Pardes Biosciences™

2022 Annual Report

April 20, 2023

Dear Pardes Biosciences Stockholders,

2022 was a significant year at Pardes Biosciences, one that I was delighted to be a part of in my role as CEO and Chair of the Board of Directors. I have been inspired by the creativity, innovation, and tireless dedication exhibited by every member of the Pardes team in pursuing our shared vision: to tackle pandemic-sized problems head-on. I am honored to serve in this role, and I want to thank each employee, partner, study participant, and stockholder for their work, contributions to, and support of our mission.

Pardes was founded in 2020 with the belief that pandemics could be prevented. We began by addressing the most urgent public health crisis faced in decades: COVID-19. Through the diligent work by our entire team as well as the support from you, our stockholders, we advanced our novel antiviral pomotrelvir (formerly known as PBI-0451) from discovery stage through a Phase 2 clinical trial in three years, an achievement of which we are quite proud.

Based on the clinical evidence generated through pre-clinical and Phase 1 clinical trials, we believed very strongly in the potential of pomotrelvir as a standalone, potent oral antiviral that could fill a crucial gap in the current landscape of treatment options for COVID-19, a disease that has had, and continues to have, devastating effects across the globe.

Unfortunately, recent results from our Phase 2 trial have led us to the difficult decision to suspend further development of this program and explore a range of strategic alternatives to best maximize company value for you, our stockholders. While we know this is a disappointing development, we continue to believe in the need for a stand-alone COVID antiviral with the utility to address a broader range of patients, and I am deeply proud of the work done at Pardes to get us to this point and our shared pursuit of this goal. We are deeply grateful to all the participants and investigators involved in our clinical trials for their participation and support.

Our focus going forward will be centered around best capitalizing on our assets and the value we have created to date and exploring a range of options including, but not limited to, acquisition, merger, business combination, divestiture of assets, or other transaction that may maximize our value.

I want to conclude by thanking each of our stockholders for their belief in us, our science, and most importantly, our mission to help patients everywhere get better sooner. We very much appreciate your trust and support as we diligently evaluate the next steps for Pardes and our goal to maximize value on your behalf.

Sincerely,

Thomas G. Wiggans
Chief Executive Officer and
Chair of the Board of Directors of Pardes Biosciences

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, 2022

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 001-40067

PARDES BIOSCIENCES, INC.

(Exact name of registrant as specified in its Charter)

Delaware	**85-2696306**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2173 Salk Avenue, Suite 250 PMB#052 Carlsbad, CA	**92008**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 649-8758

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	**PRDS**	**The Nasdaq Stock Market, LLC**

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 was approximately $114.5 million as of June 30, 2022, based on the closing price of $3.07 as reported on The Nasdaq Global Market on such date. Shares of the registrant's common stock held by executive officers, directors, and their affiliates have been excluded from this calculation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of registrant's common stock outstanding as of March 10, 2023 was 61,716,745.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2023 Annual Meeting of Stockholders (the 2023 Proxy Statement), which will be filed with the Securities and Exchange Commission (SEC) not later than 120 days after December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K. With the exception of the portions of the 2023 Proxy Statement expressly incorporated into this Annual Report on Form 10-K by reference, the 2023 Proxy Statement shall not be deemed filed as part of this Form 10-K.

Auditor Firm ID: 185 Auditor Name: KPMG LLP Auditor Location: Irvine, California, USA

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Form 10-K) for Pardes Biosciences, Inc. (we, us, our or Pardes) contains forward-looking statements, which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions, or strategies regarding the future, including those relating to the success, cost and timing of our product development activities and clinical trials, the potential attributes and benefits of our product candidates, our ability to obtain and maintain regulatory approval for our product candidates and our ability to obtain funding for our operations. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

Forward-looking statements relating to us in this Form 10-K include, but are not limited to, statements about:

- the impact of the COVID-19 pandemic on our operations, financial results and liquidity and capital resources, including due to the pandemic's impact on our research and development activities, clinical trials and employees;
- the ability of our clinical trials to demonstrate acceptable safety and efficacy of our product candidates, including pomotrelvir (formerly known as PBI-0451), our lead product candidate, and other positive results;
- the timing, progress and results of clinical trials for pomotrelvir and completion of studies or trials and related preparatory work;
- the period during which the results of the clinical trials will become available and the anticipated timing for public announcement of such results;
- the initiation, timing, progress, results and costs of our research and development programs and our current and future preclinical studies, nonclinical studies and clinical trials;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- the timing, scope and likelihood of regulatory filings;
- our ability to obtain emergency use authorization or marketing approval of pomotrelvir and any future product candidates on expected timelines and to meet existing or future regulatory standards or comply with post-authorization or post-approval requirements;
- our expectations regarding the potential market size, government stockpiling and the size of the patient populations for our product candidates, if approved for commercial use;
- the performance of third parties in connection with the development of our product candidates, including third-party suppliers and manufacturers;
- our intellectual property position and expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our expected future growth;
- our estimates regarding expenses, future financial performance and capital requirements;
- the impact of government laws and regulations in the United States and foreign countries;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- developments and expectations regarding our industry;
- the impact of macroeconomic conditions, including inflation, rising interest rates and volatile market conditions, and global events; and
- other risks and uncertainties indicated in this Form 10-K, including those under "*Risk Factors*" herein, and other filings that have been made or will be made with the SEC.

These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking

statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements.

In addition, statements that we "believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Form 10-K, and while we believe that such information forms a reasonable basis for such statements, such information may be limited or incomplete, and these statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

The risks and uncertainties include, but are not limited to, those factors described under the heading "*Risk Factors*" in this Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by changes in the COVID-19 pandemic (including declines in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections), and there may be additional risks that we currently consider immaterial or which are unknown. It is not possible to predict or identify all such risks. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

RISK FACTORS SUMMARY

Our business is subject to many risks and uncertainties, which may affect our future performance. If any of these risks and uncertainties described in the section titled "Risk Factors" in Part I, Item 1A of this Form 10-K occur, our business, financial condition and results of operations could be materially and adversely affected and the market value of our stock could decline. You should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors" in Part I, Item 1A of this Form 10-K. Set forth below is a summary list of the principal risk factors as of the date of the filing this Form 10-K:

- We are heavily dependent on the success of pomotrelvir (formerly called PBI-0451), our lead product candidate. If we are required to discontinue development of pomotrelvir or if pomotrelvir does not receive regulatory approval or fails to be successfully commercialized or achieve significant market acceptance, we would be substantially delayed in our ability to achieve profitability, if ever.
- We have a limited operating history and no history of successfully developing or commercializing any approved therapeutic products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability and ability to generate revenue and become profitable in the future.
- We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of pomotrelvir or any other product candidates.
- We are subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our product candidates. These manufacturing risks are heightened while we are reliant upon a single CMO for our drug product manufacturing. Any delay or interruption in our clinical supplies or, if approved, our commercial product could harm our business, operating results, prospects and financial condition.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us. If our competitors develop and market products faster or that are more effective, safer, better tolerated, or less expensive than the product candidates we develop, our ability to obtain any future funding for our development and manufacturing efforts or to ultimately commercialize a therapy for COVID-19 will be negatively impacted.
- SARS-CoV-2 continues to mutate and evolve resulting in new variants of concern globally. Some of these variants may be resistant to current and new treatments. Accordingly, there is significant uncertainty around the development of pomotrelvir as a potential treatment for coronavirus generally, and SARS-CoV-2 infections and COVID-19 specifically.
- COVID-19 continues to cause morbidity and mortality globally; however, the number of infections and the morbidity associated with those infections fluctuates significantly. As a result, we may find enrollment of patients for clinical trials to be a challenge and/or may find that the severity of disease declines over time such that it becomes challenging to enroll the number of patients required to demonstrate statistically significant improvements in endpoints. If enrollment is delayed or takes longer than expected, this could delay or prevent the collection of data sufficient to meet our endpoints and seek authorization or marketing approval.
- The regulatory pathways for our product candidates targeting COVID-19 are continually evolving, which may result in unexpected or unforeseen challenges and longer timelines than seen for earlier COVID-19 vaccines and therapeutics.
- Pomotrelvir and any other product candidates we may develop must undergo rigorous clinical trials and regulatory approvals, and results from early nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.
- Our subsequent clinical trials may reveal significant adverse events not seen in our earlier clinical trials or preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- We must attract and retain highly skilled employees to succeed. If we are not able to attract and retain key clinical, scientific, technical and management personnel, our business may materially suffer.
- Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies. Proprietary rights and technology are difficult and costly to protect, and we may not be able to ensure their protection.
- We contract with third parties for the manufacture of our product candidates for nonclinical and clinical testing and expect to continue to do so for subsequent clinical trials and for commercialization. Significant portions of our clinical manufacturing are currently conducted by third-party manufacturers outside of the United States, including China. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or that such supply will not be available to us at an acceptable cost and in accordance with anticipated timelines, which could delay, prevent or impair our development or commercialization efforts.

- We may seek to establish collaborations and if we are not able to establish them on a timely basis, on acceptable terms, or at all, we may have to delay, alter or curtail our development and commercialization plans.
- The price of our common stock has been and may continue to be volatile.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company that is focused on discovering, developing and commercializing novel therapeutics to treat and prevent viral diseases and on preventing the next pandemic, starting with our lead candidate, pomotrelvir (formerly known as PBI-0451), which targets the current coronavirus disease (coronavirus disease 2019 or COVID-19). Pomotrelvir is in clinical development to treat COVID-19 in adult and pediatric patients. COVID-19 is caused by infection with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and has emerged as the most significant pandemic threat to the world in many decades. We have completed enrollment of patients in our Phase 2 clinical trial (NCT 05543707) evaluating pomotrelvir for the treatment of COVID-19 in non-hospitalized symptomatic adults with COVID-19 who are not at increased risk of progressing to severe illness. We expect to report top-line data from this Phase 2 clinical trial in the coming weeks.

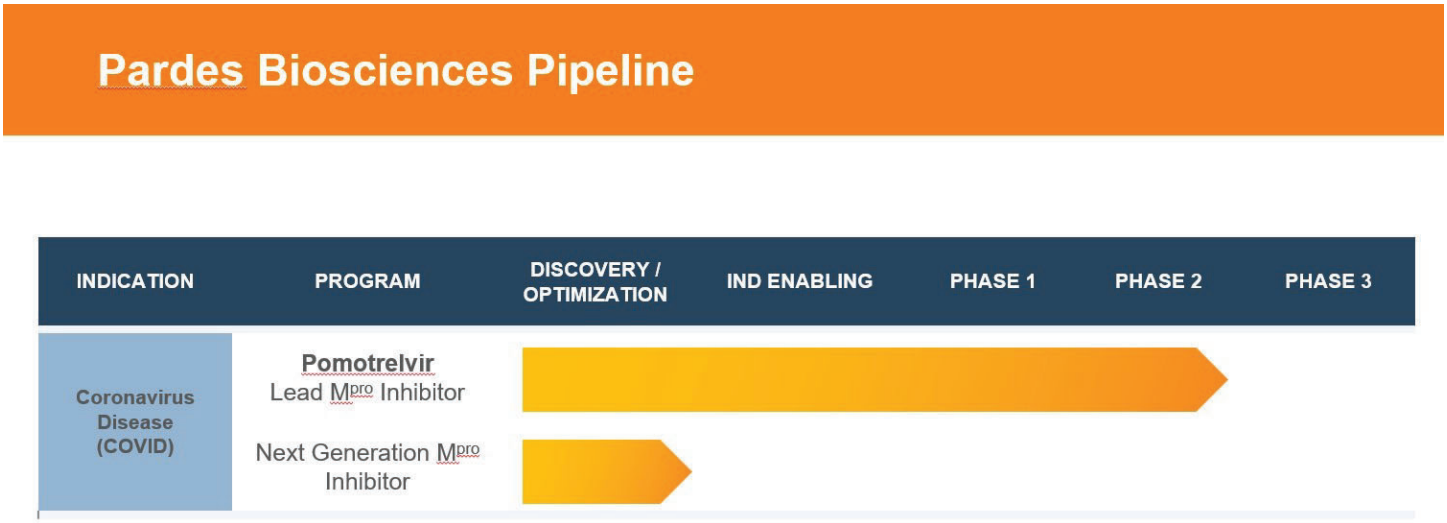
Our Strategy

By leveraging our understanding of structure-based drug design, reversible covalent chemistry and viral biology, we have discovered and are developing novel product candidates with low nanomolar potency against SARS-CoV-2 and broad activity against all known pathogenic human coronaviruses. Initially, our goal is to become a global leader in the discovery, development and commercialization of novel therapies for the treatment and prevention of COVID-19. We anticipate expanding our discovery and development efforts beyond COVID-19 to other viral diseases. To achieve our goals, we intend to:

- Complete nonclinical and clinical development and seek approval for our lead product candidate, pomotrelvir, an investigational, orally administered direct acting antiviral (DAA) drug.
- Expand our pipeline by developing additional highly selective, orally administered drug candidates against coronavirus disease and other viral diseases, as resources permit.
- Maximize the value of our product candidates.

Our Research and Development Pipeline

The following table summarizes our current product development pipeline:



Our COVID-19 Program

Our lead product candidate, pomotrelvir, inhibits the main coronaviral cysteine protease (M^{pro}), a viral protein essential for replication of all known coronaviruses, including SARS-CoV-2. In preclinical studies, pomotrelvir has demonstrated activity against all coronaviral proteases tested to date and inhibition of replication of multiple coronaviruses, including all SARS-CoV-2 clinical isolates tested to date, including Omicron variants. Moreover, in preclinical studies, pomotrelvir demonstrated the potential for oral bioavailability across multiple preclinical species and more recently, oral bioavailability in healthy volunteers in our Phase 1 clinical trials. We believe the antiviral potency seen against SARS-CoV-2 in preclinical in vitro studies and demonstrated oral bioavailability in humans supports its potential to be an oral DAA for use against COVID-19.

Background and Overview of SARS-CoV-2 and COVID-19

SARS-CoV-2 is the virus that causes COVID-19, the respiratory illness responsible for the COVID-19 pandemic. SARS-CoV-2 is the seventh known coronavirus to infect people, after 229E, NL63, OC43, HKU1, MERS-CoV, and SARS-CoV. Most people infected with the virus experience mild to moderate respiratory illness and recover over time. However, some patients will have more severe symptoms requiring hospitalization and may experience death or severe life-threatening complications, including pneumonia, or acute respiratory distress syndrome, which may trigger a systemic multi-organ collapse. Older people and those with underlying medical conditions like cardiovascular disease, diabetes, chronic respiratory disease, or cancer are more likely to develop serious illness. There are also many patients who experience continuing effects, or Post-Acute Sequelae of COVID-19 (PASC), often referred to as "long COVID," and there still is little known about the enduring effects of the disease. While the U.S. government has recently announced plans to end the declaration of a public health emergency associated with COVID-19, the COVID-19 pandemic persists. As of February 28, 2023, the World Health Organization (WHO) estimated that there have been over 758 million reported cases of people infected with SARS-CoV-2 worldwide, resulting in over 6.8 million deaths and there are more than 69 thousand new cases daily. By many estimates, the actual number of infections likely far exceeds the reported cases, especially as the prevalence of unreported rapid testing modalities have increased globally. While several newly developed vaccines are now available, uptake has not been optimal due to a number of factors. In addition, breakthrough infections and re-infections are occurring regularly due to the continued emergence of new immune-evasive SARS-CoV-2 variants and because available vaccines are not effective at preventing long-term infection or transmission. With the continuing prevalence of COVID-19 globally, there is heightened risk of new variants that could further evade the protection that is afforded by the current vaccines, resulting in increased incidences of serious illness, hospitalizations and deaths. Thus, there remains an urgent need for effective and safe oral antiviral treatments.

Scientific Background

Viruses are cellular parasites that can only replicate using a host cell's replication processes, as viruses lack the machinery required to reproduce on their own. Viruses have two primary components: nucleic acid (comprised of either RNA, which can be single or double stranded, or DNA) and a protective protein shell. The viral infection process begins when a virus attaches itself to a specific receptor site on the host-cell membrane through attachment proteins. After attachment, viral nucleic acid is released into the cell, initiating the viral replication process through production of viral components, co-opting the host cellular machinery. Our understanding of how viruses infect cells, replicate and spread within the body has resulted in multiple drug development approaches, including inhibition of viral entry into cells, viral gene replication and viral particle formation. We believe the most effective method for treating and preventing coronaviral infections is to use small molecule DAAs to target viral encoded proteases to inhibit their function. Historically, this approach has led to highly potent and clinically successful antivirals for the treatment of other viruses such as human immunodeficiency virus, and hepatitis C virus.

The coronaviral genome is one of the largest RNA-viral genomes known to date. There are four different structural proteins encoded by the SARS-CoV-2 RNA: spike protein, envelope protein, membrane glycoprotein and nucleocapsid protein. The infection cycle begins when the spike proteins bind to the cellular angiotensin-converting enzyme 2 (ACE2) receptor on the surface of the target cells. A second cell surface protein, transmembrane serine protease 2 (TMPRSS2) enables the virion to enter the cell, where it releases its RNA encoding the proteins required for replication.

Coronaviruses encode two cysteine proteases, which are enzymes that break down, or cleave, proteins into smaller pieces and are essential for viral replication: M^{pro}, which is also called 3C-like protease (3CLpro), and papain-like cysteine protease (PL^{pro}). M^{pro} cleaves at 11 sites in the viral polyprotein, which is required for creating 16 separate, non-structural proteins that constitute the structural complex that enables replication of the SARS-CoV-2 virus, and PL^{pro} cleaves three other sites within the viral polyprotein as well as multiple host proteins.

The highly conserved nature of the coronaviral M^{pro} and its indispensable role early in the viral life cycle, has suggested that M^{pro} could be a potent target for oral pan-coronaviral therapies. Moreover, humans do not have a homologous protease, which makes M^{pro} attractive as a virus specific target of particular interest for the design of anti-SARS-CoV-2 therapies.

Pomotrelvir Nonclinical Information

In vitro activity against human coronaviruses

Pomotrelvir has demonstrated broad activity against the M^{pro} from 229E, NL63, HKU1, MERS-CoV, SARS-CoV and OC43. Pomotrelvir also retains similarly potent activity against the M^{pro} of tested Omicron variants as that of the parental SARS-CoV-2. This is consistent with pomotrelvir's interactions with the conserved elements of the M^{pro} binding pocket. Antiviral activity of pomotrelvir against the protease of known human pathogenic coronaviruses is summarized in the table below.

Table 1: Biochemical activity of pomotrelvir against CoV M^{pro}

Coronavirus Mpro	Average IC50 (nM)*	Standard Deviation	N
SARS-CoV-2_WT	24	5	6
SARS-CoV-2_P132H (omicron)	34	10	6
SARS-CoV	45	17	8
MERS-CoV	379	106	8
CoV-229E	141	38	4
CoV-OC43	158	33	4
CoV-HKU1	61	29	8
CoV-NL63	206	84	8

* IC_{50} = 50% inhibitory concentration in a protease in vitro assay. The lower the IC_{50} number the more potent the compound is against the coronavirus enzyme tested.

The low nanomolar potency seen in the assays noted below, in combination with the lack of toxicity observed in the host cells treated with pomotrelvir in the absence of virus, supports the potential for potent and selective inhibition of SARS-CoV-2 in vivo.

Table 2: Cell culture activity of pomotrelvir[1]

SARS-CoV-2 Virus	Cell Line	Antiviral Assay	EC_{50} (nM)			EC_{90} (nM)		CC_{50} (nM)
			mean	SD	N	mean	SD	
WA1 (MOI 0.004)[2]	iPS-AT2	SARS-CoV-2 (PFU/ml)	32	29	4	106	103	>2,000
WA1 (MOI 0.004)[2]	iPS-AT2	SARS-CoV-2 (RNA copy/ml)	36	22	4	67	41	>2,000
Nluc (MOI 0.025)[2]	A549-ACE2	SARS-CoV-2 (nanoluciferase)	23	17	6	114	93	>10,000
Wuhan (MOI 0.001)	Vero E6 (+efflux inhibitor)	Cytopathic effect (GFP assay)	345	162	4	598	190	>10,000
B.1.1.529 Omicron (MOI 0.001)	Vero E6 (+efflux inhibitor)	Cytopathic effect (GFP assay)	200	138	4	410	316	>10,000
D614G B.1 ancestral (MOI 0.005)	A549-ACE2	Immunostaining of nucleocapsid	151	72	6	547	377	>100,000
BA.1.1 Omicron (MOI 0.005)	A549-ACE2	Immunostaining of nucleocapsid	94	4	2	213	23	>100,000
BA.2 Omicron (MOI 0.005)	A549-ACE2	Immunostaining of nucleocapsid	139	63	6	668	486	>100,000
BA.2.12.1 Omicron (MOI 0.005)	A549-ACE2	Immunostaining of nucleocapsid	60	2	2	171	10	>100,000
BA.4.1 Omicron (MOI 0.005)	A549-ACE2	Immunostaining of nucleocapsid	244	145	6	1120	768	>100,000
BA.5.2.1 Omicron (MOI 0.005)	A549-ACE2	Immunostaining of nucleocapsid	256	174	6	1270	1070	>100,000

[1]EC_{50}, half-maximal effective concentration; EC_{90}, 90% effective concentration; CC_{50}, half-maximal cytotoxic concentration; MOI, multiplicity of infection (PFU/cell); PFU, plaque-forming unit.
[2]Data generated at the laboratory of Mark Denison, Vanderbilt University Medical Center.

Results from inhibitor interaction studies that were performed demonstrated additivity between pomotrelvir and two nucleoside analogs, which is consistent with the fact that the two classes of inhibitors target different viral proteins (M^{pro} vs. viral polymerase) and supports the potential combination of pomotrelvir with viral polymerase inhibitors or nucleoside analogs, such as remdesivir and molnupiravir, in treating SARS-CoV-2 infections. However, enzymatic studies demonstrate that pomotrelvir and nirmatrelvir compete for the same binding site and suggest that co-administration of the two M^{pro} inhibitors is unlikely to offer additional improvement in efficacy.

Enzymatic characterization of in vitro selected pomotrelvir substitutions indicates that pomotrelvir has a high barrier to resistance as these M^{pro} substitutions either conferred no resistance or had a lower replication fitness, providing evidence that pomotrelvir may have a favorable resistance profile.

Nonclinical Pharmacology and Toxicology Information

Pomotrelvir was characterized for nonclinical pharmacokinetics, pharmacodynamics, and safety, including general toxicology and potential effects on specific organ systems. Pomotrelvir demonstrated oral bioavailability in all species tested to date and a favorable pharmacokinetic (PK) profile. Overall, in nonclinical animal studies, pomotrelvir was capable of achieving and maintaining concentrations above the in vitro (biochemical and cellular) inhibitory concentrations (IC_{50} and IC_{90}) against coronavirus proteases, including SARS-CoV-2, and has been observed to distribute into lung tissue. Single and multiple doses of pomotrelvir have been administered to animals at doses ranging from 0.5 to 1000 mg/kg/day.

