



DIVISION OF
CORPORATION FINANCE

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

July 17, 2024

Jun Liu
Chief Executive Officer
Curanex Pharmaceuticals Inc
2 Jericho Plaza, Suite 101B
Jericho, NY 11753

Re: Curanex Pharmaceuticals Inc
Draft Registration Statement on Form S-1
Submitted June 20, 2024
CIK No. 0002025942

Dear Jun Liu:

We have reviewed your draft registration statement and have the following comments.

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 a comment applies 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 this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Cover Page

1. Please clarify on the cover page whether you intend to take advantage of the controlled company exemptions under the Nasdaq rules.

Prospectus Summary

Corporate History and Recent Development, page 1

2. You state that you entered into a Subscription Agreement on April 15, 2024 with an investor. Please identify the investor and disclose the expected price per share to be paid.

Business Overview, page 2

3. You state that your lead product candidate, Phyto-N, has demonstrated promising efficacy in animal models and has a long history of safe use in traditional medicine. Safety and efficacy determinations are solely within the authority of the FDA or comparable foreign

regulator. Please revise or remove statements/inferences throughout your prospectus that your product candidate is safe and/or effective. You may present clinical trial end points and objective data without concluding efficacy and you may state that your product is well tolerated, if accurate.

4. You state that your lead product candidate, Phyto-N, is an extract from a single plant. Please identify the plant or otherwise advise.
5. Please balance your disclosure to discuss that although your drug development pipeline encompasses seven core indications you have only conducted preclinical studies for each. Further, please also discuss that you have not submitted an IND and that you plan to submit an IND in 2025 and begin Phase I clinical trials in 2025 for the treatment of ulcerative colitis only as you do on page 44.

Risk Factors

If we fail to raise capital when needed..., page 5

6. You state that you have very limited revenue-producing operations. We note that your single product candidate Phyto-N is in very early stages. Please discuss, here and wherever else applicable, the revenue-producing operations your business conducts.

A majority of our directors are officers and/or directors of Duraviva..., page 7

7. You state that your Chief Executive Officer, director, and President, Jun Liu, is also the President of Duraviva. Please state whether Jun Liu will be working as CEO on a non-full time basis. If so, please revise your disclosure to clearly state Jun Liu's time commitment to the company and include an appropriate risk factor.

We are dependent on our collaborative agreements..., page 7

8. You state that you currently rely, and will in the future rely, on collaborative agreements with third parties. Please identify your current collaborative agreements and disclose the material terms of those agreements and attach them as exhibits or otherwise advise. Refer to Item 601(b)(10) of Regulation S-K for guidance.

Risk Related to Ownership of Our Securities, page 13

9. We note that you anticipate that the Offering will be approximately in the range of \$5 million to \$30 million. Given the relatively small size of your offering, please 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.

Use of Proceeds, page 20

10. Please revise your use of proceeds section to provide the approximate dollar amount intended to be used for each purpose listed.
11. You state that you plan to use the net proceeds from this offering to initiate Phase I or proof-of-concept Phase II trials in inflammatory diseases, among other things. Please

specify if this relates to your product candidate Phyto-N, how far in the development process you expect to reach with the proceeds of the offering, and the specific inflammatory diseases you plan to pursue.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 25

12. You state that during fiscal year ended December 31, 2022 you generated \$26,000 from related party transactions including \$21,571 for costs of goods sold and sales of supplement products. Please identify the supplemental products and discuss if you plan to continue the sale of such products.

Business

Market Opportunities for Phyto-N, page 28

13. You state that in clinical practice, Phyto-N has shown the ability to cure certain diseases, such as ulcerative colitis, and maintain long-term remission, offering a significant advantage over existing therapies that often require continuous treatment. Please discuss your basis in claiming that Phyto-N has the ability to cure certain diseases. We also note your reference to the robust clinical experience of Phyto-N in China, if Phyto-N has been approved in other jurisdictions please state so, if not please remove such statements.
14. You state that you are actively identifying and isolating the active chemical compounds responsible for the therapeutic effects. Please identify these compounds.
15. You state that a key competitive advantage is that Phyto-N is well-positioned for an accelerated development and regulatory pathway in the US. Please expand your discussion to explain how clinical experience in China and FDA approval of other botanical drugs will accelerate your development process. Further, with a view to disclosure, please tell us how many botanical drug products to date have received FDA approval. To the extent that only a limited number of botanical drug products are FDA approved, please revise this section to disclose this information and similarly highlight this information in the Summary to convey the novelty and/or challenges of receiving approval for a botanical drug.

Product Pipelines, page 29

16. You state that Phyto-N is an alternative for patients with moderate to severe ulcerative colitis as it addresses limitations of current treatments. Please identify the limitations of the current treatments.

Market analysis of inflammatory bowel disease (IBD) treatment..., page 30

17. We note your market projections here and for each indication you intend to pursue. Given the lengthy timeline and uncertainty with regard to clinical development, please remove these estimated and projected market values as they appear to be premature and speculative given your stage of development.

Market Potential of Phyto-N IBD and Target Market, page 31

18. You state that your initial target market for Phyto-N for IBD could be Asia where clinical observations and animal studies were conducted and expansion into other major IBD

markets would require additional clinical trials and regulatory approvals. Please clarify if you have performed clinical trials in Asia, if so, specify the country, and discuss if you received regulatory approval of your product.

