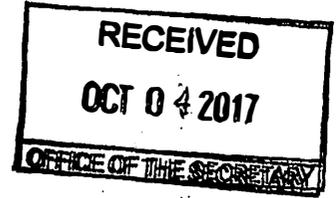


3-18203



Power of The Dream Ventures, Inc.  
1124 Budapest  
Csermely ut 4B  
Hungary

September 28, 2017

The Honorable Brenda P. Murray  
Chief Administrative Law Judge  
U.S. Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549

David S. Frye, Esq.  
Division of Enforcement  
U.S. Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549

Brent J Fields, Secretary  
U.S. Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549

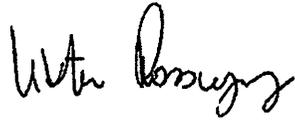
Re: Power of The Dream Ventures, Inc.

I am in receipt of your Order Instituting Administrative Proceedings and Notice of Hearing Pursuant to Section 12(j) of the Securities and Exchange Act of 1934 regarding Power of the Dream Ventures Inc. ("PWRV") (CIK No. 1377888), a Delaware corporation located in Soroksari, Hungary with a class of securities registered with the Commission pursuant to Exchange Act Section (12)g. We are in agreement that PWRV is delinquent in its period filings with the Commission, having not filed any periodic reports since it filed a Form 10-Q for the period ended September 30, 2015, which reported a net loss of \$578,512 for the prior nine months. As of September 5, 2017, the common stock of PWRV was quoted on the OTC Link, had seven market makers and was eligible for the "piggyback" exception of Exchange Act Rule 15c2-11(f)(3).

This letter is being sent from the U.S. to meet your deadline. We disagree that we failed to heed delinquency letters sent to us by the Division of Corporation Finance requesting compliance with our periodic filing obligations.

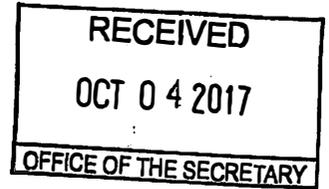
The Company's auditors are BDO. It owns a subsidiary called Genetic Immunity, Inc., a Delaware corporation, that is an immunotherapeutic vaccine company whose lead product candidate DermaVir has passed Phase II clinical trials for the cure for HIV. See letters attached. We are a legitimate company. We need an additional 90 days and we will bring this Company fully current.

Sincerely,

A handwritten signature in black ink, appearing to read "Viktor Rozsnyay". The signature is written in a cursive style with a large initial "V".

---

Viktor Rozsnyay CEO



UNITED STATES OF AMERICA  
Before the  
SECURITIES AND EXCHANGE COMMISSION

September 28, 2017

In the Matter of

POWER OF THE DREAM VENTURES INC.

File No. 500-

ANSWER

- I. Power of the Dream Ventures, Inc., the Respondent (hereinafter "DREAM") does not have sufficient knowledge whether to admit or deny
- II.
- A1 Does not apply to DREAM.
  - A2 Does not apply to DREAM.
  - A3 Does not apply to DREAM.
  - A4 Admitted.
  - B5 So much of this Paragraph as it applies to DREAM is denied.
  - B6 DREAM does not have sufficient knowledge whether to admit or deny.
  - B7 Denied.

By:

Power of the Dream Ventures, Inc.

Viktor Rozsnyay CEO

### **Expert conclusion on the experimental candidate therapeutic vaccine against HIV DermaVir**

The reviewed work is dedicated to the development of a therapeutic vaccine (TV) against HIV infection. This is an extremely relevant direction, as, despite the fact, that more than 70 million people in the world (about 40 million dead, about 35 million HIV-infected) have already suffered from HIV infection, an effective preventive vaccine has not yet been created. There are about 50 preventive vaccines at various stages of development, some of which are also used as therapeutic in combination with antiretroviral therapy.

The idea of using therapeutic vaccines is based on the fact that the vaccine will stimulate the immune response against the virus and control the viral load with the help of immune mechanisms, specifically the T-cell response. According to the data I have, currently 12 (including DermaVir) clinical trials of TV of different phases are carried out, but we can talk about 10 different candidate samples (as two candidates are tested in different formats.) The most advanced are tests of RNA vaccine, conducted by Rob Gruters in the Erasmus Medical Center (iHIVARNA-01, Phase IIa), and the French DNA vaccine in combination with lipopeptides or anti-HIV (subtype B) by the pox virus vector, which is carried out by INSERM / ANRS (Phase II).

