



Company Description

IRX Therapeutic, Inc., is a private biopharmaceutical firm focused on the discovery, development and commercialization of proprietary biologic and small molecule Th1 agonists addressing unmet medical needs in cancer, infectious disease, vaccines and allergy. IRX Therapeutics' lead product, citoplurikin, will enter pivotal clinical studies in head and neck squamous cell carcinoma in late 2007. Safe and effective Th1 agonists could advance patient care for more than 100 million in the US suffering from cancer, infectious disease, and allergy and improve the efficacy of both new and existing vaccines.

The key products in development include:

- Citoplurikin (IRX-2): IRX Therapeutics' lead program, is a proprietary, first-in-class, multi-targeted biologic in Phase 2 clinical development for the treatment of head & neck squamous cell carcinoma (H&N SCC) prior to surgery. Citoplurikin restores Th1 immunization through the activation of dendritic cells and T-cells with the aim of reducing tumor burden, improving surgical options and increasing overall survival. IRX Therapeutics' goal is to seek accelerated approval from the FDA for citoplurikin in H&N SCC while continuing clinical development in prostate and other cancers. IRX Therapeutics plans to enter pivotal clinical studies with citoplurikin in late 2007 or early 2008.
 - In single-center, Phase 1/2 clinical studies, citoplurikin demonstrated a low level of drug-related adverse events and an apparent increase in overall survival in this difficult to treat cancer.
 - Citoplurikin has been granted Fast Track and Orphan Drug designations in the U.S.
 - A Phase 2, multi-center clinical trial in H&N SCC designed to study further the safety and biologic activity of citoplurikin will be completed later this year.
- MIMP: The Company's lead small molecule; MIMP is an orally active, small molecule that stimulates, or up-regulates, Th1-mediated cellular immunity in response to a pathogen challenge. It has broad applicability in the treatment and prevention of viral diseases, such as influenza, hepatitis, HIV, and herpes.
- IRX-3: A combination of citoplurikin and an immunostimulatory peptide; IRX-3 is targeted at patients with severe immune deficiency resulting from cancer, HIV, or other diseases.
 - In a pilot Phase 1/2 study, IRX-3 was tested in cancer patients with severe T-cell deficiency after radiotherapy.
- IRX-4: A combination of IRX-2 and prostate cancer specific antigens; IRX-4 is initially targeted at patients with advanced hormone refractory prostate cancer.
 - A pilot Phase 1/2 study for IRX-4 in prostate cancer was completed in 2004. The pilot study suggests an ability by IRX-4 to stabilize the disease in certain patients with prostate cancer.
 - The Company intends to initiate a randomized, controlled Phase 1/2 clinical trial to further evaluate IRX-4 in prostate cancer.

IRX Therapeutics, headquartered in New York, has raised approximately \$34 million to fund its development programs. The company's experienced management team is supported by a distinguished board of directors and scientific advisors.