Poseida Therapeutics Reports Program Updates and Financial Results for the Second Quarter of 2021

SAN DIEGO, Aug. 12, 2021 /PRNewswire/ -- Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary genetic engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced program updates and financial results for the second quarter ended June 30, 2021.

"We made significant progress in the second quarter of 2021, advancing our science and operational capabilities and setting the stage to deliver on multiple key milestones," said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida. "We are excited for the second half of the year when we plan to generate and report additional data on P-PSMA-101, our first solid tumor CAR-T; file two INDs for our fully allogeneic CAR-T programs, P-BCMA-ALLO1 for multiple myeloma, and P-MUC1C-ALLO1 for multiple solid tumor indications; update on our BCMA franchise later in the year and advance our in vivo gene therapy pipeline."

Program Updates

BCMA Programs

P-BCMA-101 is an autologous CAR-T product candidate currently in an ongoing Phase 1 dose expansion trial and Phase 2 trial in development for the treatment of relapsed/refractory multiple myeloma. Phase 1 dose expansion enrollment continues and the Company expects to provide an update on this program later in 2021.

P-BCMA-ALLO1, the Company's first allogeneic CAR-T product candidate, is in development for the treatment of relapsed/refractory multiple myeloma. The program is proceeding as planned with an IND filing and initiation of a Phase 1 clinical trial on track for the third quarter of 2021.

PSMA Program

P-PSMA-101 is a solid tumor autologous CAR-T product candidate being developed to treat patients with metastatic castrate-resistant prostate cancer (mCRPC) currently in an ongoing Phase 1 dose escalation trial, with an additional update on the program expected later in the third quarter of 2021.

MUC1-C Program

P-MUC1C-ALLO1 is an allogeneic CAR-T product candidate in preclinical development with the potential to treat a wide range of solid tumors, including breast and ovarian cancers. P-MUC1C-ALLO1 is proceeding as planned, with an anticipated IND filing and initiation of Phase 1 clinical trial by the end of 2021.

Liver-Directed Gene Therapy Program

P-OTC-101 is the Company's first liver-directed gene therapy program for the in vivo treatment of urea cycle disease caused by congenital mutations in the ornithine transcarbamylase (OTC) gene, a condition characterized by high unmet medical need. The Company is currently evaluating whether to modify the P-OTC-101 program to move to the fully non-viral nanoparticle delivery system, which could shift timelines. The Company will update expected timing on program advancement once that evaluation is complete.

Other Operational Updates and Upcoming Events

Addition of Cynthia Collins to Board of Directors

In July, the Company announced the appointment of biotechnology industry veteran Cynthia Collins to its Board of Directors, a recognized leader in cell and gene therapies with broad expertise in gene engineering, oncology and hematology.

Ms. Collins most recently served as the CEO of Editas Medicine, Inc., previously having served as the CEO of Human Longevity, Inc.; the CEO/GM of the Cell Therapy and Lab Business of General Electric's Healthcare Life Sciences; and the CEO of Clarient Diagnostics, Inc. Ms. Collins received a

B.S. degree in Microbiology from the University of Illinois, Urbana and an MBA from The University of Chicago Booth School of Business. She is a member of the board of directors at DermTech, Inc., Certara, Inc., Biocare Medical, LLC, and Triumvira Immunologics, Inc., and previously served on the board for the ARM Foundation for Cell and Gene Medicine and Alliance for Regenerative Medicine.

Interim Update on Data from Phase 1 P-PSMA-101 Clinical Trial to be Presented at CAR-TCR Summit
The Company plans to provide an update from the Phase 1 P-PSMA-101 clinical trial to be presented by CEO, Eric Ostertag, at the 6th Annual CAR-TCR Summit virtual meeting at 10:00 am ET on August 31, 2021, entitled, "P-PSMA-101 is a High-Tscm Autologous CAR-T Targeting PSMA Producing Exceptionally Deep and Durable Responses in Castration-Resistant Metastatic Prostate Cancer."

Financial Results for the Second Quarter 2021
Research and Development Expenses
Research and development expenses were $36.0 million for the second quarter ended June 30, 2021, compared to $25.2 million for the same period in 2020. For the six months ended June 30, 2021, research and development expenses were $65.1 million, compared to $48.6 million for the same period in 2020. The increase was primarily due to increased stock-based compensation expense, headcount, external costs related to our preclinical programs and clinical stage programs, including the ongoing enrollment and manufacturing associated with our P-BCMA-101 and P-PSMA-101 clinical trials, and internal costs related to facilities development.

General and Administrative Expenses
General and administrative expenses were $8.9 million for the second quarter ended June 30, 2021, compared to $4.2 million for the same period in 2020. General and administrative expenses were $17.2 million for the six months ended June 30, 2021, compared to $9.1 million for the same period in 2020. The increase was primarily due to increased stock-based compensation expense, headcount and professional fees associated with operating as a publicly traded company.

Net Loss
Net loss was $45.7 million and $84.0 million for the three and six months ended June 30, 2021, respectively, and $30.4 million and $59.2 million for the three and six months ended June 30, 2020, respectively.

Cash Position
As of June 30, 2021, cash, cash equivalents and short-term investments were $237.3 million.

About Poseida Therapeutics, Inc.
Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac® DNA Delivery System, Cas-CLOVER™ Site-specific Gene Editing System and nanoparticle- and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our wholly-owned portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics. To learn more, visit www.poseida.com and connect with us on Twitter and LinkedIn.

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. Such forward-looking statements include statements regarding, among other things, the potential benefits of Poseida's technology platforms and product candidates, Poseida's plans and strategy with respect to developing its technologies and product candidates, and anticipated timelines and milestones with respect to Poseida's development programs. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Poseida's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry and the other risks described in Poseida's filings with the Securities and Exchange Commission. All forward-looking statement contained in this press release speak only as of the date on which they were made. Poseida undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Poseida Therapeutics, Inc.
Selected Financial Data
(Unaudited)
(In thousands, except share and per share amounts)

STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 36,008	$ 25,210	$ 65,103	$ 48,625
General and administrative	8,871	4,236	17,240	9,090
Total operating expenses	44,879	29,446	82,343	57,715
Loss from operations	(44,879)	(29,446)	(82,343)	(57,715)
Other income (expense):				
Interest expense	(843)	(892)	(1,681)	(1,806)
Other income (expense), net	17	(90)	5	309
Net loss before income tax	(45,705)	(30,428)	(84,019)	(59,212)
Income tax expense	—	—	—	—

Net loss	$ (45,705)	$ (30,428)	$ (84,019)	$ (59,212)
Net loss per share, basic and diluted	$ (0.74)	$ (2.28)	$ (1.35)	$ (4.44)
Weighted-average shares of common stock, basic and diluted	62,150,961	13,370,763	62,066,498	13,346,672

SELECTED BALANCE SHEET DATA

	June 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$237,261	$ 309,152
Total assets	299,111	371,484
Total liabilities	112,535	109,516
Total stockholders' equity	186,576	261,968

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SOURCE Poseida Therapeutics, Inc.

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