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 9, 2024**

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

Delaware	**001-41719**	**45-2406880**
(State or other jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

1025 Connecticut Avenue NW, Suite 1000 Washington, D.C.	**20036**
(Address of registrant's principal executive office)	(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 (see General Instruction A.2. below):

☐ 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	SXTP	The Nasdaq Stock Market LLC
Warrants, each warrant to purchase one share of Common Stock	SXTPW	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 (§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 July 9, 2024, 60 Degrees Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it enrolled its first patient in its clinical trial of tafenoquine for Babesiosis at Tufts Medical Center, which is the first and only study of its kind. The Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The goal of the study is to confirm the findings of an 80 percent babesiosis cure rate in humans observed in a similar population in an earlier case series of tafenoquine completed by Yale School of Public Health (YSPH) in April 2024 and published in the journal, Clinical Infectious Diseases. The YSPH case series showed a cure rate (with a 95 percent confidence interval) of 80 percent (30-100 percent) in a series of five immunosuppressed patients who were administered weekly tafenoquine following a loading dose in combination with standard of care medications.

Forward-Looking Statements

This Item 8.01 of this Current Report on Form 8-K contains "forward-looking statements." Such statements which are not purely historical (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "intends," "would," "could" and "estimates") are forward-looking statements and include any statements regarding beliefs, plans, expectations or intentions regarding the future, including but not limited to, regulatory milestones.

Actual results could differ from those projected in any forward-looking statements due to numerous factors. These forward-looking statements are made as of the date of this Form 8-K, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Although the Company believes that the beliefs, plans, expectations and intentions contained in this Form 8-K are reasonable, there can be no assurance that such goals, beliefs, plans, expectations or intentions will prove to be accurate, including but not limited to the results of the study described in this Item 8.01. Investors should consult all of the information set forth herein and should also refer to the risk factors disclosure outlined in the Company's reports and statements filed from time-to-time with the Securities and Exchange Commission.

The information set forth under this Item 8.01, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are being filed herewith:

Exhibit No.	Description
99.1	Press Release of 60 Degrees Pharmaceuticals, Inc. dated as of July 9, 2024.
104	Cover Page Interactive Data File (embedded with the Inline XBRL document).

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: July 9, 2024

By: */s/ Geoffrey Dow*
Name: Geoffrey Dow
Title: Chief Executive Officer and President

60 Degrees Pharma Announces IRB Approval of Clinical Study of Tafenoquine for Treatment of Babesiosis in Immunocompromised Patients with Persistent *Babesia* microti Despite Prior Treatment

WASHINGTON, D.C., July 9, 2024 -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) ("60 Degrees Pharmaceuticals" or the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, today announced ethics approval of an open label, expanded access study of the ARAKODA® regimen of **tafenoquine** in combination with standard of care regimens in immunosuppressed patients with persistent/relapsing babesiosis.

The goal of the study is to confirm the findings of an 80 percent babesiosis cure rate in humans observed in a similar population in an earlier case series of **tafenoquine** completed by Yale School of Public Health (YSPH) in April 2024 and published in the journal, Clinical Infectious Diseases. The YSPH case series showed a cure rate (with a 95 percent confidence interval) of 80 percent (30-100 percent) in a series of five immunosuppressed patients who were administered weekly **tafenoquine** following a loading dose in combination with standard of care medications.

Tafenoquine is approved for malaria prophylaxis in the United States under the product name ARAKODA. **Tafenoquine** has not been proven to be effective for treatment or prevention of babesiosis and is not approved by the U.S. Food and Drug Administration (FDA) for such an indication.

Babesiosis is a tick-borne illness caused by *Babesia* parasites that develop and multiply in red blood cells. Its symptoms include fevers, chills, sweats, and fatigue, and in severe cases, can be life-threatening. Incidence of the disease is rapidly rising, particularly in the Northeast. Transmitted through the bite of the black-legged (deer) tick, the vector that spreads Lyme disease, babesiosis is an orphan disease. It may be life-threatening in elderly and immunosuppressed patients.

"**Tafenoquine** is showing exciting promise in addressing babesiosis within various human patient populations," said Chief Executive Officer of 60 Degrees Pharmaceuticals, Geoffrey Dow, PhD. "With babesiosis rates now rising in key regions of the United States and given the very serious nature of this tick-borne illness, especially in the elderly and immunocompromised people, we are moving quickly in an effort to confirm Yale's observations while advancing the clinical program for hospitalized babesiosis patients which is now enrolling at Tufts Medical Center. Ultimately, we aim to re-purpose **tafenoquine** as a new babesiosis treatment."

Sometimes called "compassionate use," expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy option is available.

About the 60 Degrees Pharmaceuticals Program for Tafenoquine in Babesiosis

60 Degrees Pharmaceuticals is engaged in advancing multiple clinical trials to establish the safety and efficacy of **tafenoquine**. They are the: 1.) study of hospitalized (i.e., acute) babesiosis patients, now enrolling at Tufts Medical Center; 2.) expanded access for **Tafenoquine** in Babesiosis trial intended to confirm recent findings by Yale School of Public Health; and 3.) expanded access study being planned for chronic babesiosis, the design of which will be gated by an ongoing epidemiological study at North Carolina State College of Veterinary Medicine assessing whether *Babesia* spp parasites are present in samples from human patients who have chronic fatigue/neurologic symptoms.

The three studies address unmet medical need in three important populations of human babesiosis patients: (i) patients hospitalized with severe disease; (ii) patients with persistent disease who have risk factors for relapse; and (iii) individuals with a diagnosis of chronic babesiosis based on clinical manifestations and prior medical history. Based on eventual data from all three trials, 60 Degrees Pharmaceuticals plans to file a New Drug Application with the FDA in the second quarter of 2026 for a supplemental indication for **tafenoquine** in babesiosis.

The Company believes that the total accessible market through the end of patent protection in December 2035 in the U.S. for ARAKODA (**tafenoquine**) for babesiosis is 38,000 (hospitalized and immunosuppressed) acute patients and at least 375,000 patients with chronic babesiosis. The prevalence of patients with chronic disease may be higher and is the subject of ongoing market research and epidemiological studies being conducted by the Company. This is in addition to the potential 1.7 million travelers who could benefit from the use of ARAKODA for malaria prophylaxis over the same period.

Tafenoquine is approved for malaria prophylaxis in the United States under the product name ARAKODA®. The safety of the approved regimen of **tafenoquine** for malaria prophylaxis has been assessed in five separate randomized, double-blind, active comparator or placebo-controlled trials for durations of up to six months. **Tafenoquine** has not been proven to be effective for treatment or prevention of babesiosis and is not approved by the FDA for such an indication.

About ARAKODA® (tafenoquine)

Tafenoquine was discovered by Walter Reed Army Institute of Research with funding from the United States Army Medical Materiel Development Activity. **Tafenoquine** was approved for malaria prophylaxis in 2018 in the United States as ARAKODA® and in Australia as KODATEF®. Both were commercially launched in 2019 and are currently distributed through pharmaceutical wholesaler networks in each respective country. They are available at retail pharmacies as a prescription-only malaria prevention drug.

About 60 Degrees Pharmaceuticals, Inc.

60 Degrees Pharmaceuticals, Inc., founded in 2010, specializes in developing and marketing new medicines for the treatment and prevention of infectious diseases that affect the lives of millions of people. 60 Degrees Pharmaceuticals, Inc. achieved FDA approval of its lead product, ARAKODA® (**tafenoquine**), for malaria prevention, in 2018. 60 Degrees Pharmaceuticals, Inc. also collaborates with prominent research organizations in the U.S., Australia, and Singapore. The 60 Degrees Pharmaceuticals, Inc. mission has been supported through in-kind funding from the U.S. Department of Defense and private institutional investors including Knight Therapeutics Inc., a Canadian-based pan-American specialty pharmaceutical company. 60 Degrees Pharmaceuticals, Inc. is headquartered in Washington D.C., with a majority-owned subsidiary in Australia. Learn more at www.60degreespharma.com.

The statements contained herein may include prospects, statements of future expectations and other forward-looking statements that are based on management's current views and assumptions and involve known and unknown risks and uncertainties. Actual results, performance or events may differ materially from those expressed or implied in such forward-looking statements. The statements expressed herein are those of 60 Degrees Pharmaceuticals, Inc. and do not necessarily represent those of the U.S. Department of Defense.

Cautionary Note Regarding Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect the current view about future events. When used in this press release, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions, as they relate to us or our management, identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy, activities of regulators and future regulations and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: there is substantial doubt as to our ability to continue on a going-concern basis; we might not be eligible for Australian government research and development tax rebates; if we are not able to successfully develop, obtain FDA approval for, and provide for the commercialization of non-malaria prevention indications for **tafenoquine** (ARAKODA® or other regimen) or Celgosivir in a timely manner, we may not be able to expand our business operations; we may not be able to successfully conduct planned clinical trials; and we have no manufacturing capacity which puts us at risk of lengthy and costly delays of bringing our products to market. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission ("SEC"), including the information contained in our Annual Report on Form 10-K filed with the SEC on April 1, 2024, and our subsequent SEC filings. Investors and security holders are urged to read these documents free of charge on the SEC's web site at www.sec.gov. As a result of these matters, changes in facts, assumptions not being realized or other circumstances, the Company's actual results may differ materially from the expected results discussed in the forward-looking statements contained in this press release. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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