



December 5, 2022

VIA EDGAR CORRESPONDENCE

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549
Attn: Mr. Joshua Gorsky

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

Dear Mr. Gorsky:

On behalf of 60 Degrees Pharmaceuticals, Inc. (the “**Company**”), we have set forth below responses to the comments of the staff (the “**Staff**”) of the Securities and Exchange Commission (the “**SEC**”) contained in its letter of November 14, 2022 with respect to the Company’s Draft Registration Statement on Form S-1 (the “**Form S-1**”) referenced above.

For your convenience, the text of the Staff’s comments is set forth below in bold, followed in each case by the Company’s responses. Please note that all references to page numbers in the responses are references to the page numbers in the amended Draft Registration Statement on Form S-1/A (the “**Form S-1/A**”) submitted concurrently with the submission of this letter in response to the Staff’s comments.

Draft Registration Statement on Form S-1 filed 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.

The Company does not anticipate on being a controlled company under the rules of The Nasdaq Stock Market LLC (“Nasdaq”) upon the completion of the public offering,

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.

We have revised the disclosure on pages 5 and 65 of the Form S-1/A to include the requested pipeline table depicting the Company's clinical development programs, the specific indications being pursued, the phase or status of development for each product candidate including arrows showing where each program has progressed, indicating the timing of expected data from trials.

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.

We have revised the disclosure on pages 6 and 66 of Form S-1/A to provide further detail with regard to the Company's research and development agreement with the U.S. Army and disclosed the material provisions of this agreement. Under the “cooperative research and development agreement with the United States Army” the Company agreed to submit a New Drug Application for tafenoquine to the FDA (as Arakoda) while the U.S. Army agreed to finance the bulk of the necessary development activities in support of that goal. Financial support was obtained from the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense via another transactional authority agreement. There are no prospective obligations of any milestone or royalty payments.

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.

On pages 6, 20 and 66 of the Form S-1/A, we have indicated which variant of SARS-CoV-2 was represented in this investigation and whether the results of this study may not be applicable to newer variants on page 20 of the Form S-1/A.

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.

We have revised the applicable statements on pages 7 and 67 of the Form S-1/A indicating or implying that our 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.

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.

On pages 7 and 67 of the Form S-1/A, we have indicated that the clinical study of Celgosivir was conducted in Singapore and its results were accepted for publication in the peer-reviewed journal Lancet Infectious Diseases.

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.

On pages 8 and 68 of the Form S-1/A, we have provided an illustrative data graph figure to support the above-referenced 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.

On pages 9 and 68 of the Form S-1/A, we revised the above referenced disclosure note that, as indicated on page 57, upon the fulfillment of our 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.

We have a quality and contract manufacturing agreement relating to Arakoda in place with Knight Therapeutics, which allows for the potential supply of Kodatef to Russia. Since inception, we have not supplied any of our products to Russia. The import and export control restrictions and sanctions related to Russia’s invasion of Ukraine are not applicable to our business. In the section “Suppliers” on page 10 of the Form S-1/A, we included supplemental disclosure.

We also previously discussed the potential impact on our operations relating to Russia’s invasion of Ukraine on pages 39 and 56 of the Form S-1/A in the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” respectively.

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.

We have included this risk factor in the “Summary Risk Factors” section on page 13 of the Form S-1/A.

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.

We have disclosed on page 98 of the Form S-1/A the rights and preferences of the Series A Preferred Stock that will be issued immediately prior to the closing of the initial public offering of the Company in exchange for the accrued interest on the Knight Loan.

12. For the warrants described in footnote 3, please disclose the exercise prices.

The exercise price of the warrants will be equal to the price per share in the initial public offering of the Company. We have included the applicable disclosure on page 16 of the Form S-1/A.

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.

We have disclosed that the use of the majority of the proceeds will be for the execution of a clinical trial to confirm that Arakoda accelerates recovery from COVID-19 symptoms on pages 15 and 51 of the Form S-1/A.

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.

We have added the above referenced disclosure to our “Risk Factors” section on page 46 of the Form S-1/A.

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

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

We have included the full word on page 26 of the Form S-1/A.

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.

On page 57 of the Form S-1/A, we have revised the above-referenced disclosure to note the termination date of August 31, 2022 for our contract with the Department of Defense.

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.

On page 59 of the Form S-1/A, we have updated the above-referenced disclosure to clarify our government research partner, the United States Army Medical and Materiel Development Activity.

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.

We have included a section entitled “Key Relationships & Licenses” which includes a summary of the material terms of these agreements. Note that we intend to file the agreements with the U.S. government as exhibits after we obtain its consent.

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.

We have provided further details about the Phase II clinical investigation of the safety and efficacy of Arakoda in outpatients with mild-moderate COVID-19 disease on pages 6 and 66 of the Form S-1/A.

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.

On pages 8 and 68 of the Form S-1/A, we have provided additional clarification regarding our additional non-clinical studies.

Intellectual Property, page 70

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

1. **US 20210267963 A1:** Methods For The Treatment And Prevention Of Lung Infections Caused By Gram-Positive Bacteria, Fungus, Or Virus By Administration Of Tafenoquine
2. **US 20180360809 A1:** Novel Dosing Regimens Of Celgosivir For The Prevention Of Dengue
3. **US 20170360768 A1:** Novel Regimens Of Tafenoquine For Prevention Of Malaria In Malaria-Naive Subjects
4. **US 20160030403 A1:** Novel Dosing Regimens Of Celgosivir For The Treatment Of Dengue

Note that the intellectual property counsel to the Company is still reviewing and we intend to disclose the expiration dates for the patent applications in a future filing.

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.

We have included the merger agreement in the Exhibit Index on page II-6 of the Form S-1/A.

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.

Per Item 404(d) of Regulation S-K, a smaller reporting company (such as the Company) need not include such disclosure. Hence, we are omitting this information.

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.

On pages 59 and 63 of the Form S-1/A, we have provided a description of business activities constituting Research Revenue for 2021 and 2020 that includes linkage to associated research and development activities and contractual arrangements and the methods and key assumptions underlying the Company's accounting treatment for these revenues. We have also expanded the "Results of Operations" section within the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to describe factors driving the significant increase in Research Revenue from \$368,107 in 2020 to \$5,192,516 in 2021 and explained 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.

Prior to the effective date of the registration statement, we will provide the Staff with all written communications, as defined in Rule 405 under the Securities Act, that the Company, or anyone authorized to do so on its behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. To date, we are unaware that any such communications exist.

We trust that our foregoing responses and the revisions included in the Form S-1/A are responsive to your comments. Should you have any questions relating to the above or wish to discuss any aspect of the Company's filing, please contact me at 646-838-1310.

Sincerely,

/s/ Ross Carmel

Ross Carmel, Esq.
Carmel, Milazzo & Feil LLP
