### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 30, 2022

## Poseida Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-39376 (Commission File Number) 47-2846548 (I.R.S. Employer Identification No.)

92121 (Zip Code)

9390 Towne Centre Drive, Suite 200, San Diego, California (Address of principal executive offices)

Registrant's telephone number, including area code: (858) 779-3100

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

	Trading	Name of each exchange
Title of each class	Symbol(s)	on which registered
Common Stock, par value \$0.0001 per share	PSTX	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company  $\boxtimes$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

#### Item 1.01 Entry into a Material Definitive Agreement.

On July 30, 2022, Poseida Therapeutics, Inc. (the "Company") and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche") entered into a collaboration and license agreement (the "Collaboration Agreement"), pursuant to which the Company will grant to Roche:

- an exclusive, worldwide license under certain Company intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from each of the Company's existing P-BCMA-ALLO1 and P-CD19CD20-ALLO1 programs (each, a "Tier 1 Program");
- an exclusive option to acquire an exclusive, worldwide license under certain Company intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from each of the Company's existing P-BCMACD19-ALLO1 and P-CD70-ALLO1 programs (each, a "Tier 2 Program");
- (iii) an exclusive license under certain Company intellectual property to develop, manufacture and commercialize allogeneic CAR-T cell therapy products from the up to six (6) Collaboration Programs (as defined below) designated by Roche; and
- (iv) an option for a non-exclusive, commercial license under certain limited Company intellectual property to develop, manufacture and commercialize certain Roche proprietary cell therapy products for up to three (3) solid tumor targets to be identified by Roche ("Licensed Products").

For each Tier 1 Program, the Company will perform development activities through a Phase 1 dose escalation clinical trial, and Roche is obligated to reimburse a specified percentage of certain costs incurred by the Company in its performance of such activities, up to a specified reimbursement cap for each Tier 1 Program. For each Tier 2 Program, the Company will perform research and development activities either through selection of a development candidate for IND-enabling studies or, subject to Roche's election and payment of an option maintenance fee, through completion of a Phase 1 dose escalation clinical trial. In addition, for each Tier 2 Program for which Roche exercises its option for an exclusive license, Roche is obligated to pay an option exercise fee. For each Tier 1 Program and Tier 2 Program, the Company will perform manufacturing activities until the completion of a technology transfer to Roche.

The parties will conduct an initial, two-year research program to explore and preclinically test a specified number of agreed-upon next generation therapeutic concepts relating to allogeneic CAR-T therapies. Subject to Roche's election and payment of a specified fee, the parties would subsequently conduct a second research program of 18 months under which the parties would explore and preclinically test a specified number of additional agreed-upon next generation therapeutic concepts relating to allogeneic CAR-T therapies. Roche may designate up to six (6) heme malignancy-directed, allogeneic CAR-T programs from the two (2) research programs, for each of which the Company will perform research and development activities through selection of a development candidate for IND-enabling activities (each, a "Collaboration Program"). Upon its designation of each Collaboration Program, Roche is obligated to pay a designation fee. After the Company's completion of lead optimization activities for a Collaboration Program, Roche may elect to transition such program to Roche with a payment to the Company or terminate it. Alternatively, Roche may elect, for a limited number of Collaboration Programs, to have the Company conduct certain additional development and manufacturing activities through the completion of a Phase 1 dose escalation clinical trial, in which case Roche will pay certain milestones and reimburse a specified percentage of the Company's costs incurred in connection with such development and manufacturing activities. For each Collaboration Program, the Company will perform manufacturing activities until the completion of a technology transfer to Roche.

Under the Collaboration Agreement, Roche is obligated to make an upfront payment to the Company of \$110.0 million. The Company could also receive up to \$110.0 million in near-term fees and milestone and other payments. Subject to Roche exercising its Tier 2 Program options, designating Collaboration Programs, and exercising its option for the Licensed Products commercial license and contingent on, among other things, the products from the Tier 1 Programs, optioned Tier 2 Programs and Collaboration Programs achieving specified development, regulatory, and net sales milestone events, the Company is eligible to receive certain reimbursements, fees and milestone payments in the aggregate up to \$6.0 billion, comprised of approximately (i) \$1.5 billion for the Tier 1 Programs; (ii) \$1.1 billion for the Tier 2 Programs, (iii) \$2.9 billion for the Collaboration Programs; and (iv) \$415.0 million for the Licensed Products. The Company is further entitled to receive, on a product-by-product basis, tiered royalty payments in the mid-single to low double digits on net sales of products from the Tier 1 Programs, optioned Tier 2 Programs and in the low to mid-single to low double digits for Licensed Products.

