B Lab Statement on Pangea Botanica's B Corp Certification
B Lab's independent Standards Advisory Council has rendered the following decision and guidance regarding eligibility for B Corp Certification for companies in the pharmaceutical industry:

"B Lab and its independent Standards Advisory Council have determined that pharmaceutical companies are eligible for B Corp Certification if they have not engaged in specific prohibited practices in the last five years AND are meeting additional industry specific practice requirements outlined below…"

Pangea Botanica is required to disclose a summary of how it complies with these industry requirements as a part of its B Corp Certification. For more information on the specific requirements, please refer to B Lab's position statement on Pharmaceutical Companies here.

Summary of Company

Pangea Bio is a trade name of Pangea Botanica Ltd. and is a pre-clinical stage drug discovery and development company that focuses on the development of medicines to treat neurological and neuropsychiatric disorders with a large unmet medical need. Pangea Bio's subsidiary Kanna Health is a clinical stage biotech company developing novel therapeutics that addresses areas of significant unmet need in sexual and mental health. As a pre-clinical and clinical stage company, Pangea Bio along with their subsidiary company Kanna Health are currently not selling any products and are therefore considered pre-revenue companies.

Pangea Bio's research and development programs, in line with FDA/EMA regulatory requirements, are expecting to begin their first human clinical studies in Q1-2025. Pangew Bio is working with development partners in the Netherlands, Italy, France and the UK. In addition to these partner locations, Pangea Bio also has offices located in the UK and Germany.

Pangea Botanica's Disclosure on Prohibited Practices

Pharmaceutical companies engaged in the following practices in the last five years, as demonstrated through company disclosures or through material, justified, and unresolved stakeholder concerns, are currently ineligible for B Corp Certification:

- Companies engaged in any form of lobbying or policy advocacy that endanger consumer safety, promote an anti-competitive environment (e.g. by opposing increased transparency measures), inhibit affordable pricing, or limit equitable access to medicine.

This includes membership, Board involvement, or funding of industry associations that engage in such lobbying activities.

- Companies utilizing intellectual property strategies for branded products to influence an unjustified delay to the introduction of an authorized generic product to the market (e.g. “evergreening” patents).
- Companies engaged in price gouging as evidenced by significant and unjustified year-over-year price increases to their products.

Pangea Bio has been reviewed in accordance with B Corp Certification’s Disclosure Questionnaire and background check requirements, including disclosure of its involvement in lobbying and advocacy activities, intellectual property strategies, and price changes in order to verify it is meeting the above requirements regarding prohibited industry practices. The company’s approach to managing these material topics to the industry are further detailed below.

Pangea Botanica’s Disclosure on Required Best Practices

1. *Adherence to credible national and/or international standards of safety, quality, and efficacy covering all relevant stages of the drug life cycle (i.e. drug development, supply chain, manufacturing, and distribution), which should include explicit systems to manage the risk of substandard medicines.*

   Pangea Bio is committed to uploading the highest standards of safety and quality throughout the drug discovery and development process ensuring the alignment with the regulatory processes of MHRA, FDA and EMA.

   The company’s lead compound is in preclinical stage of development, entering into toxicology and safety pharmacology studies.

   - Preclinical development: The preclinical package for the company’s lead compound OT-003 includes safety assessment studies compliant with ICH Safety Guidelines. Their CRO partner holds GLP accreditation by the Italian Ministry of Health and AAALAC-accreditation, ensuring adherence to OECD, EMA, and FDA guidelines. Efficient study designs are used in order to meet the three Rs of animal welfare aspects (replacement, reduction, refinement) in line with regulatory guidance, while ensuring that proper scientific rigor, including fully blinded studies, is achieved. The CRO have successfully delivered multiple phase 1-enabling packages for regulatory submission which have served sponsors to achieve clinical trial authorisations / IND acceptance. As such, Pangea Bio is confident that following the package completion, they will be able

to obtain successful authorization from regulatory agencies to initiate their first-in-human Phase 1 clinical trial with OT-003.

- Manufacturing: Pangea Bio's manufacturing partner in the Netherlands, operates GMP-certified and FDA-inspected facilities, ensuring compliance with regulatory standards..

2. *A Code of Ethics and/or other policies applicable to all company employees and critical third parties that establish minimum expectations with regard to anti-corruption and bribery, lobbying and advocacy activities, company interactions with healthcare professionals/organizations, and ethical marketing (where applicable). The company must also have clear processes to enforce the Code, including an accessible whistleblowing channel, and regular training of staff and third parties on the Code.*

   The company has an Employee Handbook that each employee receives and is required to read as a part of their onboarding process. This handbook contains their anti-corruption and bribery policy, as well as their whistleblowing policy. In addition, Pangea Bio enforces a Code of Ethics policy which is also shared as a part of a new employee's onboarding package. As a part of their onboarding session, each new employee also receives a legal onboarding session that is repeated for all employees on a regular basis.

3. *Public disclosure detailing the company's approach to government affairs, inclusive of lobbying/advocacy and political activities. This should include disclosure of the material issues that the company lobbies/advocates for, their trade associations, and the controls they have in place in regards to political contributions, lobbying/advocacy on the company's behalf, revolving door policy, political contributions and donations.*

   Pangea Bio is not engaged in any government affairs, political contributions or lobbying activities.

4. *For companies involved in research & development, public disclosure of its R&D and intellectual property strategies and disclosure of annual resources invested in both internal and collaborative R&D activities.*

   Pangea Bio protects their innovations primarily with patents meaning their innovation is placed into the public domain and their rights are time-limited by the duration of patent protection. The company prosecutes all of their intellectual property in a legally, and ethically, compliant manner, and will not prosecute IP in developing countries or use their IP to prevent access to their medicines.

5. *For companies involved in research & development for priority diseases, conditions, and pathogens identified in the Access To Medicine Index, R&D processes for both internal and collaborative R&D activities must include a framework to develop equitable access plans for such projects. Access plans must be project-specific and include detailed commitments and strategies to improve access to such products in low- and middle- income countries (LMICs).*

   As Pangea Bio is a pre-clinical stage company and their subsidiary, Kanna Health, started their clinical trials in November 2023, the company is not yet at the stage where they can receive FDA/EMA approval. The company expects this approval to take at least 6 more years at which time they can start commercialisation of their product, pending successful trials. Because of this, the company has not developed processes and strategies for equitable access, but will do so at a later stage. In the meantime, the company has committed to the Nagoya Protocol which sets out core obligations in relation to access to genetic resources, benefit-sharing and compliance.

   Pangea Bio is aware that Central Nervous System conditions that the company is focusing on, such as Alzheimer's Disease or Schizophrenia, are within the scope of the Access to Medicine Index (AMI) and their goal is to seek maximum uptake of their compounds at an affordable price, in line with their mission to improve the lives of patients with neurological disorders.

6. *For companies involved in sales, public disclosure of its approach to pricing which, at a minimum, utilizes pricing instruments that are generally accepted by public health agencies to set prices in all markets (such as internal reference pricing, external reference pricing, and value-based pricing). Additionally, for sales in LMICs, pricing strategies must prioritize the payer's ability to pay across different segments of a country's population and aim to improve access to those in need.*

   Pangea Botanica is not selling any products yet.

7. *For companies involved in sales, companies have financial incentive structures for sales agents/teams designed to encourage responsible sales practices and minimize the risk of overselling (for example, by decoupling bonuses from sales volume).*

   Pangea Botanica is not selling any products yet.