

PapiVax Biotech Inc.

Company Overview :

- PapiVax Biotech Inc. (PBI) is a company specializing in development of DNA Immunotherapeutic vaccine technology. Dedicated to eradicating of human papillomavirus (HPV) infections and cancers. Our vision is to become a global leader in DNA immunotherapy.

Unmet Medical Needs and Potential Markets :

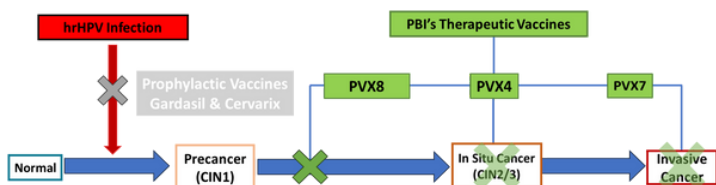
- In the US and EU, persistent HPV infection (estimated 672,000 new cases and US\$ 0.53B in revenues) and advanced cancer (estimated US\$ 0.8-1.6B in revenues per year).
- Over the past decade, the global incidence of oropharyngeal and head and neck cancers has increased by 23%, showing rapid growth. Compared to the global average incidence rate (9 per 100,000), Taiwan has the highest incidence rate of oropharyngeal cancer (32.5 per 100,000), indicating a huge market potential.
- PBI's immunotherapy platform can be applied to chronic viral infections and personalized cancer vaccines, with promising technological prospects.

Platform Technologies :

- The DNA vaccine technology is licensed from Johns Hopkins University, USA. After improvements by PBI, the company has obtained its own global patent.
- The fusion protein technology (TA-CIN, TA-HPV), using a heterologous prime-boost vaccination approach, can safely and effectively stimulate a potent immune response specific to HPV.
- The TriGrid electroporation technology platform has been shown to significantly increase the protein expression of DNA vaccines by over a hundredfold.
- The Albumin-Fit3L technology was licensed from JHU and can be used in combination therapy for various cancers, enhancing effectiveness when combined with traditional radiotherapy or chemotherapy.

Product and Clinical Progress :

- The PVX-4 product, designed with DNA and the TriGrid system, targets patients with high-grade lesions (CIN/VaIN/VIN/AIN 2/3). Phase I clinical trials at JHU and UAB have shown that approximately 80% of patients have completely cleared the HPV 16 virus, with remission of in situ cancer, demonstrating the vaccine's excellent immune activation capability.
- PVX7 utilizes DNA priming vaccination and recombinant vaccinia boost (TA-HPV), combined with an immune checkpoint inhibitor, to target HPV16/18+ advanced cervical cancer (IND for phase II study in VUMC approved by US FDA NCT05799144)
- A DNA vaccine designed to target persistent infections of HPV16/18, using the TriGrid electroporation platform. The next-generation drug and placebo have been produced and the Phase II clinical trial for PVX-8 is scheduled to commence in Q4 2024.



Product	Indication	2024	2025	2026	2027
PVX-4	HPV16 cervical intraepithelial neoplasia (CIN2-3)	Phase I	Manufacture	Phase II	
	HPV16 Vulvar or Vaginal intraepithelial neoplasia (VIN2/3)/(VaIN2/3)		Orphan drug, Breakthrough therapy designation	Phase II	
PVX-7	HPV+ advanced oropharyngeal cancer (with Pembrolizumab treatment)	Phase II			Out-licensing
	HPV16/18 Advanced cervical cancer		Phase II		Out-licensing
PVX-8	HPV16/18 Persistent infection with CIN1		Phase II		Out-licensing
Alb-Fit3L Fusion protein	Various cancers	Pre-clinical study	Manufacture, toxicity and safety test	IND	Phase I

Business Plan :

- Depending on the results of the Phase II trial, external licensing will be considered. An IPO is planned for 2027 Q2, and M&A opportunities will be considered at any time.