The Collaboration Agreement will become effective upon the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), and continue on a product-by-product and country-to-country basis until there is no remaining royalty or other payment obligations. The Collaboration Agreement includes standard termination provisions, including for material breach or insolvency and for Roche's convenience. Certain of these termination rights can be exercised with respect to a particular product or license, as well as with respect to the entire Collaboration Agreement.

#### Forward-Looking Statements

Statements contained in this report 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 the upfront payment and other potential fees, milestone and royalty payments and development activities under the Collaboration Agreement, the potential benefits of the Company's technology platforms and product candidates, the clearance of the Collaboration Agreement under the HSR Act, 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 fact that the Collaboration Agreement may not become effective based on HSR Act clearance, or the effectiveness may be substantially delayed, or may be terminated early, the fact that the Company will have limited control over the efforts and resources that Roche devotes to advancing development programs under the Collaboration Agreement and the Company may not receive the potential fees and payments under the Collaboration Agreement or fully realize the benefits of the collaboration, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry, the fact that future preclinical and clinical results could be inconsistent with results observed to date and the other risks described in the Company's filings with the Securities and Exchange Commission. All forward-looking statements contained in thi

#### Item 7.01 Regulation FD Disclosure.

On August 3, 2022, the Company issued a press release announcing the execution of the Collaboration Agreement. A copy of this press release is furnished herewith as Exhibit 99.1 to this report. In addition, in connection with the announcement of the Collaboration Agreement, members of Company management are providing an update on the Company and making available the presentation attached as Exhibit 99.2 to this report.

The information in this Item 7.01 of this report (including Exhibits 99.1 and 99.2) is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

 
 Exhibit No.
 Description

 99.1
 Press Release

- 9.1 Press Release of Poseida Therapeutics, Inc., dated August 3, 2022.
- 99.2 Presentation of Poseida Therapeutics, Inc., dated August 3, 2022.

104 Cover Page Interactive Data File

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

#### Poseida Therapeutics, Inc.

Date: August 3, 2022

 
 By:
 /s/ Harry J. Leonhardt

 Name:
 Harry J. Leonhardt

 Title:
 General Counsel, Chief Compliance Officer and Corporate
 Secretary



#### Poseida Therapeutics Announces Strategic Global Collaboration with Roche Focused on Allogeneic CAR-T Cell Therapies for Hematologic Malignancies

Leveraging Poseida's novel approach to cell therapy and Roche's expertise in developing and commercializing therapies to transform cancer care, the collaboration is focused on advancing multiple existing and additional next generation allogeneic CAR-T programs directed to hematologic malignancies

Poseida will receive \$110 million upfront, could receive up to \$110 million in near-term milestones and other payments, and is eligible for future development and commercial milestones and tiered royalty payments

Poseida to host a brief conference call today at 8:30 a.m. ET

SAN DIEGO, August 3, 2022 – 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 it has entered into a broad strategic collaboration and license agreement with Roche, focused on developing allogeneic CAR-T therapies directed to hematologic malignancies. The global collaboration covers the research and development of multiple existing and novel "off-the-shelf" cell therapies against targets in multiple myeloma, B-cell lymphomas and other hematologic indications.

"We are excited to partner and collaborate with Roche, one of the world's largest biotechnology companies, which has a successful track record in the discovery, development and commercialization of innovative medicines," said Mark Gergen, Chief Executive Officer of Poseida. "Roche is an ideal strategic partner for Poseida with its industry-leading R&D capabilities in oncology, complementary technologies and expertise, and global regulatory and commercial capabilities. Working together, we look forward to advancing novel allogeneic cell therapies based upon Poseida's technologies for patients battling cancer."

