

Phoenix Biotechnology, Inc. (PBI) focuses on developing technologies to meet unmet medical needs, particularly life-threatening endemic viral infections in underdeveloped countries. The company also targets efforts towards difficult to treat cancers having high mortality rates. PBI, however, is a small budget-constrained privately funded company that would benefit greatly from receipt of a Patents for Humanity award.

HTLV-1 is endemic to tropical equatorial regions and is considered an emerging health threat. It is estimated there are 10–15 million HTLV-1-infected individuals worldwide with a majority in underdeveloped countries. HTLV-1 causes adult T-cell leukemia/lymphoma, which exhibits aggressive hematological malignancy with high rates of therapy-resistance and poor clinical outcomes. At present there is no approved effective therapy for HTLV-1. PBI is answering this unmet medical need. The company's lead orally available drug candidate PBI-05204 is effective *in vitro* against HTLV-1.

Zika virus (ZIKV) poses a major threat to global public health. The virus has now spread to 84 countries rendering ZIKV a worldwide health threat. This is especially alarming as the virus can cause microcephaly/brain injury in fetuses. There is no approved effective therapy for treating ZIKV. PBI is answering this unmet medical need. PBI-05204 is effective *in vitro* against ZIKV and will hopefully prevent microcephaly due to its demonstrated ability to readily cross the blood brain barrier.

Filoviruses, e.g. Ebolavirus (EBOV) and Marburgvirus (MARV), are among the most pathogenic viruses known that cause hemorrhagic fever outbreaks with fatality rates of up to 90%. These infections occur primarily in underdeveloped countries. There is no approved therapy for treating or preventing EBOV and MARV infections. PBI is answering this unmet medical need. PBI-05204 and its key component oleandrin are effective *in vitro* against EBOV and MARV, and preliminary *in vitro* evidence suggests possible prophylactic use.

By 2040, the global cancer burden is expected to grow to 27.5 million new cancer cases with 16.3 million cancer deaths. Pancreatic, liver, esophageal, lung, bronchial, and brain (glioblastoma, GBM) cancers have the highest mortality rates with little to no responsiveness toward conventional chemotherapy. Usual treatment protocols are typically highly ineffective because of the inability to determine in advance whether the type of cancer might be responsive to a particular chemotherapeutic agent. PBI is answering this unmet medical need. PBI developed a highly predictive *in vitro* prognostic assay to identify cancers, in strains of pancreatic, colon, and breast cancer, that are responsive to PBI-05204 and oleandrin. Moreover, since oleandrin crosses the BBB, PBI determined it would be effective for treating GBM. PBI

further undertook clinical studies (Phase I and II) of PBI-05204 in advanced cancer patients and found the product to be safe at therapeutic doses.

The above potentially game-changing inventions resulted from inventors' discovery of the multiple mechanistic pathways through which components of PBI-05204 exhibit efficacy. PBI has protected its antiviral related intellectual property so that others might benefit from its research discoveries. The company owns numerous U.S. patents and pending applications and continues to expand its portfolio; however, doing so has required a significant financial commitment. Receipt of this award would help reduce burdensome costs by advancing prosecutorial timelines and encourage outside investments.

PBI has partnered with universities and the armed services to further expand this technology with a focus on meeting global humanitarian challenges and through large-scale commercialization to provide low-cost, and perhaps even no-cost, access to PBI-05204 in underdeveloped countries. PBI is willing to offer its patent protected technology at no cost to those who might assist in the design and conduct of clinical trials in needy populations infected with these devastating viral diseases. In fact, PBI has offered its knowledge and patents to the Bill and Melinda Gates Foundation at no cost in the hopes that they could help finance Phase III trials of PBI-05204.

PBI sustainably promotes the U.S. economy. The key component of PBI-05204 is an extract of *Nerium oleander* plant obtained from a dedicated farm in Texas, the largest such farm worldwide. Several hundred thousand organically grown plants, which are known to live many decades and which produce abundant foliage, are trimmed semi-annually to harvest the leaves from which the extract is produced. Farming, harvesting and extraction techniques have been optimized to provide an affordable and scalable process that provides many millions of doses of PBI-05204 on a sustainable annual basis.

We believe this game-changing technology would help meet global humanitarian challenges.