

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):
October 2, 2024

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

Delaware

(State or other jurisdiction
of Incorporation)

001-41719

(Commission File Number)

45-2406880

(IRS Employer
Identification Number)

**1025 Connecticut Avenue NW, Suite 1000
Washington, D.C.**

(Address of registrant's principal executive office)

20036

(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 October 3, 2024, 60 Degrees Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the Company had commenced a nine-month promotional pilot to bring greater awareness of ARAKODA[®] (tafenoquine) and its benefits to patients and healthcare providers who prescribe it. The pilot program includes inside, or virtual, sales representatives who will conduct outreach to prospective and current ARAKODA customers to promote the company program and increase sales.

The information set forth under 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.

The following exhibits are being filed herewith:

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | Press Release of 60 Degrees Pharmaceuticals, Inc. dated as October 3, 2024. |
| 104 | Cover Page Interactive Data File (embedded within 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.

Date: October 8, 2024

60 DEGREES PHARMACEUTICALS, INC.

By: /s/ Geoffrey Dow

Name: Geoffrey Dow

Title: Chief Executive Officer and President



60 Degrees Pharmaceuticals Inc. Announces ARAKODA® Promotional Pilot in Advance of Expanded U.S. Launch

- Highlights include increased ARAKODA® (**tafenoquine**) brand awareness and utilization through virtual sales outreach using digital behavioral analytics and a co-pay program to assist consumers with out-of-pocket costs.
- ARAKODA is the only new antimalarial in over a decade and is differentiated by a broad efficacy against all malaria stages, a convenient weekly dosing schedule, and a well-established safety profile.

WASHINGTON, D.C., October 3, 2024 -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTIP; SXTIPW) (the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today that the Company has commenced a nine-month promotional pilot to bring greater awareness of ARAKODA® (**tafenoquine**) and its benefits to patients and healthcare providers who prescribe it.

ARAKODA (**tafenoquine**) is an antimalarial indicated for the prevention of malaria in patients aged 18 years and older.

"This pilot is intended to provide valuable insight into how healthcare professionals view ARAKODA as an antimalarial, and how they make decisions around how and when to prescribe it," said 60 Degrees Pharmaceuticals, Inc., Chief Executive Officer and President, Geoffrey Dow. "The purpose of the pilot is to equip ourselves with data that will improve the success of a planned expanded U.S. sales effort in 2025."

The pilot program includes inside, or virtual, sales representatives who will conduct outreach to prospective and current ARAKODA customers to promote the co-pay program and increase sales.

Part of the pilot entails development of a co-pay assistance program to assist with out-of-pocket costs for people traveling to malaria-endemic regions. Usage data generated by such a program will further inform the Company on questions related to ARAKODA customer demographics, pricing, prescription trends, and how and where to focus promotional efforts to increase sales.

ARAKODA is the only FDA-approved prophylactic therapy approved by the U.S. Food and Drug Administration ("FDA") that provides protection against all stages of malaria. Further, ARAKODA is recommended by the Centers for Disease Control and Prevention for travelers to malaria-endemic regions, due in part to its convenient weekly dosing regimen and established safety profile.

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. 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 16 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, 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. 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.

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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