Under the agreement, Roche will receive from Poseida either exclusive rights or options to develop and commercialize a number of allogeneic CAR-T programs in Poseida's portfolio that are directed to hematologic malignancies, including P-BCMA-ALLO1, an allogeneic CAR-T for the treatment of multiple myeloma and for which a Phase 1 study is underway, and P-CD19CD20-ALLO1, an allogeneic dual CAR-T for the treatment of B-cell malignancies with an IND expected in 2023. Building on complementary expertise and capabilities, the parties will also collaborate in a research program to create and develop next-generation features and improvements for allogeneic CAR-T therapies, from which they would jointly develop additional allogeneic CAR-T product candidates directed to existing and new hematologic targets. For a subset of both the Poseida portfolio programs licensed or optioned to Roche and the parties' future collaboration programs, Poseida will conduct the Phase 1 studies and manufacture clinical materials before transitioning the programs to Roche for further development and commercialization. Roche will be solely responsible for the late-stage clinical development and global commercialization of all products that are subject to the collaboration.



"We are excited to partner with Poseida to further explore the potential of allogeneic cell therapies to transform cancer care by developing off-the-shelf products that can address high unmet medical needs for a broad patient population," said James Sabry, Global Head of Pharma Partnering at Roche. "Poseida's differentiated platform technologies complement our ongoing internal efforts and partnerships to discover and develop cell therapies as a next generation of medicines for patients."

Under the agreement, Poseida will receive \$110 million upfront and could receive up to \$110 million in near-term milestones and other payments in the next several years. In addition, Poseida is eligible to receive research, development, launch, and net sales milestones and other payments potentially up to \$6 billion in aggregate value, as well as tiered net sales royalties into the low double digits, across multiple programs.

"We are thrilled that Roche has embraced the opportunity to partner with us and use Poseida's unique allogeneic approach to develop CAR-T product candidates," said Devon J. Shedlock, Ph.D., Chief Scientific Officer, Cell Therapy at Poseida. "Using our proprietary technologies and manufacturing process including our booster molecule, we have the potential to develop and manufacture a product with high levels of stem cell memory T cells, which are correlated with potent antitumor efficacy in the clinic, at a scale that can potentially reach more patients and enable broad commercial use."

The effectiveness of the agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act (HSR Act).

#### Poseida Therapeutics Conference Call and Webcast Information

Wednesday, August 3, 2022 at 8:30 a.m. ET

Poseida's management team will host a conference call and webcast today at 8:30 a.m. ET to discuss the collaboration and Poseida's novel approach to allogeneic cell therapy. The dial-in numbers for domestic and international callers are 800-267-6316 and 203-518-9814, respectively. The conference ID number for the call is PSTX0803.

Participants may access the live webcast on the Investors & Media Section of the Poseida website, <u>www.poseida.com</u>. An archived replay of the webcast will be available for approximately 30 days following the event.

#### 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<sup>™</sup> 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 <u>www.poseida.com</u> and connect with us on <u>Twitter</u> and <u>LinkedIn</u>.



#### 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 upfront payment and other potential fees, milestone and royalty payments and development activities under the collaboration agreement, the potential benefits of Poseida's technology platforms and product candidates, the clearance of the collaboration agreement under the HSR Act, 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, the fact that the collaboration agreement may not become effective based on HSR Act clearance, or the effectiveness may be substantially delayed, or may be terminated early, the fact that the Company will have limited control over the efforts and resources that Roche devotes to advancing development programs under the collaboration agreement and Poseida may not receive the potential fees and payments under the collaboration agreement of the collaboration risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry, the fact that future preclinical and clinical results could be inconsistent with results observed to date, 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 m

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#### Media contact:

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The Next Wave of Cell and Gene Therapies with the Capacity to Cure

August 3, 2022

## Disclaimer

This presentation and any accompanying oral commentary contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts and include, without limitation, statements related to future events; our future financial performance or condition; business strategy; expected timing and plans with respect to development milestones, clinical trials, and regulatory activities; estimated market opportunities for product candidates; statements regarding the upfront payment and other potential fees, milestone and royalty payments we may receive pursuant to our collaboration agreements; and future results of anticipated development efforts. Words such as "expect(s)," "feel(s)," "believe(s)," "will," "may," "anticipate(s)", "potentially" or negative of these terms or similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on management's current expectations of future events only as of the date of this presentation and are subject to a number of important risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the fact that collaboration agreements may not become effective based on HSR Act clearance, of the effectiveness may be substantially delayed, or may be terminated early; the fact that we will have limited control over the efforts and resources our collaborators devote to advancing development programs under our collaboration agreements and Poseida may not receive the potential fees and payments under some collaboration agreements or fully realize the benefits of such collaboration; risks and uncertainties associated with conducting clinical trials; whether any of our product candidates will be shown to be safe and effective; our ability to finance continued operations; our reliance on third parties for various aspects of our business; competition in our target markets; our ability to protect our intellectual property; our ability to retain key scientific or management personnel; and other risks and uncertainties described in our filings with the Securities and Exchange Commission, including under the heading "Risk Factors". Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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On a Mission to Redefine Cell and Gene Therapy For Patients with Cancer, Rare Diseases and Beyond

