Pardes Biosciences Reports Third Quarter 2022 Financial Results and Provides Business Update

November 7, 2022

Phase 2 trial evaluating PBI-0451 for treatment of COVID-19 ongoing, with data expected in first quarter of 2023

CARLSBAD, Calif., Nov. 07, 2022 (GLOBE NEWSWIRE) -- Pardes Biosciences, Inc. (NASDAQ: PRDS), a clinical-stage biopharmaceutical company developing PBI-0451 as a potential novel oral antiviral drug candidate for the treatment and prevention of COVID-19 in adult and pediatric patients, today reported financial results for the third quarter ended September 30, 2022 and provided a business update.

"We made significant progress in our pursuit to bring a stand-alone, easily administered oral treatment to patients suffering from COVID-19, highlighted by the commencement of our PBI-0451 Phase 2 trial in September 2022," said Thomas G. Wiggans, Chief Executive Officer, and Chair of Pardes Biosciences. "There is continued demand for new COVID antivirals, especially among patients on existing medications facing challenges with current treatment options. We believe PBI-0451, with its potential best-in-class safety profile and potent antiviral activity without the need for ritonavir boosting, could be the preferred treatment option to alleviate the burden of COVID-19 amongst the broadest group of patients. We look forward to sharing the preliminary results from this study in the first quarter of 2023."

Recent Corporate Updates

- Commenced a Phase 2 trial in September 2022 evaluating PBI-0451 for the treatment of COVID-19. The ongoing trial expects to enroll 210 non-hospitalized symptomatic adults with COVID-19 who are not at increased risk of progressing to severe illness at approximately 75 sites in the United States. Given the favorable drug-drug interaction profile observed to date, the use of concomitant medications for underlying health conditions is not restricted in the Phase 2 clinical trial. The clinical trial is evaluating antiviral activity, safety, and efficacy of PBI-0451 versus placebo. The primary objective is to determine the proportion of patients below the limit of detection in nasal swab samples for infectious SARS-CoV-2 on day three. Secondary objectives assessed include additional virologic assessments, safety and tolerability, time to sustained clinical recovery through day 28 defined as key COVID-19 symptoms, and hospitalizations and deaths. Data from the Phase 2 clinical trial is expected in the first quarter of 2023.
- Subject to Phase 2 clinical trial results and continued discussions with the U.S. Food and Drug Administration and global regulatory authorities on clinical design elements, we are currently planning to initiate our Phase 3 program in the first half of 2023.
- Appointed Laurie Smaldone Alsup, M.D. and John C. Pottage, Jr., M.D. to its Board of Directors. Dr. Smaldone Alsup and Dr. Pottage bring extensive clinical development and global regulatory strategy experience, with expertise in infectious diseases.

Third Quarter 2022 Financial Results
Pardes reported a net loss of $23.3 million and $72.4 million for the three and nine months ended September 30, 2022, respectively, as compared to a net loss of $11.5 million and $24.2 million for the three and nine months ended September 30, 2021, respectively. Net loss for the reporting period was driven by an increase in research and development expenses, as well as increased costs related to the infrastructure needed to support Pardes' growth and transition to operating as a public company.

Research and development expenses were $17.4 million for the quarter ended September 30, 2022, compared to $8.1 million for the quarter ended September 30, 2021, an increase of $9.3 million. Research and development expenses were $50.9 million for the nine months ended September 30, 2022, compared to $17.8 million for the nine months ended September 30, 2021, an increase of $33.1 million. These increases were primarily driven by increased costs related to advancing our lead product candidate, PBI-0451, into the clinic and higher personnel costs, including stock-based compensation, as we have grown our organization.

General and administrative expenses were $6.9 million for the quarter ended September 30, 2022, compared to $3.4 million for the quarter ended September 30, 2021, an increase of $3.5 million. General and administrative expenses were $22.7 million for the nine months ended September 30, 2022, compared to $6.4 million for the nine months ended September 30, 2021, an increase of $16.3 million. These increases were due to increased personnel costs, including stock-based compensation, increased professional fees related to legal, pre-commercial planning and consulting services, and costs associated with being a public company, including directors' and officers' insurance and compliance fees.

Pardes' cash and cash equivalents as of September 30, 2022, were $209.1 million compared to $228.6 million as of June 30, 2022. The company expects that the cash and cash equivalents on hand as of September 30, 2022, will be sufficient to fund operating expenses and capital expenditures for the next 12 months.

About Pardes Biosciences, Inc.
Pardes Biosciences is a clinical-stage biopharmaceutical company created to help solve pandemic-sized problems, starting with COVID-19. We are dedicated to discovering and developing potent and easy-to-prescribe oral antiviral drug candidates so that patients everywhere can get well sooner. For more information, please visit www.pardesbio.com.

About PBI-0451

PBI-0451 is a potential stand-alone, novel, direct-acting oral antiviral drug candidate for the treatment and prevention of COVID-19 in Phase 2 clinical development (Study PBI-0451-0002, NCT 05543707). PBI-0451 was developed to inhibit the main cysteine protease (Mpro) of all known coronaviruses, including SARS-CoV-2. Inhibiting Mpro prevents the liberation and assembly of the viral replication complex, blocking replication before it begins. The potent antiviral activity observed across SARS-CoV-2 variants in preclinical in vitro studies as well as the favorable safety and tolerability data from Pardes Biosciences' Phase 1 clinical trials support continued clinical development of PBI-0451, which we believe has the potential to be a safe, effective and easy-to-prescribe oral antiviral for preventing and treating COVID-19 in adult and pediatric patients, including patients unable or unwilling to take currently authorized or approved therapies.

