



Titan Pharmaceuticals | TTNP | Profile | Summary

Titan Pharmaceuticals, Inc. is a biopharmaceutical Company developing proprietary therapeutics primarily for the treatment of serious medical disorders.

Titan's principal asset is Probuphine®, the first slow-release implant formulation of buprenorphine hydrochloride ("buprenorphine"), designed to maintain a stable, round-the-clock blood level of the medicine in patients for up to six months following a single treatment. The outpatient treatment of opioid dependence with daily dosed sublingual buprenorphine formulations represents a \$1.3 billion market in the U.S., and a seven day transdermal patch formulation of buprenorphine for the treatment of chronic pain was launched in the U.S. in 2011. This

novel implant formulation is inserted
subdermally

in a patient's upper arm providing continuous medication, and has the potential to enhance patient compliance to treatment, and limit diversion for illicit use and accidental exposure to the sublingual formulations.

The New Drug Application (NDA) was submitted to the FDA in October, 2012 seeking approval for treatment of opioid dependence. In December 2012, Titan entered into a license agreement with Braeburn Pharmaceuticals Sprl (“Braeburn”) that grants Braeburn exclusive commercialization rights to Probuphine® in the United States and Canada. Titan received a non-refundable up-front license fee of \$15.75 million and will receive a \$50 million milestone payment upon the approval of the NDA by the FDA. Additionally, Titan will be eligible to receive up to \$130 million upon achievement of specified sales milestones and up to \$35 million in regulatory milestones in the event of future NDA submissions and approvals for additional indications, including chronic pain. Titan will receive tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties.

Probuphine is the first product to utilize ProNeura™, a novel, proprietary, long-term drug delivery technology. The ProNeura technology has the potential to be used in developing products for the treatment of other chronic conditions, such as Parkinson's disease, where maintaining stable, round-the-clock blood levels of a drug can benefit the patient and improve medical outcomes.

Continuous Drug Delivery Technology

The continuous drug delivery system consists of a small, solid rod made from a mixture of ethylene-vinyl acetate ("EVA") and a drug substance. The resulting product is a solid matrix that is placed subcutaneously, normally in the inner part of the upper arm in a simple office procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released slowly, at continuous levels, through the process of dissolution. This results in a stable blood level similar to intravenous administration. Such long-term, linear release characteristics are generally desirable as this avoids peak and trough level dosing that poses problems for many Central Nervous System ("CNS") and other disease settings.

This continuous drug delivery technology was developed to address the need for a simple, practical method to potentially provide continuous drug administration on an outpatient basis over extended periods of up to 6-12 months. In addition to Probuphine, which is the first product to complete clinical testing that has utilized this proprietary continuous drug delivery technology, Titan has conducted initial non-clinical studies with long-term delivery of dopamine agonists demonstrating the potential of this product in the treatment of Parkinson's disease in non-clinical models of the disease.

Strategic Alliances

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Novartis Pharma, AG, has licensed the rights to commercialize Fanapt in the U.S. and Canada, and commenced marketing the product in the U.S. in Q1, 2010. Titan is entitled to receive a royalty of 8-10% on the global net sales of this product. Titan does not incur any expenses related to this product.

Source: Titan Pharmaceuticals, [OxBridge Research](#), [Daily Stock Deals](#), [OTC King](#), [PSM](#)



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