

NEWS RELEASE

July 1, 2025

NIH Renews Year 2 of \$2.9 Million SBIR Phase IIB Grant for Plakous Therapeutics to Carryout IND-Enabling Studies

WINSTON-SALEM, N.C.— Plakous Therapeutics, Inc. completed year 1 of our recently awarded Phase IIB Small Business Innovation Research (SBIR) grant providing up to \$2,925,000 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health (NIH).

The grant will help Plakous translate a novel therapy for premature babies, to prevent the devastating and costly disease of Necrotizing Enterocolitis (NEC), by providing support to conduct IND enabling preclinical safety studies for our lead therapeutic, Human Placental Extract (HPE). Plakous Therapeutics' VP of Engineering, Michael Berger, PhD, is the Principal Investigator for the three-year project.

“This grant, combined with our recent pre-IND interactions with the FDA, allows Plakous to take the next steps toward preventing NEC, which has no approved treatment or diagnostic tests. Plakous is delighted to receive the renewal of its SBIR IIB grant from the NIH. This funding catalyzes our developmental activities and helps us generate GMP-grade product for definitive safety studies,” said Robert Boyce, Chief Executive Officer of Plakous Therapeutics.

“This award will support manufacturing and preclinical safety milestones in the large animal toxicology study necessary for an Investigational New Drug (IND) filing for HPE, an orally delivered cell-free biotherapeutic being developed by Plakous from post-delivery placentas. The grant will complement our \$20M Series A fundraising campaign to complete both the IND filing requirements and a Phase 1b/2a clinical trial in at risk preemies.” said Boyce.

NEC is a devastating disease caused by inflammation and lack of development of the intestine. More than 90% of the 3,000 annual cases in the United States occur in premature babies born less than 30 weeks completed gestational age. NEC carries a 30% mortality rate. Managing NEC consumes an estimated \$4 billion in NICU and hospital costs for these vulnerable babies. Plakous seeks to prevent NEC with HPE by accelerating intestinal maturation of premature infants and improve weight gain in the entire premature target population.

About Plakous Therapeutics, Inc.

Plakous Therapeutics is a biotherapeutic company dedicated to researching and developing placenta derived regenerative therapies to improve patient outcomes and reduce health care costs. For more information, please visit the company's website at plakoustherapeutics.com.

Disclaimer: Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health



under Award Number R44HD100243. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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