About COVID-19

COVID-19 has resulted in an unprecedented and persistent global health emergency. Over two and a half years into the pandemic, COVID-19 remains a leading cause of death in the U.S., with greater than 6.5 million deaths worldwide and millions of newly documented cases monthly[1]. As the long-term implications of mild-to-moderate SARS-CoV-2 infection and "long-COVID" remain unclear, the infectivity and mutability of SARS-CoV-2 likely represents a substantial threat for years to come. The rapid emergence of new variants supports the need for continued development of next generation therapeutics. In addition, there are a significant number of patients unable or unwilling to take currently authorized or approved therapeutics. Existing treatment options are being eliminated or falling short due to lack of efficacy against new variants, safety concerns, significant drug-drug interactions, risk of viral rebound, limited access, and other factors. Notably, the most commonly prescribed oral therapy in the U.S. is contraindicated with dozens of commonly prescribed medications, leaving millions of patients with high unmet medical need vulnerable to severe COVID-19. Over 80% of adults over 60 are on at least 1 other medicine and over 30% are taking at least 5 other medicines.[2] Many of these common, contraindicated drug classes should not be stopped or paused (e.g., blood thinners, antipsychotics, antidepressants and antiarrhythmics). These patients are at high risk of severe disease and left with unacceptable alternatives. New therapeutics are urgently needed to address this need, prepare for future variants, and advance care for all patients.

Availability of Other Information about Pardes Biosciences

Pardes Biosciences intends to use the Investors page of its website (https://ir.pardesbio.com) as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor Pardes Biosciences' Investors website, in addition to following Pardes Biosciences' press releases, Securities and Exchange Commission (SEC) filings, public conference calls, presentations and webcasts.

[1] https://www.kff.org/coronavirus-covid-19/issue-brief/global-covid-19-tracker/

[2] https://www.cdc.gov/nchs/data/databriefs/db347-h.pdf

Forward Looking Statement

This press release contains statements that relate to future events and expectations and, as such, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When or if used in this press release, the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "outlook," "plan," "possible," "predict," "should," "will," and similar expressions and their variants, as they relate to Pardes Biosciences (Pardes), may identify forward-looking statements. All statements that reflect Pardes' expectations, assumptions or projections about the future, other than statements of historical fact, are forward-looking statements, including, without limitation, statements regarding the company's future financial or business performance, conditions, plans, prospects, trends or strategies and other financial and business matters, including expectations that its current cash and cash equivalents on hand as of September 30, 2022, will be sufficient to fund operating expenses and capital expenditures for the next 12 months; PBI-0451's potential as a safe, well-tolerated and easy to prescribe COVID-19 oral antiviral treatment for all patients; and the planned timing and conduct of the company's clinical trial program for PBI-0451 and timing on the availability of data from the Phase 2 clinical trial. Forward-looking statements reflect Pardes' current beliefs, expectations, and assumptions regarding the future of its business, its future plans and strategies, its development plans, its preclinical and clinical results, future conditions and other factors Pardes believes are appropriate in the circumstances. Although Pardes believes the expectations and assumptions reflected in such forward-looking statements are reasonable, Pardes can give no assurance that they will prove to be correct. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and changes in circumstances that are difficult to predict, which could cause Pardes' actual activities and results to differ materially from those expressed in any forward-looking statement. Such risks and uncertainties include, but are not limited to: (i) risks and uncertainties related to Pardes' ability to advance, obtain regulatory approval of and ultimately commercialize its product candidates; (ii) the timing and results of preclinical studies and clinical trials; (iii) Pardes' ability to maintain financial resources necessary to continue its clinical trials and fund development goals and business operations; (iv) the impact of the COVID-19 pandemic on Pardes' business, clinical trials, financial condition, liquidity and results of operations; (v) Pardes' ability to protect its intellectual property; and (vi) other risks and uncertainties described under the heading "Risk Factors" in Pardes' Annual Report on Form 10-K for the year ended December 31, 2021, Quarterly Report on Form 10-Q to be filed for the quarter ended September 30, 2022, and other SEC filings. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. The statements in this press release speak only as of the date of this press release, even if subsequently made available by Pardes on its website or otherwise. Pardes disclaims any intention or obligation to update publicly any forward-looking statements, whether in response to new information, future events, or otherwise, except as required by applicable law.

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Select Financial Information:

Pardes Biosciences, Inc.
Condensed Statements of Operations
(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 17,375	$ 8,081	$ 50,918	$ 17,792
General and administrative	6,919	3,434	22,736	6,389
Total operating expenses	24,294	11,515	73,654	24,181
Other income:				
Interest and other income, net	959	3	1,242	10
Net loss and comprehensive loss	$ (23,335)	$ (11,512)	$ (72,412)	$ (24,171)
Net loss per share, basic and diluted	$ (0.40)	$ (3.76)	$ (1.25)	$ (11.73)
Weighted-average number of common shares - basic and diluted	58,381,918	3,064,829	57,720,591	2,059,855

Pardes Biosciences, Inc.
Condensed Balance Sheets
(Unaudited)
(in thousands)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 209,055	$ 268,678
Prepaid expenses and other current assets	4,986	6,581
Total current assets	214,041	275,259
Total assets	$ 214,041	$ 275,259
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,569	$ 2,385
Accrued expenses	10,459	6,580
Total current liabilities	12,028	8,965
Total liabilities	12,028	8,965
Stockholders' equity:		
Common stock	6	6
Additional paid-in capital	325,943	317,812
Accumulated deficit	(123,936)	(51,524)
Total stockholders' equity	202,013	266,294
Total liabilities and stockholders' equity	$ 214,041	$ 275,259