

Dear Shareholders,

As we embark on a new year, I am pleased to provide this summary to you. In it you will find highlights from 2023 and our plans for Q1, 2024.

Clinical Trial Update

The phase 1 trial being conducted at the Medical College of Wisconsin (MCW) continues to warrant our full attention. Patients are enrolling at the 2000 mg dose level and are experiencing no significant side effects. The goal of phase 1 is still unmet in that the maximum tolerated dose (MTD) has yet to be determined. The clinical team is reviewing all data and discussing what, if any, criteria could be used in lieu of MTD to define the recommended phase 2 dose (RP2D). This would then result in phase 1 being closed and allow the preparation for a phase 2 trial to hit full stride.

While the phase 1 trial maintains momentum, significant regulatory milestones have been achieved that formally validate the promising potential of GaM (as well as remind us of the lack of viable treatment alternatives for brain tumor patients). In late December, the FDA designated the development of oral GaM for the “treatment of adult patients with relapsed or refractory glioblastoma, IDH-wildtype” as Fast Track. The Fast Track Designation (FTD) process facilitates the development of new drugs that treat serious conditions and fill unmet clinical needs. Going forward, we intend to fully leverage the increased communication and collaboration with the US FDA afforded by this process.

Along with the two Orphan Drug Designations (ODD) received last year, these regulatory accomplishments have boosted the enthusiasm of our internal team and that of the leadership at the Medical College of Wisconsin (MCW). Motivated by these accomplishments, we are launching an Expanded Access Program (EAP). The benefits of an EAP are multi-faceted, and I will touch upon a few significant ones here. First, the agent itself is very stable and does not require special storage or handling. Thus, an oral agent that can be taken at home is an ideal candidate for executing an EAP. Second, the EAP would make the agent accessible to patients throughout the U.S. and allow patients to obtain GaM who otherwise could not participate, due to proximity to MCW or the inclusion/exclusion criteria of the phase 1, etc. Based on the data obtained from phase 1, albeit limited, we believe the agent has potential benefit for these patients. Third, additional data from the EAP would be obtained faster than the traditional phased trial pathway and would be considered “real-world-data” (RWD). RWD is increasingly valued as it is a truer representation of the normal population of patients. RWD can also identify critical information, such as biomarkers, that can significantly influence the size, scope, and cost of subsequent phases. This data could then be used in a New Drug Application (NDA) to the FDA. In fact, there have been agents approved by the FDA that relied solely on EAP data, and even more agents whose approval relied primarily on data obtained from EAPs. Finally, as part of the EAP, we will qualify a 2nd source of supply of GaM. This is an FDA requirement necessary for commercialization.

We have an opportunity to help patients that are in dire need of treatment alternatives. We also have an opportunity to obtain quality data necessary for final FDA review and approval much faster than typical drug development timelines (which can last well over a decade). The FDA does allow direct costs to be recovered under an EAP. As an unapproved agent, patients would have to incur the direct costs of receiving the agent and we are aggressively working to make this as affordable as possible.

On the horizon is a decision to be made by the Office of Orphan Product Development (OOPD) regarding our Pediatric Rare Disease (PRD) designation request. We anticipate a decision will be made by mid Q1 assuming that no (or few) requests for additional information are received by the OOPD. As previously communicated, two pre-clinical studies were conducted in the laboratory of Dr. Kathleen Schmainda, PhD, of MCW, each led by Dr. Mona Al-Gizawiy, PhD, which have demonstrated overall survival (OS) benefit in preclinical models of two pediatric cancers (GBM and atypical teratoid rhabdoid tumor, or ATRT). These two studies provided the data to support the ODD designations received earlier in the year. This data was also integral to the PRD designation request. If granted PRD designation and GaM receives FDA approval, the FDA may award us a priority review voucher (PRV) which can be redeemed (for the review of a subsequent new drug application) or sold to another sponsor. There are no active phase 1 trials studying GaM in pediatric brain tumor patients. There is also limited toxicology or dosing levels identified for children. There is a possibility, however, that an EAP could be launched to provide access to GaM for pediatric patients. We intend to explore that option as we move forward with our planned EAP.

Overall, the core team celebrated many milestones in 2023. All those milestones were reflected in long hours, scientific discovery, and ultimately a passion to help patients.

Our Focus in 2024

Our core imaging business remains our backbone, however, we must stay focused on the continued advancement of oral GaM for cancer patients. The promise of delivering an effective cancer treatment command us to do so. That said, we are acutely aware of the lengthy development timelines associated with pharmaceutical agents and look forward to working closely with the FDA via the Fast Track Designation process and bringing this to market as soon as possible. In the interim, increasing sales revenue of our imaging products is pivotal.

We will continue supporting our major channel partners, whether through technical support and troubleshooting or joint marketing and sales efforts. We are also committed to releasing automated “fractional tumor burden” (FTB) mapping which will provide an attractive upgrade for existing clients and an incentive for new clients to adopt. We anticipate having the initial version ready for demonstration at the annual American Society of Functional Neuroradiology meeting in August. Likewise, our efforts to implement longitudinal reporting capabilities continue and may be ready at that time. Recently, IB Nimble has received the attention of our development team as we continue to “industrialize” the code base adopted when we licensed the application. This work includes incorporating enhancements requested by current and prospective users.

Our IB User’s Group webinars will continue. On deck at the end of January is Dr. Joe Bovi, MD, who will discuss the clinical utility of IB Nimble. And our collaborative relationship with Phoenix Children’s Hospital (PCH) has culminated in a planned study using output generated from IB Zero G. The tentative plans are to have two to three experienced pediatric neuroradiologists compare IB Zero G’s output against real “ground truth” images. Depending on the results and feedback from the clinicians, a 510(k) submission may be prepared with revised indications for use (IFU) specific to pediatric patients. Finally, every indication is that a phase 2 trial is imminent, and we are preparing to continue our sponsorship. We will be working very closely with the clinical team as they define the protocol and size of phase 2 and identify other participating sites. There will be a gap between the conclusion of phase 1 and phase 2. Data analysis and documentation needs to be submitted to the FDA and the phase 2 protocol needs FDA approval. This makes an EAP even more strategic as it enables an aggressive pathway to continue our efforts towards full commercialization.

Other Updates

Since submitting our Current Procedure Terminology (CPT) code application to the American Medical Association in November, we have had multiple productive exchanges with the CPT Editorial Panel. Based on their excellent feedback and guidance regarding our code change application, we decided to revise and resubmit the application later this year. Specifically, and as suggested, the revised application will incorporate additional feedback from content experts and specialty societies such as the American Society of Neuroradiology, the American College of Radiology, and others. We will also focus on the post-processing component and forgo the acquisition of the data, which was determined to be covered under an existing CPT code.

Sincerely yours,
Michael Schmainda,
CEO, Imaging Biometrics, LLC
Director IQ-AI Ltd

The Directors of the Company accept responsibility for the contents of this announcement.