4P-PHARMA

One line pitch:
Stimulants prescribed to treat ADHD are being abused/misused at an alarmingly high rate. Our technology aims at preventing such misuse.

Market Analysis:
Stimulants are used to treat Attention Deficit and Hyperactivity Disorder (ADHD). According to the FDA, between 10 and 16.2 millions of Americans suffer from ADHD. The total ADHD market accounts for 13.68 billion $, with a growth rate of up to 8% per year. Within the ADHD market, 90% of medicines used to treat hyperactivity are stimulants, accounting for 12.3 billion $. However, stimulants can be abused for recreational purposes via alternative modes of administration (sniffing or injection). In the USA, this phenomenon of abusing/misusing prescription drugs represents a public health issue denounced by the FDA and the total economic loss due to stimulant abuse is estimated at 23.4 billion $.

Value proposition:
No abuse-deterrent technology is currently available on the stimulant market, but its economic and social potential makes this technology very appealing, particularly for the FDA that is enforcing stimulants regulation in that sense. Our product delivers stimulant at clinical doses (equivalent to standard drug used to treat ADHD that does not have abuse deterrent mechanism), but contains a deterrent agent. Breaking of our capsule in order to misuse/abuse it via non-standard routes of administration (i.e. intranasal) will cause the release of the deterrent agent, that will both activate a negative feedback completely reversing the stimulant-induced reward effect and induce a discomfort event.

Business Model:
Our goal is to out-license our product after pilot clinical study (ongoing on Q3/Q4 2017). We aim at targeting pharmaceutical groups that produce and commercialize branded stimulants but that do not have/sell abuse deterrent mechanisms. We will target in priority medium to small-sized firms, generic manufacturers or specialists, for which in-licensing agreements are frequent and strategic, mostly US companies and companies located outside the US that sell in the US. The US represents in fact 85% of the global stimulants market and they are the country where stimulant abus is most stigmatized, by the media and the FDA.

IP and Regulatory situation:
No abuse deterrent formulation for stimulants is currently available on the market, and we secured our product innovation with patents in 2015 and 2017. Opioids have been associated to abuse-deterrent technologies since 2010 and in recent times the FDA have been enforcing regulation in this field, by denying approval of any generic version of opioids that is not abuse deterrent. Regulators therefore believe that FDA will provide guidance for drugs other than opioids (i.e. stimulants) in the very next future, since FDA stated in 2015 that “it [FDA] is supporting and encouraging efforts by drug manufacturers to modify formulations to reduce the risk of abuse, including for CNS stimulant drugs”