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):
August 3, 2022

Poseida Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

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

9390 Towne Centre Drive, Suite 200, San Diego, California	92121
(Address of principal executive offices)	(Zip Code)

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)

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

☐ 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:

Title of each class	Trading Symbol(s)	Name of each exchange 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 ☒

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 2.02 Results of Operations and Financial Condition.

On August 3, 2022, Poseida Therapeutics, Inc. (the "Company," "we," "us" and "our") filed a preliminary prospectus supplement with the Securities and Exchange Commission (the "SEC") in which we disclosed that, based on currently available information, we expect our cash, cash equivalents and short-term investments as of June 30, 2022 to be approximately $142.6 million.

The preliminary results set forth above are based on management's initial review of our operations for the quarter ended June 30, 2022 and are subject to completion of financial closing procedures. The preliminary financial results in this Item 2.02 have been prepared by, and are the responsibility of management. Actual results may differ materially from these preliminary results as a result of the completion of financial closing procedures, final adjustments, and other developments arising between now and the time that our financial results are finalized. In addition, these preliminary results are not a comprehensive statement of our financial results for the quarter ended June 30, 2022, should not be viewed as a substitute for full financial statements prepared in accordance with generally accepted accounting principles, and are not necessarily indicative of our results for any future period. PricewaterhouseCoopers LLP has not audited, reviewed, compiled, or applied agreed-upon procedures with respect to the preliminary financial results. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

Item 8.01 Other Events.

We are filing the following information for the purpose of supplementing and updating certain disclosures contained in our prior filings with the SEC, including those discussed under the heading "Risk Factors" in our most recent Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 12, 2022 (the "Quarterly Report") and certain aspects of our publicly disclosed description of our business contained in our other filings with the SEC.

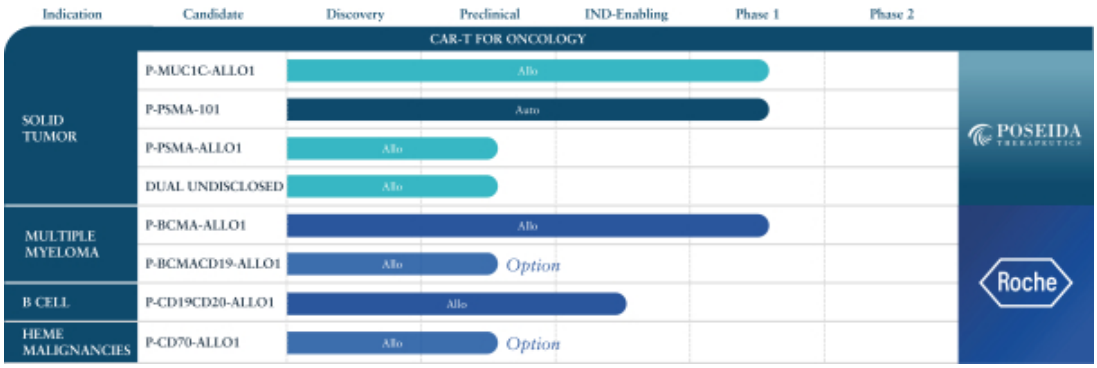
Company Overview

We are 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.

Within cell therapy, we believe our technologies allow us to create product candidates with engineered cells that engraft in the patient's body and drive lasting durable responses that may have the capacity to result in single treatment cures. Our CAR-T therapy portfolio consists of both autologous and allogeneic, or off-the-shelf, product candidates. We are advancing a broad pipeline and have multiple CAR-T product candidates in the clinical phase in both hematological and solid tumor oncology indications. Within gene therapy, we believe our technologies have the potential to create next-generation therapies that can deliver long-term, stable gene expression that does not diminish over time and that may have the capacity to result in single treatment cures.

CAR-T for Oncology

The following table summarizes our current CAR-T for oncology product candidate portfolio, including a representation of programs that we partnered with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively "Roche") in July 2022:



Our most advanced investigational clinical programs are:

