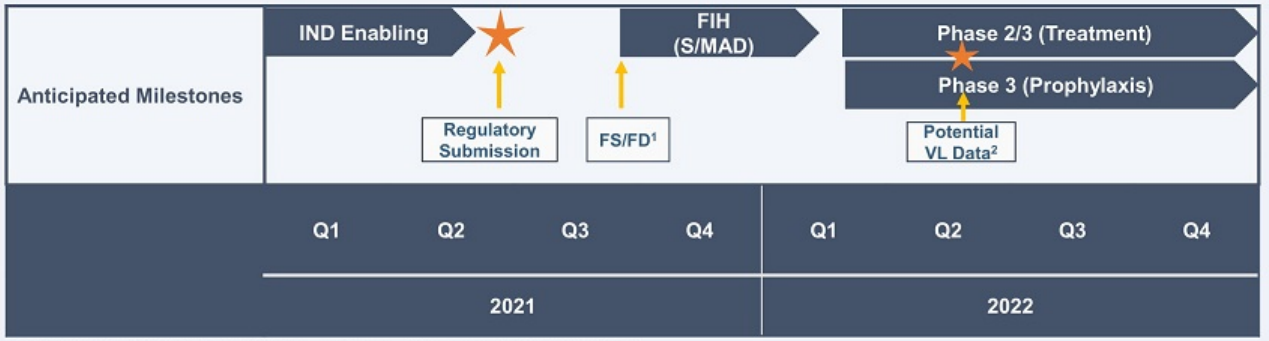

Parion Biosciences
PBI-0451 Clinical Development Plan*
Phase 1
Healthy Volunteer
Enabling Phase 1 program
• Adaptive First-in-Human
• Drug-drug interaction
• Mass balance
• Special population PK
Phase 2/3
Treatment
Seamless Ph 2 → Ph 3
• Potential outpatient emphasis
• Asymptomatic and symptomatic
• Early look at viral load as potential efficacy biomarker
• Clinical endpoints likely to evolve over time
Phase 3
Prophylaxis
Pair w/ treatment study
• Leverage Ph 2 enrollment
• Expand safety database
• Prophylaxis > treatment market
• Potential for pandemic planning
• Potential for parallel marketing application submission
Potential EUA
*Development plan subject to discussions with regulatory agencies and prior study results
24

# PBI-0451: Anticipated Timing and Milestones




1) FS/FD = Projected First Subject/First Dose, pending regulatory approvals; 2) VL = Viral Load

- Phase 2/3 studies (Treatment and Prophylaxis) planned as adaptive studies, with potential for early (Ph 2) evaluation within first few hundred patients
- Study designs and endpoints subject to discussion with, and approval by, regulatory agencies

