Oncolix

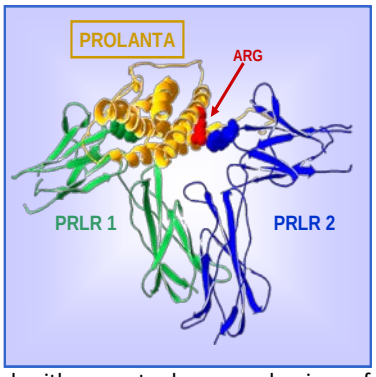
ONCX: OTCQB

January 2018

Oncolix is a public biotechnology company (ONCX) specializing in the development of a novel therapeutic protein (Prolanta™), which has shown evidence to be an ideal candidate for targeting gynecological cancers. The Company is currently conducting a Phase I ovarian cancer study cleared under an US IND for a Phase I open label trial in patients diagnosed with metastatic Ovarian Cancer (OC). In its collaboration with MD Anderson Cancer Center, Prolanta has shown to be a treatment that could be used as a stand-alone monotherapy or in combination with chemotherapy to treat cancers that have historically been demonstrated to be resistant to existing Standard of Care. Oncolix believes Prolanta could be a breakthrough therapy that transforms the way gynecological cancers such as OC, Breast Cancer (BC) and Uterine Cancer (UC) are treated today.

Key Relationships:
Monsanto: Developed the proprietary, high-yielding recombinant E. coli expression system used to manufacture Prolanta.
MD Anderson Cancer Center: Discovered the mechanism of action of Prolanta, helped develop our clinical trial strategy and is performing the biomarker analysis of the Phase I clinical trial.
Greenville Hospital System: Originated the technology and has invested more than $7 million.
Texas Emerging Technology Fund: Has awarded Oncolix $3.9 million
PoC Capital/Integrium: Invested $1.5 million in Oncolix and is the CRO for the Phase I trial.

Unmet Medical Needs: In the United States, 22,000 new OC patients are diagnosed and 14,000 women die of this deadly disease annually. While the five-year survival rate is 75% when diagnosed in an early stage, once the disease has spread, five year survival is reduced to 20%. Most women are diagnosed after the disease has spread. The current standard for treatment is a combination of carboplatin and paclitaxel. Renal toxicity, nausea, neuromotor toxicity, cardiovascular events, neutropenia, thrombocytopenia and anemia occur in up to 90% of patients using carboplatin and paclitaxel.



Solution: Oncolix is developing a novel therapeutic protein for the treatment of OC. Prolanta is the first drug to target prolactin receptors, which are overexpressed in gynecological cancers, including OC, UC, BC, and other cancers. According to research performed at MD Anderson, monotherapy with Prolanta shows strong activity in a xenograft mouse model of human OC, substantially reducing both tumor volume and the number of tumors in a dose-dependent manner with no apparent toxicity noted. Prolanta preclinical data support the potential to be used in combination with chemotherapy or as a monotherapy for patients resistant to or those who cannot tolerate chemotherapy. Prolanta could be the first cancer drug approved with an autophagy mechanism of action. Furthermore, Prolanta blocks human prolactin from binding to prolactin receptors, which is well known for causing chemoresistance.

Science: Prolanta is an analog to human prolactin, identical except for a single amino acid substitution at the 129th position of this 199 amino acid protein. Prolanta is designed to bind to the prolactin receptor and block the effects of human prolactin, which is associated with many cancers. Prolanta targets multiple signaling pathways and has both anti-prolactin and anti-HER2 activity, which are relevant targets for OC. Prolanta has shown significant anti-tumor activity in both xenograft and transgenic mouse models of human OC. The autophagy mechanism of action was discovered and published by MD Anderson Cancer Center in *Cell*. Furthermore, the 2016 Nobel Prize winner in Chemistry was Dr. Yoshinori Ohsumi, who is the considered the pioneer in autophagy.

Company Profile:
Industry: Pharma/Biotech
Founded: 2007
Location: Houston, TX

Management:
CEO: Michael Redman
SVP: Donald Payne
Regulatory Officer: William Gannon, MD

Board of Directors:
Jerry Youkey, MD, (Dean of the U of SC School of Medicine and VP Greenville Hospital System)

Joseph Podolski (CEO, Repros Therapeutics)

Dale Zajicek (former president, BioVectra)

John Holaday, PhD

Michael Redman

Advisors:
George Peoples, MD (clinical)
Ed Calamai, PhD (mfg)
Bill Spanogle, PhD (mfg)

Collaborators:
Anil Sood, MD - MD Anderson Cancer Center
Larry Gluck, MD – Greenville Hospital System

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Market Opportunity: Prolanta is under development as a stand-alone or combination therapy for OC and UC. Given the poor tolerability, short-term efficacy and low survival rate of these patient groups, there is a real need for a targeted therapy to address the unmet medical needs of these diseases. The potential success of Prolanta in its clinical trials could ultimately translate into a multi-billion dollar opportunity. Prolanta received Orphan Designation from the FDA for the treatment of ovarian cancer.

Development Highlights:

- Received Orphan Designation from FDA
- Publication of Prolanta mechanism of action in *CELL*
- Commenced Phase I clinical trial in ovarian cancer – preliminary results available

Product Development Status:

Product	Indication	Mfg Optimization	Pre-clinical	IND	Phase I	Phase IIa	Phase IIb
Prolanta	Ovarian Cancer (monotherapy)	→	→	→	→	N/A	N/A
	Ovarian Cancer (with chemotherapy)	→	→	→	2018	2018	2019
	Uterine Cancer	→	→	→	2018	2019	2020
	Breast Cancer	Requires pharmaceutical partner or post approval of ovarian indication					

Management Team and Scientific Collaborations: Oncolix has assembled an experienced management team in the areas of drug development, clinical trial management and manufacturing. Michael Redman, MBA is the CEO with over 20 years of pharmaceutical and biotech experience. He has extensive licensing experience and has consummated deals with several large pharmaceutical companies. Donald Payne, MBA, has extensive management, financial and drug development experience.

Intellectual Property: Oncolix holds in its name eight issued US patents and additional foreign patents with additional pending applications. Oncolix pays no milestones or royalties on these patents. Prolanta has been granted Orphan Drug designation in the US, which provides seven years of marketing exclusivity. In addition, the Healthcare Reform Bill provides 12 years of data exclusivity for biological products. Orphan status in Europe and Japan would provide 10 years of market exclusivity.

Regulatory Path: Oncolix intends to develop Prolanta primarily as a combination with chemotherapy in ovarian and other cancers. The next indication targeted for Prolanta will be UC/uterine sarcoma. Oncolix intends to commence a Phase IIa trial with a combination of Prolanta with chemotherapy in 2018. Oncolix has the potential to file for Breakthrough Status with the FDA. Oncolix will also evaluate Prolanta in preclinical efficacy studies for the treatment of UC with MD Anderson Cancer Center in 2018.

Business Model: Oncolix intends to add value from Prolanta clinical trials until a desirable exit strategy is achieved. Anticipated future milestones include strengthening board, acquiring a new drug asset, an Asian partner and eventual uplisting to NASDAQ.

Financing: Oncolix has raised $16 million to date. The current investors include the Greenville Hospital System, the Texas Emerging Technology Fund, PoC Capital, BioVectra (now Mallinckrodt), Ernest Mario Family Fund (former CEO of Glaxo) and company management. Oncolix intends to raise additional capital necessary to complete its upcoming Phase IIa trial in ovarian cancer.