In in vitro toxicology studies, we observed a lack of mutagenic or genotoxic potential, phototoxicity or teratogenicity. We have also conducted fertility, embryo fetal development, and pre-/post-natal development toxicology studies with pomotrelvir that have not identified drug-related adverse findings. No direct drug-related adverse findings were observed at the highest doses tested in 14-day or 28-day good laboratory practice (GLP) toxicology studies conducted across multiple preclinical species. Pomotrelvir does not require ritonavir boosting and we believe pomotrelvir has the potential to be used broadly by patients due to an observed favorable drug-drug interaction profile.

Clinical Development Program

Our development program initially intends to assess the use of pomotrelvir for the treatment of COVID-19. In January 2022, the United States Food and Drug Administration (FDA) cleared our Investigational New Drug (IND) application for pomotrelvir. In June 2022, the FDA designated the investigation of pomotrelvir for treatment and prevention of SARS-CoV-2 infection and associated diseases (i.e., COVID-19) as a fast track development program.

Phase 1 Clinical Trials

In March 2022, we completed our first-in-human, placebo-controlled, blinded, randomized, dose-escalation Phase 1 clinical trial (NCT 05011812) with pomotrelvir. The Phase 1 clinical trial assessed single and multiple ascending doses, food effect, formulation, and CYP3A4/P-glycoprotein drug drug-drug interactions. In that clinical trial, there were zero drug discontinuations and no drug-related grade 2, 3, 4 or serious adverse events (collectively, AEs) and no evidence of a relationship between dose/exposure and severity, relatedness or incidence of AEs. The most common AEs considered possibly related or probably related are gastrointestinal-related (abdominal bloating, decreased appetite, diarrhea, dyspepsia, flatulence, nausea) and headache; no AEs of dysgeusia were reported. No clinically significant treatment emergent adverse findings in laboratory values, vital signs or electrocardiogram assessments were reported. Pomotrelvir was well tolerated at doses up to 2100 mg/day for ten days.

Pomotrelvir demonstrated oral bioavailability in healthy volunteers in Phase 1 clinical trials.

Phase 2 Clinical Trial

In September 2022, we initiated our Phase 2 clinical trial (NCT 05543707) evaluating the antiviral activity, safety, and clinical efficacy of pomotrelvir for the treatment of mild-to-moderate COVID-19. This double-blind, randomized study enrolled approximately 251 patients at 63 sites within the United States and evaluated pomotrelvir compared with placebo in non-hospitalized, COVID-19 direct test positive, symptomatic, otherwise healthy adults from 18 to 65 years of age. Eligible participants were vaccinated against SARS-CoV-2 and did not have medical conditions associated with risk factors for progressing to severe illness. Participants were randomized 2:1 with pomotrelvir as compared to the matching placebo. The dosing regimen was 700 mg (2 x 350 mg tablets) administered orally twice daily (BID) (1400 mg/day) with food for five days (ten total doses). The use of concomitant medications for underlying health conditions was not restricted in this study. This Phase 2 study was powered to assess the primary objective of the proportion of patients below the limit of detection for infectious SARS-CoV-2 on day three of treatment by infectious virus assay from nasal swab samples. Secondary objectives assessed include additional virologic assessments including the dynamics and time to negativity in SARS-CoV-2 viral load by qRT-PCR and by rapid antigen testing, safety and tolerability, and clinical efficacy through assessment of COVID-19 symptoms, and hospitalizations and deaths through Day 28. Study participants will continue in long term follow-up for a total duration of 24 weeks to explore long term outcomes, including those associated with long COVID. This study is fully enrolled with all participants having completed assessments through Day 28. Top-line data from the Phase 2 clinical trial is expected in the coming weeks.

Potential Phase 3 Development

We are conducting pre-study start-up activities, including site feasibility, in parallel with continued discussions with the FDA and the European Medicines Agency (EMA) regarding our Phase 3 clinical development program for pomotrelvir, including specifics of clinical trial design to evaluate the safety and efficacy of pomotrelvir as compared to the matching placebo in otherwise healthy patients. We anticipate evaluating the impact of pomotrelvir on the time to the alleviation of key COVID-19 symptoms.

Initiation of the pomotrelvir Phase 3 clinical development program is subject to, among other things, positive Phase 2 results and alignment with applicable regulatory agencies, including the FDA. Currently, we plan to be in position to initiate our Phase 3 development program mid-2023.

Clinical Supplies

We have clinical supplies and matching placebos sufficient to initiate Phase 3 clinical development and have commenced a manufacturing campaign at a third-party contract manufacturing organization (CMO) to satisfy our anticipated remaining material requirements for our Phase 3 clinical development program. Additionally, we are engaged, through our CMO, in the optimization of the synthetic process and formulation for commercial scale manufacture of pomotrelvir should we be successful in clinical development.

Next Gen Coronavirus M^{pro} Inhibitor Program

We believe that developing a next generation pan-coronavirus clinical development candidate may be important as the current SARS-CoV-2 virus continues to evolve and also in helping to prepare for the next coronavirus pandemic. By leveraging our understanding of structure-based drug design, reversible covalent chemistry and viral biology, we have discovered additional novel pre-clinical next generation compounds with low nanomolar potency against SARS-CoV-2 and broad activity against all known pathogenic human coronaviruses. Selection of a potential next generation pan-coronavirus clinical development candidate will depend upon successful completion of nonclinical and IND-enabling studies.

Competition

As a biopharmaceutical company, we face competition from a wide array of companies, including both small and large organizations. Specifically, with respect to our coronavirus disease indication, there are numerous approaches that pharmaceutical and biotechnology companies are taking to address the SARS-CoV-2 virus that causes COVID-19. These strategies include monoclonal antibodies against SARS-CoV-2, anti-inflammatory therapeutics, vaccines (protein-based; RNA-based, DNA-based, viral-based), and either host-directed or direct-acting antiviral treatments. We may also compete with the intellectual property, technology, and product development efforts of academic, governmental, and private research institutions. Our competitors may have significantly greater financial resources, longer operating histories, established presence in the market, and greater expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, marketing, and management personnel, establishing clinical trial sites and patient registration for clinical trials, engaging governmental agencies for funding and support, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of any product candidates that we develop, if approved, are likely to include their efficacy, safety, convenience, price, ease of prescribing, and the availability of reimbursement from government and other third-party payors. The commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products with better profiles in these areas. There are numerous approaches that pharmaceutical and biotechnology companies are taking to address the SARS-CoV-2 virus that causes COVID-19. These strategies include monoclonal antibodies against SARS-CoV-2, anti-inflammatory therapeutics, vaccines (protein-based; RNA-based, DNA-based, viral-based), and either host-directed or direct-acting antiviral treatments. As of March 1, 2023, the only fully approved DAA treatment for COVID-19 is remdesivir (VEKLURY™, Gilead Sciences, Inc.), a polymerase inhibitor that is administered by IV infusion over three consecutive days. Additionally, ritonavir-boosted nirmatrelvir (PAXLOVID™, Pfizer, Inc.), a 3CL protease inhibitor, and molnupiravir (LAGEVRIO™, Merck & Co., Inc.), a polymerase inhibitor, have received emergency use authorizations (EUAs) in the United States as oral antiviral treatments for non-hospitalized, high-risk patients with mild-to-moderate COVID-19. Further, both drugs have recently received updated authorizations from the FDA to be prescribed and administered to patients without a prior positive test for SARS-CoV-2. Similarly, ensitrelvir fumaric acid (XOCOVA™, Shionogi, Inc.), a 3CL protease inhibitor, has received conditional approval in Japan. Our competitors may enter into government purchase or stockpiling agreements for their competitive products upon receiving conditional approval or emergency authorization, such as has occurred with Pfizer and Merck in the United States and Shionogi in Japan. Moving forward, given the limited resources of governments, these activities may prevent or limit our ability to enter into similar purchase or stockpiling agreements for pomotrelvir, even if authorized or approved.

Merck reported results from a Phase 3 study of molnupiravir in high-risk outpatients infected with COVID-19, which showed a 50% reduction in hospitalization or death through one month after treatment compared to placebo. Molnupiravir is currently authorized in the United States under EUA but is limited to situations where other FDA-authorized treatments for COVID-19 are inaccessible or are not clinically appropriate. Nirmatrelvir is dosed twice daily in combination with a low dose of ritonavir, a metabolic boosting agent, which results in significant drug interactions with numerous other commonly prescribed medications and other limitations on use. There remains an unmet need for novel SARS-CoV-2 direct-acting antivirals to treat patients potentially ineligible for existing therapies, as well as for treatments that are safe, efficacious, easy to prescribe and convenient for use in the broader population of otherwise healthy adults and pediatric patients.

Other competitor product candidates in Phase 2 or Phase 3 studies include but are not limited to Enanta Pharmaceuticals, Inc.'s EDP-235 (3CL protease inhibitor), Atea Pharmaceuticals, Inc.'s bemnifosbuvir (polymerase inhibitor), and Gilead Sciences, Inc.'s GS-5245 (isobutyl ester prodrug of GS441524 (RDV)). Further, our competitors have additional compounds in preclinical development or Phase 1 studies, including a potential next generation 3CL protease inhibitor candidate by Pfizer.

In addition, multiple vaccines have been developed for prevention of COVID-19 progression to hospitalization and death. We view further development of oral antivirals as highly complementary to continued vaccine development, and a necessary component of a comprehensive prevention and treatment strategy as the virus becomes endemic in the global population and continues to evolve.

Intellectual Property

As part of our business strategy, we seek to protect our product candidates and other proprietary technology, inventions and improvements by filing U.S. patent applications and, when appropriate, filing foreign patent applications in major foreign jurisdictions. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

As of March 1, 2023, our owned patent estate includes five issued U.S. patents, five pending U.S. patent applications, one issued foreign patent, over 25 pending foreign patent applications, six pending Patent Cooperation Treaty (PCT) applications, and two pending provisional patent applications.

Pomotrelvir

Specifically, with respect to our lead candidate, as of March 1, 2023, we own one patent family with claims directed to the composition of matter of pomotrelvir that includes two issued U.S. patents, one foreign issued patent, three pending U.S. patent applications and over 25 pending foreign patent applications in various jurisdictions such as Australia, Canada, Europe, China, Japan, Mexico, Singapore and South Africa. These patents and patent applications, if issued, are expected to expire in 2041, not including any patent term extensions, adjustments or restorations of term that may be available in the United States. We also have three pending PCT applications that are directed to solid forms, formulation(s), and process/manufacturing of pomotrelvir. The expected year of expiration for patents issued from any of these PCT applications, if valid and enforceable, is 2042, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

Commercialization

We have no product candidate that has received marketing approval. Given the stage of development of our lead asset, pomotrelvir, we have not yet invested significantly in our commercial infrastructure and global distribution capabilities. However, critical path activities and planning to support potential commercialization of pomotrelvir in the event of marketing approvals in the United States and Europe are underway. We currently plan to establish our own commercial organization in the United States and potentially in other select markets. In parallel, we are evaluating the extent to which collaboration with regional partners in select markets would enhance global commercial market capabilities, accelerate access to funding for global scale commercial manufacturing and our timeline to securing regulatory approvals in markets outside the United States.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of preclinical, nonclinical or clinical product candidates, nor do we have plans to develop or operate our own manufacturing operations in the near future. To date, we have relied upon third-party CMOs, including manufacturers in China, to produce our drug substances and product candidates for preclinical, nonclinical and clinical use. While we anticipate that we will be able to engage more than one CMO for the manufacture of pomotrelvir in the future, we currently rely upon one CMO in China to manufacture the quantities of pomotrelvir required for our Phase 3 clinical development program and, if approved, initial commercial quantities of pomotrelvir. We believe that any raw materials and key intermediates required for the manufacture of our product candidates could be obtained from more than one source.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, as well as in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, post-approval monitoring and reporting and export and import of drug products such as those we are developing.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA), and its implementing regulations. We, along with our vendors, collaboration partners, clinical research organizations (CROs), clinical trial investigators, and CMOs are required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct clinical trials or seek approval of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's issuance of a clinical hold, refusal to approve pending applications, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with the FDA's good laboratory practice (GLP) requirements and other applicable regulations;
- submission to the FDA of an investigational new drug (IND) application which must become effective before human clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an independent institutional review board (IRB) or ethics committee (EC) at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (GCP) requirements, to establish the safety and efficacy of the product candidate for its proposed intended use;
- submission to the FDA of a new drug application (NDA) after completion of all pivotal trials;
- payment of user fees for FDA review of the NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities at which the drug will be produced to assess compliance with current good manufacturing practice (cGMP), requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the clinical trial sites that generated the data in support of the NDA to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of chemistry, formulation and stability, as well as in vitro and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety and toxicology studies. In the United States, the results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND application.

An IND application is a request for authorization from the FDA to administer an IND product to humans. The central focus of an IND application is on the general investigational plan and the protocol(s) for clinical trials. The IND application also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. Once submitted, the IND

automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, institutes a clinical hold. The IND sponsor must resolve any outstanding concerns or questions to the FDA's satisfaction before the clinical trial can begin. Some long-term preclinical testing may continue after the IND application is submitted.

The clinical stage of development involves the administration of the investigational product to human participants (healthy volunteers or patients having the disease) under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research participants provide their informed consent for their participation in any clinical trial. Investigators are generally physicians not employed by or under trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, dosing procedures, participant selection and exclusion criteria, and 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 that must be provided to each clinical trial participant before the clinical trial begins at that site and must monitor the study until completed.

The FDA, the IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Further, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Some clinical trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial 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 participants or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries. In the United States, information about applicable clinical trials, including clinical trials results, must be submitted within specific time frames for publication on the *www.clinicaltrials.gov* website.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Human clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1:* The product candidate is initially introduced into a limited population of healthy human participants, or in some cases, patients with the target disease or condition. These clinical trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- *Phase 2:* The product candidate 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 product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

During the development of a new drug, sponsors are given opportunities to request meetings with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may also be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. In addition, 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 and to identify appropriate storage conditions for the product candidate.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other things, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators 15 days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible and in no case later than seven calendar days after the sponsor's initial receipt of the information.

Expanded Access

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational products under an IND sponsored by either the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND application.

There is no requirement for a company to provide expanded access to its investigational product. However, if a company decides to make its investigational product available for expanded access, the FDA reviews each request for expanded access and determines if treatment may proceed. Expanded access may be appropriate when all of the following criteria apply: the patient has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context of the disease or condition to be treated; and providing the investigational product for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides an additional mechanism for patients with a life-threatening condition who have exhausted approved treatments and are unable to participate in clinical trials to access certain investigational products that have completed a Phase 1 clinical trial, are the subject of an active IND, and are undergoing investigation for FDA approval. Unlike the expanded access framework described above, the Right to Try Act does not require the FDA to review or approve requests for use of the investigational product. There is no obligation for a company to make its investigational products available to eligible patients under the Right to Try Act.

Under the FDCA, sponsors of one or more investigational products for the treatment of a serious disease or condition must make publicly available their policy for evaluating and responding to requests for expanded access for individual patients, such as by posting the policy on the manufacturer's website or on the Reagan-Udall Foundation Expanded Access Navigator web page. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study, or 15 days after the investigational drug receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

We have posted on the Reagan-Udall Foundation Expanded Access Navigator that our compassionate use/expanded access policy provides that expanded access to pomotrelvir is not yet available.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including clinical trials initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be marketed in the United States.

The submission of an NDA is subject to the payment of substantial user fees under the Prescription Drug User Fee Act, as amended (PDUFA); a waiver or reduction of such fees may be obtained under certain limited circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

In the United States, the FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the PDUFA goals that are currently in effect, the FDA has a goal of ten months from the date of filing of a standard NDA for a new molecular entity to review and act on the submission and six months from the filing date of a priority review NDA. The review process may be extended by three months if the FDA classifies a response to an FDA request for additional information or clarification as a major amendment.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After the FDA evaluates an NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA will issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter describes the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA addressing all of the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the regulatory criteria for approval. If those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations or restrictions on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA 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 a product's approval if compliance with 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 4 post-market clinical trials 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 clinical trials.

Expedited Development and Review Programs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include fast track designation, breakthrough therapy designation, priority review and accelerated approval.

New drugs 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. Fast track designation provides

increased opportunities for sponsor interactions with the FDA during preclinical and clinical development and the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted upon satisfaction of certain conditions.

In addition, a new drug may be eligible for breakthrough therapy designation if the product candidate is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product, alone or in combination with one or more other products, 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 FDA organizational commitment to expedite development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

A drug is eligible for priority review if it is intended to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review original NDAs with priority review designations within six months of the filing date as compared to ten months for review of NDAs under standard review.

In addition, a product may be eligible for accelerated approval. Drugs intended to treat a serious or life-threatening disease or condition that generally provides a meaningful therapeutic advantage to patients over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the predicted clinical benefit. The Food and Drug Omnibus Reform Act (FDORA) was recently enacted, which included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study, which may include milestones such as a target date of study completion and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of the study. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required clinical trials in a diligent manner, or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

Pediatric Information

Under the Pediatric Research Equity Act, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan (PSP) within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or clinical trials that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric clinical trials along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Prior to commencing a Phase 3 clinical trial for pomotrelvir, we will need to submit a PSP.

Post-approval Requirements

Any drug products for which we may receive FDA approvals would be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or more frequently for specific events, product sampling and distribution, complying with certain electronic records and signature requirements 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.

We rely, and expect to continue to rely, on third parties for the production of clinical and, if approved, commercial quantities of our product candidates. Drug manufacturers and their subcontractors involved in the manufacture and distribution of approved products 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 drug 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. Manufacturers and other parties in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. 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. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution.

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 trials 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;
- warning or untitled letters;
- holds on clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved NDAs, or suspension or revocation of product approvals;
- product recall, 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
- fines, injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims that are approved by the FDA and in accordance with the provisions of the approved labeling. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), rules for conducting industry-sponsored scientific and educational activities and promotional activities involving the internet. The FDA and other agencies actively enforce these laws and regulations. Failure to comply with these requirements can result in, among other things, immediate discontinuation of noncomplying materials, adverse publicity, warning or untitled letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. 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 marketers' communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

Emergency Use Authorization

The Secretary of the U.S. Department of Health and Human Services (HHS) may authorize unapproved medical products or unapproved uses of approved medical products to be marketed in the context of an actual or potential emergency that has been designated by the U.S. government. On February 4, 2020, HHS issued a determination under Section 564 of the FDCA that COVID-19 was a public health emergency and based upon that determination HHS issued four EUA declarations, including one for drugs and biological products. After an emergency has been announced, the Secretary of HHS may authorize the issuance of and the FDA Commissioner may issue EUAs for the use of specific products based on criteria established by the FDCA, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA is a mechanism to facilitate the availability and use of medical countermeasures during public health emergencies, such as the COVID-19 pandemic. An EUA is subject to additional conditions and restrictions and is product-specific. An EUA is not a long-term alternative to obtaining FDA approval, licensure or clearance for a product. The FDA may revoke an EUA for a variety of reasons, including where it is determined that the underlying health emergency no longer exists or warrants such authorization, so it is not possible to predict how long an EUA may remain in place. On January 30, 2023, President Biden issued a Statement of Administration Policy announcing the administration's intent to end the COVID-19 national emergency and public health emergency on May 11, 2023. The FDA has stated that the ending of the public health emergency declared by HHS under Section 319 of the Public Health Service Act will not impact the FDA's ability to authorize treatments for emergency use. Existing EUAs will remain in effect and the agency may continue to issue new EUAs going forward so long as the applicable EUA declaration remains in effect and when criteria for issuance are met. The FDA intends to issue a Federal Register notice regarding how HHS' determination to end the COVID-19 public health emergency declared under the Public Health Service Act will impact the FDA's COVID-19-related guidance and which guidance it is temporarily extending or letting expire.

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our future product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of our clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions authorized under the FDCA, which are independent of patent status and any patent related extensions, can delay the submission or the approval of certain marketing applications of other companies seeking to reference another company's NDA. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application (ANDA), or an NDA

submitted under Section 505(b)(2) (505(b)(2) NDAs) by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The Hatch-Waxman Amendments require NDA applicants to identify to the FDA each patent whose claims cover the applicant's drug or approved method of using the drug. Upon approval of a drug, the applicant must update its listing of patents to the NDA in timely fashion and each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredient(s), strength, route of administration, and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution.

The FDCA also provides three years of marketing exclusivity for an NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent for the other conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical and nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for a six-month extension of patent and non-patent marketing exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services (CMS), other divisions of the HHS (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, state attorney generals and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the federal False Claims Act (FCA), the privacy and security provisions of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), and similar state laws, each as amended from time to time. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended from time to time. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act (VHCA), drug companies are required to offer certain pharmaceutical products at a reduced price to a number of federal agencies including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and certain private Public Health Service—designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

We are also potentially subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and local jurisdictions in which our business is conducted that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the FCA, which may constrain the business or financial arrangements and relationships through which companies research, sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy laws can apply to the activities of pharmaceutical manufactures. The applicable U.S. federal and state healthcare laws and regulations that can affect our operations include without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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

the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but such exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- The federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- HIPAA, which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act (ACA), and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, covered manufacturers also are required to report information regarding their payments and other transfers of value to physician assistants, and nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- Analogous 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 and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy

and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical studies, marketing authorization, commercial sales and distribution of our products, pricing and reimbursement. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods.

Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. For example, in the European Union, a clinical trial application (CTA), must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed. To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application to the European Medicines Agency (EMA). The application used to file an NDA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, marketing authorization, commercial sales and distribution, pricing and reimbursement vary from country to country. In all cases, the clinical trials need to be conducted in accordance with International Conference on Harmonization (ICH) / WHO Good Clinical Practice standards and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product candidate is typically separate from the process for setting the price or reimbursement rate that the payor will pay for the product candidate once coverage is approved. In the United States, there is no uniform policy among payors for coverage or reimbursement. Decisions regarding whether to cover any of a product, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement 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 can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain any FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Additionally, 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.