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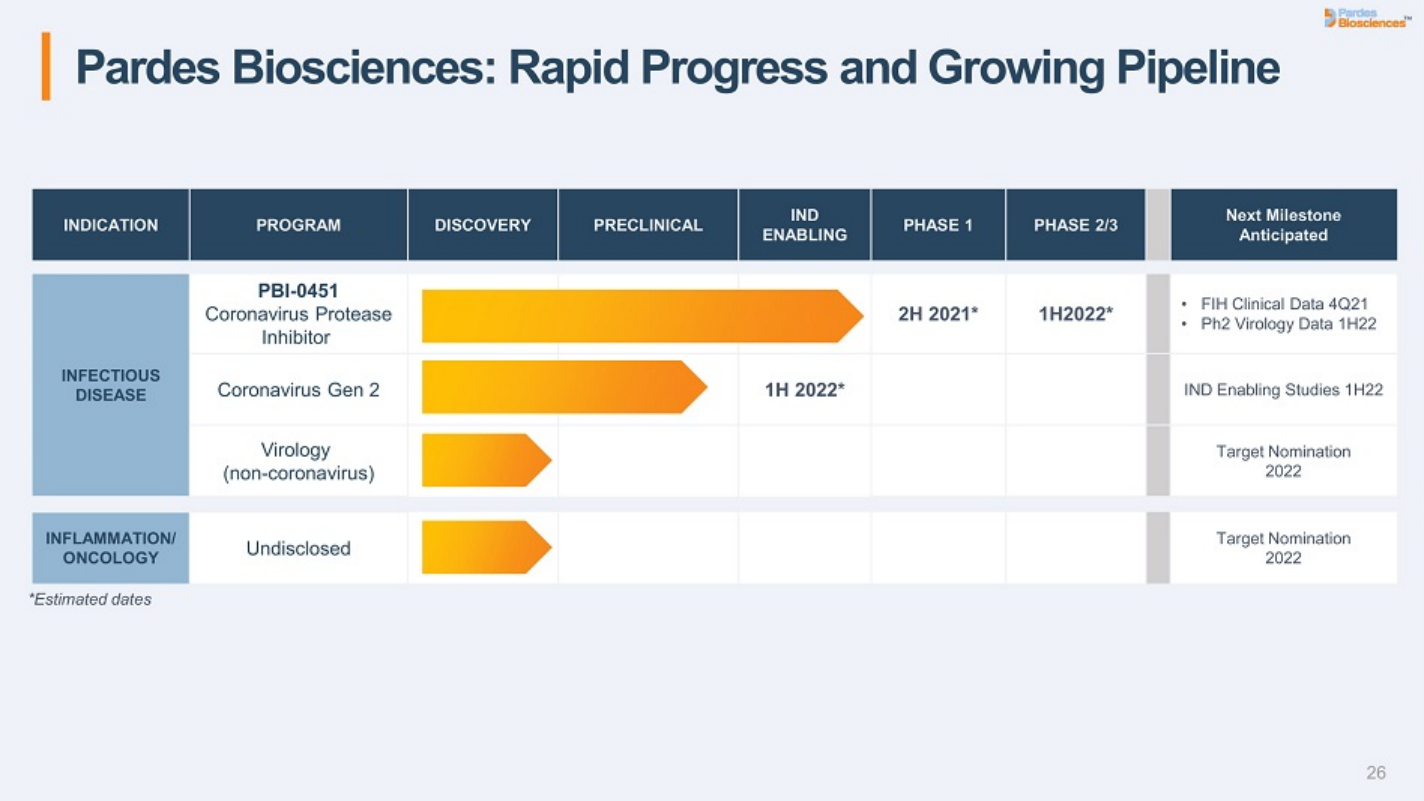
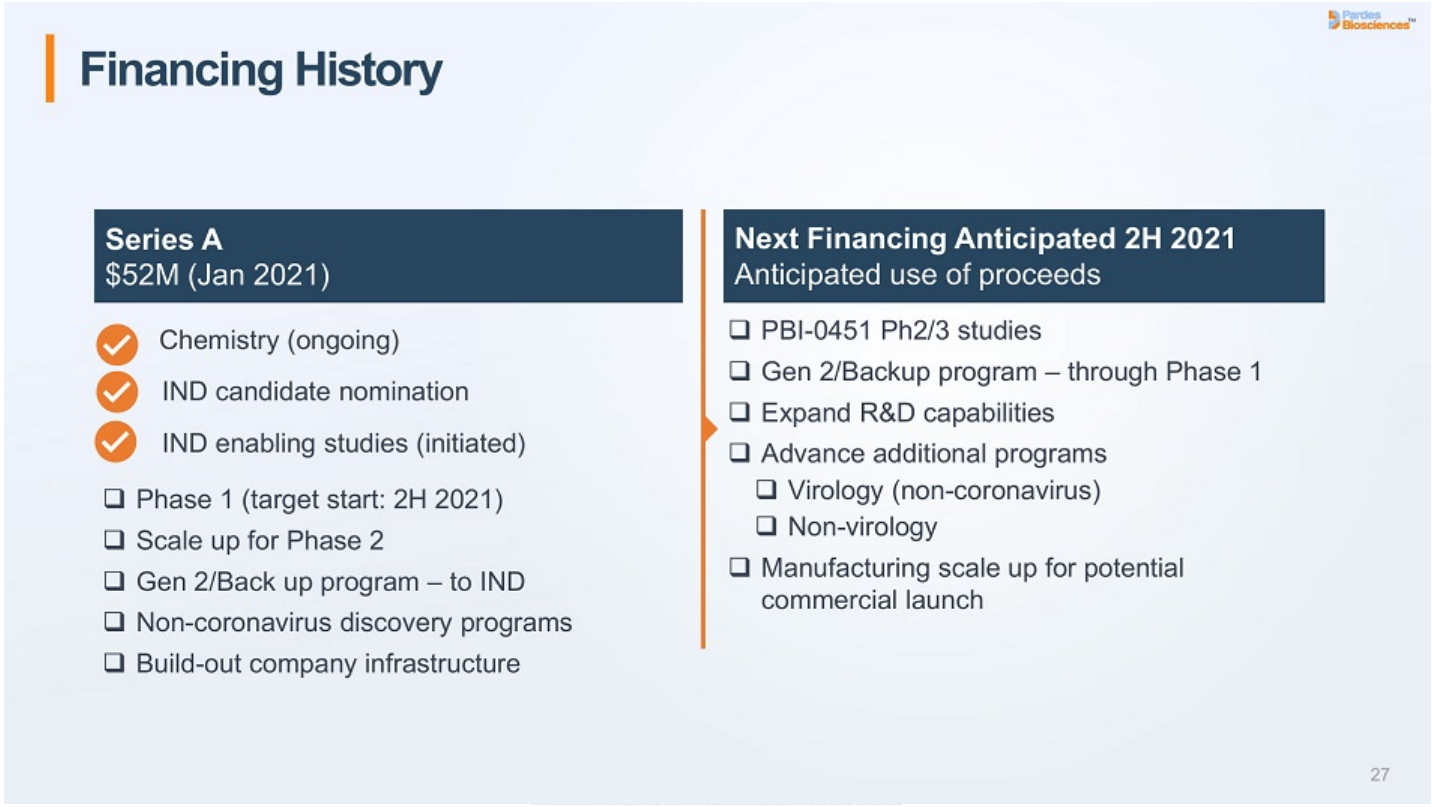