Thus, DermaVir is a competitive development in a prospective field. The material that was submitted for analysis consists of 2 presentations, 4 articles and 1 thesis. Presented materials cover the period of years 2004 – 2016 and were executed by an authoritative consortium of scientists from Hungary, Germany, Italy and the United States. The competence of the participants is beyond doubt. The materials are published in high-ranked journals. It should be noted that the approach proposed by the authors goes beyond anti-HIV therapy and can be used to treat certain allergic and oncological diseases (materials on allergy to ovalbumin in mice are presented).

Before evaluating DermaVir, let's make 2 comments:

1. There was a paradigm shift in HIV treatment - now, regardless of the number of CD4+ cells, treatment for HIV infection is recommended to start immediately after detection;
2. The materials mention the possible prospects for the use of TV DermaVir in Russia.

HIV infection, unfortunately, continues to spread in Russia at an accelerated rate, and the number of infected in our country exceeds that in all of Europe. But for Russia, a modification of the plasmid (antigen) is necessary, since currently the subtype A (and not B) is the dominant subtype, and according to the data I have, the A/G-recombinant and the new recombinant viruses are actively spreading. In 2017, more than 21 billion rubles have been allocated from the state budget to purchase antiretroviral medications, which allows treating about 250,000 people. By 2020, the Ministry of Health plans to cover with treatment about 370,000 people, although 850,000 people need treatment already.

The combination of antiviral and immune therapy can be very useful, but this requires changing treatment standards and introducing new technologies. In general, TV is a promising class of new immunobiological drugs.

Preclinical studies of TV DermaVir, as well as the presented materials on clinical trials of phases I and II, convincingly prove the safety, immunogenicity and satisfactory effectiveness of the drug. Tests on macaques using pathogenic strain SIV251 demonstrate that DermaVir is capable to reliably control viral load. The mechanism of action of TV DermaVir is associated with potentiation of T-cell immunity,

namely, memory T-cells. However, additional experiments will be required on target groups of volunteers. Final conclusions can be made only after clinical trials of phase III.

Some features of TV DermaVir provide it with competitive advantages, since the formulation in the form of virus-like particles increases immunogenicity, and unique delivery method ensures the ease of injection and effectiveness in priming of targeted immune system cells.

I briefly described competitive research products above, but, in my opinion, DermaVir outperforms similar products, and with the combination of its features it is a unique medication. An important criterion for comparison will be the market price, which is difficult to assess now.

For this stage of development, the studies conducted are fairly complete, although many recommendations can be given (in particular, to estimate the CD32a marker).

The program of planned research is understandable, but it is not clearly stated in the presented materials. It would be useful to check the therapeutic value of TV DermaVir in combination with chemotherapy.

In general, I consider TV DermaVir to be a promising immunobiological medication which can be widely used for HIV/AIDS therapy in combination with ART, and, subject to further development, in the treatment of allergic and oncological diseases.

Head of Department Laboratory of immunochemistry of the National  
Research Center for Epidemiology and Microbiology  
named after N.F. Gamaleya of the Ministry of Health of the Russian Federation,  
UNAIDS Expert, Doctor of Biological Sciences, Professor



E.V. Karamov

## Dendritic cell-targeting, therapeutic vaccine technology platform

### Context of the consultancy:

Expert scientific assessment of the **therapeutic HIV vaccine** technology (DermaVir) developed by the Hungarian company **Genetic Immunity**. The company seeks an investment of **1.5M €** from the **European Medical Center** in Moscow to obtain "fast-track" and "breakthrough therapy designation" with the US FDA.

**Provided information:** Genetic Immunity corporate slide deck, multiple scientific articles directly related to the technology, and facilitated interview with the company's CEO Mr. Viktor Rozsnyay.

### Technology assessment:

The scientific technology and team supporting the development of DermaVir by Genetic Immunity have an outstanding track in the field of HIV-1 infection and the translational immunology associated to this disease.

The corporate slide deck is clear and carefully describes the evolution of the technology from the POC to the clinical phase II studies performed in HIV-1-infected subjects with and without antiretroviral therapy.

