Poseida Therapeutics Provides Updates and Financial Results for the Third Quarter of 2022

Entered into a strategic collaboration with Roche to develop allogeneic CAR-T cell therapies for hematological indications; received $110 million upfront payment and achieved the first clinical milestone of $35 million

Roche transaction and public offering, with net proceeds of $75.3 million, executed concurrently in third quarter extend cash runway based upon current plans into at least mid-2024

SAN DIEGO, Nov. 10, 2022 /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 business updates and financial results for the third quarter ended September 30, 2022.

"Throughout the quarter we have advanced our wholly-owned and partnered portfolios of cell and gene therapies for patients with cancer and rare diseases. Despite macro-economic and market challenges facing our industry, we continue to focus on executing on our top priorities," said Mark Gergen, Chief Executive Officer of Poseida. "We are excited about our collaborations with Takeda and Roche, which have already begun to deliver as we achieved our first clinical milestone under the Roche collaboration. In addition, we are advancing our fully allogeneic CAR-T portfolio and look forward to sharing initial data from both the BCMA and MUC1-C programs soon. While we remain encouraged by the results in our autologous P-PSMA-101 program, we have stopped enrollment in the Phase 1 trial and deprioritized this program as we believe that our allogeneic platform is the key to unlocking the promise of cell therapies."

Program Updates

CAR-T Programs

In cell therapy, the Company is focused on two allogeneic CAR-T programs progressing in Phase 1 clinical trials:

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. Poseida is currently evaluating P-MUC1C-ALLO1 in a Phase 1 clinical trial and plans to share an initial early clinical data update on the program at the European Society for Medical Oncology Immuno-Oncology (ESMO I-O) 2022 Annual Congress, which is taking place in Geneva, Switzerland and online in December 2022.

BCMA Program

P-BCMA-ALLO1 is an allogeneic CAR-T product candidate targeting relapsed refractory multiple myeloma partnered with Roche. Poseida is currently evaluating P-BCMA-ALLO1 in a Phase 1 clinical trial and plans to share an initial early clinical data update on the program at ESMO I-O, which is taking place in Geneva, Switzerland and online in December 2022.

Autologous PSMA Program

P-PSMA-101 is a solid tumor autologous CAR-T product candidate targeting prostate-specific membrane antigen, or PSMA, being developed to treat patients with metastatic castrate-resistant prostate cancer and salivary gland carcinoma. The Company has been evaluating P-PSMA-101 in a Phase 1 trial, however, has made the strategic decision to stop further enrollment. The clinical data from the Phase 1 trial is still being collected and analyzed and will be utilized to inform other solid tumor allogeneic programs, including the Company's preclinical allogeneic program, P-PSMA-ALLO1.

Gene Therapy Programs

In gene therapy, the Company is advancing multiple gene therapy programs in liver-directed diseases:

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.

FVIII Program

The Company is advancing its P-FVIII-101 program partnered with Takeda, 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 plans to present preclinical data from this program at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition being held in New Orleans and online in December 2022.

Financial Results for the Third Quarter 2022

Revenues

Revenues were $116.3 million for the three months ended September 30, 2022, and $120.4 million for the nine months ended September 30, 2022, consisting of revenue earned from the collaboration and license agreement with Takeda that the Company entered into in the fourth quarter of 2021 and the Roche Collaboration Agreement which became effective in the third quarter of 2022, compared to no revenues for the same periods in 2021.

Research and Development Expenses

Research and development expenses were $35.1 million for the three months ended September 30, 2022, compared to $32.5 million for the same period in 2021. The increase was primarily due to an increase in personnel expenses as a result of increased headcount, which included an increase in stock-based compensation expense, offset by the wind-down of the Company's P-BCMA-101 autologous program as the Company transitions to the allogeneic program.

