



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

November 14, 2022

Geoffrey S. Dow, Ph.D.  
President and Chief Executive Officer  
60 Degrees Pharmaceuticals, Inc.  
1025 Connecticut Avenue NW Suite 1000  
Washington, D.C. 20036

**Re: 60 Degrees Pharmaceuticals, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted on October 18, 2022**  
**CIK No. 0001946563**

Dear Geoffrey S. Dow:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1, Submitted on October 18, 2022

Cover Page

1. We note your disclosure on page 96. Please advise whether you will be a controlled company under the Nasdaq rules upon the completion of your offering. If so, please include appropriate disclosure on the prospectus cover page and in the Prospectus Summary, and provide risk factor disclosure of this status and disclose the corporate governance exemptions available to a controlled company. To the extent you will be a controlled company, the cover page and Prospectus Summary disclosure should include the identity of your controlling stockholder(s), the amount of voting power the controlling stockholder(s) will own following the completion of the offering and whether you intend to rely on any exemptions from the corporate governance requirements that are available

to controlled companies.

Prospectus Summary, page 4

2. Please revise your disclosure here and in your Business section to include a pipeline table depicting your clinical development programs, the specific indications being pursued, the phase or status of development for each product candidate including separate columns for preclinical development, Phase 1, Phase 2 and Phase 3 trials with arrows showing where each program has progressed, and a column indicating the timing of expected data from trials. If the pursuit of any of the indications may be delayed or are contingent on additional resources (such as marketing Arakoda as a malaria preventative treatment), please clearly note that in your table.

Arakoda, page 6

3. We note your disclosure that you entered into a "cooperative research and development agreement with the United States Army in 2014" and that in 2021 "with financial support from the US Army [you] conducted a Phase II clinical investigation of the safety and efficacy of Arakoda[.]" Please revise your disclosure here and elsewhere to provide further detail with regard to your research and development agreement with the U.S. Army. Please disclose the material provisions of this agreement including, but not limited to, the term of the agreement and whether there are any milestone or royalty payment requirements.
4. We note your disclosure regarding the Phase II clinical investigation of the safety and efficacy of Arakoda in outpatients with mild-moderate COVID-19 that was completed in October 2021. If known, please indicate which variant of SARS-CoV-2 was represented in this investigation and, if the results of this study may not be applicable to newer variants, please include appropriate balancing disclosure.
5. We note your disclosure that "Arakoda has the potential to improve patient outcomes in terms of recovery from yeast infections, and prevention of fungal pneumonias in immunosuppressed patients[.]" that "Arakoda has the potential to reduce the duration of treatment with antibiotic therapy in immunosuppressed patients and the time to parasite clearance in non-immunosuppressed patients[.]" and that "[o]nce appropriate clinical studies have been conducted, it is likely that Arakoda would be quickly embraced for post-exposure prophylaxis of babesiosis in patients with tick bites and suspected of being co-infected with Lyme disease." Given that Arakoda is currently approved by the FDA only for the prevention of malaria in individuals 18 years or older, please revise these and similar statements indicating or implying that your product is, or will be determined to be, safe and effective for indications other than the prevention of malaria in individuals 18 years or older. Safety and efficacy determinations are solely within the authority of the FDA or similar regulators and those decisions are rendered only after pivotal trials have been completed. If these statements indicate your beliefs, please revise accordingly.

Celgosivir, page 7

6. We note your disclosure that a clinical study of Celgosivir confirmed its safety. Please indicate where this study was conducted, whether the study was powered for statistical significance and if the applicable regulatory authorities agreed with your conclusion. If true, please also indicate that other regulatory agencies may not agree with the study's safety conclusions and that you may need to conduct further studies in other jurisdictions.

Strategy, page 8

7. We note your disclosure that it is your belief that "Arakoda has the potential to reduce the time to sustained clinical recovery [of COVID-19] by about three days." In an appropriate location in your prospectus, please provide data that supports this disclosure.
8. We note your disclosure that one of the three routes for the commercialization of Arakoda for the malaria prevention market is "the prospect of additional U.S. Department of Defense [] and government agency procurement in the future[.]" Please revise your disclosure here to note that, as indicated on page 57, upon the fulfillment of your existing contract with the Department of Defense, the Department of Defense has not issued any further contracts nor contract modifications to allow additional procurement.

Suppliers, page 10

9. We note your disclosure that you have quality and contract manufacturing agreements relating to Arkoda in place with Knight Therapeutics, among other entities, "to allow supply of Arakoda/Kodatef to Australia, Europe, Canada/Israel/Latin America and Russia[.]" Please identify whether any import or export control restrictions and sanctions related to Russia's invasion of Ukraine are applicable to your business and describe the impact on the company and investors.

Summary of Risk Factors, page 11

10. We note your last risk factor on page 43 regarding the potential for generic competition for Arakoda for malaria. Please tell us why including a summary of this risk factor in this section would not be appropriate or revise as applicable.

Common stock to be outstanding after the offering, page 15

11. We note your disclosure on page F-18 that preferred stock will be issued for accrued interest on the Knight Loan. If appropriate, please disclose these securities and their conversion terms in this section.
12. For the warrants described in footnote 3, please disclose the exercise prices.