### **CELL THERAPY**

CAR-T Therapy for Oncology Focusing on Fully Allogeneic CAR-T

# Roche

#### **GENE THERAPY**

In Vivo Liver-Directed Gene Therapy



# PLATFORMS & PARTNERSHIPS

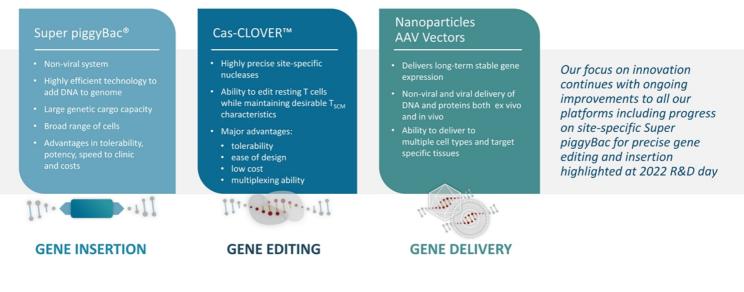
Platform Development, Partnerships and Collaboration

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C POSEIDA

# We Are the Next Wave of Genetic Engineering

Broad differentiated in-house technology platforms have the potential to develop treatments in many therapeutic segments and disease indications.

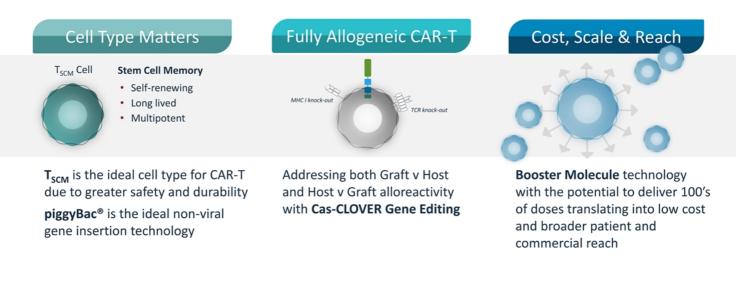


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**POSEIDA** THERAPEUTICS

# Disruptive Innovation in CAR-T

Allogeneic CAR-T Therapy for Oncology



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## **Disruption in Gene Therapy**

### In Vivo Gene Therapy for Rare Diseases and Hard-to-Treat Juvenile Populations



### **Fully Integrating**

**piggyBac** integrates into DNA enabling the potential for single treatment cures



Addressing Challenges of Viral Delivery

**piggyBac** and **Nanoparticle** technology can address limitations of AAV



### **Broad Application**

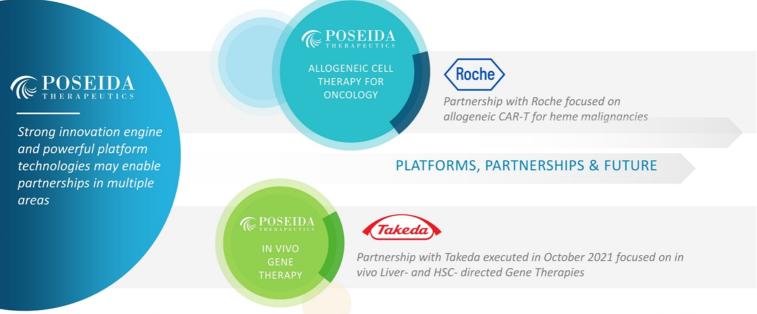
**piggyBac** cargo capacity addresses more indications and piggyBac can treat juvenile populations