- **P-PSMA-101**, which is an autologous CAR-T product candidate targeting prostate-specific membrane antigen ("PSMA") being developed to treat patients with metastatic castrate-resistant prostate cancer and salivary gland carcinoma. We are currently evaluating P-PSMA-101 in a Phase 1 clinical trial. We presented encouraging preliminary results from our Phase 1 clinical trial of P-PSMA-101 in our first solid tumor indication on February 17, 2022 at the American Society of Clinical Oncology Genitourinary Cancers Symposium and may provide a further clinical update likely in 2023. We also have a second-generation program, P-PSMA-ALLO1, which is an allogeneic program, targeting PSMA utilizing a VH binder, in preclinical development.
- **P-BCMA-ALLO1**, which is a fully allogeneic CAR-T product candidate targeting BCMA, being developed to treat relapsed/refractory multiple myeloma patients. We are currently evaluating P-BCMA-ALLO1 in a Phase 1 clinical trial and we expect initial clinical data from our Phase 1 clinical trial in the second half of 2022 subject to coordination with our partner, Roche. While P-BCMA-ALLO1 is currently manufactured at a contract manufacturing organization, we previously announced our plan to transition manufacturing of P- BCMA-ALLO1 to our internal pilot manufacturing plant and these transition efforts are ongoing. In July 2022, we entered into a collaboration and license agreement (the "Roche Collaboration Agreement") with Roche pursuant to which P-BCMA-ALLO1 will be exclusively licensed to Roche. Roche will be responsible for a majority of future development costs for P-BCMA-ALLO1 and will assume future development activities following the completion of the Phase 1 clinical trial.
- **P-MUC1C-ALLO1**, which is a fully allogeneic CAR-T product candidate for multiple solid tumor indications. We believe P-MUC1C-ALLO1 has the potential to treat a wide range of solid tumors derived from epithelial cells, such as breast, colorectal, lung, ovarian, pancreatic and renal cancers, as well as other cancers expressing a cancer-specific form of the Mucin 1 protein. We are currently evaluating P-MUC1C-ALLO1 in a Phase 1 clinical trial and we expect initial clinical data from our Phase 1 clinical trial in the second half of 2022. P-MUC1C-ALLO1 is the first program for which clinical product will be sourced from our internal pilot manufacturing facility.

We manufacture these product candidates using our non-viral piggyBac DNA Delivery System. Our fully allogeneic CAR-T product candidates are developed using well-characterized cells derived from a healthy donor as starting material with the goal of enabling treatment of potentially hundreds of patients from a single manufacturing run. Doses are cryopreserved and stored at treatment centers for future off-the-shelf use. In addition, our allogeneic product candidates use our proprietary Cas-CLOVER Site-specific Gene Editing System to reduce or eliminate reactivity, as well as our booster molecule technology for manufacturing scalability.

Our most advanced preclinical cell therapy program is:

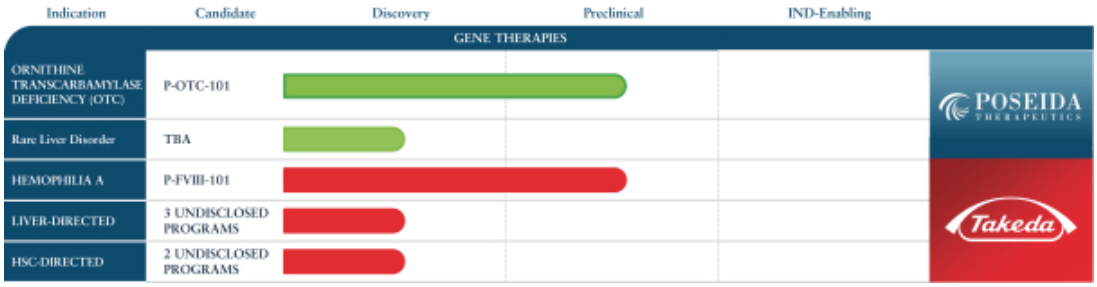
- **P-CD19CD20-ALLO1,** which is a fully allogeneic CAR-T product candidate for B-cell hematological indications. This is our first Dual CAR program, which contains two fully functional CAR molecules to

target cells that express at least one of the two intended targets. We believe that our ability to include two fully functional CAR molecules into a T cell could provide a competitive advantage compared to current therapies. We anticipate an IND filing and initiation of a Phase 1 clinical trial in the first half of 2023. P-CD19CD20- ALLO1 will also be exclusively licensed to Roche pursuant to the Roche Collaboration Agreement and Roche will be responsible for a majority of future development costs for P-CD19CD20-ALLO1 and will assume future development activities following the completion of the Phase 1 clinical trial.

Gene Therapy

Our gene therapy product candidates have been developed by utilizing our piggyBac technology together with AAV to overcome the major limitations of traditional AAV gene therapy. We believe that our approach can result in integration and long-term stable expression at potentially much lower doses than AAV technology alone, thus also conferring cost and tolerability benefits. Our eventual goal is to completely replace AAV with our non-viral nanoparticle technology, freeing future product development in gene therapy of AAV limitations.

