**Project title:** *A Platform for Pioneering Proper Treatment of the Forgotten HIV-Infected Paediatric Patient*

**Project summary:**

The current project aims to provide a versatile pharmaceutical formulation solution for the challenges involved with the administration of antiretroviral drugs to treat paediatric HIV using a versatile and durable WaferMat formulation constituting an ultra-fast dissolving polymer matrix that can be placed on the inside of a child’s cheek for effectively and effortlessly treating HIV. This would provide a much needed alternative to the use of current adult-based formulations (tablets and capsules) whereby mothers have immense difficulty in ensuring effective antiretroviral therapy of their small children. Current liquid formulations result in significant drug stability issues for many front-line antiretrovirals and therefore liquid formulations are not available as a dosage form. Mothers are therefore forced to utilize tablet/capsule formulations that are designed for adult use by titrating the required doses accordingly. However, this is hardly possible due to the intricacies of drug stability in various solutions (e.g. if dissolved in the child’s milk, water, fruit juice or other liquids) and the inability of many mothers to actually understand the requirements of exact dosing science. Eventually this leads to inferior antiretroviral therapy, drug resistance and intensifying the scourge of HIV. The proposed WaferMat formulation will be manufactured with dimensions that will conform to the buccal route of administration for paediatrics. Prototype formulations will contain model antiretroviral (ARV) drugs such as abacavir and zidovudine (AZT) as well as newer NNRTIs such as etravirine and rilpivirine. When applied to the buccal cavity, the formulation will be difficult to spit out, will pose no risk of choking and taste-masking technology will be included for bitter tasting antiretroviral drugs. Permeation enhancers will also be added to allow maximal drug absorption across the buccal mucosa.

The proposed WaferMat formulation will introduce the most ideal and convenient dosing system for better patient compliance and an optimal therapeutic outcome for treating paediatric HIV. It will be designed as an innovative oral dosage form with customized ‘ultra-fast’ release profiles of potent orally administered antiretroviral drugs with varied solubilities, maximizing their efficiency and masking the taste. The WaferMat formulation will be suitable for paediatrics and geriatrics. The formulation will be able to deliver antiretroviral medication without the need for water, chewing or swallowing. The wafers can be placed against the inside of the cheek to release the antiretroviral drug directly into the systemic circulation. The Ultra-Fast release feature will ensure that the wafer fully dissolves in the oral cavity within 3 seconds. The formulation may also be suitable for patients who are unconscious, mentally retarded, uncooperative, nauseous or on reduced liquid-intake/diets, have difficulties swallowing oral dosage forms, and patients under emergency conditions. The WaferMat formulation will be prepared based on gel-like barrier formation and dissolution regulation that will yield a unique smooth surfaced macroporous architecture. The formulation will also possess permeation enhancing capabilities to allow for effective and efficient absorption of the antiretroviral drug. The formulation components will be selected to provide a synergistic rigidity profile forming a robust matrix with rapid dissolution properties. This project will involve development of the WaferMat up to in vivo animal studies using antiretroviral drug molecules of varied solubility and permeation profiles. A development goal would be to ensure that the WaferMat formulation is able to provide enhanced drug absorption and onset, reduced frequency of drug intakes,
complete matrix dissolution with no remnants, a non-gritty mouth feel, and improved drug bioavailability. This would translate into lower drug doses required and a reduction in potential side-effects. A PCT patent application has been filed to protect the preliminary invention.

*As taken from original proposal template, question 5.*