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**POSEIDA** THERAPEUTICS

# Announcing Our Global Partnership with Roche\*

Broad Platform Technology Delivers Powerful Strategic Partnerships



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# C POSEIDA

ALLOGENEIC CELL THERAPY FOR ONCOLOGY

## Strategic Rationale



- Roche is one of the most scientifically discerning companies in pharma and a leader in oncology and hematologic malignancies
- Broad scope across hematologic malignancies drives alignment and leverages synergies and brings strong partner in competitive space
- Poseida retains rights to platform technologies for allogeneic T cell solid tumor applications including P-MUC1C-ALLO1 and P-PSMA-ALLO1
- Deal expected to deliver significant upfront and near-term non-dilutive capital

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### **POSEIDA**

ALLOGENEIC CELL THERAPY FOR ONCOLOGY

Roche

Partnership with Roche focused on

allogeneic CAR-T for heme malignancies

## **Collaboration Scope**



- Exclusive license to P-BCMA-ALLO1 and P-CD19CD20-ALLO1 programs
- Exclusive option to P-CD70-ALLO1 and P-BCMACD19-ALLO1 programs
- Research collaboration with initial two-year term and right for Roche to nominate 6 additional product candidates in hematologic malignancies
- Roche responsible for all late-stage development and commercialization worldwide of licensed programs
- Option for non-exclusive license for certain Poseida technologies for other limited applications

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## **Economic Summary**



- Upfront payment of \$110 million expected to be received in 2H 2022
- Up to \$110 million in near-term fees and milestone and other payments Poseida believes are highly achievable

C POSEIDA

- Roche to take over development and expense after Phase 1 for licensed programs
- Development and commercial milestones per program
- Potential aggregate payments assuming full success up to \$6 billion plus tiered royalties on net sales up to low double digits

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**POSEIDA** THERAPEUTICS

# **Cell Therapy Pipeline**

### Primary Focus on Allogeneic CAR-T for Solid and Liquid Tumors



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# Strategic Partnership with Takeda in In Vivo Gene Therapy

Partnership in Liver- and HSC- Directed In Vivo Gene Therapy with Takeda Validates Approach, Generates Resources – While Preserving Large Gene Therapy Opportunity for Poseida



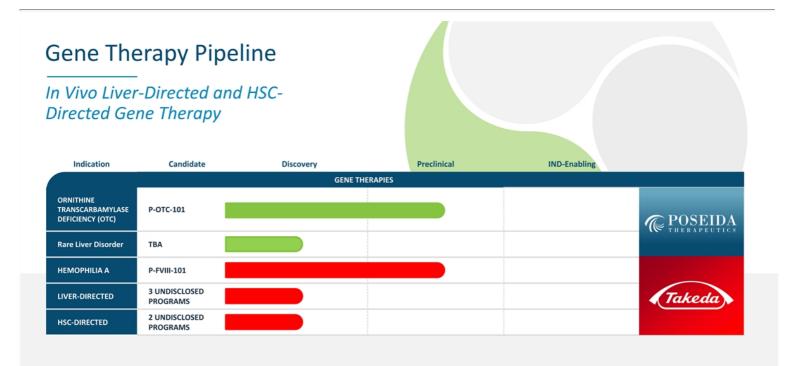
- Poseida retains rights to P-OTC-101 and all other liver- and HSC- directed targets not subject to collaboration
- Poseida retains rights to in vivo gene therapy for all other tissue types
- Poseida retains right to all ex vivo gene therapy applications





- Strategic Partnership in In Vivo Gene Therapy for Rare Diseases
  - Six initial disease targets including P-FVIII-101 for Hemophilia A
  - Option to add 2 additional targets
- Broad technology access for specific targets
- Up to \$3.6 Billion in potential milestones plus royalties

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## Focused on Key Priorities to Drive Value Creation

Working to Create Single-Treatment Cures for Cancer, Genetic Diseases and Beyond

- Strong Validating and Empowering Strategic Collaborations and Partnership with Roche and Takeda
- Cell therapy focus on novel fully allogeneic high-T<sub>SCM</sub> CAR-T approach in liquid and solid tumors
- Gene therapy focus on single treatment cures addressing the shortcomings of AAV and other approaches
- Innovation on platforms continues including emerging Site Specific Super piggyBac









## Thank You

The Next Wave of Cell & Gene Therapies with the Capacity to Cure