The marketability of any products for which we may receive regulatory approval for commercial sale is dependent on the availability of adequate coverage and reimbursement from government and third-party payors. In addition, the emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, in the ACA, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

Among the provisions of the ACA of importance to our potential drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs under the Bipartisan Budget Act of 2018 (BBA);
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program;
- requirements to report financial arrangements with physicians and teaching hospitals;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and 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 many judicial, administrative, executive and legislative 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. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 2022, due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction was in place between April 1, 2022 through June 30, 2022, and the 2% payment reduction resumed on July 1, 2022. In January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024. These laws may result in additional reductions in Medicare and other healthcare funding.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent United States Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, at the federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (1) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (2) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. In addition, in September 2020, the FDA issued a final rule, which went into effect on November 30, 2020, that sets up a legal framework for allowing the importation of certain prescription drugs from Canada, and the CMS issued guidance that addresses the treatment of certain imported drugs under the Medicaid Drug Rebate Program. In September 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation (MFN) Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. On December 27, 2021, CMS rescinded an interim final rule that would have implemented former President Trump's MFN executive order tying Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. For example, the Inflation Reduction Act of 2022 (IRA), introduces some of the most significant changes to Medicare payment for prescription drugs since the ACA. Among its many provisions, the IRA authorizes the Medicare program to negotiate pricing for certain high-cost drugs, including physician-administered and self-administered drugs, that have been on the market for a minimum amount of time without generic competition. Each year, beginning with calendar year 2026, the Secretary of the HHS will implement a negotiated price, known as the "Maximum Fair Price" (MFP), that will be made public and apply to the drug's Medicare utilization if the drug is among the top ten drugs with the highest Medicare spending. Manufacturers who fail to offer the MFP, or fail to come to the table to negotiate after the Secretary has determined their drug is eligible for negotiation, will incur an excise tax of up to 95% for each sale of the drug in the United States. Depending on the share of Medicare spending each year that is attributed to pomotrelvir or any other drug we may develop or out-license, and whether or not those drugs become eligible for Medicare negotiation, those drugs and our revenue may be adversely impacted by this provision.

The IRA also will require manufacturers, beginning in 2023, to rebate the Medicare program for Medicare utilization of drugs that have price increases faster than the rate of inflation. The benchmark to which price increases are compared will vary depending on the drug. Although manufacturers are generally familiar with inflation rebates under the Medicaid program, where they have existed for decades, the IRA represents the first time that the CMS has extended inflation rebates to the Medicare program.

The IRA also redesigns the Medicare prescription drug benefit in several important ways, beginning in calendar year 2025. First, the IRA places an annual out-of-pocket cap on Medicare beneficiary cost sharing amounts, which will actually take effect in calendar year 2024 before the full benefit redesign. Previously, beneficiaries' out-of-pocket costs were uncapped, even if heavily subsidized. Second, the IRA requires that manufacturers share in the cost of prescription drugs throughout the prescription drug benefit. Previously manufacturers only needed to offer discounted pricing for a single phase of the prescription drug benefit. Finally, the IRA shifts the majority of liability in the "catastrophic phase"—the phase of the prescription drug benefit that only the costliest of Medicare beneficiaries enter—to the private Part D plans, thereby encouraging them to better manage costs. Previously, the Federal government incurred the vast majority of liability during the catastrophic phase. Together, these changes to the Medicare prescription drug benefit will create new pricing dynamics for payors and manufacturers.

The IRA permits the HHS Secretary to implement many of the IRA provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of us placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our drug candidates.

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 and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, certain individual states as well as regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. The states of Louisiana and Washington used bidding procedures in 2019 and more recently, Minnesota did so in 2021, to secure contracts with suppliers of certain antiviral therapeutics for certain populations, including those covered by Medicare and those in correctional institutions. Other states are currently engaged in similar discussions. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

The marketability of any drug candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical drug pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

New Legislation and Regulations

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amount that federal and state governments will pay for drug products and healthcare services, which could result in reduced demand for our product candidates once approved or additional pricing pressures.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products.

It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be. The same is also true in foreign countries.

Employees

As of December 31, 2022, we had 57 employees, all of which were full-time. Of these full-time employees, 14 employees have M.D., Ph.D. or PharmD degrees and 30 employees are engaged in research and development activities. Our workforce expanded during fiscal year 2022; new employees were primarily hired to support our clinical development program, including technical operations, and general and administrative functions. From time to time, we retain independent contractors or other service providers to support our organization. We continually evaluate our business needs and opportunities and strive to balance inhouse expertise and capacity with outsourced expertise and capacity. Currently, we outsource substantially all clinical trial work to CROs and drug substance and drug product manufacturing to CMOs.

None of our employees are represented by a labor union or covered by a collective bargaining agreement. All of our employees work remotely. We consider our relationship with our employees to be good.

Human Capital

Competitive pay and benefits

We believe that our single most important asset that differentiates us now and into the future is our employees. Our human capital resource objectives include finding and attracting the best talent and inspiring them to bring their best to us each and every day. We strive to achieve these objectives through competitive compensation programs and insurance benefits that are intended to meet employees where they are. We monitor our compensation programs closely and provide what we consider to be a very competitive mix of compensation and insurance benefits for all our employees. To attract qualified applicants, we offer a total rewards package consisting of a base salary and cash target bonus, a comprehensive benefits package and equity compensation for all full-time employees. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on company and individual performance.

Diversity and inclusion

We have, since our inception, worked to create a high-performing, inclusive and diverse workforce, which is a core element of our operating culture. We have deliberately sought to secure top talent with a diversity of thoughts, experiences and backgrounds who are committed to making a difference in the lives of patients. We believe that, by embracing differences, we have a unique advantage in challenging the status quo to apply innovative thinking to the current pandemic. As of December 31, 2022, our workforce was approximately 54% women and 49% Asian, Hispanic, Latino, Black or African American, and our senior leadership was approximately 44% women or minorities. We strive to be inclusive and diverse in though, action and in the people who join us.

Culture

Our culture underpins all that we do and is anchored in our core values of (i) lead with humility, respecting the diversity that makes us stronger, and encourage open and inclusive debate, (ii) being a change-maker, by solving problems through experience, expertise, resilience and ingenuity, (iii) innovating with integrity, and (iv) cultivating our chemistry through teamwork and accountability. We strive to conduct our business and operations in a manner consistent with our core values.

Corporate and Other Information

We were initially a blank check or special purpose acquisition company called FS Development Corp. II (FSDC II), incorporated in Delaware on August 21, 2020, formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses or entities. On December 23, 2023 (Closing Date), FSDC II, Pardes Biosciences, Inc., a Delaware corporation and privately held corporation prior to the Closing Date (Old Pardes), and Orchard Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of FSDC II (Merger Sub), consummated a business combination (Business Combination) pursuant to the terms of the Agreement and Plan of Merger, dated as of June 29, 2021 (as amended on November 7, 2021, the Merger Agreement) by and among FSDC II, Merger Sub, Old Pardes and Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact for the securityholders of Old Pardes immediately prior to the Business Combination (Shareholders Representative).

Old Pardes was incorporated in Delaware on February 27, 2020, and at the time of the Business Combination was a clinical stage biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics to improve the lives of patients suffering from life-threatening disease, starting with its lead candidate, pomotrelvir, which was in Phase 1 clinical development.

On the day immediately prior to the closing of the Business Combination, Old Pardes changed its name to "Pardes Biosciences Sub, Inc." Pursuant to the Merger Agreement, on the Closing Date, (i) FSDC II changed its name to "Pardes Biosciences, Inc" and (ii) Old Pardes and Merger Sub consummated the merger pursuant to the Merger Agreement (Merger), with Old Pardes as the surviving company in the Merger and, after giving effect to such Merger, Old Pardes becoming a wholly-owned subsidiary of Pardes Biosciences, Inc. (f/k/a FS Development Corp. II) (Pardes). Old Pardes was merged with and into Pardes on January 31, 2022. For additional information, see Note 1, *Description of Business,* and Note 5, *Business Combination*, to the financial statements in this Form 10-K.

Our corporate mailing address for our principal executive office is 2173 Salk Avenue, Suite 250, PMB#052, Carlsbad, California 92008, and our telephone number is 415-649-8758. Our website address is https://pardesbio.com and we regularly post copies of our press releases as well as additional information about us on our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. The information disclosed on our website could be deemed to be material information. As such, we encourage investors, the media, and others to review the information disclosed on our website. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act, are available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information contained on or accessible through our website is not a part of this Form 10-K, and the inclusion of our website address in this Form 10-K is an inactive textual reference only.

Part I

Item 1A. Risk Factors.

Our business is subject to many risks and uncertainties. If any of the following risks, or other risks not presently known to us or that we currently believe to not be material, are realized, our business, financial condition and results of operations could be materially and adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment. You should carefully review and consider the full discussion of our risk factors below, together with all other information in this Annual Report on Form 10-K (Form 10-K), including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto.

Risks Related to our Business

We have a limited operating history and no history of successfully developing or commercializing any approved therapeutic products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability and ability to generate revenue and become profitable in the future.

We are a clinical-stage biopharmaceutical company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, developing our technology, identifying and developing our lead product candidate, pomotrelvir, conducting nonclinical studies, Phase 1 and Phase 2 clinical trials of pomotrelvir, and conducting start-up activities for our potential Phase 3 clinical trials and potential commercialization. We have not yet demonstrated our ability to complete any late-stage or pivotal clinical trials, obtain regulatory approval, formulate and manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization or arrange for third parties to do these activities on our behalf. Investment in biotechnology and pharmaceutical product development is highly speculative because it entails substantial upfront expenditures in CROs and CMOs and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. If we successfully develop a product candidate, we will eventually need to transition from a company with a research and development focus to a company capable of supporting late-stage and commercial activities. We may not be successful in this transition.

We do not expect to receive revenue from pomotrelvir until we obtain marketing approvals, if ever. To date, we have not generated any revenue from product sales and we will not be able to generate product revenue unless and until pomotrelvir, or any other product candidate, successfully completes clinical trials, receives regulatory approval and is commercialized. We may seek to obtain revenue from collaboration or licensing agreements with third parties or funding from government sources. Our ability to generate future product revenue from pomotrelvir or any other product candidates also depends on a number of additional factors, including our or our future collaborators' (if any) ability to:

- initiate and complete successful nonclinical studies and clinical trials for pomotrelvir and any future product candidates we may develop;
- conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of pomotrelvir or any future product candidates if we are required to do so by the U.S. Food and Drug Administration (FDA) or similar foreign regulatory authorities;
- to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety and efficacy and acceptable risk to benefit profile of pomotrelvir or any future product candidates;
- seek and obtain marketing approvals for any product candidates that complete clinical development;
- establish and maintain supply and manufacturing relationships with third parties and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize any product candidates for which we obtain marketing approval and, if launched independently, successfully establish a sales, marketing and distribution infrastructure;
- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;
- demonstrate the actual and perceived benefits of pomotrelvir, if approved, relative to existing and future alternative therapies for COVID-19 based upon availability, cost, risk and safety profile, drug-drug interactions, ease of administration, side effects and efficacy;

- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for any approved products;
- address any competing technological and market developments;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter in the future and perform our obligations under such collaborations;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biopharmaceutical product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or comparable foreign regulatory authorities in other jurisdictions where we may pursue regulatory approval, to perform nonclinical studies or clinical trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing any approved product.

If we 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 our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value also could cause you to lose all or part of your investment.

We have incurred significant losses since our inception and expect to incur losses for the foreseeable future.

To date, we have devoted almost all of our financial resources to research and development, including preclinical and clinical development activities, and we expect to continue to incur significant research and development and other expenses related to our ongoing operations and the development of our lead therapeutic candidate, pomotrelvir. As a result, we are not profitable and have incurred significant losses since our inception in February 2020. As of December 31, 2022, we had an accumulated deficit of $148.2 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we seek to advance pomotrelvir through clinical development, seek regulatory approval of pomotrelvir if clinical development is successful, and, if we receive regulatory approval, commercialize pomotrelvir. Additionally, we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business for any reason, including as a result of the evolving and unpredictable COVID-19 pandemic. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of pomotrelvir or any other product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance pomotrelvir through clinical development.

We believe our existing cash and cash equivalents will fund our current planned operations for at least 12 months from the issuance date of the audited financial statements included in this Form 10-K. Our forecast of the period of time through which our financial reserves will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "*Risk Factors*" section. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of nonclinical studies and anticipated clinical trials for pomotrelvir or any other product candidates we may develop;
- any COVID-19 related delays or other effects the disease progression may have on our development programs;
- the outcome, timing and cost of seeking and obtaining regulatory approval from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or require our clinical trial designs to differ from those currently contemplated;

- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technologies, such as vaccines, antibody therapies and other oral antivirals, the evolution of COVID-19 from a pandemic to an endemic and the announced intention of the Biden administration to end the national emergency and public health emergency declaration relating to COVID-19 as of May 11, 2023;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- the stability, scale, yield and cost of manufacturing our product candidates for clinical trials, in preparation for regulatory approval and in preparation for commercialization;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize;
- the ability to establish, nature and timing of potential partnerships around current or future pomotrelvir assets; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all.

Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, government funding, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we could be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

In January 2023, we filed a shelf registration statement on Form S-3, which has been declared effective by the SEC, which provides for the offering, issuance and sale by us of up to an aggregate of $200.0 million of our securities (the 2023 Shelf). Simultaneously with the 2023 Shelf, we entered into a Sales Agreement (ATM Sales Agreement) with SVB Securities LLC (Sales Agent), pursuant to which we may sell up to $50.0 million of our common stock from time to time in "at-the-market" offerings. Given the decrease in the market price of our common stock and volatility in the capital markets, we may not be willing or able to raise equity capital through our ATM Sales Agreement.

If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or, if marketing approval is obtained, commercialization of pomotrelvir and/or further delay, scale back or discontinue our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We are heavily dependent on the success of pomotrelvir, our lead product candidate. If we are required to delay or discontinue development of pomotrelvir or if pomotrelvir does not receive regulatory approval, or fails to be successfully commercialized or achieve significant market acceptance, we would be substantially delayed in our ability to achieve profitability, if ever.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to our lead product candidate, pomotrelvir. Accordingly, our business and future success currently depends heavily on the successful development, regulatory approval and commercialization of pomotrelvir for treatment of COVID-19. We cannot be certain that pomotrelvir will commence or successfully complete later stage clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we are required to discontinue development of pomotrelvir or if pomotrelvir does not receive regulatory approval or fails to achieve significant market acceptance, we would be substantially delayed in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, promotion, marketing and distribution of pomotrelvir is, and will remain, subject to comprehensive regulation by the FDA and comparable foreign regulatory authorities. Failure to obtain regulatory approval for pomotrelvir will prevent us from commercializing and marketing pomotrelvir. Further, our future clinical trials of pomotrelvir may not be able to replicate the results from our preclinical and nonclinical studies and our earlier clinical trials of pomotrelvir. To the extent this occurs, our expected development time and development costs for pomotrelvir may be increased.

Even if we are able to successfully obtain approval for pomotrelvir from the FDA or comparable foreign regulatory authority, any approval might contain significant limitations related to use, including limitations on the stage of disease pomotrelvir is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications. Additionally, if we obtain regulatory approval for pomotrelvir, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize pomotrelvir, we may not be able to generate sufficient revenue to achieve profitability and continue our business.

If we are not successful in discovering, developing, receiving regulatory approval for and commercializing other product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although we plan to devote the majority of our current resources to the continued clinical testing and potential approval of pomotrelvir for the treatment of COVID-19, another key element of our strategy is to discover, develop and commercialize a broader portfolio of products. We are currently intending to do so through our internal discovery programs, but our resources are limited, and those resources that we have available have been and are largely geared towards development of pomotrelvir. Other than pomotrelvir, we have no product candidates in the clinical stage of development. Research programs to identify additional product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- a product candidate may, on further clinical trials, be shown to have harmful side effects or toxicities, be unable to achieve clinically relevant concentration after dosing or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- intellectual property, patents or other proprietary rights of third parties may cover the product candidates that we develop or potentially block our entry into certain markets or make such entry economically impracticable.

We may also explore strategic collaborations for the development or funding of new product candidates, but we may not be successful in entering into such relationships. If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed, and our business will be more vulnerable to any problems that we encounter in developing and commercializing pomotrelvir.

Nonclinical development is uncertain. Our nonclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain approval from the FDA and other major regulatory agencies in non-U.S. countries to market a new product candidate, we must demonstrate safety and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive nonclinical studies that

support our planned Investigational New Drug (IND) or clinical trial applications (CTAs), in the United States and other countries, respectively. We cannot be certain of the timely completion or outcome of our nonclinical studies, whether the outcomes will support further development of our clinical product candidates or if the FDA or other regulatory authorities will accept the outcome of our nonclinical studies. As a result, we cannot be sure that we will be able to submit INDs in the United States, or CTAs or similar applications in other jurisdictions, on the timelines we expect, if at all, and we cannot be sure that submission of INDs, CTAs or similar applications will result in the FDA or other regulatory authorities allowing additional clinical trials to begin.

Conducting nonclinical testing is a complex, lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program and often can take several years or more per program. Delays associated with programs for which we are directly conducting nonclinical studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the studies of certain programs that are the responsibility of potential future partners, if any, over which we have no control. The commencement and rate of completion of nonclinical studies for a product candidate may be delayed by many factors, including:

- financial resources;
- inability or failure by us or third parties to comply with regulatory requirements, including the requirements of GLP;
- inability to generate sufficient nonclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- challenges in obtaining sufficient quantities of our product candidates for use in nonclinical studies from third-party suppliers on a timely basis;
- delays due to the ongoing COVID-19 pandemic, including due to reduced workforce productivity as a result of the implementation of a work-from-home policy or illness among personnel, or due to delays at our third-party CROs and CMOs throughout the world for similar reasons or due to restrictions imposed by applicable governmental authorities; and
- delays due to other global-scale potentially catastrophic events, including other pandemics, terrorism, war (including Russia's invasion of Ukraine), supply chain disruptions and climate change.

Moreover, even if drug candidates from our product programs advance into clinical trials, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety or efficacy to obtain the requisite regulatory approvals for any product candidates we develop. Even if we obtain positive results from nonclinical studies or initial clinical trials, we may not achieve the same success in future trials.

Pomotrelvir and any other product candidates we may develop must undergo rigorous clinical trials and regulatory approvals, and results from early nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.

Pomotrelvir and any other product candidates we may develop will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities. The approval process is typically lengthy and expensive, and approval is never certain. We have limited experience in conducting the clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. Our clinical trials may not demonstrate that our potential products, including pomotrelvir, will be active, safe or effective or achieve sufficient exposure to be of clinical benefit. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays. Further, our future clinical trials of pomotrelvir may not be able to replicate the results from our preclinical and nonclinical studies or our earlier clinical trials. To the extent any of this occurs, our expected development time and costs for pomotrelvir may be increased.

Success in earlier nonclinical studies and earlier-stage clinical trials does not ensure that later nonclinical studies or clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of a product candidate. In addition, the design of a clinical trial can determine whether our results may support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Historically there is a high failure rate for drugs proceeding through clinical trials at every stage. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical studies and earlier-stage clinical trials. Similarly, the outcome of nonclinical studies may not predict the success of clinical trials. Moreover, data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of development of our product candidates. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

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

Our subsequent clinical trials may reveal significant adverse events not seen in our earlier clinical trials or preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical and nonclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. If the results of our preclinical and nonclinical studies and clinical trials demonstrate a safety concern associated with our product candidates, we may be prevented or delayed in obtaining authorization to initiate clinical trials. Additionally, if the results of our preclinical and nonclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. 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 clinical trial protocols and the rate of dropout among clinical trial participants. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, our product candidates could cause undesirable side effects that we have not observed yet to date. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, top-line and preliminary data and final data could significantly harm our business and financial prospects.

From time to time, we may publicly disclose data from prespecified interim analyses and top-line and preliminary data from our preclinical studies, nonclinical studies and clinical trials, which are based on a 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 interim, top-line and 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. Interim, top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line and preliminary data we previously published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available.

Prespecified interim analyses 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between interim, top-line and preliminary data as compared to final data could significantly harm our business and financial prospects. Further, disclosure of interim, top-line and preliminary data by us or by our competitors could result in volatility in the price of our common stock.

Additionally, 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 is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We are subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our product candidates. These manufacturing risks are heightened while we are reliant upon a single CMO for our drug product manufacturing. Any delay or interruption in our clinical supplies or, if approved, our commercial product could harm our business, operating results, prospects and financial condition.

We contract with third-party CMOs to make our drug substance and drug product to support current and planned clinical trials and for commercial sale, if approved. We will need to negotiate and maintain contractual arrangements with these CMOs for the supply of pomotrelvir and our future product candidates and we may not be able to do so on favorable terms, or at all. Most of our CMOs are outside the United States, including in the People's Republic of China (China). Our CMOs may not be able to adopt, adapt or scale up the manufacturing process in a timely manner to support our future clinical trials. Additionally, the ongoing impact of the COVID-19 pandemic in China could adversely affect the ability of our CMOs to manufacture the quantities of drug substance and drug product required for our future clinical trials and in accordance with proposed timelines. The process of manufacturing our product is complex, highly regulated and subject to several risks, including:

- failure to meet acceptance criteria;
- the manufacturing process is susceptible to product loss due to equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions, and even minor deviations from normal manufacturing processes could result in reduced production yields and quality as well as other supply disruptions;
- the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, changes in manufacturing lines, labor and raw material shortages, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest, politically driven embargoes or trade agreements affecting supply of raw materials and numerous other factors; and
- any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives.

Manufacturers sometimes encounter difficulties in production, especially during scale-up from the manufacturing process used for preclinical studies, nonclinical studies and early clinical trials to a validated process needed for pivotal clinical trials and commercial launch. These problems often include failure to meet target production costs and yields, sub-par quality control testing, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as failure to comply with strictly enforced federal, state and foreign regulations. We cannot assure you that any product quality issues relating to the manufacture of pomotrelvir or any other product candidates will not occur in the future.

We do not have and we do not currently plan to acquire or build the facilities or internal capabilities to manufacture bulk drug substance or filled drug product for use in clinical trials or commercialization. To a large extent, that makes us dependent on the goodwill of our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product.

Currently we rely upon one CMO in China to manufacture the clinical supplies of pomotrelvir required for clinical trials and, if approved, initial commercial supplies. While we anticipate that we will be able to train and qualify additional CMOs for the manufacture of pomotrelvir in the future, our clinical trials and, if approved, our commercial launch could be delayed, if our CMO encounters any of the difficulties noted above or noted in "-- Risks Related to Reliance on Third Parties" below.

Any delay or interruption in the supply of clinical trial materials could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials altogether. Likewise, if we obtain regulatory approval for pomotrelvir, any delay or interruption in the supply of commercial product could harm our business, operating results, prospects and financial condition.

We may develop product candidates in combination with other therapies, which exposes us to additional risks.

We may develop product candidates in combination with other product candidates or existing therapies. If any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these other therapies. Combination therapies are commonly used in antiviral treatments, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell the product candidates we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market the product candidates we develop.

Currently, we intend to progress pomotrelvir clinical development as a stand-alone therapy.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As of December 31, 2022, we had 57 full-time employees. As we continue development and pursue the potential commercialization of our product candidates, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We must attract and retain highly skilled employees to succeed. If we are not able to attract and retain key clinical, scientific, technical and management personnel, our business may materially suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it may adversely affect our ability to execute our business plan and harm our operating results. We do not maintain "key person" insurance for any of our key personnel. We currently have employment agreements with all of our executive officers. Our employment agreements with our executive officers are terminable by them without notice and our executive severance plan to which our executive officers are a party provides for severance and change of control benefits. The loss of any one of our executive officers may result in a significant loss in the knowledge and experience that we, as an organization, possesses and could cause significant delays, or outright failure, in the development and further commercialization of our product candidates.

