To: Hojvat, Sally A [redacted] Hobson, John (Peyton)
[redacted]
From: Elizabeth Holmes
Sent: Fri 9/6/2013 6:27:12 AM
Importance: Normal
Subject: FW: FDA Informational Meeting Request
Received: Fri 9/6/2013 6:27:00 AM
Theranos - FDA Informational Meeting Request.pdf

Dear Sally and Peyton:

In follow up to our conversation, we filed a formal Informational Meeting Request through the e-copy process, as discussed on our call, to further share within FDA our plans for business operations as we proceed with the filings we've discussed for turning our LDTs into FDA cleared assays.

We included a detailed overview of those business operations plans in the document we submitted; I wanted to email you a copy of what we sent in so that you could see it before we introduce this in the public domain.

We have figured out how to effectively video tape the inside of our devices executing nucleic acid amplification protocols and have been building a secure website to post that on for you to access. We will be sending this to you very shortly. This is of course highly confidential to Theranos and we appreciate your protection of it and access to it.

We have also updated our pre-submission to include both the nucleic acid amplification and immunochemistry influenza assays we discussed and will follow the video link with that pre-submission filing.

Thank you again for your time and guidance, and we look forward to the opportunity to meet with you again soon.

With my best regards,

Elizabeth

Elizabeth Holmes
CEO
Theranos, Inc.

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Attn: Sally Hojvat
U.S. Food and Drug Administration
Center for Devices and Radiological Health Pre-Sub Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

September 5, 2013

Re: Informational Meeting Request

Dear Sally,

In follow up to our conversations, we wanted to formally share our plans with you for the coming months. In accordance with this, we have included a written summary of these plans in the letter in Attachment A and would like to request an Informational Meeting to provide you and the FDA with an in-person informational briefing on these plans. We anticipate that the meeting will take no more than 1 hour. Sunny Balwani, Theranos' COO and President, and I will attend. Our regulatory counsel may attend as well. We are available to meet at your convenience. When we last spoke, you had indicated we could work to coordinate this with a pre-submission meeting, which we will be filing the formal request for shortly, so that they could be conducted around the same time, and suggested late October, which would work for us. We are available to meet at your convenience; October 21, 25, and 28 are three potential dates on which we could meet at a time convenient for you. However, if there is another date that would work better for you, please let us know, and we would be happy to meet then. We would like to reserve a room that has a conference phone and an LCD projector.

Enclosed please find two (2) paper copies of this Informational Meeting request and one (1) eCopy. The eCopy is an exact duplicate of the paper copy.

We look forward to the opportunity to meet with you.

With my best regards,

Elizabeth Holmes
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Attachment A

Dear Sally,

In follow up to our conversations, we wanted to formally share our plans with you for the coming months before making any associated announcements.

As we've had the opportunity to discuss, Theranos would like to be the first lab to convert every LDT it has or brings up into an FDA-cleared assay, as appropriate.

We have very much appreciated your guidance in our meeting last year and on our recent call.

We have been configuring our devices to collect video of the inside of the devices while running to send to you, which you will receive in parallel with this letter, and are following with the pre-submission we discussed for the initial influenza nucleic acid amplification and immunochemistry assays. We request, in advance, that you treat the video and this letter as proprietary and confidential information of Theranos in the event the FDA receives a public records request. Theranos considers the content of the video highly confidential since it reveals trade secrets and other closely guarded information about the inner workings of Theranos' proprietary technology. This letter contains Theranos' confidential future business plans. We look forward to our coming meeting and to working with you to establish a framework for additional filings from there.

In line with our discussions and FDA's guidance in our meeting last year and the minutes that followed, until Theranos receives clearance from FDA, Theranos' devices will only be used in and by Theranos' high complexity CLIA certified lab in Palo Alto, CA.

In accordance with the registration of our devices, we are developing and manufacturing our devices under GMP and in accordance with all the relevant quality controls.

All samples will be physically transported to Theranos' lab to be run through Theranos' Laboratory Developed Tests, or where relevant, on FDA approved analyzers and tests in Theranos' CLIA laboratory.

Theranos' Laboratory Developed Tests and CLIA laboratory are undergoing and will continue to undergo ongoing Proficiency Testing in accordance with our CLIA certifications.

As discussed on our call, we will begin processing micro-samples and traditional phlebotomy draws collected by trained and certified phlebotomists qualified under the appropriate state laws and employed by Theranos in early September of 2013.

The collection of micro-samples will be done in capillary collection tubes and specimen transport containers that Theranos has registered with FDA or, as relevant, that are commercially available, and all samples will be physically couriered to our certified CLIA lab in Palo Alto for processing in that CLIA lab.

All tests will be routinely ordered clinical tests, and all will be physician ordered and directed. All results will be reported back to physicians.

Theranos will be paid for its laboratory tests on a per CPT code basis which it will bill at 50% of Medicare reimbursement thresholds. Theranos will not be selling or distributing any

devices – as per above, Theranos devices will only be used by Theranos' own CLIA laboratory.

For the collection of samples, Theranos will open retail Patient Service Centers, as mentioned on our last call.

Theranos will brand its laboratory's Patient Service Centers or Collection Sites as Theranos Wellness Centers. These Wellness Centers are being built out as dedicated areas inside select retail locations.

Each Patient Service Center is operated and overseen by our CLIA laboratory staff in accordance with CLIA.

Theranos has made significant investments to establish a new standard for convenience, cleanliness, and patient environment in its sample collection sites.

Theranos will open its first Patient Service Center inside a Walgreens pharmacy store, and has procured space inside Walgreens to be able to ultimately introduce its centers inside different stores across the country.

In the month of September, 1-3 locations are planned in Palo Alto in the Bay Area, including one at Theranos' headquarters in Palo Alto.

We look forward to the opportunity to build a long term relationship with the FDA and will continue briefing you on upcoming plans, as relevant and as they develop, and as we work to complete ongoing filings of our tests with you.

With my best regards,

Elizabeth