The following table summarizes our current gene therapy product candidate portfolio including a representation of programs that we partnered with Takeda Pharmaceuticals USA, Inc. (Takeda) in October 2021:



Our most advanced gene therapy programs are:

- **P-OTC-101**, which is a liver-directed gene therapy combining piggyBac technology with AAV and nanoparticles for the *in vivo* treatment of Ornithine Transcarbamylase ("OTC") deficiency. OTC deficiency is an often fatal or morbid urea cycle disease caused by congenital mutations in the OTC gene with a high unmet medical need. We have made the decision to develop the P-OTC-101 program utilizing a hybrid of non-viral nanoparticle delivery system to deliver RNA and AAV to deliver DNA and are working on an updated timeline for the program.
- **P-FVIII-101**, which is a liver-directed gene therapy combining piggyBac technology with our nanoparticle delivery technology for the *in vivo* treatment of Hemophilia A. Hemophilia A is a bleeding disorder caused by a deficiency in Factor VIII production with a high unmet need. Our P-FVIII-101 program is included in the collaboration and license agreement with Takeda ("Takeda Collaboration Agreement") and Takeda will be responsible for all future development costs.

We expect our expenses and losses to increase substantially for the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidates, including P-PSMA-101 and P-MUC1C-ALLO1, and begin to commercialize any approved products. While we anticipate an overall increase in development costs as we continue to expand the number of product candidates in our pipeline and pursue clinical development of those candidates, we expect a decrease in our development costs on a per program basis as we are transitioning to our allogeneic platform. In addition, all or some of the development costs related to partnered gene therapy programs and cell therapy programs will be reimbursed by Takeda and Roche, respectively. We also expect our general and administrative expenses will increase for the foreseeable future to support our increased research and

development and other corporate activities. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for P-PSMA-101 and P-MUC1C-ALLO1, or any other product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution activities. Accordingly, until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potential grants, collaborations, licenses or other similar arrangements.

However, we may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. There can be no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The manufacturing process for our allogeneic product candidates is nearly identical to the process for our autologous product candidates, except for the gene editing and related steps. We work with a number of third-party contract manufacturing organizations for production of our product candidates. We also work with a variety of suppliers to provide our manufacturing raw materials including media, DNA and RNA components. We have completed construction of an internal pilot GMP manufacturing facility in San Diego, California adjacent to our headquarters to develop and manufacture preclinical materials and clinical supplies of our product candidates for Phase 1 and Phase 2 clinical trials in the future. We commenced GMP activity in the third quarter of 2021, however we expect that we will continue to rely on third parties for various manufacturing needs. In the future, we may also build one or more commercial manufacturing facilities for any approved product candidates.

RISK FACTORS

An investment in our common stock is speculative and involves a high degree of risk. Our business, reputation, results of operations and financial condition, as well as the price of our common stock, can be affected by a number of factors, whether currently known or unknown, including those described under the heading "Risk Factors" of our Quarterly Report. If any of such risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. Below are certain changes to our risk factors included in the Quarterly Report.

Risks Related to Our In-Licenses and Other Strategic Agreements

We may not realize the benefits of any acquisitions, in-license or strategic alliances that we enter into or fail to capitalize on programs that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize research programs or product candidates. A key element of our business strategy is to discover and develop additional programs based upon 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. In addition to internal research and development efforts, we are also seeking to do so through strategic collaborations, such as our collaborations with Roche and Takeda, and may also explore additional strategic collaborations for the discovery of new programs. We have also entered into in-license agreements with multiple licensors and in the future may seek to enter into acquisitions or additional licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates.

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected development or manufacturing costs, higher than expected personnel and other resource commitments, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty's operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. Further, because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of cancer, and we may forego or delay pursuit of opportunities with certain programs or products or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our program could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular program, we may relinquish valuable rights to that program through a strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such program. Alternatively, we may allocate internal resources to a program in which it would have been more advantageous to enter into a partnering arrangement. If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful program.

Our collaborators may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop or commercialize certain of our product candidates and our financial condition and operating results.

