

An opioid vaccine – business opportunity available, only right mindset need apply

LONDON, UK----1st February 2018----ExpertREACT. The development of anti-addiction OUD vaccine might get the usual pushback from large sponsors. It's not their usual area. However, the opportunity is attractive and on balance, the technical challenges might not be as high as they seem.

Today, a brand-new research study: "**MarketVIEW: Opioid use disorder (OUD) vaccines report**" has recently been added to **VacZine Analytics** portfolio offering.

The **MarketVIEW** study consists of a detailed Executive presentation (~140 .pdf slides) and comprehensive MS-Excel workbook (.xls) which forecast the potential commercial value/volume of a putative OUD vaccine across 8 major western markets from 2030. Three scenarios have been modelled which explore vaccine uptake at various access points along the patient treatment continuum. A thorough situation review (global epidemiology) is included along with a discussion of current treatments, prevention strategies, major R&D initiatives, and competitive environment. Vaccine technologies are reviewed along with TPP generation, pricing considerations and all modelling assumptions. This study is designed to inform any party wishing to understand and seek justification for the business case of this important vaccine.

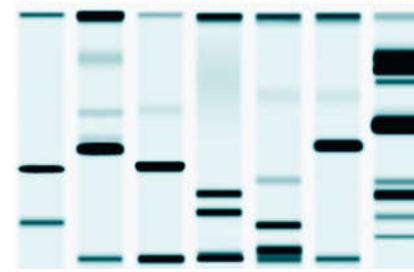
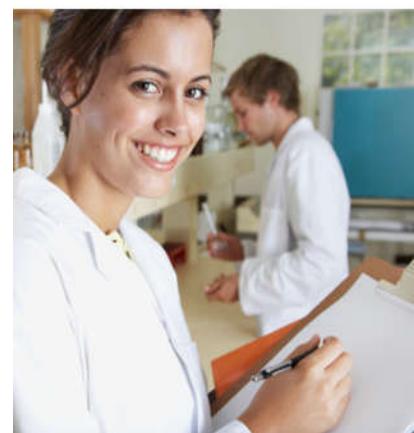
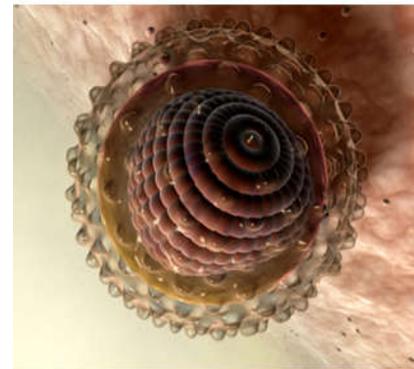
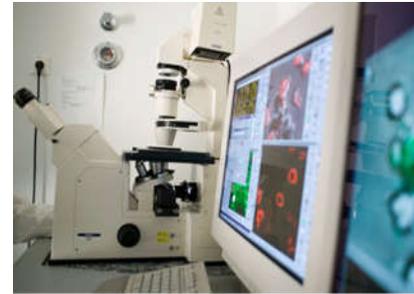
Opioid use disorder (OUD) is a chronic relapsing condition characterized by a problematic pattern of heavy, uncontrolled opioid use. In the United States, OUD usually involves consumption of either: licensed prescription painkillers such as oxycodone, hydrocodone, or illicit street drugs such as heroin and synthetic analogues such as fentanyl. Recently, the US prevalence of OUD has reached epidemic levels. During 2015, approximately **2.1m** and **0.59m** individuals had OUD associated with prescription painkillers and heroin respectively (0.8 and 0.2 per 100 persons, CDC figures, self-reported) **(1)**. Past year use numbers are as high as **13-15m** people (US) **(1)**. OUD has caused a massive surge in the number of US hospitalizations, emergency department visits and overdose deaths. The 2016 US figure of **~42,000** opioid overdose deaths was the highest on record **(2)**. OUD is now lowering the life-expectancy of the average American **(3)** and costs the US economy billions of dollars each year in both direct and indirect costs **(4)**. OUD is a global issue.

Medication-assisted therapy (MAT) treatment involving methadone (OTP only), buprenorphine and naltrexone, in combination with psychosocial counselling, can stabilize the opioid user either through detoxification or maintenance strategies. However, these treatments have strong safety considerations and are associated with high relapse or discontinuation. Moreover, only a fraction of opioid users initiate therapy. New interventions are desperately needed. Opioid hapten-based conjugated vaccine technologies have shown promising effects in preclinical models **(5,6)**. Ideally, an OUD vaccine should be **broad spectrum**, multivalent and block both the addictive and toxic effects of opioids thereby decreasing patient relapse, possibly in combination with existing therapies. An OUD vaccine could be safer, have a longer efficacy duration and thereby better compliance than existing small molecule therapies. Simplicity and a lower perceived stigma might drive more people into treatment programs.

Dr John Savopoulos, Director of Research & Analysis, who led the recent study commented, "Even with the most conservative assumptions, from a commercial perspective, there is certainly enough incentive for manufacturers to get involved. Revenues would be sufficient enough to recoup investment and, most importantly, they appear sustainable. Besides, it wouldn't take much to see whether this vaccine can raise the necessary type of antibodies in humans and hopefully see the promising signals observed in preclinical animal studies. At least we know antibodies help and opioid antagonism (by another means e.g. naltrexone) confer some benefit to the OUD sufferer."

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Some news commentators have noted that an opioid use disorder vaccine would not be a “magic bullet” and will take too long to develop, something that might dissuade large company involvement. “I don’t think there’s room for pessimism here,” Savopoulos notes. “If you look at illicit opioid production and supply on a global level there are no signs to me that this problem will go away, even if we curb prescriptions in the United States. This is a chronic global issue and no different to other relapsing health conditions that receive far more attention. Of course, we do need an aggressive multi-pronged approach on many levels, but the more tools we have the better. Innovation always takes time.”

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Sources: Corporate Press Releases and the below

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4. Florence CS et al. The economic burden of prescription opioid overdose, abuse and dependence in the United States, 2013. *Med Care*. 2016; 54(10): 901-6
5. Bremer PT et al (2017) Development of a clinically-viable heroin vaccine. *J Am Chem Soc* 139: 8601 – 8611
6. Sulima A et al. A Stable Heroin Analogue That Can Serve as a Vaccine Hapten to Induce Antibodies That Block the Effects of Heroin and Its Metabolites in Rodents and That Cross-React Immunologically with Related Drugs of Abuse. *J. Med. Chem.*, 2018, 61 (1), pp 329–343

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