For the nine months ended September 30, 2022, research and development expenses were $119.0 million, compared to $97.6 million for the same period in 2021. The increase was primarily due to an increase in personnel expenses as a result of increased headcount, which included an increase in stock-based compensation expense and an increase in overall active clinical programs offset by the wind-down of the Company's P-BCMA-101

autologous program as the Company transitions to the allogeneic program.

General and Administrative Expenses
General and administrative expenses for the three months ended September 30, 2022 and 2021, were $9.4 million and $9.1 million, respectively. For the nine months ended September 30, 2022 and 2021, general and administrative expenses were $28.2 million and $26.3 million, respectively. The increases were primarily related to an increase in personnel expenses due to an increase in headcount, which included an increase in stock-based compensation expense.

Net Income (Loss)
Net income was $70.4 million and net loss was $30.7 million for the three and nine months ended September 30, 2022, respectively, compared to net loss of $42.4 million and $126.4 million for the three and nine months ended September 30, 2021, respectively.

Financing and Cash Position
In August 2022, Poseida announced the closing of an underwritten public offering of 23,000,000 shares of its common stock for total net proceeds of $75.3 million.

In the third quarter, the Company announced the Roche collaboration, which included a $110.0 million upfront payment and $110.0 million of expected near term milestones. In Q3 2022, the Company earned the first of those milestones, totaling $35.0 million, which is classified in accounts receivable as of September 30, 2022.

As of September 30, 2022, the Company's cash, cash equivalents and short-term investments balance was $279.0 million excluding the $35 million milestone that was earned and not yet received as of September 30, 2022. Poseida expects that its cash, cash equivalents and short-term investments together with the remaining near-term milestones and other payments from Roche will be sufficient to fund operations into at least mid-2024.

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. Poseida's approach to cell and gene therapies is based on its proprietary genetic editing platforms, including its non-viral Super piggyBac® DNA Delivery System, Cas-CLOVER™ Site-Specific Gene Editing System and nanoparticle and hybrid gene delivery technologies. The Company has formed global strategic collaborations with Roche and Takeda to unlock the promise of cell and gene therapies for patients. Learn more at www.poseida.com and connect with Poseida 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, expected timing and plans with respect to clinical trials, including timing of clinical data updates; statements regarding potential fees, milestone and other payments Poseida may receive pursuant to its collaboration agreements; 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 Poseida's ability to prioritize and utilize its resources efficiently and expected benefits from any such prioritization. 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, Poseida'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; Poseida's ability to retain key scientific or management personnel; 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 and per share amounts)

STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Collaboration revenue	$ 116,306	$ —	$ 120,441	$ —
Total revenue	116,306	—	120,441	—
Operating expenses:				
Research and development	35,137	32,524	118,995	97,627
General and administrative	9,389	9,066	28,171	26,306
Total operating expenses	44,526	41,590	147,166	123,933
Income (loss) from operations	71,780	(41,590)	(26,725)	(123,933)
Other income (expense):				
Interest expense	(1,775)	(837)	(4,395)	(2,518)
Other income, net	656	3	688	8
Net income (loss) before income tax	70,661	(42,424)	(30,432)	(126,443)
Income tax expense	(252)	—	(252)	—

Net income (loss)	$ 70,409	$ (42,424)	$ (30,684)	$ (126,443)
Net income (loss) per share, basic	$ 0.92	$ (0.68)	$ (0.46)	$ (2.03)
Net income (loss) per share, diluted	$ 0.92	$ (0.68)	$ (0.46)	$ (2.03)
Weighted-average number of shares outstanding, basic	76,287,421	62,298,243	67,235,865	62,144,595
Weighted-average number of shares outstanding, diluted	76,688,382	62,298,243	67,235,865	62,144,595

SELECTED BALANCE SHEET DATA

	September 30, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 278,985	$ 206,325
Total assets	380,481	269,309
Total liabilities	164,168	113,098
Total stockholders' equity	216,313	156,211

View original content to download multimedia:https://www.prnewswire.com/news-releases/poseida-therapeutics-provides-updates-and-financial-results-for-the-third-quarter-of-2022-301674995.html

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