We have, with respect to our collaborations with Roche and Takeda, and will likely have, with respect to any additional collaboration arrangements with any third parties, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. For example, while we expect to collaborate with Takeda on the development of up to six in vivo gene therapy programs, only two such programs have been designated by Takeda and we cannot guarantee that Takeda will elect to pursue development of additional gene therapy programs under the collaboration. Similarly, while we expect to collaborate with Roche on the development of up to ten allogeneic CAR-T cell therapy programs and have granted to Roche an option to acquire licenses under certain of our intellectual property to develop, manufacture and commercialize products for up to three solid tumor targets, only two such programs have been designated by Roche and we cannot guarantee that Roche will elect to pursue development of additional cell therapy programs under the Roche Collaboration Agreement. In each case, a decision by Roche or Takeda to pursue less than the maximum number of targets or programs available for collaboration under their respective collaboration agreements will limit the potential payments we may receive under such collaboration agreements, delay our development timelines or otherwise adversely affect our business. In general, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements and otherwise to comply with their contractual obligations.

Any of our existing or future collaborations may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. In addition, the terms of any such collaboration or other arrangement may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development or manufacture of a product or product candidate or research program under collaboration and the payment we receive from our partner may be insufficient to cover the cost of this development or manufacture. For example, under the Takeda Collaboration Agreement, we are obligated to perform certain platform development activities at our own cost. In addition, under the Roche Collaboration Agreement, while Roche is obligated to reimburse us for a specified percentage of certain costs incurred in performance of development activities relating to P-BCMA-ALLO1 and P-CD19CD20-ALLO1, we will be responsible for the balance and the amount Roche is obligated to reimburse us is subject to a maximum cap.

Conflicts may arise between us and our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the division of development responsibilities or expenses, development plans, the interpretation of financial provisions, or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a collaborator could act in its own self-interest, which may be adverse to our best interests. Any such disagreement between us and a collaborator could delay or prevent the development or commercialization of our product candidates.

Further, we are subject to the following additional risks associated with our current and any future collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail:

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may enter into arrangements with our competitors and may prioritize their own programs or those of third parties, over ours;
- collaborators may fail in their development or commercialization efforts with our product candidate, in which event the development and commercialization of such product candidate could be delayed or terminated;
- collaborators may not always be cooperative or responsive in providing their services in clinical trials, may delay clinical trials, insufficiently fund a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may fail to successfully design or implement clinical trials and may collect and publish clinical trial data that are inconsistent with, or contradictory to, our clinical trial results;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may own or co-own intellectual property covering our programs or future products that results from our collaboration with them, and in such cases, we would not have the exclusive right over such intellectual property;
- collaborators may deviate from established guidelines, instructions, or best practices for product handling and storage, which may compromise the safety, purity, potency, and effectiveness of our products and potentially result in the occurrence of serious adverse events in patients using our products;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- we could experience reductions in the payments we believe are due to us pursuant to the applicable collaboration arrangement;

- collaborators could take actions inside or outside our collaboration that could negatively impact our rights or benefits under the applicable collaboration; or
- our collaborators may be unwilling to keep us informed regarding the progress of their development and commercialization activities or to permit public disclosure of their progress.

Forward-Looking Statements

Statements contained in this Current 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 development activities under the collaboration agreements; our expectations regarding the timing, scope and results of our development activities, including our ongoing and planned clinical trials; the timing of and plans for regulatory filings; the potential benefits of our product candidates and technologies; our expectations regarding the use of our platform technologies to generate novel product candidates; the market opportunities for our product candidates and our ability to maximize those opportunities; our business strategies and goals; estimates of our cash balance, expenses, capital requirements, any future revenue, and need for additional financing; our expectations regarding manufacturing capabilities and plans; the performance of, and reliance on, our third-party suppliers and manufacturers; our ability to attract and/or retain new and existing collaborators with development, regulatory, manufacturing and commercialization expertise and our expectations regarding the potential benefits to be derived from such collaborations; the sufficiency of our existing cash and cash equivalents to fund our operations; and future events and uncertainties described under the "Risk Factors" heading of this Current Report. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would" or the negative of these words or other similar terms or expressions. 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 our 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 Roche Collaboration Agreement may not become effective based on Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, clearance, or the effectiveness may be substantially delayed; our collaboration agreements may be terminated early; the fact that we will have limited control over the efforts and resources that Roche or Takeda devote to advancing development programs under their respective collaboration agreements and that we may not receive the potential fees and payments under either collaboration agreement or fully realize the benefits of such collaborations; 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 our filings with the SEC, including in this Current Report and under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives and financial needs. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Current Report to conform these statements to actual results or to changes in our expectations, except as required by law.

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