There is intense competition for qualified personnel, including management in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful research, development and commercialization of our product candidates. In particular, we have experienced a very competitive hiring environment in California, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we can offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

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

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the law or regulation, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and comparable foreign regulatory authorities, fails to provide true, complete and accurate information to the FDA and comparable foreign regulatory authorities, fails to comply with manufacturing standards we have established, fails to comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or fails to 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 these laws will increase significantly, and our costs associated with compliance with these laws are also likely to increase. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. These laws may impact, among other things, our future activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. If any such actions are instituted against us, and we are not successful in defending ourself or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. It is not always possible to identify and deter employee misconduct, 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourself or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including significant competition for recruiting patients with COVID-19 in clinical trials, the availability of other therapies and changes in infection rates.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing of our product candidates. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

Factors that may generally affect patient enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites where patients are to be enrolled;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- the ability to obtain and maintain patient consents;
- the risk that enrolled participants will drop out before completion;

- declining hospitalization, mortality and infection rates for SARS-CoV-2, including as a result of prior infection, vaccination immunity or the emergence of variants that cause less severe disease;
- competition with other companies for clinical sites or patients and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new products that may be authorized or approved for the indications we are investigating; and
- other factors outside of our control, such as the ongoing and evolving nature of the COVID-19 pandemic.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same or similar therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or use other available therapies. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Further, potential patients are increasingly testing at home for SARS-CoV-2 and not reporting results to their healthcare providers, thereby reducing the number of eligible patients that might have been willing to participate in a clinical trial if they had been provided the relevant information.

Further, if any significant adverse events or other side effects are observed in any of our current or planned clinical trials or in the clinical trials of competitors, recruitment of patients to our clinical trials may be more difficult and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on us.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us. If our competitors develop and market products faster or that are more effective, safer, better tolerated, or less expensive than the product candidates we develop, our ability to obtain any future funding for our development and manufacturing efforts or to ultimately commercialize a therapy for COVID-19 will be negatively impacted.

The biotechnology and pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Many competitors, including multinational pharmaceutical companies, specialized biotechnology and pharmaceutical companies, universities and other research institutions are developing or have approved or authorized treatments for SARS-CoV-2, the virus that causes COVID-19, and other therapeutic indications that we may pursue. In particular, a number of DAAs with oral route of administration are in development by other pharmaceutical and biopharmaceutical companies. It is also possible that additional companies may commence research and development of products and therapies for the treatment of COVID-19. Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. If our competitors develop treatments more rapidly or effectively than we do, develop treatments that become the standard of care, commercialize products that are safer, more effective, have fewer or less severe side effects, have a broader label, are marketed more effectively, including gaining exclusivity for their competing products on formularies thereby excluding our products from such formularies, are reimbursed or are less expensive than any products that we may develop, develop treatments with a more convenient or preferred route of administration or are more successful at commercializing an approved treatment, we may not be able to successfully commercialize pomotrelvir for the treatment of COVID-19, even if approved, or compete with other treatments or vaccines, which could adversely impact our business and operations and our ability to raise funds.

For example, in December 2021, Pfizer, Inc. (Pfizer) received an EUA for its DAA drug candidate nirmatrelvir tablets in combination with ritonavir tablets for the treatment of mild to moderate COVID-19 in patients at high risk of hospitalization or death. The EUA for the use of nirmatrelvir tablets, then still an investigational product, allowed for use of such investigational therapy outside of clinical trials and for direct sales to governments while clinical trials were ongoing and prior to approval by the FDA. The stockpiling of investigational therapies under EUAs through government procurement and supply agreements may impact our ability to enter into similar agreements. In June 2022, Pfizer submitted a New Drug Application (NDA) to the FDA for Paxlovid for individuals at high risk for progression to severe illness of COVID-19.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market pharmaceutical or medicinal products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical or medicinal products and in obtaining regulatory approvals of human therapeutic products. Moreover, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. If our competitors develop and market products faster or that are more effective, safer, better tolerated, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. If we are unable to compete effectively, then we may not be able to develop or commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue.

Our business and operations would suffer in the event of information technology system failures, cyber-attacks or deficiencies in our or related parties' cyber security.

Our information technology systems, as well as those of our CROs, CMOs and other contractors and consultants, are vulnerable to attack, failure and damage from computer viruses and other malware, unauthorized access or other cybersecurity attacks, natural disasters (including hurricanes and earthquakes), terrorism, war, fire and telecommunication or electrical failures. In the ordinary course of our business, we directly or indirectly collect, store and transmit sensitive data, including intellectual property, confidential information, preclinical and nonclinical data, proprietary business information, personal data and clinical trial data and personally identifiable health information of our clinical trial participants, in our networks and in the data centers of our third-party service providers. The secure processing, maintenance and transmission of this information is critical to our operations. We commenced operations in February 2020, at the beginning of the COVID-19 pandemic and the commencement of stay-at-home orders by the State of California. As a result, all employees work remotely, and we have not established any physical location. We continuously review and assess the adequacy of our internal computer security measures. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access.

Despite our security measures, our information technology systems may be vulnerable to attacks by external or internal bad actors, or breached due to employee or third-party error, a technical vulnerability, malfeasance or other disruptions. Furthermore, we may have little or no control over the security measures and computer systems of third parties including any CROs we may work with in the future. The risk of a security breach or disruption, particularly through cyber-attacks 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. Additionally, the costs to us or our CROs, third-party vendors, or other contractors or consultants we may utilize to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures designed 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 system failures, interruptions, delays, cessation of service and other harm to our business and our competitive position. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages or breaches in our systems or those of our CROs and other contractors and consultants.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. If a security incident were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of data from completed, ongoing or planned preclinical studies or clinical trials could result in delays in our regulatory approval efforts. We may need to incur significant costs in order to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and such an event could disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and may not be sufficient in type or amount to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. We cannot be certain that such potential losses will not exceed our policy limits, insurance will continue to be available to us on economically reasonable terms, or at all, or any insurer will not deny coverage as to any future claim. In addition, we may be subject to changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements.

While we have not, to our knowledge, experienced any such material system failure or security breach of our internal systems to date, some of our documents and data were compromised and taken without our permission as a result of a security incident concerning a file transfer vendor used by one of our service providers in 2021. While this security incident did not result in a loss of, or damage to data, our confidential information could have been prematurely disclosed by third parties. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be hindered or delayed.

We might not be able to utilize a significant portion of our U.S. net operating loss (NOL) carryforwards and U.S. research and development tax credit carryforwards.

As of December 31, 2022, we had U.S. federal and state NOL carryforwards of approximately $65.8 million and $2.6 million, respectively, and federal and state research and development tax credit carryforwards of $1.3 million and $0.6 million, respectively. Our federal NOL carryforwards do not expire. If not utilized, our state NOL carryforwards and state research and development tax credits will expire at various dates beginning in 2037. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act of 2017, unused losses generated in taxable years beginning after December 31, 2017 will not expire and may be carried forward indefinitely. For taxable years beginning after December 31, 2017, the deductibility of such U.S. federal NOLs is limited to 80% of our taxable income in any future taxable year. In addition, under Section 382 of the Internal Revenue Code (Code), the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50% over a three-year period. We may have experienced ownership changes in the past as a result of the transactions consummated on December 23, 2021 (Business Combination) pursuant that certain Agreement and Plan of Merger, dated June 29, 2021 (as amended on November 7, 2021, the Merger Agreement), by and among FSDC II, Old Pardes, Merger Sub and Shareholders Representative and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of U.S. federal NOL carryforwards could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows. Additionally, effective January 1, 2022, research and development expenses are required to be capitalized and amortized for U.S. tax purposes, which will delay the deductibility of these expenses and potentially may increase the amount of cash taxes we pay, if any.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, clinical trials, workers' compensation, umbrella and directors' and officers' insurance.

Any product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. 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.

We also expect that, given our stage of development and intended therapeutic indication, operating as a public company will make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs and retention levels to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors (Board), our Board committees or as executive officers. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash and cash equivalents position and results of operations.

Risks Related to COVID-19

SARS-CoV-2 continues to mutate and evolve resulting in new variants of concern globally. Some of these variants may be resistant to current and new treatments. Accordingly, there is significant uncertainty around the development of pomotrelvir as a potential treatment for coronavirus generally, and SARS-CoV-2 infections and COVID-19 specifically.

We have committed and plan to continue to commit significant financial and personnel resources to the development of pomotrelvir. We seek to develop pomotrelvir as a potential treatment and prevention for COVID-19 and the current circulating strains of SARS-CoV-2 that remain highly conserved in the binding region of pomotrelvir. Even if pomotrelvir is shown in future clinical trials to be effective against the then-currently circulating strains of SARS-CoV-2 in patients, SARS-CoV-2 continues to mutate and evolve, resulting in new variant and subvariants of concern globally. Among participants in Pfizer's EPIC-HR clinical trial with sequence analysis data available at both baseline and a post-dose sample, some mutations to the binding pocket of the SARS-CoV-2 M^{pro} were detected as treatment-emergent substitutions that were more common in nirmatrelvir/ritonavir-treated participants relative to placebo-treated participants. As noted in the Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid, none of these substitutions in SARS-CoV-2 M^{pro} occurred in nirmatrelvir/ritonavir-treated participants who also experienced hospitalization. Thus, the clinical significance of these substitutions is unknown. If the SARS-CoV-2 virus develops resistance to pomotrelvir or future variants or subvariants reduce the efficacy of pomotrelvir, we may not be able to obtain approval for pomotrelvir or if approved, the long-term demand for and potential commercial success of pomotrelvir would be adversely impacted.

COVID-19 continues to cause morbidity and mortality globally; however, the number of infections and the morbidity associated with those infections fluctuates significantly. As a result, we may find enrollment of patients for clinical trials to be a challenge and/or may find that the severity of disease declines over time such that it becomes challenging to enroll the number of patients required to demonstrate statistically significant improvements in endpoints. If enrollment is delayed or takes longer than expected this could delay or prevent the collection of data sufficient to meet our endpoints and seek marketing approval.

While there is currently an urgent need for effective, easy-to-use treatments for COVID-19, the longevity and extent of the COVID-19 pandemic caused by SARS-CoV-2 is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability of vaccines or other therapies, or otherwise, the need for a treatment could decrease significantly. A decrease in hospitalizations, morbidity or mortality rates due to prior infection, vaccination immunity, availability of other treatments or due to variants that cause less severe disease, could lessen the demand for treatments or individuals willing to participate in clinical trials.

As a result of the fluctuating number of infections, hospitalizations and the morbidity associated with SARS-CoV-2 infections, we may find enrollment of patients for clinical trials a challenge and/or may find that the severity of the disease declines over time such that it becomes challenging to enroll the number of patients required to demonstrate statistically significant improvements in endpoints related to hospitalizations, morbidity, mortality and symptoms. If enrollment is delayed, takes longer than expected or is required to be increased to establish statistical significance, this could increase our expenses and delay or prevent the collection of data sufficient to meet our endpoints and seek marketing approval.

If SARS-CoV-2 evolves into a benign variant and no further pathogenic variants or subvariants of SARS-CoV-2 or other coronaviruses emerge over the next few years, then commercial, clinical and patient interest in oral antivirals may decline. If the need for a treatment decreases before or soon after commercialization of pomotrelvir, if approved, or additional treatments and preventative measures for SARS-CoV-2 infections are developed and commercialized before pomotrelvir, thereby reducing the eligible patient population for treatment, our business and prospects could be adversely impacted.

We may expend resources in anticipation of clinical trials and potential commercialization of pomotrelvir, which we may not be able to recover if pomotrelvir is not approved for the treatment of COVID-19 or we are not successful at commercializing pomotrelvir.

We believe that there is an urgent unmet need for effective, safe and easy-to-use COVID-19 treatments. If data from our development program in COVID-19 patients is positive, we may pursue, if available, certain expedited development, review and approval programs offered by the FDA or other regulatory authorities to sponsors of drugs designed to treat serious diseases and conditions. These programs may offer the potential for a more rapid approval and commercialization process than traditional review pathways. Our pursuit of such expedited pathways would depend upon an alignment with the FDA or other regulatory authorities on the design and appropriate approval endpoints of potential registration-enabling clinical trials or potential registration pathways, and there is no guarantee that the FDA or other regulatory authorities will agree with any strategy we may propose. However, to prepare for the possibility that we may be required to develop and rapidly commercialize pomotrelvir, we may enter into agreements with and make payments to CMOs in advance of obtaining any authorization or approval to market pomotrelvir for the treatment of COVID-19. As a result, we may not be able to recover these costs if pomotrelvir is not approved, which could have a material adverse effect on our business.

Further, it is not certain that any CMOs retained to manufacture pomotrelvir will be able to meet any commercial demand for pomotrelvir, and even if CMOs are able to manufacture sufficient pomotrelvir to meet commercial demand, we may be unable to purchase sufficient commercial quantities of pomotrelvir due to financial constraints.

We as an organization have never commercialized a product and may not be successful in establishing the capabilities required for commercialization. In order to commercialize pomotrelvir, we will need to rapidly establish and build sales, market access, medical affairs and marketing capabilities prior to obtaining approval to market pomotrelvir. If we do not obtain authorization or approval for pomotrelvir, we will have expended those resources prematurely and our business could be adversely affected. If pomotrelvir is approved and we are unable to meet commercial demand for any reason, we may not be able to fully capitalize on the commercial potential of pomotrelvir, which could have an adverse effect on our business.

There has also been significant media coverage regarding the pricing of vaccines and treatments for COVID-19. For example, Gilead Sciences, Inc. has come under scrutiny regarding its pricing of remdesivir, after having donated its initial supply of the drug. Pricing for drugs to treat COVID-19 continues to evolve, and we cannot be certain of the factors that will determine the sales price of pomotrelvir, if approved. If we are unable to sell pomotrelvir at a sufficient price point, our ability to profitably commercialize pomotrelvir, if approved, may be adversely affected.

The evolution of the COVID-19 pandemic or occurrence of any other public health crises may materially and adversely affect our business and financial results.

As a result of the evolving COVID-19 pandemic or the occurrence of any other public health crises, we may experience disruptions that could severely impact our business, preclinical studies, nonclinical studies and clinical trials, including:

- delays or difficulties in enrolling participants in a clinical trial, including rapidly evolving treatment paradigms and participants that may not be able to comply with clinical trial protocols if quarantines impede participant movement or interrupt healthcare services;
- difficulties in enrolling participants due to the number of competing therapies that are approved, authorized or being tested for COVID-19;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, or the overwork of existing investigators and staff;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic or other public health crises, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruptions or delays in preclinical studies, nonclinical studies or clinical trials due to restricted or limited operations at research and development laboratory facilities;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or provincial governments, employers and others or interruption of clinical trial participant visits and clinical trial procedures which may impact the integrity of participant data and clinical trial endpoints;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- interruption of or delays in receiving the supplies and materials needed to conduct preclinical studies, nonclinical studies and clinical trials;
- interruption in global shipping that may affect the transport of preclinical and clinical trial materials, such as investigational drug product;
- changes in local regulations as part of a response to the evolving COVID-19 pandemic or other public health crises that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption or delays in the operations of the FDA or other regulatory authorities which may impact review and approval timelines;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- delays in conducting on-site inspections in manufacturing facilities.

As a result of any of the above, the expected timeline for data readouts of our clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect and delay our ability to obtain regulatory approvals for pomotrelvir and increase our operating expenses. The impact to our operations due to the COVID-19 pandemic or other public health crises could be severe and could negatively affect our business, financial condition and results of operations. To the extent the COVID-19 pandemic or other public health crises adversely affects our business and financial results, the pandemic or other public health crises may also have the effect of heightening many of the other risk factors described in this "*Risk Factors*" section, such as those relating to our clinical trial timelines, our ability to enroll participants for clinical trials and obtain materials that are required for the production of our product candidates and our ability to raise capital.

Risks Related to Government Regulation

The regulatory pathways for our product candidates targeting COVID-19 are continually evolving, which may result in unexpected or unforeseen challenges and longer timelines than seen for earlier COVID-19 vaccines and therapeutics.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product and there are no adequate, approved and available alternatives. To date, COVID-19 vaccines, therapeutic antibodies and other therapeutics that have demonstrated positive results in clinical trials have moved rapidly through the FDA regulatory review and EUA process, as well as the review and authorization process in a number of other jurisdictions, including the European Union (EU). The speed at which all parties are acting to create and test many therapeutics for COVID-19 is unusual. Evolving or changing plans or priorities within the FDA or the regulatory authorities in other jurisdictions, including changes based on new knowledge of COVID-19 and how the disease affects the human body, evolving rates of infection, hospitalizations, morbidity and mortality, new data regarding potential therapeutics developed by our competitors and new variants of the virus, may significantly affect the regulatory timeline for further authorizations or approvals for therapeutics such as pomotrelvir. Results from our continued development, clinical trials and planned clinical trials, and ongoing discussions with the FDA and other regulatory bodies in relation thereto, may raise new questions and require us to redesign proposed nonclinical studies and clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects, with minimal lead time. If we are not able to successfully complete clinical trials in high-risk patients with approvable endpoints, an EUA for pomotrelvir or similar authorizations by regulatory authorities outside the United States may not be available.

On January 31, 2023, President Biden issued a Statement of Administration Policy indicating that the administration intends for the COVID-19 national emergency and public health emergency to end on May 11, 2023. When the public health emergency ends, the FDA will continue to have the authority to issue EUAs until that authority is formally terminated by the Secretary of HHS through a separate process. Pardes anticipates that the end of the public health emergency may reduce the likelihood of an EUA pathway for pomotrelvir even if the EUA declaration remains in place and that the EUA pathway will likely become unavailable within a short period after a notice of the termination of the EUA declaration is published in the Federal Register. Additionally, even if the EUA pathway and similar foreign accelerated regulatory processes remain available, if we are not able to design and successfully complete clinical trials that satisfy the criteria for issuance of an EUA, we will not be eligible for an EUA or similar authorizations by regulatory authorities outside the United States. Accordingly, even if we successfully complete registrational clinical trials of pomotrelvir demonstrating its therapeutic benefit and safety profile, it may be unlikely that the expedited EUA timelines and regulatory processes that were available to other COVID-19 therapeutics in the United States and in other jurisdictions will be available for pomotrelvir as a treatment for COVID-19.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for pomotrelvir or any other product candidate would substantially harm our business.

The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of nonclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. 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 development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application.

Pomotrelvir or our other product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authority that a product candidate is safe and/or effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- disagreement with our interpretation of data from nonclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission of an NDA or other comparable submission to a foreign regulatory authority or to obtain regulatory approval in the United States or elsewhere;
- failure to obtain approval of or identify deficiencies within the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations of the FDA or comparable foreign regulatory authorities that render our nonclinical and clinical data insufficient for approval.

The FDA or comparable foreign regulatory authorities may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval of our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to obtain approval, regulatory authorities may approve any of our product for fewer or more limited indications than we request, may require specific labeling or a Risk Evaluation Mitigation Strategy (REMS) that includes significant use or distribution restrictions or safety warnings, precautions, or contraindications, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with labeling that does not include the claims necessary or desirable for the successful commercialization of that product candidate.

Failures or delays in the commencement or completion of, or ambiguous or negative results from, our current or planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent, or limit our ability to generate revenue and continue our business.

We do not know whether any of our clinical trials will be commenced or completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA or comparable foreign regulatory authorities may not authorize us to commence our planned clinical trials or any other clinical trials we may initiate, or may suspend our clinical trials, for example, through imposition of a clinical hold and may request additional data to permit our clinical trials to proceed;
- delays in submission of additional IND applications that may be required or obtaining clearance from the FDA to proceed with clinical trials under those INDs;
- lack of adequate funding to continue our clinical trials and nonclinical studies;
- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- negative results from our nonclinical studies and clinical trials;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- the inability of CROs to perform under these agreements, including due to impacts from the COVID-19 pandemic on their workforce;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or Institutional Review Board (IRB) approval to conduct a clinical trial at a prospective site or sites;
- challenges in recruiting and enrolling participants in clinical trials, the proximity of participants to clinical sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- severe or unexpected drug-related side effects experienced by participants in a clinical trial;
- we may decide, or regulatory authorities may require us, to conduct additional nonclinical studies or clinical trials or abandon product development programs;
- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;
- the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, may require us to conduct a trial with an active comparator in lieu of a placebo-controlled trial or

may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials; and

- difficulties retaining participants who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues, or loss of interest.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in preclinical studies, nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. 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 product 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.

In addition, a clinical trial may be suspended or terminated by us, the FDA or comparable foreign regulatory authorities, the IRBs at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board that is overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- an inspection of the clinical trial operations or clinical sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including in response to the imposition of a clinical hold;
- developments on trials conducted by competitors for related technology that raises 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 our stated objectives;
- unforeseen safety issues or safety signals, including any that could be identified in our ongoing nonclinical studies or proposed clinical trials, adverse side effects or lack of effectiveness;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue clinical trials.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make changes to a product candidate, such as changes to the formulation or manufacturing, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our product candidates. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Further, conducting clinical trials in foreign countries, as we expect to do for pomotrelvir, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

We have conducted and intend 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.

We have in the past and may choose in the future to conduct clinical trials outside the United States for our product candidates. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions, or such data may not be accepted at all. The FDA will generally not consider the data from a foreign clinical trial not conducted under an IND unless (i) the trial was well-designed and well-conducted in accordance with GCP requirements, including requirements for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety and well-being of trial participants are protected, and (ii) the FDA is able to validate the data from the trial through an onsite inspection, if necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless

(i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including requirements as to the size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from the portion of our clinical trials of pomotrelvir conducted outside the United States, it would likely result in the need for additional trials for us to obtain regulatory approval to market pomotrelvir in the United States, which would be costly and time-consuming and delay or permanently halt our development of our product candidate. In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

Fast track designation for pomotrelvir may not result in faster development, regulatory review, or approval and does not increase the likelihood that pomotrelvir will receive marketing approval in the United States or other jurisdictions.

In June 2022, the FDA granted fast track designation for pomotrelvir for the treatment and prevention of SARS-CoV-2 infection and associated diseases (i.e., COVID-19). Fast track designation provides increased opportunities for sponsor meetings with the FDA during nonclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. However, even with fast track designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. Fast track designation does not assure ultimate approval by the FDA. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our product development program. Any such withdrawal could adversely affect our business, financial condition and results of operations.

A breakthrough therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for our product candidates if the clinical data support such a designation for one or more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Product candidates designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, 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.

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidates, if approved.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. See the section entitled "*Business - Government Regulation and Product Approval*" included in this Form 10-K.

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as pomotrelvir and other therapies we may develop. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably, including the ACA and the IRA. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private third-party payors. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, certain individual states as well as regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, patient organizations, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, patient organizations, customers and third-party payors 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 and develop and, if approved, market, sell and distribute our product candidates. See the section entitled "*Business – Government Regulation and Product Approval – Other U.S. Healthcare Laws and Compliance Requirements*" included in this Form 10-K. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including our relationships with physicians and other healthcare

providers who may be in the position to influence the ordering of or use of our product candidates, if approved, could be subject to challenge under one or more of such laws. Efforts to ensure that our internal operations and 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 may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity 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.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act (FTCA) and the California Consumer Privacy Act of 2018 (CCPA)), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators.

