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): September 12, 2026

60 DEGREES PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-41719**	**32-0630186**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

1025 Connecticut Avenue NW, Suite 1000
Washington, D.C. 20036
(Address of principal executive offices) (Zip Code)

(202) 327-5422
(Registrant's telephone number, including area code)

Not Applicable
(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	SXTP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§12.02 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.

Submission of Statement of Interest for Commissioner's National Priority Voucher

On September 12, 2026, 60 Degrees Pharmaceuticals, Inc. (the "Company" or "60P") submitted a Statement of Interest to the U.S. Food and Drug Administration ("FDA") requesting a Commissioner's National Priority Voucher ("CNPV") designated for an efficacy supplement to NDA 210607 for ARAKODA® (tafenoquine) for the treatment of babesiosis.

Background on Babesiosis. Babesiosis is an expanding tick-borne parasitic infection in the United States for which there is currently no FDA-approved therapy. The disease is particularly dangerous for immunocompromised patients, who may experience prolonged or relapsing infection despite months of off-label antimicrobial treatment and who have substantially increased mortality. The Company is the only sponsor with an FDA authorized randomized placebo-controlled trial and an expanded access study in babesiosis.

Efficacy Signal. Tafenoquine has produced a compelling efficacy signal in treatment-refractory babesiosis. Published case reports involving tafenoquine added to atovaquone-based therapy report cure in approximately 83% of relapsing patients, approaching 100% when treatment is sustained until parasite clearance. In the Company's FDA-authorized expanded access study (NCT06478641), all three currently evaluable patients have been cured, as confirmed using an FDA-approved RNA amplification assay.

Randomized Controlled Trial. The Company is also conducting NCT06207370, a randomized, double-blind, placebo-controlled trial of tafenoquine plus standard of care versus placebo plus standard of care in hospitalized babesiosis patients at five Northeastern hospitals. Enrollment required for the prespecified interim analysis is complete, and the Data Safety Monitoring Board ("DSMB") analysis is scheduled for October 1, 2026.

Regulatory Pathway and Target Submission. Depending on the outcome of the interim analysis, the Company intends to pursue either regular approval supported by the randomized trial or accelerated approval supported by expanded-access and published evidence, with an appropriate confirmatory study. The target supplemental New Drug Application ("sNDA") submission is March–April 2027.

Potential for First FDA-Approved Babesiosis Treatment. CNPV review could permit the first FDA-approved babesiosis treatment to be available at or before the 2027 tick season. Standard review timelines would likely extend approval beyond the 2027 tick season, while priority review could place approval near the end of that season. Earlier approval would facilitate incorporation into clinical practice, payer coverage, hospital formularies, and prescriber awareness at a time when patients most need treatment.

Federal Priorities and Manufacturing Commitments. This program directly advances federal priorities in drug repurposing and tick-borne disease. The Company has also committed to manufacture more than 50% of the value of future CNPV-supported products in the United States and to provide volume-based discounts to federal programs.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, but are not limited to, statements regarding: the Company's request for a CNPV and the potential outcome of the FDA's review of that request; the anticipated timing and results of the interim analysis of the Company's randomized controlled trial (NCT06207370); the Company's intended regulatory pathway, including whether regular or accelerated approval will be pursued; the target timing for the sNDA submission; the potential for tafenoquine to become the first FDA-approved treatment for babesiosis; the anticipated timing of potential FDA approval and the availability of tafenoquine for the treatment of babesiosis relative to the 2027 tick season; and the Company's commitments regarding U.S. manufacturing and federal program discounts.

These forward-looking statements are based on the Company's current expectations and are subject to inherent uncertainties, risks, and assumptions that are difficult to predict. Actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including, among others: the Company's ability to obtain the CNPV; the outcome of the DSMB interim analysis and the randomized controlled trial; the sufficiency of clinical data to support regulatory approval; the FDA's acceptance and review timeline for the sNDA; the ability to manufacture tafenoquine for commercial distribution; the availability of funding to support clinical development, regulatory activities, and commercialization; and general market, economic, and regulatory conditions. These and other risks are described in greater detail in the Company's filings with the Securities and Exchange Commission, including the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. The Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be 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.

60 DEGREES PHARMACEUTICALS, INC.

Date: September 14, 2026

/s/ Geoffrey Dow

Name:Geoffrey Dow
Title: Chief Executive Officer