The technology has a solid scientific base regarding the global concept (i.e. enhancing the T-cell immunity of HIV-1-infected subjects -described in the report as therapeutic vaccination or immunotherapy-). The multiple elements of the strategy are carefully considered and coordinated for an innovative and easy-to-apply approach. First the Active Pharmaceutical Ingredient (API) is a plasmid DNA optimized for the expression of multiple HIV antigens. While plasmid DNA is easy and cheap to produce with minimal expected side effects, the expression of antigens requires an intermediate step of RNA transcription that has limited its efficacy in other parallel biological strategies. The report suggests also the use of HLA-personalized therapeutic vaccination, but the technical, logistic and financial implications of such strategy are not fully analyzed. Little information is also provided on how immune scape might hamper this immunotherapy and what contingency strategies could be implemented.

The delivery mechanism through pathogen-like nanoparticles made of polyethylenimine seems appropriated. These nanoparticles are functionalized with mannose to facilitate their captured by antigen presenting cells, uptaken throughout pinocytosis by dendritic cells, processed and antigen presented to T-cells in secondary lymphoid organs. The transdermal administration is remarkably easy and feasible to implement in the regular clinical follow up of the patients.

Regarding the clinical contexts in which this technology could be better applied I would suggest alternative considerations to the proposed scenarios. I can hardly envision the use of this or other immunotherapies in patients with active infection as the antigen load is probably outcompeting any external immune intervention to strengthen the patient's own immune system. In fact the reported phase II study on treatment-naïve patients (unpublished) has a marginal effect of plasma viremia reduction when compared with the efficacy of antiretroviral therapy. The potentially more productive setting (also suggested by the company) is in HIV-1-infected subjects on effective antiretroviral therapy, in whom

T-cell responses have waned due to the lack of enough circulating viral antigen. This strategy might require some coupling with latency reactivating agents because if infected cells fail to produce any viral antigen, even primed T-cell responses might be of little help. In this regard it should be noticed that the potential market in Europe and US is greater than reported in the slide deck as current treatment guidelines recommend immediate antiretroviral treatment after HIV-1 diagnosis, regardless CD4 T-cell counts. The third scenario would be the use of this immunotherapy to enhance HIV-specific immune responses of subjects treated with antiretroviral therapy for at least 3 years, who had a significant reduction of the viral reservoir and that might be candidates for a monitored antiviral pause. Thus, upon antiviral discontinuation, a potentially well-trained immune system should be able to contain viral rebound. While this last setting is still debatable and subject of further research, it seems a promising strategy for an HIV functional cure. To some extent this aspect is supported by the experiments in rhesus macaques chronically infected with SIV (Lisziewicz *et al.* AIDS 2005).

In line with the last comments, while the efforts of the company has been focused on demonstrating enhancement of HIV-specific T-cell responses, there is no information on whether the vaccine can reduce the absolute number of infected cells or cells containing either replication competent or replication inducible virus. Additional data on how DermaVir could affect viral reservoirs would be advisable to complement their solid immunological data.

A minor aspect to mention is the use of the PHPC assay to evaluate *ex vivo* immune responses, especially in the context of clinical trials. While this is a very interesting assay, it is hard to compare with data from other immunotherapeutic interventions using regular ELISPOT assays, which might provide at least a relative comparison in terms of immune efficacy.

My personal expertise is mainly focused on HIV so I have less to say as for the potential utility of this technology in other diseases. As indicated in the report, the exploited mechanism is very general of human immunity and therefore it could be adapted to different pathological conditions. However, the data provided is very limited outside the HIV-1 infection.

My limited experience in company management and as company consultant suggests that Genetic Immunity has a solid development plan and counts with well trained professionals that should be able to gear the company through successful pathways, including an extensive intellectual property protection strategy.

In summary, the requested investment of 1.5M € seems like a reasonable risk for the proposed project if the milestones for the next year are well defined. However, the vaccine candidate has still to undergo more robust clinical trials to proof its efficacy in the context of HIV remission strategies. This might take further time and future investment. In fact, considering the available data, the expected US commercial launch in 2019 seems quite optimistic.

Javier Martinez-Picado

August 31<sup>st</sup> 2017