Subject: [EXT] FINAL--Written comment for the Nov 21 ARS Meeting of the CIRM ICOC

Oculogenex is developing a gene therapy for an unmet need in the ocular space that will benefit 2.2 million Californians (over 200 million globally). We had a favorable pre-IND meeting, and we have a clear path forward to FIH trials with strong FDA support of our plans. We submitted our CLIN1 grant proposal on July 30,2024 and were notified on October 4th that we will not proceed to the GWG merit review prior to a funding decision. No details were provided in the notification. We believe that the newly introduced qualification process could negatively impact promising CA corporations developing promising products. The objective review by CIRM staff (six items) is based on some non-objective criteria (pipeline programs, cell versus gene therapies). The subjective review of four items by two GWG members also cannot result in widely different scores (like in our case). If it does, there should be a way to reconcile the disparity or respond to the feedback, especially if misunderstandings in the therapeutic resulted in the score. We request that the qualification process be made more objective and include an opportunity for applicant to provide feedback.

Regards,

Ramaswamy (Ram) Ramkumar COO, Oculogenex, Inc. ram@oculogenex.com (562) 652-2379