

DECLARATION OF STEVE CARTT

I, Steve Cartt, declare under penalty of perjury that the following information 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 1985, I have worked for a number of biotechnology and pharmaceutical companies in a variety of different roles and capacities.

2. My educational background includes a Bachelor of Science degree in biochemistry from the University of California, Davis in 1984.

3. Following graduation, I worked in a variety of positions in both R&D and Marketing at Alza Corporation until leaving for a new position at Elan in 2000. During my employment at Alza, I obtained my Master of Business Administration (MBA) from Santa Clara University, Leavey School of Business. From 2000 – 2002, I worked at Elan Pharmaceuticals, Inc. (“Elan”) as the Senior Director of Strategic Marketing.

I. QUESTCOR AND THE INTRANASAL DIAZEPAM PROJECT

4. In 2005, I was hired by Questcor Pharmaceuticals, Inc. (“Questcor”) as its Executive Vice President of Corporate Development. I was later promoted to Chief Business Officer, and later to Chief Operating Officer. As COO, I was in charge of all of Sales and Marketing, Commercial Operations, Strategic Marketing, and for an initial period of time Medical Affairs as well. During my tenure at Questcor, I worked on a number of different projects, including the development of new pharmaceutical products. One of those projects was an intranasal diazepam spray.

5. From my previous work at Elan, I was familiar with a diazepam product on the market known as Diastat®. Diastat® was a rectal gel that was approved by FDA in 1997 for the

acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern in patients with epilepsy. Diastat® was the only approved medication for this indication, aside from treatment by intravenous administration of diazepam in the hospital.

6. At Questcor, we began exploring the possibility of developing an intranasal diazepam product. At the time, I was working with: Questcor's Director of Commercial Operations, Craig Chambliss; Questcor's Vice President of Manufacturing, David Medeiros; and Questcor's Chief Executive Officer, James Fares. Chambliss, Fares, and I all had prior experience or knowledge of Diastat® and together with Medeiros, we believed this would be a good project to pursue.

7. Medeiros and I had principal responsibility for this project, which was given the internal project-development codename of "QSC-002." Medeiros and I conducted extensive research to understand what issues or limitations might exist with developing diazepam formulations that were not based on intravenous or rectal delivery.

8. Our initial focus was to find a partner who could work with us in formulating a product that could deliver a sufficient amount of a benzodiazepine into the nasal mucosa and would achieve the same pharmacokinetic result (or better) as that which was obtained through administration of Diastat®. From 2005 – 2006, Medeiros and I met with several different biopharmaceutical companies in the U.S. and elsewhere, who had expertise in formulating biopharmaceutical products generally and nasal products more specifically. One of those companies was Aegis Therapeutics, LLC ("Aegis").

9. In approximately the Summer of 2005, I met with Edward Maggio, Aegis's president and CEO. In advance of our initial discussions regarding our QSC-002 Project, Questor

and Aegis executed a non-disclosure agreement on August 15, 2005, with me signing on behalf of Questcor and Ed Maggio signing on behalf of Aegis. Ultimately at this time, we chose not to proceed with Aegis.

10. Exhibit 2034 (Bates Neurelis-02059385) is a true and correct copy of the August 15, 2005 Non-disclosure Agreement between Aegis and Questcor. The NDA in Exhibit 2034 was made at or near the time of August 15, 2005, and it was made and kept as part of the regular business of Questcor.

II. WORKING WITH PARTICLE SCIENCES, INC. AND AEGIS

11. In approximately December 2006, I met Mark Mitchnick at Particle Sciences, Inc. (“PSI”). PSI had expertise in formulating drug substances into drug products. Medeiros and I believed that, given PSI’s experience, they could help us develop our intranasal formulation. Mitchnick introduced us to his team at PSI, Garry Gwozdz and Andrew Loxley.

12. We had several initial meetings with the PSI team in which we discussed and explored (at a high level) various formulation approaches that might include creating a solution or possibly a suspension.

13. In January 2007, the Questcor team and I decided to work jointly with PSI on the intranasal benzodiazepine project. We entered into a Confidentiality Agreement with them concerning this project, with me signing on behalf of Questcor and Mark Mitchnick signing on behalf of PSI.

14. Exhibit 2035 (Bates Neurelis-00094007) is a true and correct copy of the January 19, 2007 Confidentiality Agreement. The Confidentiality Agreement was made at or near the time of January 19, 2007, and it was made and kept as part of the regular business of Questcor.

15. After executing the Confidentiality Agreement, PSI did some preliminary work on the proposed formulation, focusing primarily on improving the solubility of diazepam. Solubility was the principal issue we faced in creating an intranasal diazepam product. In addition, Medeiros and I were also interested in exploring ways to further increase the absorption of diazepam across the nasal mucosa. The team reached out to Ed Maggio at Aegis about whether Intravail® could be used to further enhance absorption of small molecules like benzodiazepines through the nasal mucosa. Aegis had been experimenting with alkyl saccharides, which they called Intravail®, to use in formulations with large biomolecules, including proteins such as calcitonin, insulin, and human growth hormone.

16. Exhibit 2036 (Bates Neurelis-02059389) is a true and correct copy of my February 15, 2007 email to Aegis. I sent the email on February 15, 2007 on behalf of Questcor, and it was made and would have been kept as part of the regular business of Questcor.