Use of Proceeds, page 15

13. We note your disclosure on page 8 that your clinical study for Arakoda for COVID-19 will utilize the majority of the proceeds of the offering reserved for research and development activities. Please indicate this use here and in your disclosure under "Use of Proceeds" on page 51.

Risk Factors, page 17

14. We note recent instances of extreme stock price run-ups followed by rapid price declines and stock price volatility seemingly unrelated to company performance following a number of recent initial public offerings, particularly among companies with relatively smaller public floats. Revise to include a separate risk factor addressing the potential for rapid and substantial price volatility and any known factors particular to your offering that may add to this risk and discuss the risks to investors when investing in stock where the price is changing rapidly. Clearly state that such volatility, including any stock-run up, may be unrelated to your actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of your stock.

Our product candidates are subject to extensive regulation..., page 23

15. In your first paragraph on page 26, please define the "AF" indication.

Management's Discussion and Analysis of Financial Condition and Results of Operations  
Concentration of Revenues, page 57

16. We note your disclosure that you receive a majority of your revenues from sales of the Arakoda product to the Department of Defense and that you have an existing contract with the Department of Defense. Please revise your disclosure here to note the termination date of this existing contract.

Revenue, page 59

17. We note your disclosure that you have a contract that was "executed by [y]our U.S. government research partner to support commercialization efforts." Please clarify which government research partner you are referring to.

Business, page 64

18. We note the agreements you intend to file as Exhibits 10.20 through 10.23. Please describe the material terms of each such agreement, including each party's rights and obligations thereunder, the duration of each agreement and any royalty and termination provisions, or tell us why such disclosure would not be appropriate. We also note you have rights to use patents, manufacturing information and non-clinical and clinical data licensed from the United States Army for tafenoquine for all indications except *P. vivax*

malaria. Please file that agreement as an exhibit, and, in an appropriate location, disclose how your licensing arrangement, which you disclose excludes *P. vivax* malaria, would impact any targeted marketing efforts of Arakoda for its currently approved use.

Arakoda, page 66

19. We note your disclosure that you conducted a Phase II clinical investigation of the safety and efficacy of Arakoda in outpatients with mild-moderate COVID-19 disease. Please provide further details about this study including, but not limited to, where it was conducted, how many outpatients were involved, how participants were selected, whether there were any adverse effects, and whether the results were statistically significant. We note, for example, that Arakoda reduced clinical recovery time from shortness of breath, cough, and fever ( $P < 0.02$ ), and improved aggregate symptom scores five days after treatment ( $P < 0.1$ ). If any of the p-values from this study were not statistically significant, please clarify that here and include balancing disclosure in your prospectus summary. Please also clarify here and in your prospectus summary whether the trial was designed to show if the observed results could be due to the administration of Arakoda on a stand-alone basis, or prior COVID infection, prior vaccination, or both, or whether the results could be due to chance.

Strategy, page 68

20. We note your disclosure that you plan to conduct additional non-clinical studies to clarify the process by which tafenoquine interacts with COVID-19 and that such studies will attempt to determine whether tafenoquine acts as an immunomodulator (by decreasing the production of immune system molecules that cause inflammation) and/or exhibits an antiviral effect via inhibition of the host protease TMPRSS2. If it is found that tafenoquine acts as an immunomodulator, please indicate whether this could impact the approval of prescribing tafenoquine for patients in the early stages of the disease process.

Intellectual Property, page 70

21. Please disclose the expiration dates for your current patents and the expected expiration dates for your patent applications.

Certain Relationships and Related Party Transactions, page 97

22. We note your disclosure that 60P LLC entered into an agreement and plan of merger with 60 Degrees Pharmaceuticals, Inc. Please file the merger agreement as an exhibit or tell us why such agreement is not required to be filed. See Item 601(b)(2) and (10) of Regulation S-K.
23. Please disclose the standards that will be applied in determining whether to approve any of the transactions described in this section. Refer to Item 404(b)(1)(ii) of Regulation S-K.

Notes to Consolidated Financial Statements

2. Summary of Significant Accounting Policies

Revenue Recognition, page F-10

24. Please provide a description of business activities constituting Research Revenue for 2021 and 2020 that includes linkage to associated research and development activities and contractual arrangements with the Department of Defense, US Army, NIH, Florida State University and other organizations, as applicable. Describe the methods and key assumptions underlying your accounting treatment for these revenues and revise corresponding discussion in the section, Critical Accounting Policies, Significant Judgments and Use of Estimates, accordingly. In addition, expand Results of Operations within MD&A to describe factors driving the significant increase in Research Revenue from \$368,107 in 2020 to \$5,192,516 in 2021 and explain the relationship of these revenues to reported research and development expense for each year.

General

25. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Franklin Wyman at 202-551-3660 or Kevin Kuhar at 202-551-3662 if you have questions regarding comments on the financial statements and related matters. Please contact Joshua Gorsky at 202-551-7836 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Ross D. Carmel, Esq.