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Freedom Meditech looking to secure USD 8m Series B round to develop non-invasive diabetes screening device; in process of interviewing investment banks, CEO says - Pharmawire

Freedom Meditech, a San-Diego based non-invasive medical device company, is looking to secure USD 8m in Series B financing to fund continued development of its non-invasive diabetes screening device, said CEO Craig Misrach. The company currently has no financial advisor, but is in the process of interviewing a select few boutique investment banks, he added.

The company recently reached a second tranche close as part of a USD 2m Series A convertible preferred stock financing. It is now looking to secure an USD 8m Series B financing round to fund the cost of bringing the diabetes screening device to market and hiring in-house personnel such as a VP of clinical and regulatory affairs.

Misrach added that Freedom Meditech is evaluating a select few partnership arrangements that ideally would provide complementary R&D capital, near and long term marketing/sales support, and experience in distribution and manufacturing of ophthalmic equipment in the eye care setting.

Freedom Meditech's diabetes screening technology evaluates biomarkers present in the eye to identify undiagnosed diabetes and pre-diabetes candidates. The device is intended to allow for a diabetes screen during a standard comprehensive eye exam. Misrach noted that people in the age group of 35-60 who are at risk for diabetes travel through an eye care setting in extraordinary numbers and thus this channel presents a great opportunity.

Freedom Meditech is waiting for a marketing partner to aid in the decision making for the non-invasive glucose monitoring device, he noted. The company is in talks with potential companies that might be interested, but Misrach declined to comment further or disclose names. Companies in ophthalmic equipment, eye-care services, and diabetes monitoring markets could all find Freedom Meditech of interest, he added.

"I can't tell you [specific names] because we are in a talks with a few and they are confidential per NDAs in place," he noted. However, he said that ophthalmic equipment manufacturers that have a significant presence in the eye-care setting would be potential partners of interest. Retail optometry companies would also benefit from partnering with the company, he added.

When asked if the company is a takeout target, Misrach would not provide a direct comment, but noted that the company's core expertise is engineering, product development, leveraging clinical/regulatory expertise, and then working with potential partners/acquirers to get ophthalmic and diabetes medical device products to market.

"Our goal is to simply commercialize our products, and how we do that, whether through standalone capital, partnership, or acquisition is all based on the organizations we speak with and the metrics of the deal," he said.

The company's diabetes screening device did not require an investigational device exemption as it was deemed safe for human use through a formal non-significant risk determination being designated by an independent Investigational Review Board, Misrach said. Since then, clinical trial data from more than 4,000 people has been collected. Misrach noted that the company is currently planning a meeting with the FDA where efficacy data will be evaluated. The meeting will also help the company gain clarity on whether a de novo 510(k) or PMA regulatory pathway will be required going forward.

Dr Aaron Kowalski, director of strategic research projects of the Juvenile Diabetes Research Fund, expressed excitement about this device and noted that if it works, it would add great value by identifying diabetes in its early stages.

Pharmawire Article.txt

The business model for this device would be based on a small fee on top of the regular eye exam. Misrach noted that Freedom Meditech has conducted preliminary market research which suggested that patients would be willing to pay an extra amount for the diabetes screen. Additionally, the company is also talking to insurance companies that are interested in covering the cost of the test because complications cost billions of dollars annually.

Misrach did not comment on the release of data from clinical trials. He said that once the company receives more information from the FDA and international regulatory agencies, it will make the results public. He added that if the FDA mandates additional clinical trials, it will leverage the support of contract research organizations.

The device has not yet been given a name because Freedom Meditech is waiting for a marketing partner to aid in the decision making process, he added.

by Viral Gandhi