Poseida Therapeutics Provides Updates and Financial Results for the Fourth Quarter and Full Year 2021

Company announced first strategic collaboration with Takeda focused on deploying its platform technologies to develop non-viral in vivo gene therapies

Company received a safe-to-proceed letter from the FDA on its IND for P-MUC1C-ALLO1 CAR-T program for multiple solid tumors

SAN DIEGO, March 10, 2022 /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 updates and financial results for the fourth quarter and full year ended December 31, 2021.

"We continued to demonstrate strong progress on our key priorities in the fourth quarter even as the pandemic impacted all parts of our industry. In the fourth quarter, we announced our first strategic collaboration with Takeda in gene therapy as well as the FDA IND clearance for P-MUC1C-ALLO1, our allogeneic CAR-T program in solid tumor indications," said Mark Gergen, Chief Executive Officer of Poseida. "We are highly focused on our key priorities for 2022, including initial clinical data for both the P-BCMA-ALLO1 and P-MUC1C-ALLO1 programs expected in the second half of the year, additional data on P-PSMA-101 in prostate cancer, and continuing progress in our gene therapy programs as we work toward applying our technologies to redefining cell and gene therapy."

Program Highlights

BCMA Program
P-BCMA-ALLO1 is the Company's first allogeneic CAR-T program, currently being evaluated in patients with relapsed/refractory multiple myeloma (R/R MM) with initial clinical data expected in the second half of 2022. The planned shift in operational focus to allogeneic CAR-T was announced in the fourth quarter, as the Company began winding down the autologous BCMA program, P-BCMA-101.

The Company reported interim results from its Phase 1 clinical trial of P-BCMA-101 for the treatment of R/R MM at the 2021 American Society of Hematology (ASH) Annual Meeting in December. The results shown highlight that P-BCMA-101, a non-viral transposon-based autologous CAR-T, was well tolerated and demonstrated strong anti-tumor activity in advanced, late line R/R MM patients. The Company also highlighted findings from some of the novel dosing regimens explored during the trial, including the combination with rituxan, which demonstrated an ability to improve response rates, eliminate antibodies, and show an increase in both progression free survival and overall survival in that cohort. The full results of the ASH update can be found on the Company's website.

PSMA Program
P-PSMA-101 is an 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.

In February, the Company presented interim data at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU). The results presented showed notable responses even at the lowest doses in heavily pre-treated patients with mCRPC, including one patient who demonstrated evidence of near complete tumor elimination as evidenced by PSMA PET and other measures. The full ASCO GU presentation can be found on the Company's website.

MUC1-C Program
P-MUC1C-ALLO1 is an allogeneic CAR-T product candidate with the potential to treat a wide range of solid tumors derived from epithelial cells, including breast and ovarian cancers. The Phase 1 clinical trial of P-MUC1C-ALLO1 is proceeding following IND clearance in the fourth quarter of 2021, and an update on the program is expected in the second half of 2022.

Liver-Directed Gene Therapy Programs
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 shared an update on the program during the R&D Day held in February 2022, including the presentation of data showing that use of a non-viral nanoparticle delivery system utilizing piggyBac AAV plus lipid nanoparticle potentially enables curative outcomes in a mouse model of severe OTC. The Company is currently evaluating the P-OTC-101 program to determine the best path forward and will update expected timing on program advancement once that evaluation is complete.

P-FVIII-101 is a liver-directed gene therapy currently partnered with Takeda Pharmaceuticals USA, Inc. (Takeda) and in development for the in vivo treatment of Hemophilia A. P-FVIII-101 utilizes piggyBac gene modification delivered via lipid nanoparticle and has demonstrated stable and sustained Factor VIII expression in animal models. Data from preclinical studies were shared during the R&D Day and showed that the biodegradable nanoparticle in combination with super piggyBac may overcome the limitations of AAV-based systems, with the following potential benefits: larger cargo capacity than AAV delivery alone, the ability to re-dose patients, the ability to treat pediatric patients, and fewer safety concerns.

Platforms and Emerging Technologies
The Company also reviewed its core platform technologies and introduced emerging technology programs at the R&D Day. These emerging programs highlight the Company's continuing focus on innovation and include: (i) emerging preclinical work demonstrating the Company's ability to include T cell receptors (TCRs), in addition to CARs in cell therapies; (ii) early preclinical data on a version of Site-Specific piggyBac gene insertion for site-directed DNA integration; and (iii) a CAR 3.0, an approach that utilizes genetically engineered hematopoietic stem cells to treat certain cancer indications. The full presentation is currently available for a limited period of time on the Company's website.