17. As shown in Exhibit 2037, on March 28, 2007, PSI issued Quote No. QCR 135 to Questcor, which I signed on April 16, 2007 on behalf of Questcor. QCR 135 included an Appendix 1, which set forth the following goals for our formulation:

-
- | Government | Percentage |
|---------------------|------------|
| Current government | 100% |
| Previous government | 0% |

Exhibit 2037 at 3. In the early phases, we did not know whether a solution with sufficient concentration of diazepam would be feasible, so we initially focused the research on a suspension or emulsion.

18. Exhibit 2037 (Bates Neurelis-01027114) is a true and correct copy of QCR 135. QCR 135 was made and kept as part of the regular business of Questcor.

19. On April 1, 2007, Questcor and PSI entered into a Master Services Agreement (“MSA”) to govern the work that was envisioned on developing an intranasal benzodiazepine drug product. Exhibit 2030 (Bates Neurelis-00093986) is a true and correct copy of the MSA. The MSA was made at or near the time of April 1, 2007. It was made and kept as part of the regular business of Questcor.

20. On April 4, 2007, I met with Maggio to further discuss the use of Intravail® in our QSC-002 Project. Exhibit 2038 (Bates Neurelis-00895210) is a true and correct copy of an email chain between Ed Maggio and me, setting up the April 4 meeting. The emails contained in Exhibit 2038 were sent and received in the weeks leading up to April 4, 2007 and were made and kept as part of the regular business of Questcor.

21. As indicated in Exhibit 2038, the email signature from Aegis stated, “Our Intravail® drug delivery technology enables the non-invasive delivery of a broad range of protein, peptide and non-peptide macromolecular therapeutics that can currently only be administered by injection.” At that time, Maggio did not have any data or information on how, or if, Intravail® might perform with a small molecule such as diazepam.

22. Sometime later in 2007, [REDACTED], which caused the company to reassess the value of all of its existing products and projects, and consider which ones were the most profitable and which ones could be sold. The QSC-002 Project fell into

the latter category, primarily because the proposed product was still several years away from FDA approval. As a consequence, the executive team at Questcor (including myself) sought buyers who might be interested in acquiring the QSC-002 Project and bringing our intranasal diazepam product to market.

III. HALE BIOPHARMA VENTURES, LLC

23. While looking for a potential buyer, I met David Hale of Hale BioPharma Ventures, LLC (“HBV”). Hale had a very successful track record of investing in various biotechnology companies in San Diego and elsewhere and helping them bring products to market.

24. Starting in 2007, we had numerous meetings with Hale and with PSI to discuss the QSC-002 Project and its continued development. Hale was enthusiastic about the project, and he began working on plans to acquire the QSC-002 Project from Questcor and forming a new company (Neurelis, Inc.) to focus on moving the QSC-002 Project from the formulation stage to an FDA approved product.

25. Ultimately, Questcor agreed to sell the QSC-002 Project to HBV, which was memorialized in an Asset Purchase Agreement (“APA”). Exhibit 2031 (Bates Neurelis-00218626) is a true and correct copy of the APA, dated June 27, 2008, which I executed on behalf of Questcor. The APA was made and kept as part of the regular business of Questcor. As part of the transaction, the MSA and all of the underlying work undertaken between Questcor and PSI was assigned to HBV, along with all of the intellectual property that Questcor had acquired and pursued.

IV. PROVISIONAL PATENT FILINGS

26. Under the terms of the MSA, Questcor was in charge of preparing and prosecuting patent applications that were [REDACTED]

[REDACTED] Exhibit 2030 at [REDACTED] Meanwhile, any

work product that was [REDACTED] would be controlled and owned by PSI. *See* Exhibit 2030 at [REDACTED]

27. Based on my discussions with Mitchnick, it was agreed that Questcor would draft and prosecute the patent applications that pertained to the nasal spray product and formulation that we had created. On behalf of Questcor, we retained as counsel the Wilson Sonsini firm, and PSI retained its own counsel.

28. Through intentional coordination, Questcor and PSI simultaneously filed two separate provisional patent applications on the same day (March 28, 2008), so that neither application would create an impediment to the other. The PSI employees who contributed to the nasal spray formulations – Garry Gwozdz, Andrew Loxley, and Mark Mitchnick – would all be listed as inventors on the Questcor application alongside myself and Medeiros (U.S. Provisional Application 61/040,558) (the “558 Provisional”). As for the PSI application, the inventors would include only the PSI personnel (U.S. Provisional Application 61/040,281) (the “281 Provisional”).

29. After provisional applications were filed, the parties confirmed their respective rights in the applications in an agreement dated April 2, 2008. Exhibit 2040 (Bates Neurelis-00218570) is a true and correct copy of that agreement, which I executed on behalf of Questcor on April 2, 2008. In relevant part, the agreement provides:

[REDACTED]

Exhibit 2040. The agreement in Exhibit 2040 was made and kept as part of the regularly conducted business of Questcor.

30. In June 2008, HBV and Questcor finalized the terms of the APA, by which HBV would acquire all of Questcor's right, title, and interest in the QSC-002 project and step into Questcor's shoes as PSI's new joint research partner. As the successor in interest to the QSC-002 Project, HBV took over the MSA with PSI.

Date: December 23 2025



Steve Cartt