Viventia's Cancer Ambitions Go To Eleven

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Executive Summary

Merger with troubled ophthalmology biotech Eleven takes Viventia public and joins the protein-engineering and manufacturing expertise of the two firms. Lead candidate Vicinium is in Phase III for high-grade, non-muscle invasive bladder cancer.

Eleven Biotherapeutics Inc. will live on, at least in name, following a merger with Canada's **Viventia Bio Inc.**, resulting in a new company named Eleven that will focus primarily on Viventia's legacy Phase III targeted protein therapeutic *Vicinium* for bladder cancer and Phase II-ready *Proxinium* for head-and-neck cancer.

On Sept. 21, the two companies announced the transaction, effective immediately, in which Eleven purchased all outstanding shares in Viventia in exchange for the issuance of 4m-plus shares of Eleven common stock. As a result, former Viventia CEO Stephen Hurly will lead the new company, with Viventia's shareholders owning roughly a 16.7% stake in the new entity.

New company will advance a pair of epithelial cell adhesion molecule therapeutics.

Top-line Phase III data on Vicinium, an anti-EpCAM (epithelial cell adhesion molecule) fusion protein optimized for local administration, in high-grade, non-muscle invasive bladder cancer are expected in the first half of 2018. Meanwhile, Proxinium, which also targets EpCAM, is slated to enter Phase II in late-stage squamous cell carcinoma of the head and neck in early 2017.

Hurly told *Scrip* both candidates are attempts to mimic the antibody-drug conjugate model for cancer, but with a targeted protein instead of a small-molecule cytotoxic payload.

Alternative Access To Public Markets

He acknowledged that the merger basically was an alternative method for Viventia to go public after it scrapped its plans to seek an initial public offering in 2015, facing a poor climate for IPOs. [See Deal] (Also see "Biotech IPO Window Closed In November As Returns And Prices Plunged" - Scrip, 2 Dec, 2015.)

Eleven Biotherapeutics had a bad year as well. A Phase III dry eye disease trial for its lead candidate EBI-005, an engineered protein therapeutic, failed in May 2015. The company finally shelved the compound in January when it also demonstrated no significant efficacy in allergic conjunctivitis. (Also see "Eleven Biotherapeutics Shifts Focus After Trial Failure" - Pink Sheet, 18 May, 2015.)

Expectations mounted that Eleven would wind down its operations in some form after the company licensed its only remaining drug candidate, the preclinical interleukin-6 (IL-6) inhibitor EBI-031 for diabetic macular edema, to **Roche** in June. CEO Abbie

Celniker, who will be a board member at Eleven, said at the time that the company was evaluating various strategic options following the deal with Roche. (Also see "Does Deal With Roche Signal Eleven's Doomed Fate?" - Scrip, 13 Jun, 2016.)

"We viewed this as the best opportunity for us and our shareholders, combined with the Eleven shareholders, to get these products the capital and the resources they need to move the products forward," Hurly said in an interview.

The focus going forward will be on the legacy Viventia pipeline, but he did not rule out further development of Eleven's pipeline or possible licensing deals around its protein-engineering platform. A number of Eleven employees will remain with the new company, he added, including several who are working on the Roche partnership, which could still generate more than $260m in potential earn-outs. [See Deal]

More Than Using A Shell To Go Public

The deal has value to Viventia beyond a public shell through which the Canadian biotech could go public in the US, Hurly said.

Combining with Eleven also brings more protein-engineering expertise.

"What we all saw in this deal was that there were benefits to the combined company," he explained. "They're both protein-engineering companies, they both understand running trials. One of the biggest issues in protein development is manufacturing, CMC and the like. There's some real expertise at Eleven in doing that, there's some real expertise at Viventia in doing that, but the combined company, it seems, would have more expertise."

"In biotech, there are lots of strategic discussions that always are going on," the exec continued. "This is one of the few opportunities we saw with similar technology, protein engineering and protein development, that had the ability to bring each together, that had combined expertise that would make the combined teams better. Certainly, Viventia is going to benefit from the Eleven board and the reach that it brings to the table."

Hurly called the Viventia's targeted protein therapeutics (TPTs) "smart missiles" that could offer improvements over the antibody-drug conjugate model.

"The whole idea of ADCs is a good one, but we think our TPTs are engineered to take that to next level and overcome some of the challenges," he said. "We use single chain [antibody fragments] instead of full-length antibodies; we think that gets more drug to and into the tumor bed. We have protein payloads that we think bring significant benefits over small-molecule payloads in killing rapidly reproducing cells as well as quiescent or cancer stem cells. And underlying all of that, supporting our technology foundation, is our unique manufacturing system that allows us to fully express our targeted protein therapeutics in a single step."

Unlike ADCs, Hurly asserted, PTPs don't fall apart because they are a single protein. They offer improved navigation and better payloads compared to ADCs, he added, and Eleven expects benefits in efficacy, safety and cost of goods too.