For these and other discovery programs, the Company may seek partnerships or collaborations to move those applications forward.

Organizational Updates
The Company announced today that Kerry Ingalls, the Company's Chief Operating Officer (COO), intends to retire effective May 13, 2022 and will continue in a strategic advisory role with the Company through September 2022. As previously announced, effective February 1, 2022, Mark Gergen, the Company's President and former Chief Business Officer (CBO), assumed the role of Chief Executive Officer (CEO) and Eric Ostertag, the Company's founder and former CEO, assumed the role of Executive Chairman of the board of directors. In February 2022, the Company announced the appointment of Brent Warner as President, Gene Therapy, to lead the Company's gene therapy efforts including management of the collaboration with Takeda.

Financial Results for the Fourth Quarter and Full Year 2021

Revenues
Revenues were $31.2 million for both the fourth quarter and the full year ended December 31, 2021 consisting of revenue earned from the collaboration and license agreement with Takeda entered into in the fourth quarter of 2021, compared to no revenue for the same periods in 2020.

Research and Development Expenses
Research and development expenses were $39.1 million for the fourth quarter ended December 31, 2021, compared to $27.9 million for the same period in 2020. For the full year ended December 31, 2021, research and development expenses were $136.7 million, compared to $103.5 million for the same period in 2020. The increase was primarily related to an increase in personnel expenses due to an increase in headcount and an increase in stock-based compensation expense, an increase in external costs related to preclinical programs due to an increased number of early stage programs, an increase in external costs related to clinical stage programs including the enrollment and manufacturing for the P-BCMA-101 clinical trial and increased enrollment of the Phase 1 P-PSMA-101 trial, and an increase in internal costs related to facilities and other expenses primarily due to the increased activities in the pilot plant.

General and Administrative Expenses
General and administrative expenses were $9.6 million for the fourth quarter ended December 31, 2021, compared to $7.5 million for the same period in 2020. General and administrative expenses were $35.9 million for the full year ended December 31, 2021, compared to $23.0 million for the same period in 2020. The increase was primarily related to an increase in personnel expenses due to an increase in headcount combined with an increase in stock-based compensation expense, and increases in insurance costs and professional fees.

Net Income (Loss)
Net income was $1.5 million for the fourth quarter ended December 31, 2021 compared to net loss of $36.1 million for the same period in 2020. Net income for the fourth quarter was primarily driven by the revenue from the Company's Takeda collaboration and the write-off of CIRM liability related to the P-BCMA-101 grant award. For the full year ended December 31, 2021, net loss was and $125.0 million compared to net loss of $129.8 million in 2020.

Cash Position
As of December 31, 2021, cash and cash equivalents balance was $206.3 million, which does not include net proceeds of $28.3 million from the restructuring of the Company's debt arrangement, pursuant to that certain loan and security agreement with Oxford Finance LLC, that closed in the first quarter of 2022.

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 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 and manufacturing activities. 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
(In thousands, except share and per share amounts)

STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020

	(Unaudited)			
Revenue:				
Collaboration revenue	$ 31,238	$ —	$ 31,238	$ —
Total revenue	31,238	—	31,238	—
Operating expenses:				
Research and development	39,107	27,884	136,734	103,520
General and administrative	9,609	7,476	35,915	23,029
Total operating expenses	48,716	35,360	172,649	126,549
Loss from operations	(17,478)	(35,360)	(141,411)	(126,549)
Other income (expense):				
Interest expense	(840)	(852)	(3,358)	(3,506)
Other income, net	19,787	64	19,795	280
Net income (loss) before income tax	1,469	(36,148)	(124,974)	(129,775)
Income tax expense	—	—	—	—
Net income (loss)	$ 1,469	$ (36,148)	$ (124,974)	$ (129,775)
Net income (loss) per share, basic and diluted	$ 0.02	$ (0.58)	$ (2.01)	$ (3.61)
Weighted-average shares of common stock, basic	62,506,995	61,826,180	62,235,940	35,996,901
Weighted-average shares of common stock, diluted	62,980,554	61,826,180	62,235,940	35,996,901

SELECTED BALANCE SHEET DATA

	December 31,	
	2021	2020
Cash, cash equivalents and short-term investments	$206,325	$309,152
Total assets	269,309	371,484
Total liabilities	113,098	109,516
Total stockholders' equity	156,211	261,968

View original content to download multimedia:https://www.prnewswire.com/news-releases/poseida-therapeutics-provides-updates-and-financial-results-for-the-fourth-quarter-and-full-year-2021-301500542.html

SOURCE Poseida Therapeutics, Inc.

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