PMV Pharmaceuticals Reports Second Quarter 2023 Financial Results and Corporate Highlights

August 9, 2023

- Continued progress in ongoing Phase 1/2 PYNNACLE study of PC14586, a first-in-class precision oncology investigational therapy in patients with advanced solid tumors with a p53 Y220C mutation; updated Phase 1 data expected in 2H 2023
- Concluded successful End-of-Phase 1 FDA meeting with alignment on recommended Phase 2 dose and key elements of single arm, Phase 2 registrational portion of PYNNACLE study
- Ongoing enrollment in combination arm of PYNNACLE study with PC14586 and KEYTRUDA® (pembrolizumab)
- Appointed Dr. Masha Poyurovsky as Vice President of Biology

PRINCETON, N.J., Aug. 09, 2023 (GLOBE NEWSWIRE) -- PMV Pharmaceuticals, Inc. (Nasdaq: PMVP), a precision oncology company pioneering the discovery and development of small molecule, tumor agnostic therapies targeting p53, today reported financial results for the second quarter ended June 30, 2023, and provided a corporate update.

PMV recently concluded an End-of-Phase 1 meeting with the U.S. Food and Drug Administration (FDA) focused on gaining alignment with the Agency regarding the clinical and regulatory pathway for developing PC14586 for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. Alignment with the FDA was obtained on the recommended Phase 2 dose as well as key elements of the Phase 2 registrational portion of the PYNNACLE trial. PMV plans to initiate the single arm, Phase 2 portion of the PYNNACLE study in early 2024.

“Our ongoing PYNNACLE study of PC14586 in patients with advanced solid tumors continues to make good progress,” said David Mack, Ph.D., President and Chief Executive Officer. “The positive outcome of our recently held End-of-Phase 1 meeting positions us to initiate a registrational trial for PC14586 and is an important milestone in our goal of bringing PC14586 to advanced cancer patients with a p53 Y220C mutation. Furthermore, we look forward to sharing updated Phase 1 data in the second half of the year.”

Dr. Mack added, “We are also very pleased to welcome Dr. Masha Poyurovsky to PMV as Vice President of Biology. Her scientific expertise in p53 biology and proven track record in translational drug development make her the ideal candidate to lead our biology team. I look forward to Masha’s leadership and contributions as we continue to leverage the potential of p53 targeted therapies.”

Second Quarter 2023 and Recent Corporate Highlights:

- Ongoing enrollment in the combination arm of PYNNACLE evaluating PC14586 with KEYTRUDA® (pembrolizumab). PMV and Merck entered into a collaboration in 2022 under the terms of which Merck will supply KEYTRUDA for this study.
- Appointed Masha Poyurovsky, Ph.D., as Vice President of Biology. Dr. Poyurovsky has more than a decade of experience leading novel platforms and a track record of advancing therapies from concept to the clinic. From 2011 to 2023, she was employed at Kadmon (acquired by Sanofi in 2021) most recently as Vice President, Discovery Biology. Prior to working in industry, she was a Research Scientist and a Postdoctoral Research Fellow at Columbia University where she conducted studies on p53 in the laboratory of Professor Carol Prives. She is the author and co-author of numerous publications and patents in the area of cancer biology and drug discovery. Dr. Poyurovsky obtained a doctorate in biochemistry from Columbia University and a bachelor of science in biochemistry and biophysics from the University of Pittsburgh.

Second Quarter 2023 Financial Results

- PMV Pharma ended the second quarter with $218.8 million in cash, cash equivalents, and marketable securities, compared to $277.4 million as of June 30, 2022. Net cash used in operations was $27.9 million for the six months ended June 30, 2023, compared to $31.7 million for the six months ended June 30, 2022.
- Net loss for the six months ended June 30, 2023, was $36.6 million compared to $35.7 million for the six months ended June 30, 2022.
- Research and development (R&D) expenses were $28.9 million for the six months ended June 30, 2023, compared to $23.3 million for the six months ended June 30, 2022. The increase in R&D expenses was primarily related to increased headcount and clinical expenses to advance research on PC14586, the Company’s lead drug candidate.
- General and administrative (G&A) expenses were $12.7 million for the six months ended June 30, 2023, compared to $13.2 million for the six months ended June 30, 2022. The decrease in G&A expenses was primarily due to facility related costs now allocated to research as our new laboratory building in Princeton, New Jersey began operations.