19. You state that your results highlight the promising therapeutic effects of Phyto-N on various autoimmune diseases. Please discuss the results referenced.
20. You state that the actual market value may vary depending on factors such as the company's profitability, growth prospects, competition, and investor sentiment. Please balance your disclosure and include a discussion that there is no guarantee that your product candidate will be approved.

Market Analysis of Nonalcoholic Fatty Liver Disease (NAFLD) Treatments...., page 37

21. You state that there are over 40 drugs in development for NASH, that there are currently two late-stage drugs, and that the FDA recently approved the first drug for NASH, Madrigal, on March 14, 2024. Please include a discussion that although a drug has been approved and there are other late-stage drugs, this is not an indication that your product will receive regulatory approval and that your product candidate is a botanical drug and as such may face different challenges as it goes through the regulatory process.
22. You state that Phyto-N boasts superior anti-inflammatory properties and unlike recently FDA approved Rezdiffra, Phyto-N mitigates inflammation occurrence without causing adverse reaction, such as diarrhea, nausea, and potential liver enzyme elevations. Please discuss your basis for such claims.
23. You state that Phyto-N has dual preventive and therapeutic benefits and potentially better safety profile when compared to the newly approved drug Rezdiffra. Please discuss if you have conducted head-to-head studies. If not, please remove such comparisons as you do not have the basis to compare your candidate to other products.

Our Growth Strategy, page 42

24. You state that the successful completion of clinical trials would position Phyto-N as a potential first-in-class botanical drug. Please remove references throughout your prospectus to potential "first-in-class" when describing your product candidate as these descriptions imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing marketing approval.

Intellectual Property, page 43

25. Please revise here and elsewhere in the prospectus, where appropriate, to explain what a provisional patent application is and how it differs from a nonprovisional patent application. Revise the table and your risk factor disclosure to disclose the expiration dates of the provisional patents and the risks associated with not having patent coverage for the work you are conducting.
26. We note your table on page 43 listing your provisional patent applications. Please identify the applicable jurisdiction for the Plant Extract Compositions and Uses Thereof For Treating Acne.

July 17, 2024

Page 5

Our Business Plan, page 44

27. You state that you have conducted animal pharmacology studies to demonstrate efficacy in relevant disease models. Please identify the disease models.

Our Revenue Model, page 45

28. You state that you anticipate that Curanex's revenue streams will primarily derive from commercialization of your botanical drug products through product sales and collaboration and licensing agreements. Please balance your disclosure by including a discussion that your product candidate, Phyto-N, is in pre-clinical studies and that although you plan to file an IND in 2025 there is no guarantee that you will receive regulatory approval and reach commercialization. Please also identify and quantify the research grants and contracts you have received to date.

Research and Development (FDA Related Application)

Moderate to Severe Ulcerative Colitis

Human Application Case, page 45

29. We note your discussion of a patient with ulcerative colitis who took Phyto-N orally. Please discuss where this case took place and if Phyto-N has been clinically approved in any jurisdiction. Please also balance the case study to indicate that Phyto-N is in the early stages of pre-clinical development, that it will take many years to commercialize this product candidate and that there can be no guarantee that Phyto-N will achieve similar results in clinical testing.

Animal Experiment Research, page 46

30. You state that the Disease Activity Index (DAI) was significantly lower in the Phyto-N group by day 14 of the treatment and continued to improve until the end of the study. Please identify the scores referenced and discuss the significance of such results.
31. We note Figure 1 includes a reference to p-values in Note D. Please define the term at first use and discuss the significance of the p-value results shown.
32. With respect to the figures, tables, and graphics included throughout this section, please revise your tables or graphics to ensure that the text in each, including subscript or other notations, are large enough and clearly legible and that each includes a discussion of the significance of each result presented.
33. We note your discussion of the results from previously conducted animal studies for ulcerative colitis and the other seven indications you plan to pursue. Please discuss here, and for each indication, where each study was conducted and if there were any adverse or severe adverse events observed.

Regulation, page 64

34. Please revise your discussion of FDA regulation and product approval to address regulatory issues and technical challenges that are unique to botanical drug products as compared to nonbotanical drugs and include any appropriate risk factors. In this regard, we refer to the information contained in FDA's "Botanical Drug Development: Guidance for Industry" available at: <https://www.fda.gov/files/drugs/published/Botanical-Drug-Development--Guidance-for-Industry.pdf>

July 17, 2024

Page 6

35. You state that the FDA has established special provisions for botanical drugs that have a long history of safe human use. Please discuss the special provisions referenced or otherwise remove such statement.

Executive Compensation, page 74

36. You state that for fiscal years ended December 31, 2023 and 2022, the Company did not make any compensation to Dian Ying Jin. Please clarify if there were any other executive officers during fiscal years ended December 31, 2023 and 2022 that received compensation.

Certain Relationship and Related Party Transactions, page 77

37. You state that Duraviva transferred and assigned to you all of its IP assets together with \$730,000 consideration. Please identify all assets that were transferred to you as part of the asset purchase agreement as you do on page 25.

General

38. Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

Please contact Christine Torney at 202-551-3652 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Doris Stacey Gama at 202-551-3188 or Chris Edwards at 202-551-6761 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Joe Laxague, Esq.