

DECLARATION OF DAVID HALE

I, David Hale, declare under penalty of perjury that the following is true and correct to the best of my knowledge, and if called upon as a witness in these proceedings, could and would competently testify thereto.

1. Since 1971, I have worked in a variety of roles and capacities for a number of biotechnology and pharmaceutical companies.

2. My educational background includes a Bachelor of Arts in biology with a minor in chemistry. I am a serial entrepreneur and have been involved in the formation and development of a number of companies in the biotechnology, biopharmaceutical, medical device and diagnostics spaces.

I. HALE BIOPHARMA VENTURES, LLC

3. After serving as CEO and Chairman of a number of biotech companies, I formed Hale BioPharma Ventures, LLC (“HBV”) in June 2006 as an investment vehicle that would allow me to invest in different biotechnology and biopharmaceutical companies. One potential product that I was interested in pursuing was finding a better way to treat seizures other than by rectal gel (Diasat®). At that time, I did not know what alternative routes of administration were possible nor what formulations could be created.

4. Sometime in 2007, I was approached by Steve Cartt and Craig Chambliss from Questcor Pharmaceuticals (“Questcor”) about their development of an intranasal formulation of diazepam for the treatment of seizures in patients with epilepsy.

5. At the time, I understood that the asset (known as Project QSC-002) was still in development and that no clinical testing (animal or human) had been conducted. I also understood that while they had worked on the development of several formulations, a lead formulation

candidate had not yet been identified. Further, they had not conducted any clinical work or regulatory testing, which would have been needed to get the formulation to market.

6. I was interested in the opportunity and conducted due diligence on the project and the formulations that had been developed to date. During that process, I had a number of meetings with David Medeiros and Steve Cartt from Questcor. I also met with the project team from Particle Sciences, Inc. (“PSI”), which included Mark Mitchnick, Andrew Loxley, and Garry Gwozdz.

7. I learned that Questcor had engaged PSI to work with them to jointly develop an intranasal diazepam formulation. Questcor and PSI had previously entered into a Master Service Agreement, which governed the joint development work, the intellectual property that was developed, and other rights, duties and obligations of the parties.

8. In speaking with the Questcor and PSI team, I learned about some of the solubility challenges that they had encountered, and their initial approaches in trying to get a sufficient amount of diazepam into either a solution or a suspension. As a result of their joint work, I learned that they had developed novel formulations, including solutions and suspensions, that the team considered as candidates for the QSC-002 development program.

9. As a result of my diligence, I became very interested in the QSC-002 development program and I was interested in acquiring it from Questcor. I spoke with Chambliss about setting up a new company (called Neurelis, Inc.) that would eventually take control of the QSC-002 development program and be responsible for moving the drug candidate through all of the necessary trials and regulatory approval, securing funding, and ultimately handling all of the marketing and sales of future products. HBV would be the successor in interest in everything related to the QSC-002 development program, including the MSA and all intellectual property.

II. ACQUIRING QSC-002 FROM QUESTCOR AND INTRAVAIL FROM AEGIS

10. My negotiations with Questcor culminated in the Spring of 2008 with final terms upon which HBV would acquire the QSC-002 development program from Questcor. The parties negotiated and finalized an Asset Purchase Agreement (“APA”), which was signed on June 27, 2008. Pursuant to the terms of the APA, HBV took over Questcor’s place as research partner with PSI in continuing the development of intranasal diazepam. Exhibit 2031 (Bates Neurelis-00218626) contains a true and correct copy of the APA, which I signed as CEO of HBV. The APA was made and kept as part of the regularly conducted business activity of HBV.

11. During the diligence process, I learned from the Questcor and PSI teams that solubility of diazepam and absorption across the nasal mucosa had to be considered in developing a lead candidate. Questcor and PSI focused first on the solubility issues. As I became more involved, we expanded the research to discuss how it might provide incremental benefit to the formulation if an additional excipient could further increase diazepam uptake in the nasal mucosa.

12. I became familiar with Ed Maggio’s work at Aegis Therapeutics, LLC (“Aegis”) from my work in San Diego, and I became aware that Aegis was working on formulations with very large molecules such as calcitonin, insulin, and human growth hormone. In particular, they were working with Intravail®, an alkyl saccharide compound. The work was still experimental, although Ed Maggio had presented promising results that showed an increase in bioavailability for those large molecules in aqueous environments. I was interested in exploring whether adding Intravail® would provide added benefit to the nasal diazepam formulations that were under development, including for small molecules and in non-aqueous environments.

13. With the support of the Questcor and PSI teams, I reached out to Maggio and negotiated an agreement with Aegis so that we could use Aegis’s Intravail® in formulations with diazepam and other benzodiazepines, and also that Aegis would provide its technical knowhow

concerning Intravail®. Exhibit 2041 (Bates Neurelis-00282364) is a true and correct copy of the August 28, 2007 Letter Agreement, attaching a term sheet. I signed the Agreement on behalf of HBV, and it was made and kept as part of the regularly conducted business activities of HBV.

14. At that time, the parties contemplated that we would negotiate a license and supply agreement to formalize and supplant the term sheet. Those negotiations continued from 2007 to 2008 and culminated in a license and supply agreement dated May 22, 2008. Exhibit 2043 (Bates Neurelis-00046660) is a true and correct copy of the license agreement, and Exhibit 2042 (Neurelis-00077702) is a true and correct copy of the supply agreement. I signed the agreements on behalf of Neurelis, and they were made and kept as part of the regularly conducted activities of Neurelis.

15. On October 2, 2008, Aegis sent a sample of “Intravail® A3” to PSI to incorporate it into the formulations that the Questcor and PSI teams had developed. Exhibit 2044 (Bates Neurelis-02059390) is a true and correct copy of the transmittal notice from Aegis, which was made and kept as part of the regularly conducted activity of HBV. To help with the experimentation, Maggio provided detailed information about “Intravail® A3” (chemical name: *n*-dodecyl beta-D-maltoside) and some experimental information about using it in the QSC-002 formulations.

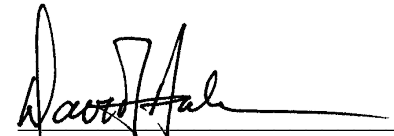
III. PATENT FILINGS

16. As part of the acquisition from Questcor, HBV obtained the right title and interest in the provisional patent application that Questcor filed on March 28, 2008 (U.S. Provisional Application 61/040,558) (the “’558 Provisional”).

17. After the transaction closed, I worked with the Wilson Sonsini law firm to prepare and timely file a non-provisional application claiming priority to the ’558 Provisional. As part of that process, the Questcor team, the PSI team, Ed Maggio (a consultant of HBV), and I discussed

the various formulations that had been jointly developed to date and also the incorporation of Intravail® A3 or *n*-dodecyl beta-D-maltoside into the formulation. On or about March 27, 2009, as successor-in-interest to Questcor, HBV filed non-provisional application 12/413,439 (the “’439 Application”), which contained our joint research.

Date: December 24, 2025



David Hale