

# \$20m Andromeda strains Hyperion as fake data ends diabetes drug development



By [Dan Stanton](#) 09-Sep-2014

**Hyperion says it is “*shocked and disheartened*” after discovering Phase III trial data for a type 1 diabetes candidate was manipulated by employees of recently acquired Andromeda Biotech.**

In June Hyperion Therapeutics bought Andromeda from Israel-based Clal Biotechnology Industry for \$20m (€15.5m) in order to take its lead candidate DiaPep277 - an immune intervention therapy for Type 1 (juvenile) diabetes – through late stage clinical trials and into commercialisation.

However, three months on and Hyperion has been forced to terminate development after uncovering evidence certain Andromeda employees, along with a third party biostatistics firm in Israel, manipulated data from the candidate’s DIA-AID 1 Phase III trial in order to obtain a favourable result.

*“Additional evidence indicates that the biostatistics firm and certain Andromeda employees continued the improper practice of sharing and examining un-blinded data from the ongoing DIA-AID 2 trial,”* Hyperion CEO Donald Santel said in a conference call yesterday.

*“We have suspended the Andromeda employees known to be involved, notified relevant regulatory authorities and are continuing to investigate in order to explore our legal remedies,”* he told shareholders.

## **Detection**

Such manipulation was only detected following the ordinary course of finalising the statistical plan for the ongoing DIA-AID 2 trial. When the data from the first trial was analysed, it was found Andromeda excluded 34 patients based on study entry criteria.

When this data set was re-entered, the positive results of DiaPep were lost, which Santel said was *“a curious result”* as these patients had apparently been excluded on a blinded process.

This led to a greater inquiry discovering Andromeda had excluded patients from the efficacy trial on the basis of unblinded data and the primary endpoint of the trial was changed. The same employees continued to receive unblinded data in the DIA-AID 2 while collating statistics and while taking “*extensive measures to conceal their wrongdoing.*”

## **Due Diligence**

This misconduct was “*obviously*” not revealed by Andromeda, before the \$20m purchase, Santel added, and Hyperion had carried out thorough due diligence before signing its share purchase agreement.

*“Andromeda’s co-ordinated effort to conceal and mislead thwarted our substantial due diligence process,”* he said. *“Simply put, certain Andromeda employees actively and consistently lied to our team.*

*“We are shocked and disheartened at the serious misconduct and deceit by the implicated Andromeda employees. We feel that this new information leaves us with no regulatory path forward for DiaPep277.”*

Santel was unable to disclose whether the acquisition could be overturned following this information, or whether a case like this was unprecedented. *“We have exquisitely talented lawyers who have helped us uncover the truth,”* he said, adding for shareholders to: *“Count on us to rely on exquisite advice going forward.”*

However, he said Hyperion would go ahead and complete the DIA-AID 2 trial, despite the minimal chance of producing positive, untainted results, as the firm believes *“it is in the best interest for the Type 1 diabetes community to do so.*

*“We want to make sure the data is usable by the community in the event that it reveals important insights into the history of Type 1 diabetes. We expect the study to be completed in the first quarter of 2015.”*

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