KEYTRUDA® (pembrolizumab) is a registered trademark of Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Condensed Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 68,209	$ 108,297
Restricted cash	822	822
Marketable securities, current	118,878	132,757
Prepaid expenses and other current assets	2,504	5,130
Total current assets	190,413	247,006
Property and equipment, net	11,136	10,955
Marketable securities, noncurrent	31,757	2,495
Right-of-use assets	8,729	9,539
Other assets	181	313
Total assets	$ 242,216	$ 270,308
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,489	$ 2,996
Accrued expenses	7,940	7,308
Operating lease liabilities, current	18	528
Total current liabilities	11,447	10,832
Operating lease liabilities, noncurrent	12,960	13,448
Total liabilities	24,407	24,280
Stockholders' equity:		
Additional paid-in capital	495,744	487,516
Accumulated deficit	(277,607)	(241,043)
Accumulated other comprehensive loss	(328)	(445)
Total stockholders' equity	217,809	246,028
Total liabilities and stockholders' equity	$ 242,216	$ 270,308

PMV Pharmaceuticals, Inc.

Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 13,843	$ 11,462	$ 28,916	$ 23,297
General and administrative	6,279	6,423	12,686	13,206
Total operating expenses	20,122	17,885	41,602	36,503
Loss from operations	(20,122)	(17,885)	(41,602)	(36,503)
Other income (expense):				
Interest income, net	2,696	604	5,022	832
Other income (expense), net	(6)	(31)	20	(72)
Total other income (expense)	2,690	573	5,042	760
Loss before (benefit) provision for income taxes	(17,432)	(17,312)	(36,560)	(35,743)
(Benefit) provision for income taxes	4	(2)	4	—
Net loss	(17,436)	(17,310)	(36,564)	(35,743)
Unrealized (loss) gain on available for sale investments, net of tax	(212)	(357)	117	(945)
Comprehensive loss	$ (17,648)	$ (17,667)	$ (36,447)	$ (36,688)
Net loss per share -- basic and diluted	$ (0.38)	$ (0.38)	$ (0.80)	$ (0.79)
Weighted-average common shares outstanding	45,813,132	45,571,067	45,793,355	45,518,845

About PC14586

PC14586 is a first-in-class, small molecule, p53 reactivator designed to selectively bind to the crevice present in the p53 Y220C mutant protein, hence, restoring the wild-type, or normal, p53 protein structure and tumor-suppressing function. The U.S. Food and Drug Administration granted Fast Track designation to PC14586 for the treatment of patients with locally advanced or metastatic solid tumors that have a p53 Y220C mutation. For more information about the Phase 1/2 PYNNACLE trial (PMV-586-101), refer to www.clinicaltrials.gov (NCT study identifier NCT04585750). About PMV Pharma

About PMV Pharma

PMV Pharma is a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53. p53 mutations are found in approximately half of all cancers. The field of p53 biology was established by our co-founder Dr. Arnold Levine when he discovered the p53 protein in 1979. Bringing together leaders in the field to utilize over four decades of p53 biology, PMV Pharma combines unique biological understanding with pharmaceutical development focus. PMV Pharma is headquartered in Princeton, New Jersey. For more information, please visit www.pmvpharma.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the Company’s future plans or expectations for PC14586, including expectations regarding timing for its Phase 1 clinical and regulatory update and the Phase 2 initiation for the PYNNACLE study, as well as expectations regarding success of its current clinical trial for PC14586 and any future commercialization plans for the product candidate. Any forward-looking statements in this statement are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the Company’s product candidate development activities and planned clinical trials, the Company’s ability to execute on its strategy and operate as an early clinical stage company, the potential for clinical trials of PC14586 or any future clinical trials of other product candidates to differ from preclinical, preliminary or expected results, the Company’s ability to fund operations, and the impact that the current COVID-19 pandemic will have on the Company’s clinical trials, supply chain, and operations, as well as those risks and uncertainties set forth in the section entitled “Risk Factors” in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 1, 2023, the Company’s Quarterly Report on Form 10-Q for the three months ended March 21, 2023, filed with the SEC on May 10, 2023, and its other filings filed with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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