The State of California, for example, recently adopted the CCPA, which became effective January 2020. The CCPA establishes a privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State, imposing special rules on the collection of consumer data from minors and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. The CCPA was expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 (CPRA) took effect, amending the CCPA. The CPRA, among other things, gives California residents the ability to limit use of certain sensitive personal information, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action and establish a new California Privacy Protection Agency to implement and enforce the new law. Additionally, some observers have noted that the CCPA and CPRA have marked the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. Notably, comparable consumer privacy laws are set to take effect in 2023 in other states including the Virginia Consumer Data Protection Act (effective January 1, 2023), the Colorado Privacy Act and the Connecticut Data Privacy Act (both effective July 1, 2023), and the Utah Consumer Privacy Act (effective December 31, 2023). The new laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates and respond to consumer rights requests. Compliance with this new privacy legislation may result in additional costs and expense of resources to maintain compliance.

In addition, 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 the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers) and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations.

As we begin to conduct clinical trials globally, we may also become subject to privacy restrictions in various foreign jurisdictions around the world. For example, the collection, use, storage, disclosure, transfer, or other processing of personal information regarding individuals in the European Economic Area (EEA), including personal health data, is subject to the General Data Protection Regulation 2016/679 (GDPR). The GDPR is wide-ranging and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities.

Importantly, the GDPR prohibits the transfer of personal data from the EEA to the United States and other countries in respect of which the European Commission or other relevant regulatory body has not issued a so-called "adequacy decision" (known as "third countries"), unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data to the United States was the EU-U.S. Privacy Shield framework administered by the U.S. Department of Commerce. However, the European Union Court of Justice invalidated the EU-U.S. Privacy Shield framework in January 2020. In addition, certain recent EU court decisions cast doubt on the ability to use one of the primary alternatives to the EU-U.S. Privacy Shield, namely the European Commission's Standard Contractual Clauses, to lawfully transfer personal data to the United States and other third countries. In addition, the European Commission published the Standard Contractual Clauses, which has been required for all new transfers of personal data from the EEA to third countries (including the United States) since December 2022. Use of the Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional supplementary technical, organizational and/or contractual measures and/or contractual provisions may need to be put in place.

At present, there are few, if any, viable alternatives to the Standard Contractual Clauses, and there remains some uncertainty with respect to the nature and efficacy of such supplementary measures in ensuring an adequate level of protection of personal data. As supervisory authorities issue further guidance on personal data export mechanisms (including circumstances where the Standard Contractual Clauses can and cannot be used) and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines. If we are unable to transfer personal data between and among countries and regions in which we conduct clinical trials, operate, engage providers and/or otherwise transfer personal data, this could affect the manner in which we receive and/or provide our services, the geographical location or segregation of our relevant systems and operations and could adversely affect our financial results and generally increase compliance risk as a result. Additionally, other countries outside of the EEA have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business.

As a result of the United Kingdom's (UK) exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020, but subject to certain UK-specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned with the EU's data protection regime. Importantly, the UK Information Commissioner's Office has developed its own bespoke version of the Standard Contractual Clauses to govern cross-border data transfers, which could necessitate the implementation of both UK and EEA versions of Standard Contractual Clauses, depending on the locations of our clinical trials. This would require significant resources and result in significant cost to implement and manage. Further, non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. It is possible that if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, or severe criminal or civil sanctions, all of which may have a material adverse effect on our business, operating results, reputation, and financial condition.

Compliance with current and evolving U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating

results and business. Moreover, clinical trial participants, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information, which may prevent us from undertaking or publishing essential research and development, manufacturing, and commercialization. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in a material adverse effect on our business, results of operations, reputation, financial condition and prospects.

Even if we are able to obtain regulatory approvals for our product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if we receive regulatory approval for pomotrelvir or any of our other product candidates, we will have tested them in only a small number of patients during our clinical trials. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects, or the duration of such clinical trials may not be sufficient to identify when those events may occur. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. There have been other products that have been approved by the regulatory authorities but for which safety concerns has been uncovered following approval. Such safety concerns have led to labeling changes or withdrawal of products from the market, and any of our product candidates may be subject to similar risks. Additionally, we may be required to conduct additional nonclinical and clinical trials, require additional warnings on the label of our products, reformulate our products or make changes, create or modify a REMS, such as a medication guide outlining the risks of such side effects for distribution to patients and obtain new approvals for our and our suppliers' manufacturing facilities for pomotrelvir and any other product candidates. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our products if and when regulatory approvals for such products are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved products or substantially increase the costs and expenses of commercializing and marketing of our products.

Even if our product candidates receive regulatory approval, they will remain subject to extensive regulatory scrutiny and may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, regulatory authorities may still impose significant restrictions on the product candidate, including restrictions on our indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval clinical trials. Further, even if we obtain regulatory approval for a product candidate, we would be subject to ongoing requirements by regulatory authorities as to the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information for the product. 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.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements, regulations and standards. Manufacturers and manufacturers' facilities are also required to comply with applicable tracking and tracing requirements for prescription drug products. If we or a regulatory agency discover 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, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- require revisions to the labeling, including limitation on approved uses or the addition of additional warnings, including boxed warnings, contraindications or other safety information, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing clinical trials;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

- require us to create a REMS which could include a medication guide outlining the risks of such side effects for distribution to patients or distribution or use restrictions;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend or place on hold any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or request or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the HHS' Office of Inspector General, state attorneys general, members of Congress and the public. Violations of applicable regulations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations and civil and criminal sanctions by the government. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these federal False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label product uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with applicable laws and regulations, our policies and other legal or contractual requirements, which may give rise to regulatory enforcement action, liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common stock.

Healthcare insurance coverage and reimbursement may be limited or unavailable for our product candidates, if approved, which could make it difficult for us to sell our product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, commercial payors and health maintenance organizations. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which products and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval processes apart from Medicare determinations. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

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

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

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

Even if our products are approved for marketing in the United States, in order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining comparable foreign regulatory approvals and compliance with comparable foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

Also, regulatory approval for our product candidates may be withdrawn if we fail to comply with regulatory requirements as a result of problems that occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain comparable foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of our product candidates by comparable foreign regulatory authorities, we will be unable to commercialize our product in that country and the commercial prospects of that product candidate and our business prospects could decline.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Changes in funding for, and other disruptions to, the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new or existing product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees and statutory, regulatory and policy changes. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those 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 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 and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections) and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the FDA determine that an inspection is necessary for approval but that an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine that a remote interactive evaluation is adequate, the agency has stated that it generally intends, depending on the circumstances, to either issue a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to 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 other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If the FDA becomes unable to continue its current level of performance, we could experience delays and setbacks for our product candidates and for any approvals we may seek which could adversely affect our business.

Risks Related to Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies. Proprietary rights and technology are difficult and costly to protect, and we may not be able to ensure their protection.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for pomotrelvir and our other product candidates and methods of use, as well as on our ability to operate without infringing upon the proprietary rights of others. If we are unable to obtain and maintain sufficient intellectual property protection for our lead product candidate or other product candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize product candidates similar or identical to ours and our ability to successfully commercialize our product candidates and other product candidates that we may pursue may be impaired. We generally seek to protect our proprietary position by filing patent applications in the United States and at the appropriate time in those jurisdiction abroad as deemed appropriate, related to our product candidates, proprietary technologies and their uses that are important to our business. Finally, we maintain our non-patented, but proprietary technologies, as company trade secrets. We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage or 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.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file for patent protection of the inventions claimed in our patent applications.

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. 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. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

U.S. provisional patent applications that we file are not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not timely file any non-provisional patent application, we may lose our priority date with respect to the provisional patent application and any patent protection on the inventions disclosed in the provisional patent application. We cannot be certain that the claims in any U.S. pending nonprovisional patent application or the provisional patent applications when converted to nonprovisional patent applications will be considered patentable by the United States Patent and Trademark Office (USPTO), courts in the United States or by the patent offices and courts in foreign countries.

The patent process is subject to numerous risks and uncertainties, and there can be no assurance that we, or any of our potential future collaborators, will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- 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, 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 that protect our product candidates;
- patents 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 us and 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/or sell our potential product candidates;
- 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 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 or in all jurisdictions where protection may be commercially advantageous. 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.

In addition, 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, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors 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.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

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.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products.

Our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

Our issued patents and future patents if issued may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive.

The requirements for patentability may differ in certain countries, particularly in developing countries. Consequently, competitors and other third parties 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 may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug and other countries, like India, certain countries in Europe and certain developing countries, including Thailand, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents and could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and pharmaceuticals. This could make it difficult for us to stop the infringement of our patents if issued or the marketing of competing products in violation of our proprietary rights, generally. 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, could place 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.

In June 2022, the World Trade Organization's (WTO) member states agreed to waive certain intellectual property rights on coronavirus vaccines in lower-income countries under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Member States also agreed to decide within six months, by December 17, 2022, whether to extend this intellectual property waiver to COVID-19 therapeutics and diagnostics. While the December 17, 2022 deadline has passed, discussions regarding a deadline extension are ongoing and the impact, if any, of such an extension on us remains uncertain. Governmental actions, such as the potential waiver of intellectual property protection or imposition of compulsory licenses, or other potential waivers of intellectual property during emergencies, if applicable to any of our product candidates could harm our ability to successfully and profitably commercialize our product candidates. Requirements such as the foregoing could limit our ability to fully exploit and, in the future, monetize our product candidates and patents, as well as place potential additional difficulties on our enforcement efforts in those jurisdictions.

Obtaining and maintaining our 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.

Periodic maintenance and annuity fees on issued United States patents and most foreign patent applications and patents must be paid to the USPTO and foreign patent agencies, respectively, in order to maintain such patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application, examination and issuance processes. While an inadvertent lapse can, in some cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition and results of operations.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe or misappropriate or otherwise violate our intellectual property rights. In the future, we may initiate legal proceedings to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity or scope of intellectual property rights we own or controls. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, competitors or third parties may challenge the scope, validity or enforceability of our patents requiring us to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Moreover, the outcome following legal assertions of invalidity and unenforceability is unpredictable. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation reexamination, or *inter partes* review, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidates without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Even if we obtain a license, our license may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patent applications is threatened, that could dissuade companies from collaborating with us to license, develop or commercialize product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and we may 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 collaborations.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or our counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us.

An unfavorable outcome in any such proceeding could require us to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to us from the prevailing party, which may not be available on commercially reasonable terms, or at all.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

A third party may hold proprietary rights that could prevent our product candidates from being marketed. Moreover, it is possible that we are or may become aware of patents or pending patent applications that we think do not relate to our product candidates or that we believe are invalid or unenforceable, but that may nevertheless be interpreted to encompass our product candidates and to be valid and enforceable. If any third-party intellectual property claims are asserted against us, even if we believe the claims are without merit, there is no assurance that a court would find in our favor, e.g., on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. To successfully challenge the validity of any such third-party U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or other commercialization partners and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we and other commercialization partners may be prevented from commercializing our product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, we could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. Many foreign jurisdictions also have rules of discovery that are different than those in the United States and which may make defending or enforcing our patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

We may be subject to claims by third parties asserting that our employees or that we have misappropriated a third party's intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights and non-disclosure agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our product candidates receive approval, they may be subject to The Drug Price Competition and Patent Term Restoration Act of 1984, as amended (also referred to as the Hatch-Waxman Act), in the United States, which can increase the risk of litigation with generic companies trying to sell our products and may cause us to lose patent protection.

Because our clinical candidates are small molecules reviewed by the Center for Drug Evaluation and Research of the FDA, after commercialization they will be subject in the United States to the patent litigation process of the Hatch-Waxman Act, as currently amended, which allows a generic company to submit an ANDA to the FDA to obtain approval to sell a generic version of our drug on the basis of bioequivalence data rather than clinical endpoint studies. Under the Hatch-Waxman Act, we will have the opportunity to list our patents that cover our drug product or our method of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book.

Currently, in the United States, the FDA may grant five years of exclusivity for new chemical entities (NCEs), for which our product candidates may qualify. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. A generic company can submit an ANDA to the FDA four years after approval of our product. The submission of the ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable or not infringed. If the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. This will initiate a challenge to one or more of our Orange Book-listed patents based on arguments from the generic company that our listed patents are invalid, unenforceable or not infringed. Under the Hatch-Waxman Act, if a lawsuit is brought, the FDA is prevented from issuing a final approval on the generic drug until 30 months after the end of our data exclusivity period, or a final decision of a court holding that our asserted patent claims are invalid, unenforceable or not infringed. If we do not properly list our relevant patents in the Orange Book, do not timely file a lawsuit in response to a certification from a generic company under an ANDA, or if we do not prevail in the resulting patent litigation, we can lose our proprietary protection, and our product can rapidly become generic. Further, even if we do correctly list our relevant patents in the Orange Book, bring a lawsuit in a timely manner and prevail in that lawsuit, the generic litigation may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator drug at the same time, so we may be faced with the cost and distraction of multiple lawsuits. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity or enforceability of our patent.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, in our activities we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our proprietary information, and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our proprietary information will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, 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.

Intellectual property rights do not necessarily address all potential threats.

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 products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our future collaborators, might not have been the first to make the inventions covered by our patents or pending patent applications;
- we, or our future collaborators, might not have been the first to file patent applications covering certain of our or their 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 or those that we may own in the future will not lead to issued patents;
- issued patents that we own currently or in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- 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;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents that cover our product candidate could be found invalid or unenforceable if challenged in court or the USPTO.

If we initiate legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patent such that they no longer cover our product candidate. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part and perhaps all of the patent protection on our product candidate. A loss of patent protection for our product candidate could have a material adverse impact on our ability to commercialize or license our technology and product candidate and, resultantly, on our business, financial condition, prospects and results of operations.

Our European patents and patent applications could be challenged in the recently created Unified Patent Court (UPC) for the European Union, which is expected to be fully ratified in 2023. We may decide to opt out our European patents and patent applications from the UPC's Unitary Patent system. However, if certain formalities and requirements are not met, or if we do not elect to opt our patents out of the UPC system, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, even if we decide to opt out of the UPC system. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. A successful invalidity challenge to a European patent before the UPC would result in loss of patent protection in each of those countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection across numerous European countries, rather than patent validity being adjudicated on a country-by-country basis in Europe, as has historically been the case. 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.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity and obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances, weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. 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, the USPTO and equivalent bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act (Leahy-Smith Act), as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents, when issued. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a "first-to-invent" to a "first-inventor-to-file" patent system and may also affect patent prosecution and litigation, such as by allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-inventor-to-file" provisions, became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of issued patents all of which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Reliance on Third Parties

We rely on and will continue to rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We do not have the ability to independently conduct certain nonclinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support certain nonclinical studies and our clinical development program. We control only certain aspects of their activities and have limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical trial protocols. Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our nonclinical studies or clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, regulatory authorities

will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with products produced under cGMP requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

The third parties who conduct our clinical trials are and will not be our employees and, except for remedies that may be available to us under our agreements with those third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf.

We have negotiated and expect to continue negotiating our budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates in a timely manner or at all. As a result, our results of operations, financial results and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding new CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We contract with third parties for the manufacture of our product candidates for nonclinical and clinical testing and expect to continue to do so for subsequent clinical trials and for commercialization. Significant portions of our clinical manufacturing are currently conducted by third party manufacturers outside of the United States, including China. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or that such supply will not be available to us at an acceptable cost and in accordance with anticipated timelines, which could delay, prevent, or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of nonclinical, clinical or if approved commercial supplies of the product candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a nonclinical, clinical or commercial scale. We rely on third parties for the supply of our nonclinical and clinical drug supplies (including key starting and intermediate materials), and our strategy is to outsource all manufacturing of our product candidates and products to third parties.

In order to conduct clinical trials of product candidates, we will need to have the product candidates manufactured in potentially large quantities. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our clinical drug supplies (including key starting and intermediate materials) in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time.

Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourself. Any disruption in supply from any supplier or manufacturing location, including on account of the COVID-19 pandemic or the ongoing conflict in Ukraine, could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. To the extent any issues arise with our third-party manufacturers, we may be unable to establish any agreements with any other third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or comparable foreign regulatory requirements. The facilities used by our CMOs to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of and will be completely dependent on our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product

candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulators, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If our CMOs are unable to maintain a compliance status acceptable to the FDA or other regulatory agencies, if the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if such agency finds deficiencies or 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.

Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations.

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If any one of our current contract manufacturers cannot perform its obligations as agreed, we may be required to replace that manufacturer, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies, including potentially clinical bridging studies, between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement CMO. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of our product candidates involves multi-step processes and we may encounter delays and difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The lengthy multi-step manufacturing processes for our product candidates are expensive, highly-regulated and subject to multiple risks. Further, as product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of clinical trials or other future clinical trials.

In addition, the manufacturing process for any products that we may develop is subject to FDA and other comparable foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and comparable foreign regulatory authority requirements, including, for example, complying with cGMPs, on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging or comparability nonclinical or clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and has an adverse effect on our business, financial condition, results of operations and growth prospects.

We may seek to establish collaborations and if we are not able to establish them on a timely basis, on acceptable terms, or at all, we may have to delay, alter or curtail our development and commercialization plans.

The advancement of pomotrelvir and its potential commercialization will require substantial additional cash to fund expenses. We may pursue collaborations as a way to secure additional cash and expertise to develop and commercialize pomotrelvir and other product candidates. We face significant competition in seeking appropriate collaborators and some potential collaborators may have competing programs. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidates.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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 reduce or curtail the development of the product candidate for which we are seeking to collaborate, delay our 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 our product candidates or bring them to market and generate product revenue.

Risks Related to Commercialization

Even if we commercialize our product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product 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 or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors determine which medications they will cover and establish reimbursement levels. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval, if any. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which marketing approval is obtained, if any.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a 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 may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products 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. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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 currently have an infrastructure for the sales, marketing and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, commercial operations, managed care, customer operations, channel distribution, government price reporting, managerial and other non-technical capabilities, or make arrangements with third parties to perform these services. 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 account management team 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 establishes 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.

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 ourself. 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 and they could expose us to regulatory enforcement and legal risk in the execution of their sales and commercialization activities. 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.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected.

Our product candidates may not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors and private insurers, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Third-party payors closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. We cannot be certain that third-party payors will sufficiently reimburse sales of our product, or enable us to sell our product at a profitable price. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many regions outside the United States where we may pursue regulatory approvals and market our products, the pricing of prescription drugs is controlled by the government or regulatory agencies.

Regulatory agencies in these countries could determine that the pricing for our products should be based on prices of other commercially available products for the same disease, rather than allowing us to market our products at a premium as new drugs. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by clinics and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including vaccines and other anti-viral therapeutics;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors;
- the relative convenience and ease of administration, for example, dosage form, pill burden or number of days of therapy per course;
- the additional healthcare economic evidence generated, as supported by real-world data or other non-interventional trials, demonstrating cost-effectiveness or budget impact of therapy;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to our product candidates or similar therapeutics.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Product liability lawsuits against us could cause the company to incur substantial liabilities and to limit commercialization of any products that we may develop and insurance coverage may not be adequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, their family members, healthcare providers or others using, administering, selling or otherwise coming into contact with our products. If we cannot successfully defend ourself against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products, if approved for commercial sale, that we may develop;

- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or other claimants;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- a decline in our stock price.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician adoption of our product or expand our business.

Risks Related to our Common Stock

An active trading market for our common stock may never develop or be sustained, which may make it difficult to sell the shares of our common stock you purchase.

An active trading market for our common stock may not develop or continue or, if developed, may not be sustained, which would make it difficult for you to sell your shares of our common stock at an attractive price (or at all). The market price of our common stock may decline below your purchase price, and you may not be able to sell your shares of our common stock at or above the price you paid for such shares (or at all).

The price of our common stock has been and may continue to be volatile.

We cannot predict the prices at which our common stock will continue to trade. From the closing of the Business Combination on December 23, 2021 through December 31, 2022, our closing stock price has ranged from $0.85 to $17.02. The price of our common stock may fluctuate due to a variety of factors, including:

- changes in the industries in which we and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;
- significant decreases in new infections caused by SARS-CoV-2;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us, our competitors or our industry;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;

- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt or the anticipation thereof;
- rising interest rates and inflation;
- the volume of shares of our common stock available for public sale; and
- the impact of general economic and political conditions such as recessions, interest rates, inflation rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism, including geopolitical instability caused by the Russian invasion of Ukraine.

These market and industry factors may materially reduce the market price of share of our common stock regardless of our operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and seriously harm our business.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our shares of common stock.

The trading market for our common stock will depend in part on the research and reports that securities research analysts publish about our business. We do not have any control over these analysts and such analysts may establish and publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline.

The future sales of shares by existing stockholders and future exercise of registration rights may adversely affect the market price of our common stock.

Sales of a substantial number of shares of our shares of 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 intend to sell shares, could reduce the market price of our shares of common stock. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock. Moreover, as restrictions on resale end and the registration statements (that we have filed following the closing date of the Business Combination to provide for the resale of such shares from time to time) are available for use, the market price of our shares of common stock could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders, such as raising capital through equity financings. For example, in January 2023, we filed the 2023 Shelf and simultaneously with the 2023 Shelf we entered into the ATM Sales Agreement with the Sales Agent pursuant to which we may sell up to $50.0 million of our common stock from time to time in "at-the-market" offerings. Additionally, we expect to grant equity awards to employees, directors and consultants under our stock incentive plans. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests, voting rights and the per share value of our common stock to decline.

Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

We have no current plans to pay cash dividends on our common stock. The declaration, amount and payment of any future dividends will be at the sole discretion of our Board. Our Board may take into account general economic conditions, our financial condition and operating results, our available cash, current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, implications on the payment of dividends by us to our stockholders and such other factors as our Board may deem relevant. Accordingly, we may not pay any dividends on our common stock in the foreseeable future. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

We will continue to incur significant additional costs as a result of being a public company, which may adversely affect our operating results and financial condition.

As a public company, we incur significant costs associated with public company reporting and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act), the SEC and Nasdaq. Our management and other personnel devote a substantial amount of time to these compliance initiatives and these rules and regulations have increased our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. For example, we are required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. To comply with the applicable provisions of Section 404 for this filing, we engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging.

Furthermore, if material weaknesses are identified or arise in the future, 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 are required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934 (Exchange Act). Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences. We will incur significant costs to remediate any material weaknesses we identify through these efforts. The increased costs will increase our net loss and may require us to reduce costs in other areas of our business. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

Additionally, new laws and regulations, as well as changes to existing laws and regulations affecting public companies, including the provisions of Sarbanes-Oxley Act, Dodd-Frank Act and rules adopted by the SEC and Nasdaq, would likely result in increased costs as we respond to their requirements, which may adversely affect our operating results and financial condition.

