



# **Preliminary company profile**

*Market: Ready Personalized Therapeutics for  
multiple-medication in HIV treatments*

**Company description**  
**Patient Needs and Technology Platform**  
**Product Line**

# Executive Summary

*Market :Ready Personalized Therapeutics for HIV in multi-compound treatments*

## **Company description**

BIOSTRANDS is a market-focused biotechnology company developing new diagnostics for drug and therapy monitoring based on a consolidated technology platform.

The Company has developed a line of TDM – ELISA kits for therapeutic drug monitoring of protease inhibiting drugs (PIs) in HIV patients.

BIOSTRANDS has been busy over the past years finalizing the development of the TDM-ELISA kits and collaborating with leading Italian and European HIV treatment reference centres to set the clinical grounds, obtain high-level endorsement and publications enabling current market development.

## **Patient Needs and Technology Platform**

TDM-ELISA allows to cost-effectively monitor treatment efficacy, enabling clinicians to establish the optimal management of the therapeutic regimen of HIV-positive patients undergoing HAART (Highly Active Anti Retroviral Therapy).

TDM-ELISA is a cost-effective, simple to use alternative to other TDM methods based on expensive HPLC (High Performance Liquid Chromatography) instrumentation. Due to the requirement for specialized diagnostic personnel, HPLC use is very limited and restricted to patients in severe conditions.

On the contrary, simplicity of use enables widespread utilization of TDM-ELISA. The product therefore allows to meet specific therapeutic needs of Patients based upon their personal individual response to HAART.

Therapeutic drug monitoring by an ELISA method (TDM-Elisa) consists of performing a colorimetric competitive enzyme immunoassay to determine the concentration of protease inhibiting drugs (PIs) in plasma. The kits are based on specific polyclonal antibodies.

Correct concentrations of PIs in plasma are needed to ensure therapy is effective and to avoid side effects, thus enabling the clinician to establish the optimal management of the therapeutic regimen of his HIV-positive patient.

Owing to their high sensitivity and specificity, TDM – ELISA kits are a reliable and cost effective method for routine monitoring of patients.

<b>Benefits of HIV Therapeutic Drug Monitoring (TDM)</b>		
Clinical Results	Economic Results	Results for the patients
<ul style="list-style-type: none"> <li>• Greater efficacy of treatment</li> <li>• Less toxicity risk</li> <li>• Greater patient' satisfaction</li> </ul>	<ul style="list-style-type: none"> <li>• Lower pharmaceutical treatment cost per each successful case</li> <li>• Lower overall sanitary cost</li> </ul>	<ul style="list-style-type: none"> <li>• Avoid hospitalisation</li> <li>• Lower risk of therapeutic failure</li> </ul>

### **Market profile**

According to WHO, the number of HIV-positive individuals is 1,250,000 patients. This corresponds, at saturation, to a potential market in Western Europe and North America estimated at 2,250,000 tests/year .

### **Business Model**

BIOSTRANDS currently manufactures and commercializes directly the TDM – Elisa kits needed for the initial pilot phase and to obtain further endorsements by leading Italian and EU clinicians. A clinical study by SIMIT (Italian Society Infectious and Tropical Diseases) is ongoing: “Correlation between C trough of different Protease Inhibitors (PIs) as determined by an ELISA technique and HIV plasma Viraemia “

Under the current perspective, the growth phase should be supported by alliances with licensee companies acquiring from BIOSTRAND the key reagents for manufacturing the ELISA Kits. Licensees would be expected to manufacture and commercialize the kits through own distribution channels.

As a viable alternative, taking into account the fact that the number of HIV treatment centers is relatively small, a VC-backed strategy would allow Biostrands to serve the market directly with own sales and distribution channels, achieving the double objective of reducing cost for the end user and maximizing revenues and profits.

## Product Line

BIOSTRANDS has currently developed the following products:

REF	DESCRIPTION	FORMAT
1678	TDM-Elisa APV/Fos APV (Amprenavir)	96 wells
2678	TDM-Elisa LPV (Lopinavir)	96 wells
3678	TDM-Elisa NFV + M8 (Nelfinavir)	96 wells
7678	TDM - Elisa RTV booster (Ritonavir)	96 wells
5678	TDM – ELISA ATV (Atazanavir)*	96 wells
6678	TDM – ELISA IDV (Indinavir)	96 wells

