Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

May 19, 2026

Michaela Damin
Barth Syndrome Trust
1 The Vikings
Romsey, Hampshire
SO51 5RG United Kingdom

Re: 4TAZPOWER (SPIBA-401) Phase 3/4 clinical trial – Bristol, UK site

Dear Michaela:

As we've discussed, the informed consent(s) for the 4TAZPOWER trial provide that patients who complete the trial (through week 72) can elect to participate in an open-label extension (OLE), in consultation with their healthcare provider (HCP), during which we will provide access to elamipretide until "marketing authorization" is granted. As the informed consent is a regulatory document, the regulatory milestone of MHRA "marketing authorization" was the most appropriate assurance to provide in this context.

We understand that following MHRA marketing authorization, and prior to securing commercial access for patients, additional steps including a Health Technology Assessment by the National Institute for Health and Care Excellence (NICE) and, potentially, negotiation of Commercial Access Agreements or even exploration of specialized funds may be required. We recognize that patients electing to participate in the OLE may have concerns about interruption of therapy while these processes are pursued.

In our decade plus journey working with the Barth syndrome global community, we have consistently committed to use our best efforts not to interrupt access to elamipretide for any patient utilizing the therapy. That commitment continues in the context of the 4TAZPOWER trial. We expect to provide access to elamipretide for open label participants in the UK until country-level access is secured. We will work closely with our partner, Pharmanovia, to ensure that they are also aligned with and understand the rationale for this commitment.

We are happy for you to share this communication with your community.

Kind regards,

Reenie McCarthy

Reenie McCarthy

Chief Executive Officer