Pardes Biosciences: Rapid Progress and Growing Pipeline
INDICATION
PROGRAM
DISCOVERY
PRECLINICAL
IND ENABLING
PHASE 1
PHASE 2/3
Next Milestone Anticipated
INFECTIOUS DISEASE
PBI-0451 Coronavirus Protease Inhibitor
2H 2021*
1H2022*
• FIH Clinical Data 4Q21
• Ph2 Virology Data 1H22
Coronavirus Gen 2
1H 2022*
IND Enabling Studies 1H22
Virology (non-coronavirus)
Target Nomination 2022
INFLAMMATION/ ONCOLOGY
Undisclosed
Target Nomination 2022
*Estimated dates
26


Financing History
Series A
$52M (Jan 2021)
Chemistry (ongoing)
IND candidate nomination
IND enabling studies (initiated)
Phase 1 (target start: 2H 2021)
Scale up for Phase 2
Gen 2/Back up program – to IND
Non-coronavirus discovery programs
Build-out company infrastructure
Next Financing Anticipated 2H 2021
Anticipated use of proceeds
PBI-0451 Ph2/3 studies
Gen 2/Backup program – through Phase 1
Expand R&D capabilities
Advance additional programs
Virology (non-coronavirus)
Non-virology
Manufacturing scale up for potential commercial launch
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Risk Factors
Pardes Biosciences
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# Risk Factors

**Certain Risks Related to Pardes Biosciences**

*All references to "Pardes Biosciences," "we," "us," "our" or the "Company" refer to the business of Pardes Biosciences, Inc. and its affiliates. The risks presented below are certain of the general risks related to the business of the Company, and such list is not exhaustive. The list below has been prepared solely for purposes of the private placement transaction, and solely for potential private placement investors, and not for any other purpose. Accordingly, the list below is qualified in its entirety by disclosures contained in future documents filed or furnished with the United States Securities and Exchange Commission ("SEC"), including the documents filed or furnished by the Company and/or the special purpose acquisition company (the "SPAC") in connection with the proposed business transaction. The risks presented in such filings will be consistent with those that would be required for a public company in their SEC filings, including with respect to the business and securities of the Company and the SPAC and the proposed business transaction between the Company and the SPAC, and may differ significantly from and be more extensive than those presented below.*

- There is significant uncertainty around our development of PBI-0451 as a potential treatment for SARS-CoV-2.
- We may expend resources in anticipation of potential clinical trials and commercialization of PBI-0451, which we may not be able to recover if PBI-0451 is not approved for the treatment of SARS-CoV-2 or we are not successful at commercializing PBI-0451.
- The market for therapeutics for the treatment of SARS-CoV-2 may be reduced, perhaps significantly, if uptake of vaccines that are effective in providing immunity continues to increase and vaccine induced protection persists.
- The SARS-CoV-2 pandemic continues to rapidly evolve and may materially and adversely affect our other business opportunities and financial results.
- Our business is highly dependent on the success of our most advanced product candidate, PBI-0451. If this product candidate fails in preclinical or clinical development, does not receive regulatory approval or is not successfully commercialized, or is significantly delayed in doing so, our business will be harmed.
- We may not be successful in our efforts to identify and successfully develop additional product candidates.
- Interim, topline and preliminary data from our clinical 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.
- We cannot predict the effect that health care reform and other changes in government programs may have on our business, financial condition or results of operations.
- We are highly dependent on our management, directors and other key personnel and we must attract and retain highly qualified scientist, clinical, quality control, medical, scientific and other technical personnel in order to execute our business plan.

