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) May 18, 2026

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

Delaware	**001-40288**	**82-3929248**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

6005 Hidden Valley Road, Suite 110
Carlsbad, California **92011**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code: (858) 293-4900

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, $0.0001 par value per share	DSGN	The 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 8.01 Other Events.

On May 18, 2026, Design Therapeutics, Inc. (the "Company") announced biomarker and clinical data from the ongoing Phase 1/2 RESTORE-FA trial evaluating DT-216P2 in patients with Friedreich ataxia ("FA").

RESTORE-FA Key Data Highlights

RESTORE-FA is a Phase 1/2 clinical trial evaluating DT-216P2 in patients with FA, designed to assess safety, pharmacokinetics, pharmacodynamics, and exploratory clinical endpoints. As of May 17, 2026, 16 patients had completed treatment with weekly intravenous DT-216P2 across dose cohorts of 0.1, 0.3, 0.6, and 1 mpk (n=4 per cohort) for four weeks.

Clinical Outcomes

After four weeks of DT-216P2 treatment at the 1 mpk dose cohort, patients demonstrated mean improvements from baseline of 6.4 points in the modified Friedreich's Ataxia Rating Scale and 2.7 points in the Upright Stability Score. Further, DT-216P2 demonstrated changes of greater than five points in patient-reported fatigue, as measured by the PROMIS Fatigue Scale, both at the end of four weeks of treatment and two weeks following the last dose. These data exceeded the three-point threshold generally considered to be a minimal important change in fatigue.

Biomarker and Safety Results

Dose-dependent increases in endogenous frataxin ("FXN") were observed following treatment with DT-216P2 across FXN mRNA and protein assays in whole blood, as well as FXN mRNA measurements in affected muscle tissue, demonstrating activity in both blood and muscle.

Following four weeks of treatment at 1 mpk, whole blood FXN mRNA levels increased by 65% from baseline ($p < 0.001$). Whole blood FXN-M and FXN-E protein levels increased by 22-27% from baseline two weeks following the last dose ($p < 0.001$). Muscle FXN mRNA levels increased by 42% from baseline ($p = 0.015$). Together, these findings demonstrate comprehensive biomarker activity with meaningful increases in FXN mRNA and protein, as well as activity in both blood and muscle caused by DT-216P2 treatment. The biomarker data provide mechanistic support for the observed clinical improvements in FA patients.

DT-216P2 was generally well-tolerated, with no serious adverse events or treatment discontinuations reported. All adverse events were mild or moderate. Adverse events considered possibly or probably related to DT-216P2 occurring in more than one patient included mild to moderate transient alanine transaminase ("ALT") elevations observed in three patients, all of which were asymptomatic with no associated increases in bilirubin and on background omaveloxolone. Transient ALT elevations are anticipated with enhanced mitochondrial activity, a downstream consequence of FXN restoration.

Next Steps for DT-216P2

Based on these data, the Company intends to pursue a registrational path and provide an update on its plans in the fourth quarter of 2026.

Forward-Looking Statements

Statements in this Current Report on Form 8-K that are not purely historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to: the progression of studies and clinical trials for DT216P2; plans to advance DT-216P2 towards registrational development with an update to be provided in the fourth quarter of 2026; and projections and expectations arising from early-stage programs, nonclinical data and interim and early-stage clinical data. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "designed to," "anticipates," "capable of," "plans to," "expects," "estimate," "intends," "will," "potential" and similar expressions are intended to identify 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 and the timing of events 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: the data we observe from early clinical and nonclinical studies may impact our clinical development plans; pursuing a biomarker-driven clinical development strategy carries increased risks as there are currently a limited number of approved biomarker-specific therapies; nonclinical development activities and results of nonclinical studies; conducting a clinical trial and patient enrollment and retention, which are affected by many factors, and any difficulties or delays encountered with such clinical trial or patient enrollment or retention may delay or otherwise adversely affect the Company's clinical development plans; the process of discovering and developing therapies that are safe and effective for use as human therapeutics and operating as a development stage company; undesirable side effects or other undesirable properties, which could cause the Company or regulatory authorities to suspend or discontinue clinical trials and thereby delay or prevent the Company's product candidates' development or regulatory approval; the Company's ability to develop, initiate or complete nonclinical studies and clinical trials for its product candidates on the timeframe anticipated, or at all; whether promising early research or clinical trials will result in demonstrated safety and/or efficacy in later clinical trials; changes in the Company's plans to develop its product candidates; the data results described herein are based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data and such data may not accurately reflect the complete results of the trial; reliance on third parties to successfully conduct clinical trials and nonclinical studies; competitive products, which may make any products we develop or seek to develop obsolete or noncompetitive; the Company's reliance on third parties, including contract manufacturers and contract research organizations; the Company's ability to raise any additional funding it will need to continue to pursue its business and product development plans; regulatory developments in the United States and foreign countries; the Company's ability to obtain and maintain intellectual property protection for its product candidates; and the Company's ability to recruit and retain key scientific or management personnel. For a more detailed discussion of these and other factors, please refer to the Company's filings with the Securities and Exchange Commission ("SEC"), including under the "Risk Factors" heading of the Company's Quarterly Report on Form 10-Q for the quarter March 31, 2026, as filed with the SEC on April 28, 2026. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and the Company undertakes no obligation to revise or update this Current Report on Form 8-K to reflect events or circumstances after the date hereof, 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 thereunto duly authorized.

DESIGN THERAPEUTICS, INC.

Date: May 18, 2026

By: /s/ Pratik Shah
Pratik Shah, Ph.D.
President, Chief Executive Officer and Chairperson