We are an "emerging growth company" and "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.24 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the closing of the FSDC II initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- being permitted to present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" disclosure in our Form 10-K;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same adoption timelines for new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company," as defined in Item 10(f)(1) of Regulation S-K. We will continue to be a smaller reporting company until the last day of the fiscal year in which (1) the market value of our shares of common stock held by non-affiliates equals or exceeds $250 million as of the end of that year's second fiscal quarter, and (2) our annual revenues equaled or exceeded $100 million during such completed fiscal year or the market value of our shares of common stock held by non-affiliates equals or exceeds $700 million as of the end of that year's second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

As a public company, we are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Once required, an independent assessment of the effectiveness of our internal controls over financial reporting by our independent registered public accounting firm could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

As of March 1, 2023, our executive officers, directors and their affiliates, in the aggregate, owned approximately 38% of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly influence all matters submitted to our Board or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

Provisions in our second amended and restated certificate of incorporation and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our second amended and restated certificate of incorporation and bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our Board. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our Board to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our Board;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause and the prohibition on removal of directors without cause;
- the ability of our Board to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our Board to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our bylaws or repeal the provisions of our second amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the Board, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our Board or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to anti-takeover provisions under Delaware law, which could discourage, delay, defer or prevent a merger, tender offer, proxy contest or other change of control transaction that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares of common stock held by our stockholders. These anti-takeover provisions as well as certain provisions of Delaware law could make it more difficult for a third party to acquire us, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. If prospective takeovers are not consummated for any reason, we may experience negative reactions from the financial markets, including negative impacts on the price of our common stock. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing and to cause us to take other corporate actions that our stockholders desire.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that, with certain limited exceptions, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (the Court of Chancery) is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders; (3) any action asserting a claim arising pursuant to the Delaware General Corporation Law, or our second amended and restated certificate of incorporation or bylaws (as each may be amended from time to time); (4) any action to interpret, apply, enforce or determine the validity of our second amended and restated certificate of incorporation or amended and restated bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a state law claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our 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 have a material adverse impact on our business. The choice of forum provision in our amended and restated bylaws will not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the Exchange Act or the Securities Act. In addition, our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the U.S. District Court for the Southern District of California is the sole and exclusive forum for resolving an action asserting a claim arising under the Securities Act.

General Risk Factors

Our business may be impacted by macroeconomic conditions, including inflation, rising interest rates and volatile market conditions as well as political events, war, terrorism, business interruptions and other geopolitical events and uncertainties beyond our control.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. In addition, current macroeconomic conditions have caused turmoil in the banking sector. For example, on March 10, 2023, Silicon Valley Bank (SVB), one of our banking partners, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. At the time of the closure, we held assets valued at approximately $1.0 million in a deposit account with Silicon Valley Bank. While we were afforded full access to our deposit account on March 13, 2023, we may be impacted by other disruptions to the U.S. banking system caused by the recent developments involving SVB, including potential delays in our ability to transfer funds whether held with SVB or otherwise and in the short-term potential delays in making payments to vendors while new banking relationships are established.

Additionally, war, terrorism, geopolitical uncertainties and other business interruptions could cause damage to, disrupt or cause us to cancel the conduct of our clinical trials on a global or regional basis, which could have a material adverse effect on our business. Such events could also decrease patient demand to enroll in our clinical trials, make it difficult or impossible for us to deliver products and services to our clinical investigational sites or impact the vendors with which we do business. In addition, territorial invasions could lead to cybersecurity attacks on companies, such as ours, located far outside of a conflict zone. In the event of prolonged business interruptions due to geopolitical events, we could incur significant losses, require substantial recovery time and experience significant expenditures in order to resume our business or clinical operations. We have no operations in Russia or Ukraine, but we do not and cannot know if the ongoing conflict in Ukraine may escalate and result in broad and adverse economic and security conditions or rationing of medical supplies, which could limit our ability to conduct clinical trials or otherwise materially impact our business.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates and other similar effects. As a result of inflation, we may experience cost increases. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective, our business, financial condition, results of operations and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost of inflation is incurred.

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

Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. 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. 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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Not applicable.

Item 3. Legal Proceedings.

From time to time, we may become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of December 31, 2022, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the 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.

Not applicable.

PART II

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

Market Information

Our common stock trades on the Nasdaq Global Market under the ticker symbol "PRDS."

Holders of Our Common Stock

As of March 10, 2023, we had 35 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We have never declared or paid any cash dividends on our capital stock. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Form 10-K.

Issuer Purchases of Equity Securities

The following table contains information relating to our repurchase of unvested restricted common stock from a former employee during the three months ended December 31, 2022.

Period	Total Number of Shares Purchased	Average Price Paid per Share
October 1 - October 31, 2022	—	$ —
November 1 - November 30, 2022	—	—
December 1 - December 31, 2022	586,581	$ 0.00000711
Total	586,581	

Recent Sales of Unregistered Securities and Use of Proceeds

None.

Item 6. [Reserved.]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the notes thereto included elsewhere in this Form 10-K. As discussed under the heading "Cautionary Note Regarding Forward-Looking Statements," this discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in Part I, Item 1A, "Risk Factors" of this Form 10-K. Actual results may differ materially from those described in or implied by any forward-looking statements. You should carefully read "Cautionary Note Regarding Forward-Looking Statements" and Part I, Item 1A, "Risk Factors."

Overview

We are a clinical-stage biopharmaceutical company that is focused on discovering, developing and commercializing novel therapeutics to treat and prevent viral disease and on preventing the next pandemic, starting with our lead product candidate, pomotrelvir (formerly known as PBI-0451), which targets COVID-19. Pomotrelvir is in clinical development to treat COVID-19 in adult and pediatric patients. COVID-19 is caused by infection with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and has emerged as the most significant pandemic threat to the world in many decades. By leveraging our understanding of structure-based drug design, reversible covalent chemistry and viral biology, we have discovered novel product candidates with low nanomolar potency against SARS-CoV-2 and broad activity against all known pathogenic human coronaviruses.

At this time, we are focusing on pomotrelvir and our next generation coronavirus M^{pro} inhibitor program. Given the highly conserved nature of the main coronaviral cysteine protease (M^{pro} or 3CLpro) target, which is shared among all known coronaviruses, including emerging variants of concern, we believe M^{pro} inhibitors, like pomotrelvir, will likely continue to retain their potency and activity against current and most emerging SARS-CoV-2 variants of concern. Our lead product candidate, pomotrelvir, inhibits the M^{pro}, a viral protein essential for replication of all known coronaviruses, including SARS-CoV-2. In preclinical studies, pomotrelvir has demonstrated activity against all coronaviral proteases tested to date, as well as inhibition of replication of multiple coronaviruses, including SARS-CoV-2 clinical isolates, including Omicron variants. Moreover, in preclinical studies, pomotrelvir demonstrated the potential for oral bioavailability across multiple preclinical species and more recently, oral bioavailability in healthy volunteers in our Phase 1 clinical trials. We believe the anti-viral potency seen against SARS-CoV-2 in preclinical in vitro studies and demonstrated oral bioavailability in humans supports its potential to be an oral direct acting antiviral (DAA) for use against COVID-19.

We initially plan to develop pomotrelvir for oral treatment of COVID-19 in adult and pediatric patients. We have completed enrollment of patients in our Phase 2 clinical trial (NCT 05543707) evaluating the antiviral activity, safety and clinical efficacy of pomotrelvir for the treatment of mild-to-moderate COVID-19. We expect to report top-line data from this Phase 2 clinical trial in the coming weeks.

Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization or partnership for one or more of our product candidates.

On December 23, 2021, we completed the Business Combination with FSDC II, which resulted in FSDC II acquiring 100% of Old Pardes' issued and outstanding securities. Together with FSDC II's cash resources, additional funding for our operations was provided through a private investment in public equity (PIPE Investment), which was completed concurrently with the Merger.

We accounted for the Business Combination as a reverse recapitalization which is the equivalent of Old Pardes issuing stock for the net assets of FSDC II, with FSDC II treated as the acquired company for accounting purposes. The net assets of FSDC II were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included in this Form 10-K for periods prior to the Business Combination are those of Old Pardes. The shares and corresponding capital amounts and loss per share related to Old Pardes' outstanding redeemable convertible preferred stock and common stock prior to the Business Combination have been retroactively restated to reflect the conversion ratio established in the Merger Agreement. For additional information, see Note 5, *Business Combination*, to the financial statements in this Form 10-K.

Since inception in 2020, we have devoted substantially all our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates, preparing and filing related patent applications and conducting research and development activities for our product candidates. We have not yet successfully completed any Phase 2 clinical trials evaluating the efficacy of any of our product candidates, including pomotrelvir, nor have we obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities. We do not have any products approved for sale and we have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product.

Recent Developments

In January 2022, the United States Food and Drug Administration (FDA) cleared our Investigational New Drug (IND) application for pomotrelvir. In June 2022, the FDA designated the investigation of pomotrelvir for the treatment and prevention of SARS-CoV-2 infection and associated diseases (i.e., COVID-19) as a fast track development program.

We have completed our first-in-human Phase 1 clinical trial (NCT 05011812) with pomotrelvir that assessed single and multiple dosing, food effect, formulation, and CYP3A4/P-glycoprotein drug drug-drug interactions. In that clinical trial, there were no drug discontinuations and no drug-related grade 2, 3, 4 or serious adverse events (collectively, AEs) and no evidence of relationship between dose/exposure and severity, relatedness or incidence of AEs. No clinically significant treatment emergent adverse findings in laboratory values, vital signs or electrocardiogram assessments were reported. We believe pomotrelvir at 700 mg (two 350 mg tablets) administered twice daily with food has the potential to achieve and maintain exposures expected to demonstrate potent antiviral activity.

We have also completed a food effect study for our clinical and intended commercial tablet formulation of pomotrelvir. In in vitro toxicology studies, we observed a lack of mutagenic or genotoxic potential, phototoxicity or teratogenicity. We have also conducted fertility and embryo fetal development toxicology studies with pomotrelvir that have not identified drug-related adverse findings. No direct drug-related adverse findings were observed at the highest doses tested in 14-day or 28-day good laboratory practice (GLP) toxicology studies conducted across multiple preclinical species. Pomotrelvir does not require ritonavir boosting and we believe pomotrelvir has the potential to be used broadly by patients due to an observed favorable drug-drug interaction profile.

In September 2022, we initiated our Phase 2 clinical trial (NCT 05543707) evaluating the antiviral activity, safety, and clinical efficacy of pomotrelvir for the treatment of mild-to-moderate COVID-19. This Phase 2 clinical trial was powered to assess the primary objective of the proportion of patients below the limit of detection for infectious SARS-CoV-2 on day three of treatment by infectious virus assay from nasal swab samples. Secondary objectives assessed include additional virologic assessments including the dynamics and time to negativity in SARS-CoV-2 viral load by qRT-PCR and by rapid antigen testing, safety and tolerability, and clinical efficacy through assessment of COVID-19 symptoms, and hospitalizations and deaths through Day 28. Study participants will continue in long term follow-up for a total duration of 24 weeks to explore long term outcomes, including those associated with long COVID. This study is fully enrolled with all participants having completed assessments through Day 28. Top-line data from the Phase 2 clinical trial is expected in the coming weeks.

We are conducting pre-study start-up activities, including site feasibility in parallel with continued discussions with the FDA and input from the European Medicines Agency (EMA) regarding our Phase 3 clinical development program for pomotrelvir, including specifics of clinical trial design to evaluate the safety and efficacy of pomotrelvir as compared to the matching placebo in otherwise healthy patients. We anticipate evaluating the impact of pomotrelvir on the time to the alleviation of key COVID-19 symptoms. Initiation of the pomotrelvir Phase 3 clinical development program is subject to, among other things, positive Phase 2 results and alignment with applicable regulatory agencies, including the FDA. Currently, we plan to be in position to initiate our Phase 3 development program mid-2023.

Liquidity Overview

As of December 31, 2022, cash, cash equivalents and short-term investments were $197.3 million and we believe that our existing cash resources will be sufficient for at least 12 months from the issuance date of these financial statements to allow us to fund current planned operations, including supporting working capital and capital expenditure requirements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. For additional information, see "—*Liquidity and Capital Resources*" below. Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations.

Through December 31, 2022, we have primarily funded our operations with gross cash proceeds of $44.5 million from sales of preferred stock and net proceeds of approximately $257.5 million in connection with the Business Combination and the PIPE Investment. For additional information, see Note 1, *Description of Business*, to the financial statements in this Form 10-K.

We have incurred operating losses since our inception. As of December 31, 2022, we had an accumulated deficit of $148.2 million and had not yet generated revenues from product sales. In addition, we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses and capital requirements will continue to increase substantially in connection with our ongoing development activities, particularly if and as we:

- continue preclinical and nonclinical studies and initiate new clinical trials for pomotrelvir, our lead product candidate being tested for the treatment of COVID-19;
- advance the research and development of our next generation coronavirus M^{pro} inhibitor program or other product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory authorization or approval;
- expand our infrastructure to accommodate our growing employee base and operating as a public company;
- increase manufacturing requirements for our clinical development activities and commercial preparedness; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, and any future commercialization efforts.

Furthermore, we expect to continue to incur significant costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time, if ever, as we can generate significant revenue from product sales, we expect to finance our operations through a combination of private and public equity offerings, debt financings or other capital sources, which may include collaborations with other companies, government funding, or other strategic transactions. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, existing ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or other strategic transactions with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

On January 12, 2023, we filed a shelf registration statement on Form S-3, which was declared effective by the U.S. Securities and Exchange Commission on January 20, 2023 (2023 Shelf). The 2023 Shelf covers the offering, issuance and sale by us of up to an aggregate of $200.0 million of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, subscription rights to purchase our common stock, preferred stock or debt securities and/or units consisting of some or all of these securities. In connection with the 2023 Shelf, on January 11, 2023, we entered into a Sales Agreement (Sales Agreement) with SVB Securities LLC (Sales Agent), pursuant to which we may offer and sell up to $50.0 million of our common stock, from time to time at our sole discretion, through the Sales Agent, in “at-the-market” offerings under the 2023 Shelf. As of the filing of this Form 10-K, no sales have been made pursuant to the Sales Agreement.

Impact of COVID-19 Pandemic and Other Macroeconomic Conditions

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. In January 2023, the World Health Organization stated that COVID-19 remains a global health emergency of international concern as the world enters the fourth year of the pandemic; however the world may be transitioning out of the emergency phase by the end of 2023. In the United States, President Biden has announced that it is the intent of his administration to end the national emergency and U.S. public health emergency on May 11, 2023. As a clinical-stage biopharmaceutical company with a lead product candidate, pomotrelvir, which targets COVID-19, our financial performance and prospects will depend on future developments related to the COVID-19 pandemic, including the duration of the outbreak, rates of infections, the emergence of new variants and subvariants, public sentiment, governmental advisories and restrictions and competing products. For example, to the extent rates of infections decrease significantly, public perception regarding the seriousness of the pandemic subsides or our competitors develop products which are perceived as superior to our lead product candidate, our financial condition and prospects could be materially and adversely impacted.

Additionally, while to date our operations have not been significantly impacted by the COVID-19 pandemic, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic or other public health crises will have on our operations, including ongoing and planned clinical trials and other operations required to support those clinical trials and research and development activities to advance our pipeline.

Moreover, uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including as a result of increases in inflation, rising interest rates, geopolitical factors, including the ongoing conflict between Russia and Ukraine and the responses thereto, and supply chain disruptions. While we are closely monitoring the impact of the current macroeconomic conditions on all aspects of our business, including the impacts on our patients, employees, suppliers, vendors and business partners, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period of time. As a result, we are subject to continuing risks and uncertainties and continue to closely monitor the impact of the current conditions on our business. For additional information, see Part I, Item 1A, "Risk Factors" of this Form 10-K.

Components of Our Results of Operations

Revenue

Since inception, we have not generated, and do not expect to generate, any revenue from the sale of products in the near future, if ever. If our development efforts are successful and we commercialize our products, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, as well as upfront, milestone and royalty payments from such collaboration or license agreements, or a combination thereof.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for research activities, including drug discovery efforts and the development of our potential product candidates. We expense research and development costs as incurred, which include:

- expenses incurred to conduct the necessary preclinical studies, nonclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with contract research organizations (CROs) that are primarily engaged in the oversight and conduct of our drug discovery efforts, preclinical studies and clinical trials and contract manufacturing organizations (CMOs) that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative site and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions; and
- costs related to compliance with regulatory requirements.

We recognize research and development expenses as incurred. Any advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered. We estimate and accrue for the value of goods and services received from CROs, CMOs and other third parties each reporting period based on an evaluation of the progress to completion of specific tasks. This process involves reviewing open contracts and purchase orders, communicating with our personnel and service providers to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs.

At any one time, we may be working on multiple programs. We do not allocate employee costs and overhead costs associated to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources to manage our research and discovery as well as our preclinical, nonclinical, manufacturing and clinical development activities. To date, substantially all of the research and development costs incurred have been in connection with the development of our lead product candidate, pomotrelvir.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of the following:

- the scope, progress, outcome and costs of our preclinical and nonclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety and efficacy profile with clinically enabling trials;
- successful patient enrollment in and the initiation and completion of clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulations;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical, nonclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries and related benefits, travel and stock-based compensation for personnel in executive, business development, finance, human resources, legal, information technology and administrative functions. General and administrative expenses also include insurance costs and professional fees for legal, patent, consulting, investor and public relations, pre-commercial planning, accounting and audit services. Our general and administrative costs are expensed as incurred.

Income Taxes

We have incurred net losses in every period since our inception and have not recorded any U.S. federal or state income tax benefits for the losses, as they have been offset by valuation allowances.

Interest and Other Income (Expense), Net

Interest and other income (expense), net consists primarily of interest income.

Results of Operations

Comparison of the years ended December 31, 2022 and 2021

The following table sets forth our results of operations for the periods presented (in thousands):

	Year Ended December 31,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 70,350	$ 28,152	$ 42,198
General and administrative	29,467	10,336	19,131
Total operating expenses	99,817	38,488	61,329
Interest and other income (expense), net	3,183	(30)	3,213
Net loss	$ (96,634)	$ (38,518)	$ (58,116)

Research and Development Expenses

The following table summarizes the components of research and development expenses for the periods presented (in thousands):

	Year Ended December 31,		
	2022	2021	Change
External costs:			
Pomotrelvir	$ 45,000	$ 13,063	$ 31,937
Next generation and discovery programs	9,246	9,528	(282)
Total external costs	54,246	22,591	31,655
Internal costs:			
Salaries and benefits	10,031	3,671	6,360
Stock-based compensation	5,007	461	4,546
Other unallocated costs	1,066	1,429	(363)
Total internal costs	16,104	5,561	10,543
Total research and development expenses	$ 70,350	$ 28,152	$ 42,198

Research and development expenses were $70.4 million for the year ended December 31, 2022, compared to $28.2 million for the year ended December 31, 2021, an increase of $42.2 million. As indicated in the table above, the increase was primarily driven by increased costs related to advancing our lead product candidate, pomotrelvir, into a Phase 2 clinical trial and higher personnel costs, including stock-based compensation, as we have grown our organization.

We expect that our research and development expenses will increase substantially over the next couple of years as we commence Phase 3 clinical trials for pomotrelvir, as well as conduct preclinical and clinical development activities, including submitting regulatory filings, for our other product candidates. We also expect our related personnel costs will increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, will increase above historical levels.

General and Administrative Expenses

General and administrative expenses were $29.5 million for the year ended December 31, 2022, compared to $10.3 million for the year ended December 31, 2021, an increase of $19.2 million. The increase was due to increased personnel costs of $6.2 million, stock-based compensation expense of $4.8 million, professional fees related to legal, accounting and audit, pre-commercial planning and consulting services of $3.7 million, and directors' and officers' insurance of $3.7 million.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the continued development of our product candidates. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

Interest and Other Income (Expense), Net

Interest and other income (expense), net was $3.2 million for the year ended December 31, 2022 compared to a nominal amount for the year ended December 31, 2021, an increase of $3.2 million. The increase was due to higher interest rates on a greater balance of earning assets.

Liquidity and Capital Resources

Sources of Liquidity and Capital

Since inception, we have not generated any revenue from product sales and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates, and we do not expect to generate revenue from sales of any product candidates for several years, if ever. Through December 31, 2022, we have primarily funded our operations with gross cash proceeds of $44.5 million from sales of preferred stock and net proceeds of approximately $257.5 million in connection with the Business Combination and the PIPE Investment. For additional information, see Note 1, *Description of Business*, to the financial statements in this Form 10-K.

As of December 31, 2022, we had cash, cash equivalents and short-term investments of $197.3 million and an accumulated deficit of $148.2 million. We believe that our existing cash resources will be sufficient for at least the next 12 months from the issuance date of these financial statements to allow us to fund current planned operations, including supporting working capital requirements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In the long term, our ability to support working capital and capital expenditure requirements will depend on many factors, including our ability to raise additional capital to finance our operations. See "— *Liquidity Overview*" above.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (71,976)	$ (36,918)
Net cash used in investing activities	(137,021)	—
Net cash (used in) provided by financing activities	(397)	302,186
Net (decrease) increase in cash and cash equivalents	$ (209,394)	$ 265,268

Operating Activities

During the year ended December 31, 2022, net cash used in operating activities was primarily due to a net loss of $96.6 million, partially offset by a decrease in our prepaid expenses and other assets of $3.8 million, increases to our accrued expenses of $8.9 million and accounts payable of $2.5 million, and a non-cash charge of $10.6 million to stock-based compensation expense. The changes to our assets and liabilities relate mostly to the timing of vendor invoicing and payments, and the increase in stock-based compensation expense are attributable to increased headcount and the accelerated recognition of $2.7 million in stock compensation expense for our former Chief Executive Officer and President, Dr. Uri Lopatin, who transitioned to a consultant on July 31, 2022. For additional information, see Note 10, *Stock-Based Compensation*, to the financial statements in this Form 10-K.

During the year ended December 31, 2021, net cash used in operating activities consisted of a net loss of $38.5 million, partially offset by a non-cash charge of $1.2 million related to the change in stock-based compensation expense, and a net increase of working capital of $0.8 million due to increases to prepaid expenses and other current assets, accounts payable, and accrued expenses. The increases to prepaid expenses and other current assets, accounts payable, and accrued expenses was primarily due to growth in our operations, the advancement of our lead product candidate, pomotrelvir, and other potential product candidates, and the timing of vendor invoicing and payments.

Investing Activities

Net cash used in investing activities of $137.0 million for the year ended December 31, 2022 was primarily due to $138.2 million used to purchase available-for-sale securities, partially offset by $1.2 million provided from the sale of available-for-sale securities.

Financing Activities

During the year ended December 31, 2022, net cash used in financing activities of $0.4 million was related to payments for transaction costs associated with the Business Combination.

