

Voyageur Pharmaceuticals Completes Milestone with the FDA and Continues to Move Towards Commercialization on Three Fronts

written by Raj Shah | May 18, 2022

May 18, 2022 ([Source](#)) – Voyageur Pharmaceuticals Ltd. (“Voyageur” or the “Company”) (TSXV:VM) is pleased to announce that it is progressing with its product development, regulatory pathway and material processing/manufacturing operations that could result in revenue generation in Canada this year and more importantly revenue generation in the United States early next year.

Product Development

As part of the product development process, Voyageur has recently completed the design and testing of the first batch runs of its smoothie product line of barium sulfate contrast agents used for medical CT imaging. Further, the Company is currently working through the scaled batch requirements for quality control and for meeting various regulatory requirements and specifications.

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.

FDA Activity

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.

Voyageur's plan for revenue generation is close to being executed, which will support financing and full integration of the Frances Creek project.

Barium Processing/Manufacturing

Voyageur has engaged the engineering firm ACH Engineering Inc. ("ACH") to develop a detailed plan for the construction of two linked facilities. An Active Pharmaceutical Ingredient ("API") plant to refine the barium concentrate from its quarry into an API grade product. ACH will design the automated Good Manufacturing Practice ("GMP") drug and device pharmaceutical manufacturing facility.

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.

Upon completion of the facility designs and detailed cost and schedule, Voyageur will begin to seek financing for this

strategic buildout of the Company's fully integrated drug and device manufacturing.

Voyageur recognises the strategic value of being fully integrated, owning and extracting its own APIs. The Company's barium resource is critical and strategic for customers, currently threatened by global supply chain constraints and increasing geopolitical risks. Voyageur will be able to provide supply security to customers over long-term contracts, with reduced risk to supply disruptions and volatility.

About ACH Engineering Inc

ACH Stands for "A Cleanroom Hub", which is its core business moto that enables ACH to push its boundaries and, expand to be a specialized controlled environment solutions provider, operating from Ontario to Alberta (Canada) and covering the North American market needs.

ACH's story starts with its clients, whether its clients need a controlled environment or a cleanroom for a LAB, Manufacturing Process or any other application ACH stands behind its clients and the clients business needs by understanding their process requirements. ACH then tailors the optimized solution and converts it into reality.

ACH's unmatched capabilities stem from its people who carry outstanding qualifications and experience to provide robust turnkey solutions that contribute to the clients vision.

Contract Manufacturing

Alberta Veterinarian Laboratories ("AVL") has completed construction of their GMP pharmaceutical plant. The plant is operational and has completed testing and passed inspections. AVL is currently ramping up production for over thirty products.

AVL's goal is to produce over 50 products including Voyageur's barium contrast product line.

About Voyageur

Voyageur is a Canadian public company listed on the TSXV under the trading symbol VM. Voyageur is focused on the development of barite and iodine API and high-performance cost-effective imaging contrast agents for the medical radiology marketplace. Voyageur's goal is to initially generate positive cash flow from operations using third party GMP pharmaceutical manufacturers in Canada and internationally. Ultimately, Voyageur has plans to build all the required infrastructure to become 100% self-sufficient with all manufacturing. Voyageur owns a 100% interest in three barium sulphate (barite) projects including the Frances Creek property, suitable in grade for the pharmaceutical barite marketplace, with interests in a high-grade iodine, lithium & bromine brine project located in Utah, USA.

Voyageur is moving forward with its business plan of becoming the only fully integrated company in the radiology medical field, by controlling all primary input costs under the motto of: "From the Earth to the Bottle".

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Cautionary Statement Regarding “Forward-Looking” Information

This news release may contain certain forward-looking information and statements, including without limitation, statements pertaining to: the timing of revenue generation in Canada and the United States; the timing and success of the development of the Company's products including the smoothie product line of barium sulfate contrast agents; the Company's products meeting various regulatory requirements and specifications; the timing and success of the Company's licence application to the FDA; the timing and success of the Company's financing, design and construction of the API plant and GMP drug and device pharmaceutical manufacturing plant, manufacturing costs and margins and whether the manufacturing costs will be low enough to provide the Company with a sufficient advantage to gain market share over other competitors; AVL's ability to manufacture Voyageur's barium contrast product line in a timely and cost effective manner; and the Company's long term plans, including with respect to becoming 100% self-sufficient with all manufacturing. All statements included herein, other than statements of historical fact, are forward-looking information and such information involves various risks and uncertainties. There can be no assurance that such information will prove to be accurate, and actual results and future events could differ materially from those anticipated in such information. A description of assumptions used to develop such forward-looking information and a description of risk factors that may cause actual results to differ materially from forward-looking information can be found in the Company's disclosure documents on the SEDAR website at www.sedar.com. Voyageur does not

undertake to update any forward-looking information except in accordance with applicable securities laws.