Newsletter to shareholders

January 2025

Dear Madam, Dear Sir,
Dear Shareholders,

As 2025 begins, I would like to send my best wishes for health and success in your personal and professional undertakings. I also wish to offer my heartfelt thanks for your trust and commitment in us.

The year 2024 was marked by significant progress in our journey, thanks to the unwavering commitment of our teams, financial partners, and shareholders.

Financial Management

Throughout the year, the company achieved a significant reduction in operating expenses through rigorous and optimized cash management.

The company was refinanced on four occasions, for a total of €18.5 million. We were able to count on renewed support from our historical investors, whom I warmly thank, and in addition, we welcomed new investors. These successful financing rounds demonstrate the potential of GenSight and its product portfolio.

Thanks to our banking partners and their support, we renegotiated our financial obligations in June 2024, including the terms of State-Guaranteed Loans (PGE) and of the convertible bonds granted to Heights Capital.

These various actions enabled the continuation of manufacturing operations and the preparations for the resumption of the Early Access Program in France.

At the same time, we maintained discussions with potential partners regarding opportunities for strategic collaboration.

Lumevoq® Production

The production of a drug product batch of Lumevoq® in 2024, derived from the blending of two drug substance batches produced in 2023, yielded over 120 vials, enabling treatment access for about 60 patients.

This one-time operation was successfully carried out in July 2024. Some of the vials arrived in August at our provider in France to support the resumption of the Early Access Program. The remaining vials will be shipped to France at a later date.

Lumevoq® successfully passed all the quality control tests required for the pharmaceutical release of the batch in September.

Early Access program Regulatory Application

The application was submitted to the ANSM (French National Agency for Medicines and Health Products Safety) on November 12, 2024. The company responded in early January 2025 to questions from the competent authority, with whom we maintain regular and constructive exchanges. These discussions reflect a mutual commitment to advancing towards the official authorization to resume the Early Access Program (AAC) in France.

Thanks to ongoing collaboration with the highly committed administrative and medical teams at the 15-20 National Hospital, the site is ready to perform the first injections.

We are currently awaiting authorization to resume the Early Access program.

The follow-up of GS030 patients (our optogenetic product candidate for retinitis pigmentosa), treated as part of the Phase I/II PIONEER clinical trial, is ongoing. Interim study results are expected over the course of 2025.

Maintaining Scientific Communication and Presence at Major Medical Events

We have ensured high-quality and consistent communication with medical teams. In 2024, key efficacy results for Lumevoq® were published, including the 4-year results from the REFLECT study, the 5-year results from the RESTORE study, and a meta-analysis showing greater efficacy of Lumevoq® in ND4-LHON patients compared to the natural progression of the disease.

We have also maintained a presence at major ophthalmology congresses such as ARVO, AAO, EUNOS, EVER, and NANOS.

Last July, we issued a newsletter to keep retail investors updated on the company's developments, introduce our team, and delve more deeply into specific topics. We have received many responses, and we are grateful for your feedback!

This past year has indeed been eventful, and we are proud to have stayed the course with our mission: making Lumevoq® available to patients! We successfully completed all the necessary actions and eagerly await the resumption of the first treatments.

The year 2025 promises to be just as exciting and dynamic. We will focus our efforts on the launch of the pivotal RECOVER clinical study, the submission to the UK regulatory agency (MHRA), and the GS030 development plan.

May this new year be one of action and confidence.

I wish you all an excellent year!

Laurence Rodriguez
CEO GenSight Biologics

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