During the year ended December 31, 2021, net cash provided by financing activities primarily consisted of $257.5 million in net proceeds from the Business Combination and the PIPE Investment and $44.3 million in net proceeds from the sale of convertible preferred stock.

Funding Requirements

Our primary use of cash is to fund operating expenses, predominantly related to our research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly if and as we advance our clinical development program for pomotrelvir. We also incur and will continue to incur additional costs associated with operating as a public company, including significant insurance, legal, accounting, investor relations and other expenses that we did not incur as a private company. The timing and amount of our operating expenditures will depend largely on our ability to:

- initiate Phase 3 clinical trials of pomotrelvir;
- manufacture, or have manufactured on our behalf, our preclinical, nonclinical and clinical drug material and develop processes for late stage and commercial manufacturing;
- seek regulatory authorizations and/or approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs, managed care and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;
- manage the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- manage the costs of operating as a public company.

Working Capital

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

- the scope, progress, results and costs of researching and developing our product candidates and conducting preclinical and nonclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and necessary inventory to support a potential future commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from the commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Contractual Obligations and Commitments

We enter into short-term and cancellable agreements in the normal course of operations through purchase orders, statements of work under master services agreement or other documentation, or that are undocumented except for an invoice. Such short-term agreements are generally outstanding for periods less than one year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be cancelled upon prior notice of 90 days or less. Payments due upon cancellation generally consist only of payments for services provided and expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. Agreements for manufacturing services with contract manufacturing organizations and development services with contract research organizations may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2, *Summary of Significant Accounting Policies*, to the financial statements in this Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we make estimates our accrued research and development expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, based on a pre-determined schedule or when contractual milestones are met, but some require advance payments. If timelines or contracts are modified based upon changes in the protocol or scope of work to be performed, we modify our estimates and accruals accordingly on a prospective basis.

There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock option grants, estimated in accordance with the applicable accounting guidance, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. We recognize forfeitures as they occur.

The fair value of stock options is estimated using a Black-Scholes valuation model on the date of grant. The Black-Scholes option-pricing model requires inputs based on certain subjective assumptions. Changes to these assumptions can materially affect the fair value of stock options and ultimately the amount of stock-based compensation expense recognized in our financial statements. These assumptions include:

- *Fair Value of Common Stock* - Prior to our Business Combination, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuation of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation to the date of the grant. Since the completion of our Business Combination, the fair value of each share

of common stock underlying stock option grants is based on the closing price of our common stock on The Nasdaq Global Market as reported on the date of grant.

- *Expected Term* - We have opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally ten years.
- *Expected Volatility* - Due to our limited operating history and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Risk-Free Interest Rate* - The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options.
- *Expected Dividend* - To date, we have not issued any dividends and do not expect to issue dividends over the life of the options and therefore have estimated the dividend yield to be zero.

Recent Accounting Pronouncements

We evaluated the recently issued accounting pronouncements and, based on our assessment, do not believe any will have a material impact on our financial statements or related disclosures. See Note 2, *Summary of Significant Accounting Policies*, to the financial statements in this Form 10-K for additional discussion of our adopted accounting policies.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012 (JOBS Act) contains provisions that, among other things, relax certain reporting requirements for qualifying public companies. We qualify as an "emerging growth company" and under the JOBS Act are allowed to comply with new or revised accounting pronouncements based on the effective date for private (not publicly traded) companies. We are electing to delay the adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company" we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.24 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the closing of the FSDC II initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds $250 million as of the prior June 30, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the prior June 30.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

Please see our financial statements beginning on page F-1 of this Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports required by the Exchange Act is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-K. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022 at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022, based on criteria established in the framework in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

As an emerging growth company and a smaller reporting company with less than $100 million in annual revenues, we are not subject to attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002; therefore, this Form 10-K does not include an attestation report of our independent registered public accounting firm.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Because of these limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become ineffective because of changes in conditions or that the degree of compliance with established policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no material changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. Other Information.

None.

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

Not applicable.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below will be set forth in our definitive proxy statement for our 2023 Annual Meeting of Stockholders (Proxy Statement) to be filed with the SEC within 120 days after the end of the fiscal year covered by this Form 10-K and is incorporated into this Form 10-K by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The Code of Business Conduct and Ethics is available on our website at *www.pardesbio.com*. Information contained on or accessible through such website is not a part of this Form 10-K, and the inclusion of the website address in this Form 10-K is an inactive textual reference only. We intend to disclose any amendments to the Code of Business Conduct and Ethics, or any waivers of our requirements, on our website to the extent required by the applicable rules and exchange requirements.

Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year covered by this Form 10-K and is incorporated into this 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 set forth in our Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year covered by this Form 10-K and is incorporated into this Form 10-K by reference.

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

The information required by this item will be set forth in our Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year covered by this Form 10-K and is incorporated into this Form 10-K by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be set forth in our Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year covered by this Form 10-K and is incorporated into this Form 10-K by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the financial statements of this Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
2.1†	Merger Agreement, dated as of June 29, 2021, by and among Pardes Biosciences, Inc., Shareholder Representative Services LLC, FS Development Corp. II, and Orchard Merger Sub, Inc.		Annex A to the Proxy Statement/Prospectus on Form 424B3	December 1, 2021	333-258442
2.2†	Amendment No. 1 to Merger Agreement, dated as of November 7, 2021, by and among Pardes Biosciences, Inc., Shareholder Representative Services LLC, FS Development Corp. II, and Orchard Merger Sub, Inc.		Annex A to the Proxy Statement/Prospectus on Form 424B3	December 1, 2021	333-258442
3.1	Second Amended and Restated Certificate of Incorporation of FS Development Corp. II		Exhibit 3.1 on Form 8-A12B/A	December 23, 2021	001-40067
3.2	Amended and Restated Bylaws of Pardes Biosciences, Inc.		Exhibit 3.2 on Form 8-A12B/A	December 23, 2021	001-40067
4.1	Form of Specimen Common Stock Certificate		Exhibit 4.1 on Form S-4/A	November 17, 2021	333-258442
4.2	Description of Pardes Biosciences Inc.'s securities registered under Section 12 of the Securities Exchange Act of 1934, as amended		Form 8-A12B/A	December 23, 2021	001-40067
10.1	Registration Rights Agreement, dated December 23, 2021, by and among Pardes Biosciences, Inc. and the stockholders party thereto		Exhibit 10.1 on Form 8-A12B/A	December 23, 2021	001-40067
10.2	Voting Agreement, dated December 23, 2021, by and among Pardes Biosciences, Inc. and the other parties thereto		Exhibit 10.2 on Form 8-K	December 30, 2021	001-40067
10.3	Form of Subscription Agreement		Annex F to the Proxy Statement/Prospectus on Form 424B3	December 1, 2021	333-258442
10.4	Letter Agreement, dated June 29, 2021, by and among FS Development Corp.		Exhibit 10.6 on Form 8-K	June 29, 2021	001-40067

	II, Pardes Biosciences, Inc. and Gilead Sciences, Inc.			
10.5#	2021 Stock Option and Incentive Plan	Annex E to the Proxy Statement/Prospectus on Form 424B3	December 1, 2021	333-258442
10.6#	Forms of Award Agreements under the 2021 Stock Option and Incentive Plan	Exhibit 10.5 on Form 8-K	December 30, 2021	001-40067
10.7#	2022 Inducement Plan	Exhibit 99.3 to Form S-8	March 2, 2022	333-263229
10.8#	Form of Award Agreements under the 2022 Inducement Plan	Exhibit 99.4 to Form S-8	March 2, 2022	333-263229
10.9	Form of Indemnification Agreement for Directors of Pardes Biosciences, Inc.	Exhibit 10.6 on Form 8-K	December 30, 2021	001-40067
10.10#	Form of Indemnification Agreement for Executive Officers of Pardes Biosciences, Inc.	Exhibit 10.7 on Form 8-K	December 30, 2021	001-40067
10.11#††	Amended and Restated Offer Letter, dated December 21, 2020, by and between Pardes Biosciences, Inc. and Uri A. Lopatin, M.D.	Exhibit 10.9 on Form 8-K	December 30, 2021	001-40067
10.12#††	Offer Letter, dated January 20, 2021, by and between Pardes Biosciences, Inc. and Heidi Henson	Exhibit 10.10 to Form S-1	January 21, 2022	333-262279
10.13#††	Employment Agreement dated March 1, 2022, by and between Pardes Biosciences, Inc. and Thomas G. Wiggans	Exhibit 10.18 to Form 10-K	March 29, 2022	001-40067
10.14#††	Offer Letter, dated September 21, 2020, by and between Pardes Biosciences, Inc. and Brian P. Kearney, PharmD.	Exhibit 10.11 on Form 8-K	December 30, 2021	001-40067
10.15#	Amendment No. 1 to Offer Letter, dated December 23, 2020, by and between Pardes Biosciences, Inc. and Brian P. Kearney, PharmD.	Exhibit 10.12 on Form 8-K	December 30, 2021	001-40067
10.16#††	Executive Severance Plan	Exhibit 10.13 on Form 8-K	December 30, 2021	001-40067
10.17#	Senior Executive Cash Incentive Bonus Plan	Exhibit 10.13 to Form S-1	January 21, 2022	001-40067
10.18#††	Transition and Separation Agreement and General Release of Claims dated March 25, 2022, by and between Pardes Biosciences, Inc. and Uri A. Lopatin, M.D.	Exhibit 10.21 to Form 10-K	March 29, 2022	001-40067

10.19#	Consulting Agreement dated March 25, 2022, by and between Pardes Biosciences, Inc. and Uri A. Lopatin, M.D.		Exhibit 10.22 to Form 10-K	March 29, 2022	001-40067
10.20#††	Transition and Separation Agreement and General Release of Claims dated October 14, 2022, by and between Pardes Biosciences, Inc. and Philippe Tinmouth	x			
10.21	Sales Agreement dated as of January 11, 2023, by and between Pardes Biosciences, Inc. and SVB Securities LLC		Exhibit 1.2 to Form S-3	January 12, 2023	333-269192
23.1	Consent of KPMG LLP	x			
24.1	Power of Attorney (included on signature page)	x			
31.1	Certification of 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 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†††	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	x			
32.2†††	Certification of 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			
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 Document	x			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	x			

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	x
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	x
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	x
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	x

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Schedules and exhibits to this Exhibit omitted pursuant to Regulation S-K Item 601(a)(5) or 601(b)(2). The registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

†† Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because the Company has determined that the information is not material and is the type that the Company treats as private or confidential.

††† These certifications will not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act except to the extent specifically incorporated by reference into such filing.

Item 16. Form 10-K Summary

Not applicable.

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.

PARDES BIOSCIENCES, INC.

Date: March 14, 2023

By: /s/ Thomas G. Wiggans
Thomas G. Wiggans
Chief Executive Officer and
Chair of the Board of Directors
(*Principal Executive Officer*)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas G. Wiggans and Heidi Henson, and each of them, as his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the SEC, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may 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/ Thomas G. Wiggans **Thomas G. Wiggans**	Chief Executive Officer and Chair of the Board of Director (Principal Executive Officer)	March 14, 2023
/s/ Heidi Henson **Heidi Henson**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2023
/s/ Laurie Smaldone Alsup, M.D. **Laurie Smaldone Alsup, M.D.**	Lead Independent Director	March 14, 2023
/s/ Mark Auerbach **Mark Auerbach**	Director	March 14, 2023
/s/ Deborah M. Autor **Deborah M. Autor**	Director	March 14, 2023
/s/ Laura J. Hamill **Laura J. Hamill**	Director	March 14, 2023
/s/ J. Jay Lobell **J. Jay Lobell**	Director	March 14, 2023
/s/ Uri A. Lopatin, M.D. **Uri A. Lopatin, M.D.**	Director	March 14, 2023
/s/ John C. Pottage, Jr., M.D. **John C. Pottage, Jr., M.D.**	Director	March 14, 2023
/s/ James B. Tananbaum, M.D. **James B. Tananbaum, M.D.**	Director	March 14, 2023
/s/ Michael D. Varney, Ph.D. **Michael D. Varney, Ph.D.**	Director	March 14, 2023

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Pardes Biosciences, Inc.:

Opinion on the Financial Statements
We have audited the accompanying balance sheets of Pardes Biosciences, Inc. (the Company) as of December 31, 2022 and 2021, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2021.
Irvine, California
March 14, 2023

PARDES BIOSCIENCES, INC.
BALANCE SHEETS
(in thousands, except share and par value data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 59,284	$ 268,678
Short-term investments	138,056	—
Prepaid expenses and other current assets	3,062	6,581
Total current assets	200,402	275,259
Other assets	219	—
Total assets	$ 200,621	$ 275,259
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,929	$ 2,385
Accrued expenses	15,496	6,580
Total current liabilities	20,425	8,965
Total liabilities	20,425	8,965
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock: $0.0001 par value; 10,000,000 shares authorized as of December 31, 2022 and December 31, 2021; no shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock: $0.0001 par value and 250,000,000 shares authorized; 61,734,343 and 62,378,996 shares issued as of December 31, 2022 and December 31, 2021, respectively; and 59,542,714 and 56,765,533 shares outstanding as of December 31, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	328,372	317,812
Accumulated other comprehensive loss	(24)	—
Accumulated deficit	(148,158)	(51,524)
Total stockholders' equity	180,196	266,294
Total liabilities and stockholders' equity	$ 200,621	$ 275,259

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

PARDES BIOSCIENCES, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 70,350	$ 28,152
General and administrative	29,467	10,336
Total operating expenses	99,817	38,488
Other income (expense):		
Interest and other income (expense), net	3,183	(30)
Net loss	$ (96,634)	$ (38,518)
Net loss per share, basic and diluted	$ (1.66)	$ (10.13)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	58,127,385	3,800,506
Unrealized loss on available-for-sale securities	$ (24)	$ —
Comprehensive loss	$ (96,658)	$ (38,518)

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

PARDES BIOSCIENCES, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	$0.0001 Par Value				
Balance at December 31, 2020	—	$ —	—	$ —	$ —	$ —	$ (13,006)	$ (13,006)
Issuance of convertible preferred stock for cash, net of issuance costs of $176	13,756,122	44,324	—	—	—	—	—	—
Conversion of 2020 SAFE agreements into shares of convertible preferred stock	5,845,071	14,808	—	—	—	—	—	—
Conversion of preferred stock	(19,601,193)	(59,132)	19,601,193	2	59,130	—	—	59,132
Issuance of common stock in connection with the Business Combination, net of transaction costs of $16,472	—	—	25,758,750	3	184,898	—	—	184,901
Redemption of common stock in connection with the Business Combination	—	—	(243,989)	—	(2,440)	—	—	(2,440)
Common stock issued through PIPE financing	—	—	7,500,000	1	74,999	—	—	75,000
Vesting of restricted stock awards into common stock	—	—	4,148,171	—	—	—	—	—
Exercise of options	—	—	1,408	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	1,221	—	—	1,221
Net loss	—	—	—	—	—	—	(38,518)	(38,518)
Balance at December 31, 2021	—	$ —	56,765,533	$ 6	$ 317,812	$ —	$ (51,524)	$ 266,294
Vesting of restricted stock awards into common stock	—	—	2,777,181	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	10,560	—	—	10,560
Other comprehensive loss	—	—	—	—	—	(24)	—	(24)
Net loss	—	—	—	—	—	—	(96,634)	(96,634)
Balance at December 31, 2022	—	$ —	59,542,714	$ 6	$ 328,372	$ (24)	$ (148,158)	$ 180,196

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

PARDES BIOSCIENCES, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2022	**2021**
Operating activities:		
Net loss	$ (96,634)	$ (38,518)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net amortization of premiums (accretion of discounts) on available-for-sale securities	(1,059)	—
Stock-based compensation expense	10,560	1,221
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,837	(6,386)
Interest receivable	(318)	—
Accounts payable	2,779	756
Accrued expenses	8,859	6,009
Net cash used in operating activities	(71,976)	(36,918)
Investing activities:		
Purchases of available-for-sale securities	(138,201)	—
Proceeds on sale of available-for-sale securities	1,180	—
Net cash used in financing activities	(137,021)	—
Financing activities:		
Proceeds from issuance of common stock in connection with the Business Combination	—	198,933
Proceeds from PIPE	—	75,000
Payment of the Business Combination and PIPE transaction costs	—	(16,075)
Proceeds from issuance of convertible preferred stock	—	44,500
Payment of issuance costs for convertible preferred stock	—	(176)
Proceeds from issuance of convertible notes	—	10,000
Repayment of convertible notes	—	(10,000)
Cash paid for deferred offering costs	(397)	—
Proceeds from exercise of common stock options	—	4
Net cash (used) provided by financing activities	(397)	302,186
(Decrease) increase in cash and cash equivalents	(209,394)	265,268
Cash and cash equivalents at beginning of period	268,678	3,410
Cash and cash equivalents at end of period	$ 59,284	$ 268,678
Non-cash financing activities:		
Conversion of convertible preferred shares into common stock	$ —	$ 59,132
Conversion of 2020 SAFE agreements into shares of convertible preferred stock	—	14,808
Deferred offering costs included in accounts payable and accrued expenses	219	397

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

Note 1. Description of Business

Description of Business

Unless the context otherwise requires, references in these notes to "Pardes," "the Company," "we," "us," "our" and any related terms are intended to mean Pardes Biosciences, Inc.

Pardes Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing novel oral-antiviral therapeutics to improve the lives of patients suffering from life-threatening disease, starting with our lead product candidate, pomotrelvir (formerly known as PBI-0451), which is in clinical development and intended to treat COVID-19 in adult and pediatric patients. COVID-19 is caused by infection with the severe acute respiratory syndrome coronavirus (SARS-CoV-2). Pomotrelvir inhibits the main coronaviral cysteine protease, a viral protein essential for replication of all known coronaviruses, including SARS-CoV-2.

Business Combination

On December 23, 2021 (Closing Date), Pardes Biosciences, Inc. (Old Pardes) and FS Development Corp. II (FSDC II) completed the transactions contemplated by the Agreement and Plan of Merger, dated as of June 29, 2021, as amended on November 7, 2021 (Merger Agreement), by and among Old Pardes, Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact of the Company Securityholders (as defined in the Merger Agreement), FSDC II and Orchard Merger Sub Inc., a Delaware corporation and a wholly-owned subsidiary of FSDC II (Merger Sub). FSDC II was formed in August 2020 for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization, or similar business combination with one or more businesses.

On the day prior to the Closing Date, Old Pardes changed its name to "Pardes Biosciences Sub, Inc." Pursuant to the Merger Agreement, on the Closing Date, (i) FSDC II changed its name to "Pardes Biosciences, Inc." (together with its consolidated subsidiary, New Pardes) and (ii) Old Pardes merged with and into Merger Sub (Merger), with Old Pardes as the surviving company in the Merger and, after giving effect to such Merger, Old Pardes becoming a wholly-owned subsidiary of New Pardes. On January 31, 2022, Old Pardes merged with and into New Pardes.

In connection with the transactions contemplated under the Merger Agreement and described above (collectively, the Business Combination) certain investors purchased an aggregate of $75.0 million of our common stock in a private placement of public equity (PIPE Investment). Together with FSDC II's cash resources and funding of the PIPE Investment, we received net proceeds of approximately $257.5 million.

For additional information on the Business Combination, see Note 5, *Business Combination*.

Through December 31, 2022, we have primarily funded our operations with proceeds from the issuance of Simple Agreements for Future Equity (SAFEs), convertible preferred stock financing, the Business Combination and the PIPE Investment. We believe that our $197.3 million of cash, cash equivalents and short-term investments as of December 31, 2022, will enable us to fund our current planned operations for at least 12 months from the issuance date of these financial statements, though we may raise additional capital through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements, government funding and grants. Management's expectations with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us or at all and we may need to seek additional funds sooner than anticipated. If adequate funds are not available to us on a timely basis, on acceptable terms or at all, management may be required to delay, limit, reduce, or terminate certain of its research, product development or future commercialization efforts, obtain funds through arrangements with collaborators on terms unfavorable to us, or pursue merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with United States (U.S.) generally accepted accounting principles (GAAP).

Use of Estimates

The preparation of financial statements in accordance with GAAP requires our management to make estimates and assumptions that impact the reported amounts on our financial statements and accompanying notes. The amounts reported could differ under different estimates and assumptions. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Though the impact of the COVID-19 pandemic on our business and operating results presents additional uncertainty, we continue to use the best information available to form our critical accounting estimates. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

Cash Equivalents

Cash equivalents consist of highly liquid investments, readily convertible to cash without penalty, with original maturities of three months or less at the time of purchase. Our cash equivalents are short-term in nature and of high credit quality; therefore, we determined our exposure to credit losses over the life of these instruments is immaterial.

Short-Term Investments

Short-term investments are available-for-sale securities with original maturities of more than three months from the date of purchase that are specifically identified to fund current operations. These investments are classified as current assets even though the stated maturity date may be one year or beyond the current balance sheet date as this reflects management's intention to use the proceeds from the sale of these investments to fund our operations as necessary. Such short-term investments are carried at fair value with unrealized gains and non-credit-related losses recorded in other comprehensive loss and included as a separate component of stockholders' equity. The cost of short-term investments is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion, as well as dividend and interest income, are included in investment and other income (expense), net in the statement of operations and comprehensive loss. Realized gains and losses from the sale of short-term investments will be determined on a specific identification basis and included in interest and other income (expense), net on our statement of operations and comprehensive loss.

Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, pursuant to Accounting Standards Update (ASU) 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, we first assess whether we intend to sell, or if it is more likely than not that we will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding the intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For securities that do not meet the aforementioned criteria, we evaluate whether the decline in fair value has resulted from the credit losses or other factors. In making this assessment, we consider the extent to which fair value is less than amortized cost, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery, among other factors. If this assessment indicates a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized costs basis, a credit loss exists and an allowance for credit losses is recorded, limited by the amount that the fair value is less than the amortized cost basis. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive loss on the statements of operations and comprehensive loss, as applicable.

We elected the practical expedient to exclude the applicable accrued interest receivables from both the fair value and amortized cost basis of available-for-sale securities. Accrued interest receivable is recorded in prepaid expenses and other current assets in the balance sheet. Uncollectible accrued interest receivables associated with an impaired security are reversed against interest income upon identification of the impairment.

Concentration of Credit Risk

Financial instruments which potentially subject us to significant concentration of credit risk consist of cash and money market accounts. We maintain deposits in federally insured financial institutions in excess of federally insured limits. We have not experienced any losses in such accounts, and management believes that we are not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency gains and losses.

Deferred Offering Costs

We capitalize costs that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated at which time such costs are recorded in stockholders' equity as a reduction against the gross proceeds of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss.

Fair Value of Financial Instruments

Fair value is defined as 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. 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, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 — Observable inputs such as quoted prices in active markets;
Level 2 — Inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets with insufficient volume or infrequent transactions (less active markets), or model-driven valuations in which all significant inputs are observable or can be derived principally from, or corroborated with, observable market data; and
Level 3 — Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Fair value of our financial instruments is made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and, therefore, cannot be determined with precision.

