

AXIM® Biotechnologies Receives Medical Device Manufacturing License

State of California Department of Public Health Food and Drug Branch Issues the Company a License for Manufacturing of its Diagnostic Assays

SAN DIEGO, May 29, 2024 -- [AXIM Biotechnologies, Inc. \(OTCQB: AXIM\)](#) (“AXIM Biotech,” “AXIM” or “the Company”), an international healthcare diagnostic solutions development company, today announced that it received a Medical Device Manufacturing License from State of California Department of Public Health Food and Drug Branch. The license allows AXIM to manufacture medical devices, such as its ophthalmological diagnostic assays, for either commercial or clinical use.

The Medical Device Manufacturing License broadly allows companies to manufacture any type of medical device, further enabling AXIM the ability to develop novel diagnostic solutions for use in clinical studies as well as for commercial use, pending any additional regulatory approval requirements. AXIM currently has two FDA-cleared ocular diagnostic assays, its T-POC TOTAL IgE Immunoassay and T-POC LACTOFERRIN Immunoassay Kits. Both are being marketed through the Company’s commercialization partner Verséa Ophthalmics and address a critically unmet need in the areas of dry eye diagnosis and treatment planning.

“We believe this license illustrates the level of quality of both our facility and our manufacturing processes,” said John Huemoeller II, CEO of AXIM Biotechnologies during the presentation. “While we remain committed to focusing on the research side of diagnostics and leveraging proven manufacturing partners in order to scale sales of our approved devices, this license allows us to forge ahead on our other diagnostic programs that are in the research stage. That said, we may need to act as a secondary party in manufacturing of our approved assays if demand required so and this license allows us to do that as well. With it, we are well prepared to meet the demand for our assays in terms of manufacturing, especially important should we receive a CLIA waiver at some point, which would essentially allow for our assays to be sold to every ophthalmological clinic in the nation.”

Both of AXIM’s FDA-cleared tests are groundbreaking in that they are designed to be administered at the point-of-care and render results in eight minutes, allowing clinicians to better diagnosis and treat the dry-eye-disease (DED) at the time of a patients visit. There are approximately 344 million people worldwide that suffer from DED but the indication has been historically difficult to diagnose and treat due to insufficient diagnostic tools. AXIM seeks to address this market with its tear sample test kits and associated reader which offer clinicians quantitative insights into the underlying causes of a patient’s eye condition.

For more information on AXIM and its diagnostic solutions please visit <https://aximbiotech.com/>

About AXIM® Biotechnologies

Founded in 2014, AXIM® Biotechnologies, Inc. (AXIM) is a vertically integrated research and development company focused on improving the landscape for the diagnosis of ophthalmological conditions such as Dry Eye Disease (DED) through rapid diagnostic tests. The Company owns two of the only five FDA Cleared Diagnostic tests for Dye Eye Disease. For more information, please visit www.AXIMBiotech.com.

Forward-Looking Statements

The statements made by Axim Biotechnologies Inc., in this press release may be “forward-looking” in nature within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Forward-looking statements describe Axim’s future plans, projections, strategies and expectations, and are based on assumptions and involve a number of risks and uncertainties, many of which are beyond the control of Axim Biotechnologies, Inc. Actual results could differ materially from those projected due to there being no assurance that our diagnostic candidate will ever be approved for use by the U.S. FDA or any equivalent foreign regulatory agency. Further, Axim’s eye care diagnostic products that are FDA cleared may not be manufactured in large enough quantities or that third parties with established eye care physicians will enter into agreements or purchase from the Company, and even if the Company’s diagnostic candidates are successful, they may generate only limited revenue and profits for the Company. Various other factors are detailed from time to time in Axim’s SEC reports and filings, including our Annual Report on Form 10-K filed on April 15, 2022, and other reports we file with the SEC, which are available at www.sec.gov. Axim Biotechnologies, Inc., undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, unless otherwise required by law.

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