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):
February 13, 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 1.01 Entry into a Material Definitive Agreement.

On February 13, 2024, 60 Degrees Pharmaceuticals, Inc.'s (the "Company") majority-owned Australian subsidiary, 60P Australia Pty Ltd, and Monash University entered into the Research Services Agreement (the "Agreement") in which Monash University agreed to provide research services, including among other things, testing the efficacy of tafenoquine against candidemia, confirming suitable fungal infection dosage and determining the pharmacokinetics of tafenoquine following intraperitoneal drug administration (collectively, the "Services"). The commencement date of the Agreement was effective as of February 5, 2024, and the anticipated commencement of experiments and the completion date is in May 2024 and on November 30, 2024, respectively (each, a "Milestone"). The Company agreed to pay Monash University $90,167 AUD on April 1, 2024 and $90,167 AUD upon the completion of the Services.

Either 60P Australia Pty Ltd or Monash University may terminate the Agreement immediately by notice to the other if (i) the defaulting party is in breach of the Agreement and the defaulting party fails to remedy the breach within 20 business days of receiving written notice of the breach from the terminating party; (ii) an insolvency event occurs in relation to the defaulting party; or (iii) the parties agree that a Milestone will not be met by its anticipated completion date. Monash University may unilaterally terminate the Agreement if any of the Services contravene Australian Sanctions Law.

Item 8.01. Other Events.

On February 20, 2024, the Company issued a press release announcing the Services. 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.

The information set forth in this Item 8.01, including Exhibit 99.1, 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.

Exhibit No.	Description
99.1	Press Release dated as of February 20, 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: February 20, 2024

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

60 Degrees Pharmaceuticals to Sponsor Pre-Clinical Studies of Tafenoquine Use in *Candida* spp, Including *Candida auris*

- *Candida auris (C. auris)* is a dangerous drug-resistant fungal pathogen emerging in U.S. hospitals
- **Tafenoquine**'s presumed mode of action against *C. auris* is differentiated from standard of care treatment
- Monash University will conduct the studies beginning in second quarter of 2024

Washington, D.C., February 20, 2024 – 60 Degrees Pharmaceuticals, Inc. (the "Company," "60P" or "60 Degrees Pharmaceuticals") (NASDAQ: SXTP; SXTPW), specialists in developing and marketing medicines for infectious diseases, today announced it will, through its majority-owned subsidiary 60P Australia Pty Ltd, sponsor a series of animal studies to investigate whether single dose parenteral administration of **tafenoquine** exhibits efficacy against *Candida* spp, including *Candida auris* (*C. auris*). C. *auris*, a strain of fungal yeast, is an emerging pathogen that poses risk of serious infection in the bloodstream and elsewhere, especially in hospitalized patients.

The study will be conducted by Monash University in Melbourne, Australia, beginning in the second quarter of 2024. Results are expected by the end of 2024.

Tafenoquine is the active ingredient in an anti-malarial approved by the U.S. Food and Drug Administration (FDA) in 2018 and is indicated for the prophylaxis of malaria in patients aged 18 years of age and older.

"The rapid transmission of *Candida auris* in healthcare facilities is a very real threat and the need for a safe, effective treatment option is becoming more urgent every day," said 60 Degrees Pharmaceuticals Chief Executive Officer and President, Geoff Dow. "This important study could certainly yield valuable insights into how **tafenoquine** may be used toward that end. We are pleased to serve as the study sponsor working with Monash University and look forward to reviewing results in coming months."

"It is well known that *Candida auris* can cause severe illness in hospitalized patients," said Professor Anton Peleg, a Professor at Central Clinical School, Monash University, and the principal investigator for the studies. "Even more concerning is the fact that many strains of this fungal infection are now completely resistant to currently available therapies. We are optimistic that the results of our study using **tafenoquine** will point the way toward development of a new treatment to address this clear, unmet medical need."

The journal, *New Microbes and New Infections* recently published non-clinical study results showing **tafenoquine** exhibits broad spectrum antifungal activity against several species of *Candida*, including *C. auris*, within in vitro broth culture. That research was funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Like other 8-aminoquinoline antimalarials, **tafenoquine** is expected to kill fungi by disrupting cellular responses to oxidative stress, differentiating it from other antifungals.

About *Candida auris*

Candida auris (C. auris) is an emerging fungus that presents a serious global health threat, according to the Centers for Disease Control and Prevention (CDC). *C. auris* is often multi-drug-resistant, meaning that it is resistant to multiple antifungal drugs commonly used to treat *Candida* infections.

C. auris carries a high mortality rate, killing more than 1 in 3 people with infections. Infections often emerge in healthcare settings, where people are particularly vulnerable. Rates are rising; the CDC reports annual cases of *C. auris* in the United States have risen from fewer than 500 in 2019 to nearly 1,500 in 2023.

About ARAKODA® (tafenoquine)

Tafenoquine was discovered by Walter Reed Army Institute of Research. **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.

According to the Centers for Disease Control and Prevention, the long terminal half-life of **tafenoquine**, which is approximately 16 days, may offer potential advantages in less frequent dosing for prophylaxis for malaria. ARAKODA is not suitable for everyone, and patients and prescribers should review the Important Safety Information below.

Neither ARAKODA nor **tafenoquine** has been approved by the FDA for treatment or prevention of fungal infections.

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:

- Patients with Glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status.
- Lactating women who are breastfeeding 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.
- Patients with 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, motion sickness, insomnia, depression, abnormal dreams, and anxiety.

Drug Interactions

Avoid co-administration with drugs that are substrates of organic cation transporter-2 or multidrug and toxin extrusion 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 at 1- 888-834-0225 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. **ARAKODA** full prescribing information is 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. 60 Degrees Pharmaceuticals achieved FDA approval of its lead product, ARAKODA® (tafenoquine) for malaria prevention, in 2018. 60 Degrees Pharmaceuticals also collaborates with prominent research organizations in the U.S., Australia and Singapore. The 60 Degrees Pharmaceuticals mission has been supported through in-kind funding from the United States Department of Defense and private institutional investors including Knight Therapeutics Inc., a Canadian-based pan-American specialty pharmaceutical company. 60 Degrees Pharmaceuticals is headquartered in Washington D.C., with a majority-owned subsidiary in Australia. Learn more at www.60degreespharma.com.

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 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 our Annual Report on Form 10-K and our subsequent Quarterly Reports on Form 10-Q. 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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