



Corporate Summary

Last updated: February 2022

Overview:

Dr. Stead and Mrs. Colley founded Holburn Biomedical Corporation (Holburn) in 1995; and they grew the business into a multimillion dollar corporation with 50 employees. Holburn has performed contract research work in the field of irritable bowel syndrome (IBS) & visceral hypersensitivity for GlaxoSmithKline (GSK), Novartis, Johnson and Johnson (J&J; both Beers and Springhouse divisions), Solvay, Movetis, Shire and Lexicon; immunology studies for Sanofi Pasteur (including earlier studies conducted for Connaught), Ikaria, Shire and Luitpold Pharma (Luitpold); and in the pathology test and equipment development arena for Sakura Finetek (Sakura), Cytochroma, Cytokinetics and Panacea Global.

Drug Development:

One of the earlier and extensive projects was conducted for Luitpold (now Sankyo Pharma). This was on a vaccine-like product for upper respiratory tract infections. The project included a thorough review of Luitpold's pharmacology and toxicology dossier; development of an assay to localize target cells; preparation and submission of a Canadian Investigative New Drug (IND) application; and managing and monitoring a clinical trial with local otorhinolaryngologists. Thus, Holburn laid the groundwork for the internal application of all stages of drug development, to facilitate future studies.

Major Collaborations:

Holburn worked for several years with Janssen (part of J&J) on the development of therapeutics for IBS. This involved the establishment of novel mouse models of post-infectious visceral hypersensitivity; and testing a range of novel compounds for their abilities to modulate chemical or mechanical sensitivity of the intestines. Using retrograde labelling of dorsal root ganglion neurones, Holburn was able to identify, using DNA micro-arrays, thousands of potential targets that were up-regulated or down-regulated in infected animals; and forty of those targets were significantly changed. Drug agonists and antagonists were tested in the new mouse model, which revealed significant modulation of sensory mesenteric nerves.

Pathology Development:

Holburn has performed contract work on pathology projects, including the later stages of development of an immunohistochemistry (IHC) staining system. Dr. Stead had invented this product line and obtained patent protection for the devices. These patents were sold to Sakura, who contracted back to Holburn the bulk of the subsequent development work.

Molecular Pathology:

As the gastrointestinal pharmaceutical business was changing in 2006–2008, Holburn looked for opportunities in the pathology space. This resulted in a partnership with Dynacare (then Gamma-Dynacare), using their licenses and Holburn's equipment and skills. Starting in November 2009,



Holburn built a molecular and cellular pathology team with a team of 20 employees; and then brought in a genetics group, which doubled the staff. This combined laboratory was recognized as one of the top Molecular Pathology laboratories in the province; and was the first to provide country-wide Companion Diagnostic services for Keytruda (Merck). As Laboratory Director, Dr. Stead was accountable to the Ministry of Health for all aspects of patient safety and test quality in this facility. The pathology group had year-after-year increased revenue and profit.

Holburn Projects:

The research nature of Holburn's work enabled recovery of significant SR&ED tax credits, which allowed Holburn to fund independent development programmes. This included test development for IBS, in which Holburn evaluated a series of antibodies that recognize intestinal IBS-related receptors; and tested the best of these in a clinical study on IBS patients and controls. The levels of the target were found to be changed in IBS, which suggests that the assay could be used to predict responsiveness to treatment. Holburn is looking for a partner pharmaceutical company to do further clinical trials on this diagnostic test. Additionally, earlier J&J studies focussed on mediators of inflammation and neuroplasticity in mouse models. However, Holburn has a lot of data on inflammation and intestinal plasticity in rats. Accordingly, Holburn independently developed a separate, novel, multiple-infection rat model. Using this model, significant visceral hypersensitivity can be achieved and blocked, in part, with known antagonists. This led to several alternative therapeutic strategies, which Holburn is currently pursuing.

Other:

Holburn has supported many other companies, covering all aspects of pathology, immunology and neurophysiology; and Dr. Stead and Mrs. Colley have participated in key opinion leader boards for Novartis, GSK, Sakura Finetek and Dako (now Agilent). Dr. Stead has a successful academic career since 1987, when he received his first faculty appointment. Today, he is an Honorary Professor of Medicine at a major medical school in Germany (University of Tübingen). Mrs. Colley was a university lecturer and holds registered advanced certification in histopathology (CSMLS/CMLTO). Dr. Stead is an internationally recognized expert in gastrointestinal physiology. He has built and funded academic and industrial teams of 50 staff, both in Canada and Germany. Holburn intends to further pursue independent and collaborative R&D and commercialization of pharmaceuticals and diagnostics.

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