Our investments, which include cash equivalents and short-term investments, are measured and recorded at fair value on a recurring basis. The carrying amounts of cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses are considered to be representative of their respective fair values because of the short-term nature of those instruments. Prior to their conversion, we remeasured our SAFE agreements to fair value each reporting period.

Accrued Research and Development Expense

We estimate our expenses resulting from our obligations under contracts with vendors, consultants, contract research organizations (CRO) and contract manufacturing organizations (CMO). The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our financial statements by matching those expenses with the period in which services and efforts are expended.

We estimate our accrued research and development expenses as of each balance sheet date based on facts and circumstances known at the time. The significant estimates in our accrued expenses include costs incurred for services performed by vendors in connection with research and development activities for which we have not yet been invoiced. If timelines or contracts are modified based upon changes in the protocol or scope of work to be performed, we modify our estimates and accruals accordingly on a prospectus basis. During the course of a study or contract, we adjust our rate of expense recognition if actual results differ from our estimates.

Research and Development Expenses

Research and development expenses are charged to expense as incurred when these expenses have no alternative future uses. We are obligated to make upfront payments upon execution of certain research and development agreements. Advance payments, including nonrefundable amounts, for goods and services that will be used or rendered for future research and development activities are deferred. Such amounts are recognized as expense as the related good is delivered or related services are performed or at such time when we do not expect the goods to be delivered or services to be performed.

Research and development expenses primarily consist of costs associated with research and development activities including salaries, benefits, share-based compensation and services provided by outside organizations and consultants for preclinical and clinical development activities, manufacturing costs for non-commercial products, and supplies, equipment and materials used in research and development activities.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

Stock-based compensation expense is recognized on a straight-line basis over the vesting period of the awards. We do not apply a forfeiture rate to unvested awards and account for forfeitures as they occur. The vesting period generally approximates the expected service period of the awards. Stock-based compensation is included in research and development expenses and general and administrative expenses in our statements of operations and comprehensive loss.

We estimate the fair value of stock option grants using the Black-Scholes option pricing model on the date of grant. This method requires certain assumptions be used as inputs, such as the fair value of the underlying common stock, a risk-free interest rate, expected volatility of the common stock, expected term of the option before exercise and expected dividend yield. Options granted have a maximum contractual term of ten years. We have limited historical stock option activity and therefore estimate the expected term of stock options granted using the simplified method, which represents the arithmetic average of the original contractual term of the stock option and its weighted-average vesting term. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options. We have historically not declared or paid any dividends and do not currently expect to do so in the foreseeable future, and therefore have estimated the dividend yield to be zero.

For restricted stock awards, the fair value of the award is the estimated fair value of our common stock on the grant date.

Prior to the Closing Date of the Business Combination, the fair value of the shares of common stock had historically been determined by our board of directors (Board) as there was no public market for the common stock. The Board determined the fair value of the common stock by obtaining third-party valuations of our common stock using the option pricing method and the probability-weighted expected return method. Significant assumptions used in determining the fair value of common stock include volatility, discount for lack of marketability, and the expected timing of a future liquidity event.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize deferred tax assets to the extent that we believe these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that we would be able to realize our deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2022 and 2021, we maintained a valuation allowance against our deferred tax assets as we concluded it had not met the “more likely than not” to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

We record uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. We recognize interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. The chief operating decision maker is the chief executive officer. We view our operations and manage our business as one operating segment and one reportable segment. No product revenue has been generated since inception and all assets are held in the United States.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury-stock method. Common stock equivalents are only included in the calculation of diluted earnings per common share when net income is reported and their effect is dilutive. For the periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to our net loss position. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as shares of unvested restricted stock are considered participating securities. Our participating securities do not have a contractual obligation to share in our losses. As such, the net loss was attributed entirely to common stockholders for all periods presented.

The following outstanding shares of potentially dilutive securities were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented because including them would be anti-dilutive (in common stock equivalent shares):

	December 31, 2022	December 31, 2021
Outstanding stock options	9,269,069	3,328,138
Restricted common stock subject to repurchase or forfeiture	2,191,629	5,613,463
Total	11,460,698	8,941,601

Recently Issued and Recently Adopted

Annually, the Financial Accounting Standards Board (FASB) or other standard setting bodies issue new accounting pronouncements that we adopt as of the effective date. We evaluated the recently issued accounting pronouncements and, based on our assessment, do not believe any will have a material impact on our financial statements or related disclosures.

In June 2016, the FASB issued Topic 326 which we adopted on January 1, 2022. The standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value. This standard did not have a material impact on our financial statements.

In 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740)*, which simplifies the accounting for income taxes. The amendments in ASU 2019-12 remove certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. We adopted ASU 2019-12 on January 1, 2022, which had no significant impact on our financial statements.

Note 3. Investments

Available-for-sale securities consisted of U.S. Treasury securities, U.S. Agency bonds, commercial paper, corporate debt securities and asset-backed securities.

Our cash equivalents consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Cash equivalents		
Money market fund	$ 32,426	$ —
U.S. government and government agencies	19,869	18,355
Commercial paper	2,997	—
Corporate debt securities	2,993	—
Total cash equivalents	$ 58,285	$ 18,355

Our short-term investments that are measured at fair value on a recurring basis consisted of the following (in thousands):

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Short-term investments				
U.S. government and government agencies	$ 75,409	$ 15	$ (48)	$ 75,376
Commercial paper	59,405	—	—	59,405
Asset-backed securities	3,267	8	—	3,275
Total short-term investments	$ 138,081	$ 23	$ (48)	138,056

The contractual maturity of the short-term investments presented in the table above were all due within one year, and the amortized cost and fair value of short-term investments were both $138.1 million as of December 31, 2022. As of December 31, 2022, there were 14 short-term investments with a fair value of $49.3 million that were in a gross unrealized loss position for less than 12 months, and none were in a gross unrealized loss for 12 months or more. Based on our analysis of available-for-sale securities, we determined the unrealized losses were primarily due to changes in interest rates and not due to credit risks. As such, we did not record a credit allowance for the year ended December 31, 2022. As of December 31, 2022, the accrued interest receivable on our available-for-sale securities was $0.3 million. For the year ended December 31, 2022, we did not write off any accrued interest receivables, and there were no realized gains or losses.

Note 4. Fair Value Measurements

Below are summaries of our cash equivalents and short-term investments that were measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	December 31, 2022			December 31, 2021	
	Level 1	Level 2	Estimated Fair Value	Level 2	Estimated Fair Value
Cash equivalents					
Money market fund	$ 32,426	$ —	$ 32,426	$ —	$ —
U.S. government and government agencies	—	19,869	19,869	18,355	18,355
Commercial paper	—	2,997	2,997	—	—
Corporate debt securities	—	2,993	2,993	—	—
Total cash equivalents	$ 32,426	$ 25,859	$ 58,285	$ 18,355	$ 18,355

	December 31, 2022	
	Level 2	Estimated Fair Value
Short-term investments		
U.S. government and government agencies	$ 75,376	$ 75,376
Commercial paper	59,405	59,405
Asset-backed securities	3,275	3,275
Total short-term investments	$ 138,056	$ 138,056

Between April 2020 and December 2020, we entered into several SAFEs, (collectively the 2020 SAFEs) with certain investors. We recorded the liability related to the 2020 SAFEs at fair value and subsequently remeasured the instruments to fair value using Level 3 fair value measurements, which were determined based on significant inputs not observable in the market.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands):

Balance as of December 31, 2020	$ 14,808
Conversion into shares of convertible preferred stock	(14,808)
Balance as of December 31, 2021	$ —

Note 5. Business Combination

As described in Note 1, on December 23, 2021, Old Pardes and FSDC II completed the Business Combination pursuant to the Merger Agreement with Old Pardes surviving the Merger as a wholly owned subsidiary of FSDC II. Net proceeds from the Business Combination totaled approximately $257.5 million, which included funds held in FSDC II's trust account and the completion of the concurrent PIPE Investment.

The Business Combination was accounted for as a reverse recapitalization because Old Pardes had been determined to be the accounting acquirer under FASB's Accounting Standards Codification Topic 805, Business Combinations. The determination was primarily based on the evaluation of the following facts and circumstances taking into consideration:

- The pre-combination equity holders of Old Pardes held the relative majority of voting rights in Pardes;
- The pre-combination equity holders of Old Pardes had the right to appoint six of the directors on Pardes' Board of Directors;
- Senior management of Old Pardes comprised the senior management of Pardes; and
- Operations of Old Pardes comprised the ongoing operations of Pardes.

Under the reverse recapitalization accounting model, the Business Combination was treated as Old Pardes issuing stock for the net assets of FSDC II, with no goodwill or intangible assets recorded. The share amounts have been retroactively adjusted for all periods presented to reflect the Business Combination and reverse capitalization.

The following table summarizes the elements of the net proceeds from the Business Combination as of December 31, 2021 (in thousands):

FSDC II Trust Account balance	$ 201,266
Less: Redemptions	(2,440)
Proceeds from PIPE Investment	75,000
Less: Underwriting fees and other offering costs paid prior to December 31, 2021	(16,075)
Less: Non-cash net assets assumed from FSDC II	107
Proceeds from Business Combination, net of offering costs paid	257,858
Less: Other offering costs included in accounts payable and accrued expenses	(397)
Net proceeds from the Business Combination	$ 257,461

The following table summarizes the number of shares of common stock outstanding immediately following the consummation of the Business Combination:

FSDC II shares issued through the Business Combination, net of redemption	25,514,761
Shares issued pursuant to the PIPE Investment	7,500,000
Business Combination and PIPE Investment shares	33,014,761
Conversion of Old Pardes preferred stock for common stock	19,601,193
Conversion of Old Pardes common stock for common stock	9,763,042
Total shares of New Pardes common stock issued immediately following the Business Combination	62,378,996
Less: shares of restricted stock subject to the right of repurchase	(5,613,463)
Total shares of New Pardes common stock outstanding immediately following the Business Combination	56,765,533

Note 6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Prepaid insurance	$ 1,582	$ 5,286
Prepaid research and development costs	495	639
Other prepaid expenses and current assets	985	656
Total	$ 3,062	$ 6,581

Note 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Research and development accruals	$ 10,784	$ 4,050
Accrued compensation	3,878	1,659
Other accrued expenses	834	871
Total	$ 15,496	$ 6,580

Note 8. Simple Agreements for Future Equity

Between April 2020 and December 2020, we entered into the 2020 SAFEs, pursuant to which we received funding of $7.1 million in cash in exchange for SAFEs providing the investors the right to receive shares of our capital stock. The 2020 SAFEs were automatically converted on January 19, 2021, into preferred stock with an aggregate fair value of $14.8 million.

Note 9. Stockholders' Equity

Preferred Stock

On December 23, 2021, in connection with the closing of the Business Combination and pursuant to the Merger Agreement, all previously issued and outstanding preferred stock of Old Pardes was exchanged for shares of our common stock. All fractional shares were rounded down.

Upon the closing of the Business Combination, pursuant to the terms of the Second Amended and Restated Certificate of Incorporation (Certificate of Incorporation) dated December 23, 2021, we authorized 10,000,000 shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock are undesignated. The Board has the authority, without further action by the stockholders, to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series and to fix the designations, powers, voting and other rights, preferences and privileges of the shares. As of December 31, 2022 and December 31, 2021, there were no shares of preferred stock outstanding.

Common Stock

On the Closing Date, in connection with the closing of the Business Combination, and pursuant to the Merger Agreement, all previously issued and outstanding shares of restricted common stock of Old Pardes were converted into restricted shares of our common stock. Such restricted stock remains subject to the same terms and conditions set forth under the applicable restricted stock award agreement. As of December 31, 2022 and 2021, the repurchase liability for these shares was nominal.

In March 2022 and in December 2022, in connection with the departures of former employees, we repurchased 58,072 and 586,581 unvested shares of common stock for an aggregate purchase price of $0.41 and $4.17, respectively, and those shares were held in treasury. In September 2022 and in December 2022, we cancelled 58,072 and 586,581 shares of common stock held in treasury,

respectively. For accounting purposes, unvested restricted stock and the unvested shares repurchased by us and held in treasury are not deemed to be outstanding.

A summary of restricted common stock awards is as follows:

	Number of Unvested Shares
Balance as of December 31, 2021	5,613,463
Forfeited Shares	(644,653)
Vested Shares	(2,777,181)
Balance as of December 31, 2022	2,191,629

Pursuant to the Certificate of Incorporation, as of December 31, 2022 and December 31, 2021, there were 250,000,000 shares of common stock, par value $0.0001 per share, authorized. There were 61,734,343 and 62,378,996 shares issued as of December 31, 2022 and December 31, 2021, respectively.

Note 10. Stock-Based Compensation

2020 Stock Plan

In March 2020, we adopted the 2020 Stock Plan (as amended, the 2020 Plan). The 2020 Plan provided for the grant of incentive stock options, non-statutory stock options and restricted stock awards. Effective as of the Closing Date, the options granted under the 2020 Plan were assumed and reissued under the 2021 Stock Option and Incentive Plan (as amended, the 2021 Plan) described below and the 2020 Plan was terminated.

2021 Plan

The 2021 Plan was adopted by the Board, and approved by the stockholders, effective December 22, 2021, pursuant to which 13,000,000 shares of common stock were initially authorized for issuance, which number included outstanding awards assumed on the Closing Date. The 2021 Plan provides that the number of shares authorized and available for issuance thereunder will automatically increase on each January 1 by 5% of the number of shares of common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the administrator of the 2021 Plan (the Annual Increase). The 2021 Plan provides for us to grant incentive stock options or nonqualified stock options for the purchase of common stock, stock appreciation rights, restricted stock awards, restricted stock units, cash-based awards and unrestricted stock awards to our employees, directors and consultants. Incentive stock options may only be granted to employees.

As of December 31, 2022, the number of shares authorized for issuance under the 2021 Plan was 16,118,949, of which 7,767,224 shares remained available for grants under the 2021 Plan. Effective as of January 1, 2023, the number of shares authorized for issuance under the 2021 Plan automatically increased pursuant to the Annual Increase by 3,086,717 shares, resulting in 19,205,666 shares of common stock authorized for issuance as of that date.

2022 Inducement Plan

On February 28, 2022, the Board adopted the 2022 Inducement Plan (Inducement Plan) and reserved 1,500,000 shares of common stock for issuance. Awards under the Inducement Plan may only be granted to persons who (a) were not previously an employee or director of us or (b) are commencing employment with us following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with us and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). As of December 31, 2022, 575,000 shares remained available for grants under the Inducement Plan.

Stock option activity for employee and nonemployee awards and related information is as follows:

	Number of Shares	Weighted Average Exercise Price per Share, $	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	3,328,138	$ 5.57	9.6	$ 35,936
Granted	6,853,250	6.36		
Exercised	—			
Cancelled	(912,319)	7.39		
Outstanding as of December 31, 2022	9,269,069	5.98	9.0	30
Options vested and exercisable as of December 31, 2022	1,679,781	6.13	7.9	28

The weighted average grant-date fair value of options granted during the years ended December 31, 2022 and 2021 were $3.68 and $3.78, respectively. Options to purchase common stock generally vest over a four-year period and are granted for a term of ten years. The aggregate intrinsic values presented in the table above were calculated as the difference between the closing price of our common stock at December 31, 2021 and December 31, 2022, respectively, and the exercise price of the stock options below the applicable closing price. There were no stock options exercised during 2022.

Stock-Based Compensation Expense

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock options granted were as follows:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	1.62% - 3.85%	0.47% - 1.49%
Expected volatility	58.36% - 63.00%	78.28% - 81.56%
Expected option life (in years)	5.10 - 6.08	5.27 - 6.25
Expected dividend yield	—%	—%
Exercise price	$1.75 - $11.32	$0.01 - $9.80

Risk-free interest rate. We base the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the stock option being valued.

Expected volatility. The expected volatility assumption is based on historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies primarily in the biopharmaceutical industry.

Expected term. The expected term represents the period that options are expected to be outstanding. Because we do not have historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the weighted-average vesting period and contractual term of the option.

Expected dividend yield. We base the expected dividend yield assumption on the fact that we have never paid cash dividends and has no present intention to pay cash dividends.

The following table summarizes stock-based compensation expense for all stock-based compensation arrangements (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 5,007	$ 461
General and administrative	5,553	760
Total stock-based compensation	$ 10,560	$ 1,221

As of December 31, 2022, the total unrecognized compensation cost related to outstanding time-based options was $22.0 million, which is expected to be recognized over a weighted-average period of 2.48 years.

On March 25, 2022, our former Chief Executive Officer and President, Dr. Lopatin entered into a Transition and Separation Agreement and General Release of Claims and Consulting Agreement with us, according to which Dr. Lopatin continued as our full-time employee in the role of Chief Scientific and Strategic Advisor until April 30, 2022. For the period of May 1, 2022 through July 31, 2022, Dr. Lopatin's hours were reduced, and his annualized base salary was reduced proportionately with the reduction in hours. Starting August 1, 2022, Dr. Lopatin has performed consulting services for us. As a result, Dr. Lopatin's status as an employee has changed. We considered Dr. Lopatin's continued employment through July 31, 2022 as substantive for accounting purposes; however, his consulting service, which commenced on August 1, 2022, is not considered by us to be substantive for accounting purposes. This resulted in the recognition of the remaining unrecognized stock compensation expense related to Dr. Lopatin's stock options in the amount of $2.6 million as of March 25, 2022 over the remaining vesting period of March 25, 2022 through July 31, 2022. Stock-based compensation expense related to Dr. Lopatin's stock options for the year ended December 31, 2022 was $2.7 million.

Note 11. Income Taxes

For the years ended December 31, 2022 and December 31, 2021, due to the operating losses reported and the full valuation allowance recorded on our net deferred income tax assets, we recorded no provision for income taxes.

A reconciliation of our income taxes to the amount computed by applying the statutory federal income tax rate to the pretax loss is summarized as follows (in thousands):

	December 31, 2022	December 31, 2021
Expected income tax benefit at statutory rates	$ (20,293)	$ (8,089)
State income tax, net of federal benefit	(386)	(23)
Permanent items and other	778	101
Research and development credits	(1,527)	(15)
Change in valuation allowance	21,428	8,026
	$ —	$ —

Significant components of our deferred income taxes are as follows (in thousands):

	December 31, 2022	December 31, 2021
Deferred income tax assets:		
Net operating loss carryforward	$ 13,972	$ 8,647
Research credit carryforwards	1,725	41
Capitalized research and development	12,772	—
Other, net	2,354	704
Total deferred tax assets	30,823	9,392
Less valuation allowance	(30,823)	(9,392)
Deferred tax assets, net of valuation allowance	$ —	$ —

We established a full valuation allowance of $30.8 million against our net deferred tax assets due to the uncertainty surrounding the realization of such assets that preclude us from determining that it is more likely than not that such assets will be realized. The change in the valuation allowance was an increase of $21.4 million. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. Management's assessment as of December 31, 2022 considered the generation of pre-tax book losses in the year, no ability to carryback our operating losses, the lack of feasible tax-planning strategies, the limited existing taxable temporary differences, and the subjective nature of forecasting future taxable income into the future.

At December 31, 2022, we had federal and state net operating loss (NOL) carryforwards of approximately $65.8 million and $2.6 million, respectively. The state net operating loss carryforwards begin to expire in 2040 unless previously utilized. Our federal net operating loss carryforwards do not expire.

At December 31, 2022, we had federal and state research and development tax credits of $1.3 million and $0.6 million, respectively. In 2037, $0.1 million of the state credits begin expiring with the remaining $0.5 million of state credits being carried forward indefinitely.

Pursuant to IRC Section 382 and IRC Section 383, our ability to use NOL and research and development tax credit carry forwards (tax attribute carry forwards) to offset future taxable income is limited if we experience a cumulative change in ownership of more than 50% within a three-year testing period. We have not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of remaining tax attribute carry-forwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, deferred tax assets associated with such tax attributes could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382.

We recognize a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination by the taxing authorities. Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgement based upon new information may lead to changes in recognition, derecognition and measurement. Adjustment may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitation barring an assessment for an issue.

The following table summarizes the changes to our gross unrecognized tax benefits for the years ended December 31, 2022 and December 31, 2021, respectively (in thousands):

	For the Year Ended December 31,	
	2022	2021
Beginning balance	$ 475	$ 468
Additions related to current year positions	625	7
Additions related to prior year positions	165	—
Ending balance	$ 1,265	$ 475

As of December 31, 2022, we had an unrecognized tax benefit balance of $1.3 million. Due to the existence of the full valuation allowance, future changes in unrecognized tax benefits will not impact our effective tax rate. We do not foresee material changes to our liability for uncertain tax benefits within the next 12 months.

We were subject to taxation in the United States and various state jurisdictions. All our tax years are subject to examination by federal and state taxing authorities due to the carryforwards of unutilized net operating losses and research and development credits. Our practice is to recognize interest and penalties related to income tax matters in income tax expense. We had no accrued interest or penalties related to income tax matters in our balance sheet as of December 31, 2022 and 2021 and have not recognized interest or penalties in our statement of operations and comprehensive loss for the years ended December 31, 2022 and 2021. Further, we are not currently under examination by any federal, state or local tax authority.

Note 12. Commitments and Contingencies

Commitments

We have entered into agreements in the normal course of business with certain vendors for the provision of goods and services, which include manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement.

In the normal course of business, we are a party to a variety of agreements pursuant to which we may be obligated to indemnify the other party. It is not possible to predict the maximum potential amount of future payments under these types of agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement. Historically, payments made by us under these types of agreements have not had a material effect on our business, results of operations or financial condition.

Contingencies

From time to time, we may become subject to claims or suits arising in the ordinary course of business. We accrue a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of December 31, 2022 and December 31, 2021, we were not a party to any material legal proceedings.

Note 13. 401(k) Plan

In 2021, we established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code of 1986, as amended. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. We have not made any contributions to the 401(k) Plan for the years ended December 31, 2022 or 2021.

Note 14. Subsequent Events

On January 12, 2023, we filed a shelf registration statement on Form S-3, which was declared effective by the U.S. Securities and Exchange Commission on January 20, 2023 (2023 Shelf). The 2023 Shelf covers the offering, issuance and sale by us of up to an aggregate of $200.0 million of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, subscription rights to purchase our common stock, preferred stock or debt securities and/or units consisting of some or all of these securities. In connection with the 2023 Shelf, we entered into a Sales Agreement, dated January 11, 2023, with SVB Securities LLC (Sales Agent), pursuant to which we may offer and sell up to $50.0 million of our common stock, from time to time at our sole discretion, through the Sales Agent, in “at-the-market” offerings under the 2023 Shelf.

On March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. At the time of the closure, we held assets valued at approximately $1.0 million in a deposit account with SVB. We received full access to the funds in our deposit account on March 13, 2023. Because a substantial majority of our cash, cash equivalents and short-term investments were not maintained at SVB and in light of actions by the federal government to fully protect deposit accounts, we do not expect our operations will be materially impacted by the closure of SVB.

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