Poseida Therapeutics Provides Updates and Financial Results for the Third Quarter of 2023

Based upon progress in its allogeneic programs, the Company is announcing today acceleration and increased certainty of achieving upcoming milestones and payments related to the Roche Collaboration

Closed strategic investment by Astellas Pharma in August 2023, bringing additional funding of $50 million

Acceptance of three poster presentations at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2023, including early P-BCMA-ALLO1 data

SAN DIEGO, Nov. 9, 2023 /PRNewswire/ -- Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage cell and gene therapy company advancing a new class of treatments for patients with cancer and rare diseases, today announced updates and financial results for the third quarter ended September 30, 2023.

"In the third quarter, we continued to execute on our key priorities for 2023 while strengthening our financial position with a $50 million strategic investment from Astellas that closed in August 2023. Additionally, we have made strong progress in our Roche Collaboration, accelerating certain milestone payments," said Mark Gergen, Chief Executive Officer of the Company. "With the recent announcement of my upcoming transition to the role of Executive Chairman on January 1, 2024, I am excited about the future of Poseida under the leadership of Kristin Yarema, Ph.D., who will assume the role of President and CEO."

Based upon substantial progress in its P-BCMA-ALLO1 and P-CD19CD20-ALLO1 programs, the Company is announcing today that certain payments as well as the expected timing of achievement of upcoming milestones, have been accelerated to reflect progress in the programs and better align with expected upcoming further clinical development and manufacturing needs and timelines. Poseida may also receive additional funding and resources for select expanded research, clinical development, and manufacturing activities under the existing Roche Collaboration Agreement. As a result of this progress, the Company expects to receive certain payments sooner and/or with more certainty than originally anticipated.

"The combination of the Astellas investment and the progress in our Roche Collaboration has strengthened our financial position in the last quarter," said Johanna Mylet, Chief Financial Officer at the Company. "In addition to extending our baseline cash runway, we continue to have potential further upside in the near term under the Roche Collaboration Agreement as well as additional business development opportunities to further extend our cash runway."

The Company previously announced the acceptance of three poster presentations at the ASH Annual Meeting, taking place in San Diego and virtually in December 2023. In separate presentations, the Company plans to present interim safety and efficacy data on P-BCMA-ALLO1, the Company's Phase 1 allogeneic cell therapy program in multiple myeloma partnered with Roche, and P-FVIII-101, the Company's preclinical non-viral gene therapy program in Hemophilia A.

"As we advance our cell therapy pipeline, we continue to be excited about the significant progress we are making in our Roche partnership. The advancements we have made are being recognized with acceleration of, and increased certainty around achievement of additional near-term milestones, which extends our cash runway and further validates the progress we are making across our allogeneic cell therapies," said Dr. Yarema, President, Cell Therapy at the Company. "In addition to the clinical progress for our allo BCMA program that will be presented at ASH, we continue to expect dosing to begin in our P-CD19CD20-ALLO1 program in B-cell malignancies in early 2024. Across our allogeneic portfolio, we have seen significant improvement in raising product yields through unit operation optimization at our clinical manufacturing facility, as recently highlighted in our CAR-TCR Summit presentation. In our lead solid tumor program, P-MUC1C-ALLO1, in order to gain the full benefit of our recently implemented program learnings, such as preconditioning regimen, as well as due to market factors and slightly slower than expected enrollment in some newer key cohorts of this basket study, we have made the decision to shift the timing for an interim data update to a medical meeting in the first half of next year. As we look to 2024, we plan to provide an overall Company update and outlook in early January."

Program Updates

Cell Therapy Programs

MUC1-C Program
P-MUC1C-ALLO1 is an allogeneic CAR-T product candidate targeting solid tumors derived from epithelial cells, including breast and ovarian cancers. The Company is currently evaluating P-MUC1C-ALLO1 in a Phase 1 clinical trial. Poseida plans to provide an interim clinical update at a medical meeting in the first half of 2024.

BCMA Program
P-BCMA-ALLO1 is an allogeneic CAR-T product candidate being developed to target relapsed/refractory multiple myeloma (R/R MM) in partnership with Roche. The Company is currently evaluating P-BCMA-ALLO1 in a Phase 1 clinical trial and plans to share early safety and preliminary efficacy results at the ASH Annual Meeting, taking place in San Diego and virtually in December 2023.