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# Risk Factors

- If certain of our suppliers do not meet our needs, if there are material price increases on clinical supplies, it could negatively impact our ability to effectively develop our product candidates and could have a material adverse effect on our business, results of operations and financial condition.
- If we are unable to protect the confidentiality of our trade secrets, know-how and other proprietary and internally developed information, the value of our technology could be adversely affected.
- Risks related to intellectual property may materially and adversely affect our business and financial results, including if we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.
- If any of our product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, including any product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates, our development plans and business would be materially harmed.
- Any negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, including better than expected performance of control arms, such as placebo groups, may result in a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program, which could materially delay our growth plan and significantly increase our expenses.
- If we experience delays in enrolling subjects in clinical trials or high drop-out rates of subjects from clinical trials, this may lead to delays in obtaining results from our trials on expected timelines, increases to our expenses and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of the Company to decline and limit our ability to obtain additional financing if needed.
- Any delays in submitting an Investigational New Drug application, or IND, or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced, could delay our growth plan and result in the loss of market opportunities.
- If there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates, our expenses could increase beyond our expectations and we may lose certain market opportunities.

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## Risk Factors

- Any changes required to manufacturing methods and formulation to optimize processes and results as product candidates proceed through preclinical studies to late-stage clinical trials may also require additional testing, FDA notification or FDA approval, which could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.
- We currently plan to conduct clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.
- The FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials or with our interpretation of data from clinical trials or preclinical studies, which could delay or jeopardize governmental approval of our product candidates.
- Delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular, will delay the development and commercialization of our product candidates and result in increased costs to our business.
- If we fail to perform our clinical trials in accordance with contractual requirements, government regulations and ethical considerations, we could be subject to significant costs or liability and our reputation could be adversely affected.
- Any failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner will result in delays to our programs and increase in costs.
- Actual or perceived failures to comply with applicable data protection, privacy and security, advertising and consumer protection laws, regulations, standards and other requirements could adversely affect our business, financial condition and results of operations.
- We depend on our information technology systems, and those of our third-party vendors, contractors and consultants, and any failure or significant disruptions of these systems, security breaches or loss of data could materially adversely affect our business, financial condition and results of operations.

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## Risk Factors

- We could be adversely affected by increases in the cost to procure materials to develop our product candidates.
- If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, our business, financial condition, and results of operations could be materially adversely affected.
- Even if we complete the necessary preclinical studies and clinical trials for a product candidate, the marketing approval process, which is subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries, is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.
- Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community.
- Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful.
- If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.
- We are subject to extensive governmental regulation that may give rise to federal and state audits, investigations, lawsuits and claims against us, the outcome of which may have a material adverse effect on our business, financial condition, cash flows, or results of operations.
- We are subject to federal, state and local laws and regulations that govern our employment practices, including minimum wage, living wage, and paid time-off requirements. Failure to comply with these laws and regulations, or changes to these laws and regulations that increase our employment related expenses, could adversely impact our operations.
- Product liability lawsuits against us, which are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products, could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates.

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## Risk Factors

- We have a history of net losses, we anticipate increasing expenses in the future, and we may not be able to achieve or maintain profitability.
- Each of the SPAC and the Company will incur significant transaction costs in connection with the Business Combination.
- If the benefits of the Business Combination do not meet the expectations of investors or securities analysts, the market price of our securities may decline.
- A market for the combined company's securities may not develop, which would adversely affect the liquidity and price of such securities.
- Financial projections with respect to the Company may not prove to be reflective of actual future results.
- The Business Combination is subject to conditions, including certain conditions that may not be satisfied on a timely basis, if at all.
- The Company will incur significant costs and obligations as a result of being a public company.
- Provisions in our charter and Delaware law may inhibit a takeover of us, which could limit the price investors might be willing to pay in the future for our common stock.
- Our charter will provide, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.
- Our charter will renounce any interest or expectancy that we have in certain corporate opportunities that may be presented to our officers, directors or stockholders or their respective affiliates, other than those officers, directors, stockholders or affiliates who are our or our subsidiaries' employees. As a result, these persons will not be required to offer certain business opportunities to us and may engage in business activities that compete with us.

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Thank You
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