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Q BioMed's Diagnostic Kit Designed to Serve Unmet Need for 70 Million Glaucoma Sufferers

Q BioMed Inc. (OTC – QBIO - $2.052 - NR) and its key technology partners are set to initiate development of an industry-changing diagnostic kit for monitoring glaucoma severity and progression. Pending FDA clearance, which could come sooner than many biotech investors might expect, this kit offers the potential to improve the quality of life for glaucoma sufferers by helping preserve visual function in glaucoma patients through accurate monitoring of disease progression. As a result, this diagnostic offers substantial future value to the Company.

Diagnostic Kit Offers Critical, First-of-its-Kind Functionality

Based on the novel GDF15 biomarker, this kit's core, platform technology enables more effective measurement and management of glaucoma progression and patient treatment than any current monitoring or therapeutic approaches---a tremendous advantage. Considering that no single examination or diagnostic test is able to accurately predict disease progression, QBIO's prospective offering serves an unmet need for millions of patients. Moreover, this simple diagnostic test can be performed at a physician's office with no external expensive equipment.

Glaucoma is diagnosed via a comprehensive eye exam, including visual field testing and tonometry, which measures pressure inside the eye as a means to determine if increased risk factors for glaucoma exist. While this may be the gold standard in intraocular therapy testing, this method is not truly counted on for diagnostic purposes as it relates to determining progression. As a result, the GDF15-based tool could emerge as the industry's diagnostic standard-bearer and early-stage detector.

GDF15 Biomarker and Diagnostic Kit Overview

Q BioMed and its technology partner Mannin Research Inc. have entered into a research collaboration with the Biointerfaces Institute at McMaster University in Ontario, Canada to develop a GDF15 biomarker diagnostic kit for monitoring glaucoma severity and progression. This enabling technology will act as a companion diagnostic to the MAN-01 small molecule therapeutic with a novel mechanism of action for the treatment of Primary Open-Angle Glaucoma. The aim is to develop a simple integrated diagnostic test that can be performed at a physician's office with no external, expensive equipment.

Glaucoma, which afflicts an estimated 70 million people today, is the second leading cause of blindness and it is a lifelong disease, once diagnosed. There is no cure for the progressive disease and current therapies tend to reduce intraocular pressure elevations, which is one of the key factors that can lead to glaucoma progression. However, the biomarker's inherent advantages including early detection over conventional clinical tests position

Q BioMed and its technology partner Mannin Research as leading technology and therapeutic innovators in the segment.

The Next Steps

Q BioMed is poised to initiate, with its esteemed partners, development of the GDF15 diagnostic kit. The Biointerfaces Institute will work with Mannin Research to create, assess, and apply DNA aptamers for detecting GDF15 in aqueous humor of patients with different severities of glaucoma. The intent is to create multiple prototype assays for the detection of GDF15 which will be suitable for point-of-care (POC) testing. Thus, the prototype kits are to be validated in a clinical setting. This personalized medicine approach illustrates the underlying innovation of the platform technology whose key function is to improve disease progression measurement and patient treatment outcomes.

Interestingly, the Company has a good deal of flexibility with respect to its development process and FDA clearance pathway. It can elect to develop the kit for 510(k) FDA clearance or a PMA (Premarket Approval) designation. While this decision will be made following discussions with the FDA regarding testing protocols and design, each pathway has its own advantages. It has been our experience that the 510(k) process (commencement through clearance) tends to be faster than PMA (roughly 18 months), which means that revenue could be generated very quickly. The PMA route, while a bit longer, can sometimes provide a marketing boost as the underlying providers can advertise their device as PMA-approved or FDA-approved. Such labeling, along with the expected favorable data, could accelerate diagnostic kit deployment in ophthalmologist offices.

Major Value to Be Generated Via the QBIO Roadmap

Admittedly, it is too early to forecast specific revenue and/or value of the GDF15 platform to the Company. However, the QBIO product roadmap provides key insight into the business model from which investors can extrapolate a future, tangible value range.

<u>Diagnostic</u>
Upon clearance or approval of the diagnostic kit, Q BioMed would charge a to-be-determined fee to the ophthalmologist for each assay and analysis. Since glaucoma is a lifelong disease, these swift tests will have to be performed on a routine basis on patients to preserve visual acuity and measure progression, it renders the kit as a recurring (and compounding) revenue stream for the physician and the Company. Considering 70 million are afflicted today, and millions more could be tested for measurement and progression at earlier intervals, it is reasonable to expect that one in three patients could regularly undergo this test, generating considerable revenue.

<u>Therapeutic</u>
Leveraging a novel mechanism of action, this platform technology will act as a companion diagnostic to the MAN-01 small molecule therapeutic which Q BioMed and Mannin Research Inc. are currently developing to treat Primary Open-Angle Glaucoma. Development and potential FDA approval would likely follow that of the device, given that the research and development process is longer. However, by serving as a companion diagnostic to

the therapeutic, the device will play the role of a bridge from diagnosis/analysis/monitoring to therapeutic treatment---which could carry a price tag far greater than that of the diagnostic kit. In essence, by capturing a meaningful share of the diagnostic market for this segment due to the one-of-a-kind properties and capabilities, the migration to the higher priced and higher profit therapeutic could be considered a slam dunk.

Enter Big Pharma

As accuracy of the GDF15 biomarker is further affirmed, it could ultimately be used as a surrogate biomarker to ocular therapy clinical trial endpoints—perhaps even used as a primary endpoint in MAN-01 trials and studies. In this scenario, major pharmaceuticals engaging in glaucoma or tangentially-related glaucoma or ocular clinical trials may elect to license the biomarker so that they may have access to it for the trials.

By leveraging a single platform, QBIO has multiple shots on goal with respect to market share, revenue and profit in the multi-billion dollar glaucoma market. A unique player on the path to offering a series of “firsts”, QBIO is leading innovation in the lucrative ophthalmology segment, which carries high price/revenue multiples.

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Rob Goldman founded Goldman Small Cap Research in 2009 and has over 20 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

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