CD19CD20 Program
P-CD19CD20-ALLO1 is an allogeneic CAR-T product being developed to target B-cell malignancies in partnership with Roche. P-CD19CD20-ALLO1 is the Company's first dual CAR program and contains two fully functional CAR molecules to target cells that express either CD19 or CD20, or both. Poseida expects to dose the first patient with P-CD19CD20-ALLO1 in early 2024.

Gene Therapy Programs
The Company is in the process of strategically evaluating its gene therapy and gene editing programs including the programs previously licensed to Takeda to determine which programs it will prioritize and progress internally. In addition, the Company is actively evaluating the potential to leverage

these programs and technologies through business development. The Company intends to provide an update on this evaluation when complete, which is expected to be in the first half of 2024.

FVIII Program
The Company is advancing its P-FVIII-101 preclinical program, which is in development for the in vivo treatment of Hemophilia A. P-FVIII-101 utilizes piggyBac gene modification delivered via lipid nanoparticle that has demonstrated stable and sustained Factor VIII expression in animal models. The Company is presenting preclinical data from this program at the upcoming ASH Annual Meeting.

OTC Program
P-OTC-101 is an in vivo program for the treatment of urea cycle disease caused by congenital mutations in the ornithine transcarbamylase (OTC) gene. The Company is developing the P-OTC-101 program utilizing a hybrid delivery system and working on an updated timeline for the program. The Company received orphan drug designation for this program from the FDA in July 2023.

PAH Program
P-PAH-101 is a liver-directed gene therapy to treat Phenylketonuria (PKU), an inherited genetic disorder caused by mutations in the phenylalanine hydroxylase (PAH) gene resulting in buildup of phenylalanine in the body. If left untreated, PKU can affect a person's cognitive development. P-PAH-101 is currently in preclinical development.

Other Operational Updates and Upcoming Events

Strategic Investment
In August 2023 the Company announced a $50 million strategic investment by Astellas and granted Astellas certain strategic rights.

Leadership Updates
As previously announced, effective January 1, 2024, Dr. Yarema, the Company's current President, Cell Therapy, will transition to the role of President and CEO of the Company and Mr. Gergen, the Company's current CEO and Chairman, will transition to the role of Executive Chairman of the board of directors. Brent Warner, President, Gene Therapy, will continue to report to Mr. Gergen.

Poseida R&D Days
In recognition of its continued development and growth, and to highlight its proprietary platform technologies and preclinical research in 2024, the Company plans to hold two R&D Days – the first focusing on gene therapy in April 2024 and the second focusing on cell therapy in the fall of 2024. Additional details are expected to be announced early next year.

Financial Results for the Third Quarter 2023

Revenues
Revenues were $9.4 million for the three months ended September 30, 2023, compared to $116.3 million for the same period in 2022. The decrease was primarily due to initial license revenue recognized from the collaboration and license agreement with Roche, which became effective in the third quarter of 2022, offset by the revenue recognized related to the research services performed under the collaboration and license agreements with Roche and Takeda.

For the nine months ended September 30, 2023, revenues were $39.7 million, compared to $120.4 million for the same period in 2022. The decrease was primarily due to initial license revenue recognized from the collaboration and license agreement with Roche, which became effective in the third quarter of 2022, offset by the revenue recognized related to the research services performed under the collaboration and license agreements with Roche and Takeda, including $8.9 million of previously deferred revenue recognized as a result of the termination of its collaboration agreement with Takeda in July 2023.

Research and Development Expenses
Research and development expenses were $37.5 million for the three months ended September 30, 2023, compared to $35.1 million for the same period in 2022. The increase was primarily due to an increase in personnel expenses as a result of increased headcount, an increase in preclinical stage programs and other unallocated expenses due to an increase in research collaboration activity, offset by a decrease in clinical stage programs, primarily driven by the wind-down of the Company's clinical development activities associated with its autologous programs.

For the nine months ended September 30, 2023, research and development expenses were $114.7 million, compared to $119.0 million for the same period in 2022. The decrease was primarily due to a decrease in external costs related to the Company's autologous clinical stage programs, partially offset by an increase in personnel expenses as a result of increased headcount, an increase in external costs related to its preclinical stage programs and other unallocated expenses due to an increase in research collaboration activity.

General and Administrative Expenses
General and administrative expenses were $8.1 million for the three months ended September 30, 2023, compared to $9.4 million for the same period in 2022. The decrease was primarily due to lower professional fees and facility costs.

For the nine months ended September 30, 2023, general and administrative expenses were $28.6 million, compared to $28.2 million for the same period in 2022. The increase was primarily due to an accelerated stock-based compensation expense in the first quarter of 2023 related to a one-time modification associated with the retirement of the Company's former Executive Chairman, offset by lower facility costs.

