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PRODUCT DEVELOPMENT

Newly public Candela looks to two years of value inflection points

BY KAREN TKACH TUZMAN, SENIOR EDITOR

Less than a year after announcing a new leadership team, Candela believes it has the funding it needs to get to a pivotal readout for its lead viral immunotherapy, as well as advance its early stage programs and build a manufacturing facility.

“There are going to be a range of value-creating inflection points in the next two years,” said CEO Paul Peter Tak.

After joining Candela Therapeutics Inc. (NASDAQ:CADL) last year, the GlaxoSmithKline plc (LSE:GSK; NYSE:GSK) and Flagship Pioneering veteran revamped the company’s management team, and made it his goal to raise the funds needed to accelerate development of the company’s late-stage pipeline while adding discovery programs.

Formerly known as Advantagene Inc., Candela was founded in 1999 and spent the majority of its existence subsisting on federal funding. The company didn’t raise its first institutional financing

round until 2016, with subsequent series B and C rounds that brought its total venture capital raised to \$67.6 million.

The company’s July IPO, in which Candela raised \$79.1 million, gave it a postmoney valuation of \$222.4 million. At Friday’s close, the company’s market cap had risen to \$312.7 million.

The proceeds are fueling the company’s Phase III trial of aglatimagene besadenovec (CAN-2409) for intermediate or high-risk prostate cancer, which the company said Tuesday had completed enrollment and is planned to read out in 2024.

Aglatimagene also is in a Phase II trial for prostate cancer patients on active surveillance.

CBO Nathan Caffo said the company’s decision to opt for an IPO without a crossover round was driven by the extensive clinical data it had already accumulated. “It’s interesting to have a company at this late of a stage going public.”

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Other near-term milestones for Candel include an interim analysis of the compound's efficacy in a Phase II study in non-small cell lung cancer (NSCLC); the start of a Phase III trial in high-grade glioma, where the compound has fast track designation; and initial Phase II data in pancreatic cancer.

Aglatimagene is a replication-deficient oncolytic adenovirus that delivers the HSV thymidine kinase gene to cancer cells. Patients are then dosed with valacyclovir, which the locally expressed thymidine kinase enzyme converts into a toxic metabolite, killing the tumor cells and creating a pro-inflammatory microenvironment that leads to increased T cell infiltration.

Behind that program is CAN-3110, a replication-competent oncolytic virus licensed from Brigham and Women's Hospital that is in Phase I testing for recurrent high-grade glioma, which expresses a gene that is key for efficacy but has been linked to toxicity under the control of a glioma-specific promoter.

The company's next-gen preclinical platform is based on an HSV vector, and came from its 2019 acquisition of Periphagen Inc.

"It has a large DNA capacity and can carry up to five genes, which allows you to modulate the tumor microenvironment by design," Tak said. "I can't tell you how we will select the constructs, because that's our competitive edge."

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