To: 'Cook, Stephen D MAJ MIL USA USASOC'[stephen.d.cook@us.army.mil]
Cc: Elizabeth Holmes[eholmes@theranos.com]
From: Daniel Edlin
Sent: Thur 1/19/2012 7:28:23 AM
Importance: Normal
Subject: RE: Lab Set (UNCLASSIFIED)
Received: Thur 1/19/2012 7:28:24 AM
Theranos_USASOC Project CONFIDENTIAL - DO NOT CIRCULATE.PDF

Major Cook,

Thank you for the clarification and for outlining your proposal in detail. We understand your request and will provide you with follow up to confirm the testing feasibility and time lines you suggested below. In order that we may fully evaluate your inquiry, if you would, please provide a comprehensive list of all of the assays you plan to test.

Additionally, please see attached an overview of the Theranos - USASOC project and background information on Theranos. Given that the attached file is not encrypted and is highly confidential, we kindly ask that the disclosure and circulation be limited accordingly (military use only).

Thank you and please let us know if you have any questions. We very much look forward to working with you on this project.

Best regards,
Dan

-----Original Message-----
From: Cook, Stephen D MAJ MIL USA USASOC [mailto:stephen.d.cook@us.army.mil]
Sent: Tuesday, January 17, 2012 5:49 AM
To: Daniel Edlin
Cc: Elizabeth Holmes; michael.mcginnis@us.army.mil
Subject: RE: Lab Set (UNCLASSIFIED)

UNCLASSIFIED
Dan,

Actually my verbal requests of last week changed from my written inquiry that you answered below. As you know, we're looking to evaluate your system to determine its utility across the operations and environments in which we'd like to deploy it. In order to do so we'd like to conduct an assessment period after which we'd likely move forward with a 12 month renewable service contract that is more in-line with your current billing system.

In the absence of background materials, I am proposing an evaluation period that looks like this:

3ea devices (GPS disabled) - running up to 400 assays each per month (base deficit, international normalized ratio, hematocrit, hemoglobin, complete blood count, and chem 7) from 01MAR through 31MAY12. The 3ea units will be assessed for performance of core function as well as operation from various mobility platforms (aircraft, ground vehicles, etc) as well as various environmental conditions.

If the above is successful, deliver 7ea additional devices (GPS disabled) - for a total of 10ea devices from 01JUN through 31AUG12. The original 3ea devices will likely continue to run up to 400 assays each per month. The 7ea devices will likely run up to 100 assays per month and be used across the globe to determine deployability.

We would like to accomplish the above with a firm-fixed price contract totalling $75K that includes assays as mentioned (even if less are performed) and shipping costs. We can distribute the funds between the two phases as $18K/$57K - or any ratio that makes sense from a Theranos standpoint.

We'd be looking at 2ea contract CLIN's of "Assessment Period 1" and "Assessment Period 2" (OPTION). Upon conclusion of "Period 1", our service contract representative would likely begin work with you to determine terms of contract to facilitate seamless transition of all 10ea devices upon successful performance of "Period 2". Likely that 8ea devices would be active at any given time with 2ea devices retained as spares to employ as required.

Please provide your input on the above. If you concur, we'd like to discuss in further detail and move to a quote and

contract at the earliest opportunity.

Thank you.

Regards,

Steve

Stephen Cook

MAJ, SF

APM Soldier Systems

(comm.)

"I am not a Contracting Officer, I cannot direct work or initiate or modify contracts; I do not have the authority to commit the Government financially in any way. If the Government desires to alter your requirements as a result of the information obtained from this email discussion, changes will be issued in writing and signed by the appropriate contracting officer."

On 01/16/12, Daniel Edlin wrote:
> Major Cook,
>
> Please note that we are finalizing background materials on Theranos and will send them to you as soon as possible. I wanted to provide you with some other feedback per your questions during our conversation on Thursday. Theranos will in fact be able to provide GPS disabled devices, and we will be able to make modifications for you as well. With regard to the rough order of magnitude that would support a 12-month evaluation period, we kindly ask that you send a total list of assays you would like to test. With this information we will be able to confirm the feasibility of the timeline and magnitude of tests discussed last week.
>
> Thank you, and please indicate if you have any questions or would like to schedule a phone call to discuss further.
>
> Best regards,
> Dan
>
>
>
> -----Original Message-----
> From: Cook, Stephen D MAJ MIL USA USASOC
> [mailto:stephen.d.cook@us.army.mil](javascript:main.compose()
> Sent: Thursday, January 12, 2012 9:12 AM
> To: Daniel Edlin
> Subject: RE: Lab Set (UNCLASSIFIED)
>
> UNCLASSIFIED
> Dan,
>
> Please send your phone number.
>
> Steve
>
> On 01/12/12, Daniel Edlin wrote:
> > Major Cook,

