Voyageur Pharmaceuticals completes FDA submission milestone for first barium contrast product license application

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Radiographic contrast media are substances used in diagnostic imaging tests such as ultrasound, X-rays, CT scans and MRI to enhance the visibility of internal structures. Iodine and barium sulfate are the typically used substances to provide the contrast media. According to IQ41 Research & Consultancy Pvt. Ltd: The global addressable market for contrast media is forecast to grow from US$4.7 billion in 2021 to US$7 billion by 2028, at a CAGR of 7.7%.

As of April 2022, Voyageur Pharmaceutical reports that barium sulfate prices are up 300% in the past 12 months, to $17,000/tonne; due to a worldwide shortage of high-quality natural USP pharmaceutical barium sulfate which has forced most manufacturers to use synthetic, high-cost barite for their products.

Voyageur Pharmaceuticals Ltd. (TSXV: VM) (Voyageur) is advancing its plan to become the only fully integrated company in the radiographic contrast media field, by developing barium and iodine generic radiographic contrast media. Voyageur is unique, as it plans to source its own raw materials (barium sulfate & iodine) from its own mineral deposits located in Canada and USA respectively.

Progressing towards potentially achieving FDA approval in the USA

As announced on May 18, 2022, Voyageur has recently completed a milestone with their FDA submission. According to Voyageur: "Based on preliminary discussions with the FDA, Voyageur has submitted extensive documentation for the first barium contrast product license application. Voyageur is currently scheduled to meet with the FDA in June, to finalize submission requirements for this product and once this application is approved, the Company plans on submitting applications for additional products. Upon receipt of the application, the FDA may grant the license within 120 days, thus giving Voyageur the approval to market its first barium sulfate contrast agent in the United States."

The current timeline suggests the potential FDA licensing approvals may be obtained by October to November 2022, all going well.

Product development

Voyageur recently completed the design and testing of the first batch of its smoothie product line of barium sulfate contrast agent. Voyageur says that "once this testing is completed, the data will be used to support the initial marketing and sale of the Company's line of barium sulfate imaging products that are approved for the Canadian market and in tandem will be used for the Food and Drug Administration (FDA) submission."

Voyageur plans to achieve initial cash flow through third-party pharmaceutical manufacturing, sourcing third-party minerals, turnkey manufacturing, bottling, and distribution of barium and iodine radiographic pharmaceutical drugs. The longer-term plan is to be vertically integrated.

Voyageur Pharmaceuticals completed milestones

Source: Voyageur Resources company presentation

Next steps and a positive PEA announced in January 2022

Voyageur has engaged an engineering firm to design and build the barium processing and contrast manufacturing plant and the pharmaceutical product manufacturing plant. According to Voyager: "These two facilities will become the foundation of the only fully integrated and totally controlled entry into the global imaging market for barium sulfate contrast agents. This control is intended to provide Voyageur with a low-cost advantage that should support the gaining of market share and improved margins."

The master plan is for the plant to be fed by Voyageur's 100% owned barium sourced from the Frances Creek Project. The Project is located near the town of Radium Hot Springs, British Columbia, Canada. All of the above is subject to funding.

The Frances Creek Pharmaceutical Barium Project Preliminary Economic Assessment (PEA) was announced in January 2022, resulting in a base case pre-tax net present value 8% ("NPV8%") of C$464 million and an internal rate of return (IRR) of 168%, while the post-tax NPV8% was C$344 million with an IRR of 137%. The total capital required over 3 years for the Project was estimated at C$36 million. Operating gross margins were estimated to average 75% over the Project.

Voyageur Pharmaceuticals 2022 PEA for the Frances Creek Pharmaceutical Barium Project

Source: Voyageur Resources company presentation

Closing remarks

Voyageur Pharmaceuticals already has a very high grade (37.75%) barium sulfate Indicated Resource and has released a solid PEA for the integrated Frances Creek Pharmaceutical Barium Project.

The next major steps mostly revolve around further product development testing, FDA regulation in the USA, project funding, and finally getting into production. Beyond that is development of the Company's Iodine-lithium-bromine brine project in Utah and potentially some battery mineral projects as you can read here.

2022 looks like being a key year for Voyageur Pharmaceuticals.