



Poseida Therapeutics Reports Operational Update and Financial Results for Third Quarter 2020

SAN DIEGO, Nov. 12, 2020 /PRNewswire/ -- Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary gene engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced an operational update and financial results for the quarter ended September 30, 2020.



"During our first quarter as a publicly traded company, we continued to maintain our focus on research innovation and advancement of our clinical programs, while also building new strategic collaborations," said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida. "In early September, we released data demonstrating new manufacturing technology that has the potential to create more efficacious cell therapies and have now implemented that technology across our entire CAR-T pipeline. In October, we announced a research collaboration with TScan Therapeutics to evaluate the feasibility of producing a novel cell-based therapeutic for the treatment of COVID-19. This collaboration will expand our platforms to include T cell receptor-engineered T cell (TCR-T) therapies and further expand the indications we can potentially treat beyond oncology."

Program Updates

P-PSMA-101

P-PSMA-101 is a solid tumor autologous CAR-T product candidate being developed to treat patients with metastatic castrate resistant prostate cancer. The program started enrollment in May 2020. On November 2, 2020, the Company announced that a clinical hold placed on the trial was lifted by the FDA. The trial has now resumed with minor protocol modifications to increase patient compliance and safety. The protocol changes are specific to the P-PSMA-101 program and do not affect the ongoing P-BCMA-101 clinical trial. The Company now expects to provide an initial data update in mid-2021.

P-BCMA-101

P-BCMA-101 is an autologous CAR-T product candidate for the treatment of patients with relapsed/refractory multiple myeloma. The program is currently enrolling in an expanded Phase 1 clinical trial to inform the potentially registrational Phase 2 clinical trial. Phase 1 dose expansion enrollment continues, although at a slower pace than planned due in part to the COVID-19 pandemic. Further, the Company expects to make a Phase 2 dosing decision on P-BCMA-101 by early 2021.

At the CAR-TCR Digital Week meeting on September 16, 2020, the Company presented data related to CAR-T manufacturing optimizations and also illustrated the impact of these optimizations with preliminary clinical analysis of the first patients dosed in the P-BCMA-101 Phase 1 expansion trial.

P-BCMA-ALLO1

The Company's first allogeneic CAR-T product candidate, P-BCMA-ALLO1, is in development for the treatment of relapsed/refractory multiple myeloma and is designed to be fully allogeneic, with genetic edits designed to reduce or eliminate both host-vs-graft and graft-vs-host alloreactivity. The program is proceeding toward an IND filing which is expected in the first half 2021.

P-MUC1C-ALLO1

This allogeneic CAR-T product candidate is in preclinical development with the potential to treat a wide range of solid tumors, including breast and ovarian cancers. The program is proceeding with an expected IND filing in 2021.

P-OTC-101 Gene Therapy Program

P-OTC-101 is the Company's first liver-directed gene therapy program for *in vivo* treatment of urea cycle disease caused by congenital mutations in the OTC gene, a condition characterized by high unmet medical need. The Company now expects to submit an IND in 2022 due to pandemic related factors, including longer timelines due to COVID-19 vaccine-related capacity constraints at certain vendors.

Early Stage Development Programs

For programs in early development, including the fully allogeneic Dual CAR programs, P-PSMA-ALLO1 and P-MMUT-101, the Company expects to update specific guidance at a later date, as it gains further clarity on the timelines and any impacts of the COVID-19 pandemic.

Other Operational Updates and Upcoming Events

Collaboration agreement with TScan Therapeutics to explore developing allogeneic T cell receptor therapies for the treatment of COVID-19
In October, the Company and TScan Therapeutics announced a research collaboration and license agreement to explore the use of the Company's fully allogeneic stem cell memory T cell platform in combination with TScan's proprietary TCR platform and findings related to SARS-CoV-2. The collaboration will allow the Company to explore platform and T cell technology utilizing one or more TCRs in allogeneic cell therapy applications.

Piper Sandler 32nd Annual Virtual Healthcare Conference

The Company is participating in a virtual conference that will be made available at 10 am ET on November 23, 2020, ahead of the conference start scheduled for December 1, 2020. The audio recording of the presentation, formatted as a fireside chat, will be available through the conference coordinators and posted on the Company's website.

62nd American Society of Hematology (ASH) Annual Meeting and Exposition

The Company plans to provide an update on the P-BCMA-101 Phase 1 expansion trial in early December with an oral presentation at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition scheduled for Saturday, December 5, 2020.

Financial Results

Research and Development Expenses

Research and development expenses were \$27.0 million for the three months ended September 30, 2020, compared to \$15.7 million for the same period in 2019. For the nine months ended September 30, 2020, research and development expenses were \$75.6 million, compared to \$41.2 million for the same period in 2019. The increase in both periods was primarily due to increased headcount, external costs related to preclinical programs and clinical stage programs, including the ongoing 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 \$6.5 million for the three months ended September 30, 2020, compared to \$4.0 million for the same period in 2019. General and administrative expenses were \$15.6 million for the nine months ended September 30, 2020, compared to \$14.4 million for the same period in 2019. The increase in both periods was primarily due to increased headcount and professional fees associated with becoming a publicly traded company.

Net Losses

Net losses were \$34.4 million and \$93.6 million for the three and nine months ended September 30, 2020, respectively, and \$21.0 million and \$62.9 million for the three and nine months ended September 30, 2019, respectively.

Cash Position

As of September 30, 2020, cash, cash equivalents and marketable securities were \$341.5 million. Net proceeds from the Company's initial public offering, which closed in July 2020, were \$205.7 million.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary gene 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 Modification 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.

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 statements 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 amounts)

STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 27,016	\$ 15,696	\$ 75,636	\$ 41,189

General and administrative	6,458	4,007	15,553	14,449
Increase in contingent consideration	—	1,060	—	6,683
Total operating expenses	<u>33,474</u>	<u>20,763</u>	<u>91,189</u>	<u>62,321</u>
Loss from operations	(33,474)	(20,763)	(91,189)	(62,321)
Other income (expense):				
Interest expense	(848)	(935)	(2,654)	(2,633)
Other income (expense), net	(92)	744	216	2,040
Net loss before income tax	<u>(34,414)</u>	<u>(20,954)</u>	<u>(93,627)</u>	<u>(62,914)</u>
Income tax benefit	—	—	—	—
Net loss	<u>\$ (34,414)</u>	<u>\$ (20,954)</u>	<u>\$ (93,627)</u>	<u>\$ (62,914)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.63)</u>	<u>\$ (1.65)</u>	<u>\$ (3.43)</u>	<u>\$ (5.06)</u>
Weighted-average shares of common stock, basic and diluted	<u>54,973,788</u>	<u>12,665,834</u>	<u>27,324,297</u>	<u>12,427,367</u>

SELECTED BALANCE SHEET DATA

	September 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	\$ 341,457	\$ 125,318
Total assets	405,171	146,996
Total liabilities	109,335	74,334
Convertible preferred stock	-	222,173
Total stockholders' equity (deficit)	295,836	(149,511)

View original content to download multimedia: <http://www.prnewswire.com/news-releases/poseida-therapeutics-reports-operational-update-and-financial-results-for-third-quarter-2020-301172363.html>

SOURCE Poseida Therapeutics, Inc.

mgraham@poseida.com