> >
> > Please note we have learned that our emails have not been going through your mail delivery system, and we will try again with our IT department tomorrow. In the meantime, please indicate your availability for a phone call to review in detail the questions and concerns in your email below.
> >
> > Thank you, I look forward to our next conversation.
> >
> > Best regards,
> > Dan
> >
> >
> > -----Original Message-----
> > From: Daniel Edlin
> > Sent: Friday, January 06, 2012 5:36 PM
> > To: 'Cook, Stephen D MAJ MIL USA USASOC'
> > Cc: Elizabeth Holmes; 'michael.mcginnis@us.army.mil'
> > Subject: RE: Lab Set (UNCLASSIFIED)
> >
> > Thank you for your email, Steve. Hope you had a nice holiday. We are currently in the process of putting together feedback and will have it to you shortly.
> >
> > Best regards,
> > Dan
> >
> >
> > -----Original Message-----
> > From: Cook, Stephen D MAJ MIL USA USASOC
> > [mailto:stephen.d.cook@us.army.mil](javascript:main.compose()(javasc
> > ript:main.compose()
> > Sent: Friday, January 06, 2012 6:57 AM
> > To: Elizabeth Holmes
> > Cc: michael.mcginnis@us.army.mil; Daniel Edlin
> > Subject: RE: Lab Set (UNCLASSIFIED)
> >
> > UNCLASSIFIED
> > Elizabeth, Dan,
> >
> > Still waiting for feedback on the below inquiry. Based on your discussions with Kyle, trying to determine if our assessment will be in the form of approximately 3ea devices over a trial 12-month service contract or if you'll have to make mods or we'll have to make purchases to support an evaluation. I know Kyle had concerns with internal GPS tracking and our requirement is to have this disabled in any devices we evaluate.
> >
> > If you have any initial assessments in terms of rough order of magnitude that would support a 12-month evaluation period, please provide that as well.
> >
> > Thank you for any feedback.
> >
> > Regards,
> >
> > Steve
> >
> >
> > On 12/15/11, Elizabeth Holmes wrote:
> > > Thanks Steve. Dan Edlin, copied to this email, is the Theranos Product Manager who will be overseeing this work together. We will follow with feedback in line with your email below.
> > > We very much look forward to our coming conversations.
> > > Elizabeth.
> > >
> > > -----Original Message-----
> > > From: Cook, Stephen D MAJ MIL USA USASOC
> > > [mailto:stephen.d.cook@us.army.mil]
> > > script:main.compose()(javasc

> > > ript:main.compose()
> > > Sent: Thursday, December 15, 2011 5:31 AM
> > > To: Elizabeth Holmes
> > > Cc: michael.mcginnis@us.army.mil
> > > Subject: Lab Set
> > >
> > > Ms. Holmes,
> > >
> > >
> > > My name is Steve Cook, my partner is Mike McGinnis - cc'd above, and the two of us will be working with Kyle Sims through his requirement with you and Theranos. We were wondering if you could forward a summary of the existing technology, your impression of where Kyle Sims would like to take the technology, any challenges from your perspective, as well as your feedback on Kyle's initial comments below as they pertain to your current capabilities and further work/investment required:
> > >
> > > -More extensive environmental testing -Device function on board
> > > evacuation platforms -Communications integration (what is the best method possibly as simple as an iridium phone based on the bandwidth) -IT security considerations -Confidentiality. This system is considered disruptive technology and as such Theranos has serious concerns about the details of their system getting out before they are prepared.
> > >
> > >
> > > Your assessment and summary of the scope of the project as you understand it would be greatly appreciated.
> > >
> > >
> > > We look forward to working with you in the future.
> > >
> > >
> > > Regards,
> > >
> > >
> > > Steve
> > >
> > > Stephen Cook
> > > MAJ, SF
> > > APM Soldier Svstems
> > > (comm.)
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USASOC & Theranos, Inc.

BACKGROUND

Theranos has created a point-of-service laboratory infrastructure that generates real-time data from a finger-stick of blood or other micro-volumes of different sample types delivering higher quality data than previously possible. This technology is an industry first, with profound effects on the ability to triage and stabilize patients via quantitative reads from micro sample sizes in real-time in the field.

- Each Theranos device can run every test currently available through the traditional centralized or hospital laboratory infrastructure.
- Theranos' device can process multiple samples on a given cartridge. Sample types include blood, urine, feces, tissue and saliva, amongst others.
- The device can process individual cartridges, or up to six (6) cartridges simultaneously, with a turnaround time of 5 – 30 minutes on any combination of tests ordered.
- The cartridge can automatically perform follow-up tests when protocol dictates those additional tests are necessary.
- Theranos manufactures all of its technologies and systems within the United States.
- *Theranos has created the first CLIA-certified point-of-service laboratory technology, which is highly efficient in the provision of rapid information with a high level of accuracy for use in critical-need situations.*

DIFFERENTIATION OF TECHNOLOGY

- In today's market, the variability inherent across different "point-of-care" devices is so great that accurate decision making has not been possible; likewise all such point-of-care devices are waived tests which are not accurate enough to be used for clinical decision making under regulatory guidelines.
- Theranos' novel laboratory infrastructure generates data at unprecedented levels of quality and integrity by precisely automating the exact same laboratory processes run (manually) through central laboratories today.
- Devices can transmit data and video via satellite, short and long-wave radio, Ethernet, