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):
January 22, 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 per share	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 January 22, 2024, the Company issued a press release announcing that following a Type C meeting with the U.S. Food and Drug Administration on January 17, 2024, the Company is planning to conduct a pivotal clinical study in support of a future indication for tafenoquine for treatment of hospitalized babesiosis patients, the patient enrollment of which is scheduled to begin in the summer of 2024. The Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 January 22, 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: January 22, 2024

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

60 Degrees Pharma Plans Pivotal Babesiosis Study with Tafenoquine Following Jan 17 FDA Meeting

January 22, 2024 12:59 PM EST

- Following a Type C meeting with FDA on January 17, 2024, 60 Degrees Pharma (60P) now plans to conduct a pivotal clinical study in support of a future indication for **tafenoquine** for treatment of hospitalized babesiosis patients

- Patient enrollment to begin in summer of 2024

WASHINGTON, Jan. 22, 2024 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) ("60P" or the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today that, following a Type C meeting held on January 17, 2024 with the US Food and Drug Administration (FDA), the Company will move forward with a pivotal clinical study of **tafenoquine** in hospitalized babesiosis patients in the U.S.

In advance of the meeting, 60P provided to the FDA an information package that included a presentation of the unmet medical need for a new therapeutic for hospitalized babesiosis patients. It also included a detailed outline of the proposed study protocol. The FDA indicated in remarks during the meeting that the proposed study could be sufficient for regulatory approval, provided the Company uses a clinical endpoint rather than a surrogate marker. 60P is now revising the study protocol in light of that feedback, with the goal of initiating patient enrollment in the summer of 2024.

"Our recent Type C meeting with the FDA led to mutual alignment with respect to the design of a development plan to evaluate the ARAKODA® regimen of **tafenoquine** for treating people who are hospitalized with babesiosis," said Geoff Dow, Chief Executive Officer of 60 Degrees Pharmaceuticals. "We are excited to advance this important study, as tick-borne illnesses such as babesiosis are emerging rapidly in the U.S. and can be life-threatening. Our aim is to bring a new treatment option to healthcare providers seeking a safe, effective solution to address the needs of their hospitalized patients diagnosed with this very serious condition."

Total babesiosis patients in the U.S. may be approximately 47,000 per year based on the observation of 476,000 Lyme infections and an estimated babesiosis co-infection rate of 10 percent.

Tafenoquine is approved for malaria prophylaxis in patients aged 18 years and older 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 the Tafenoquine for Babesiosis Study

The study, titled, "Double-blind Placebo-controlled Study to Assess the Safety and Efficacy of Oral Tafenoquine plus Standard of Care versus Placebo plus Standard of Care in Patients Hospitalized for Babesiosis," is anticipated to enroll patients in the U.S. beginning in the summer of 2024. The study will be conducted at three hospitals in the northeastern United States.

The appearance of several case studies of **tafenoquine** use for babesiosis in the literature suggests that the drug is being used for this purpose in the practice of medicine in the U.S.

About Babesiosis

An estimated 47,000 cases of babesiosis (i.e., infections caused by red blood cell parasites similar to malaria that are transmitted by deer tick bites) occur in the United States each year and the incidence rate is steadily increasing. An estimated 10 percent of Lyme disease patients are co-infected with babesiosis. The mortality rate of babesiosis patients who have cardiac complications approaches 10 percent.

Babesiosis is spread by the bite of an infected blacklegged tick, Ixodes scapularis. It can also be spread by transfusion of contaminated blood.

Anyone can get babesiosis, but it can be more severe in the elderly, people who have had their spleen removed, and in people who have weakened immune systems (for example, those who have cancer, HIV/AIDS or a transplant). Most cases occur in coastal areas in the Northeast and upper Midwest, particularly in parts of New England, New York State, New Jersey, Wisconsin, Minnesota and in some European countries. In the Northeast, babesiosis occurs in both inland and coastal areas, including offshore islands such as Nantucket and Martha's Vineyard, which are off Massachusetts, as well as in Long Island and the Hudson Valley in New York State.

Hospitalizations as a result of babesiosis are usually seasonal, occurring June through August. Clinical complications include severe anemia, renal failure, cardiorespiratory failure and death. Babesiosis was designated a nationally notifiable disease in the United States in 2011, meaning that states where it was reportable were charged to voluntarily notify the Centers for Disease Control and Prevention (CDC) of cases. As of 2019, babesiosis was reportable in 40 states and the District of Columbia.

About ARAKODA® (tafenoquine)

Tafenoquine was discovered by Walter Reed Army Institute of Research and the current study was funded by 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.

ARAKODA is not suitable for everyone, and patients and prescribers should review the Important Safety Information below.

Individuals at risk of contracting malaria are prescribed **ARAKODA** 2 x 100 mg tablets once per day for three days (the loading phase) prior to travel to an area of the world where malaria is endemic, 2 x 100 mg tablets weekly for up to six months during travel, then 2 x 100 mg in the week following travel.

ARAKODA® (tafenoquine) Important Safety Information

ARAKODA® is an antimalarial indicated for the prophylaxis of malaria in patients aged 18 years of age and older.

Contraindications

ARAKODA® should not be administered to:

- Glucose-6-phosphate dehydrogenase ("G6PD") deficiency or unknown G6PD status;
- Breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown;
- Patients with a history of psychotic disorders or current psychotic symptoms; or
- Known hypersensitivity reactions to tafenoquine, other 8-aminoquinolines or any component of ARAKODA®.

Warnings and Precautions

Hemolytic Anemia: G6PD testing must be performed before prescribing ARAKODA® due to the risk of hemolytic anemia. Monitor patients for signs or symptoms of hemolysis.

G6PD Deficiency in Pregnancy or Lactation: ARAKODA® may cause fetal harm when administered to a pregnant woman with a G6PD-deficient fetus. ARAKODA® is not recommended during pregnancy. A G6PD-deficient infant may be at risk for hemolytic anemia from exposure to ARAKODA® through breast milk. Check infant's G6PD status before breastfeeding begins.

Methemoglobinemia: Asymptomatic elevations in blood methemoglobin have been observed. Initiate appropriate therapy if signs or symptoms of methemoglobinemia occur.

Psychiatric Effects: Serious psychotic adverse reactions have been observed in patients with a history of psychosis or schizophrenia, at doses different from the approved dose. If psychotic symptoms (hallucinations, delusions or grossly disorganized thinking or behavior) occur, consider discontinuation of ARAKODA® therapy and evaluation by a mental health professional as soon as possible.

Hypersensitivity Reactions: Serious hypersensitivity reactions have been observed with administration of ARAKODA®. If hypersensitivity reactions occur, institute appropriate therapy.

Delayed Adverse Reactions: Due to the long half-life of ARAKODA® (approximately 17 days), psychiatric effects, hemolytic anemia, methemoglobinemia and hypersensitivity reactions may be delayed in onset and/or duration.

Adverse Reactions: The most common adverse reactions (incidence greater than or equal to 1 percent) were: headache, dizziness, back pain, diarrhea, nausea, vomiting, increased alanine aminotransferase (ALT), motion sickness, insomnia, depression, abnormal dreams and anxiety.

Drug Interactions

Avoid co-administration with drugs that are substrates of organic cation transporter-2 (OCT2) or multidrug and toxin extrusion (MATE) transporters.

Use in Specific Populations

Lactation: Advise women not to breastfeed a G6PD-deficient infant or infant with unknown G6PD status during treatment and for 3 months after the last dose of ARAKODA®.

To report SUSPECTED ADVERSE REACTIONS, contact 60 Degrees Pharmaceuticals, Inc. at 1- 888-834-0225 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. The full prescribing information of ARAKODA® is located here.

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. 60P successfully achieved FDA approval of its lead product, ARAKODA® (**tafenoquine**), for malaria prevention, in 2018. 60P also collaborates with prominent research organizations in the U.S., Australia and Singapore. 60P's mission has been supported through in-kind funding from the DOD and private institutional investors including Knight Therapeutics Inc., a Canadian-based pan-American specialty pharmaceutical company. 60P is headquartered in Washington D.C., with a majority-owned subsidiary in Australia. Learn more at www.60degreespharma.com.

Disclaimer & Cautionary Note Regarding Forward-Looking Statements

The statements made about our tafenoquine-babesiosis clinical trial in this press release are based on both written correspondence from the FDA ahead of the Company's Type C meeting on January 17, 2024, and the Company's minutes from the meeting. The Company has not received the FDA's formal minutes from the meeting and will not do so until 30 days following January 17, 2024. Any information released by us about the protocol on clinicaltrials.gov, our website or elsewhere should be considered out of date as of the date of this press release. The Company has not yet rewritten its clinical protocol in light of FDA comments and there is no guarantee it will receive Institutional Review Board or FDA approval when resubmitted. The protocol will be resubmitted under our malaria Investigational New Drug Application, and is not subject to the minimum 30-day holding period required for a new Investigational New Drug Application. However, the FDA can at its discretion require changes to protocols at any time.

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 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 the final prospectus to our Registration Statement on Form S-1 (File No.: 333-269483), as amended, initially filed with the SEC on January 31, 2023 relating to our initial public offering, and our subsequent Quarterly Report on Form 10-Q for the period ended June 30, 2023 and 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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