Net Income (Loss)
Net loss was $31.8 million and $98.1 million for the three and nine months ended September 30, 2023, respectively, compared to net income of $70.4 million and net loss of $30.7 million for the three and nine months ended September 30, 2022, respectively.

Cash Position
As of September 30, 2023, the Company's cash, cash equivalents and short-term investments balance was $238.8 million. The Company expects that its cash, cash equivalents and short-term investments together with the remaining near-term milestones and other payments from Roche as well as the proceeds from the Astellas strategic investment will be sufficient to fund operations into the second half of 2025. Potential additional payments under the Roche Collaboration Agreement and/or potential additional business development could extend cash runway beyond the second half of 2025.

About Poseida Therapeutics, Inc.
Poseida Therapeutics is a clinical-stage biopharmaceutical company advancing differentiated cell and gene therapies with the capacity to cure certain cancers and rare diseases. The Company's pipeline includes allogeneic CAR-T cell therapy product candidates for both solid and liquid tumors as well as in vivo gene therapy product candidates that address patient populations with high unmet medical need. The Company's approach to cell and gene therapies is based on its proprietary genetic editing platforms, including its non-viral piggyBac® DNA Delivery System, Cas-CLOVER™ Site-Specific Gene Editing System and nanoparticle and hybrid gene delivery technologies as well as in-house GMP cell therapy manufacturing. The Company has formed a global strategic collaboration with Roche to unlock the promise of cell therapies for patients with hematological malignancies. Learn more at www.poseida.com and connect with Poseida on X 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, expected plans with respect to clinical trials, including timing of regulatory submissions and approvals and clinical data updates; potential fees, milestones and other payments that the Company may receive pursuant to its collaboration agreement with Roche, including related timing; anticipated timelines and milestones with respect to the Company's development programs and manufacturing activities and capabilities; the potential capabilities and benefits of the Company's technology platforms and product candidates; the quotes from Mr. Gergen, Dr. Yarema and Ms. Mylet; future contributions of the Company's directors and executive officers; the timing of the expected leadership transition; estimates of the Company's cash balance, expenses, capital requirements, any future revenue, and need for additional financing; the Company's ability to exploit and consummate additional business development opportunities, including with Roche, and any anticipated impact on the Company's cash balance and cash runway; the Company's ability to attract and/or retain new and existing collaborators with relevant expertise and its expectations regarding the potential benefits to be derived from any such collaborations; and the Company's plans and strategy with respect to developing its technologies and product candidates. 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 the Company'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, the Company's reliance on third parties for various aspects of its business; risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry; the Company's ability to retain key scientific or management personnel; the fact that the Company will have limited control over the efforts and resources that Roche devotes to advancing development programs under its collaboration agreement and the Company may not receive the potential fees and payments under the collaboration agreement and the ability of Roche to early terminate the collaboration, such that the Company may not fully realize the benefits of the collaboration; and the other risks described in the Company's filings with the Securities and Exchange Commission. 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, except as required by law.

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

STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Collaboration revenue	$ 9,352	$ 116,306	$ 39,708	$ 120,441
Total revenue	9,352	116,306	39,708	120,441
Operating expenses:				
Research and development	37,482	35,137	114,727	118,995
General and administrative	8,092	9,389	28,576	28,171
Total operating expenses	45,574	44,526	143,303	147,166
Income (loss) from operations	(36,222)	71,780	(103,595)	(26,725)
Other income (expense):				
Interest expense	(2,236)	(1,775)	(6,404)	(4,395)
Other income, net	6,787	656	12,025	688
Net income (loss) before income tax	(31,671)	70,661	(97,974)	(30,432)
Income tax expense	(107)	(252)	(107)	(252)
Net income (loss)	$ (31,778)	$ 70,409	$ (98,081)	$ (30,684)
Net income (loss) per share, basic and diluted	$ (0.35)	$ 0.92	$ (1.11)	$ (0.46)
Weighted-average number of shares outstanding, basic	91,898,347	76,287,421	88,321,943	67,235,865
Weighted-average number of shares outstanding, diluted	91,898,347	76,688,382	88,321,943	67,235,865

SELECTED BALANCE SHEET DATA

	September 30, 2023	December 31, 2022
	(Unaudited)	
Cash, cash equivalents and short-term investments	$ 238,837	$ 282,493
Total assets	302,252	351,837
Total liabilities	178,592	164,242
Total stockholders' equity	123,660	187,595

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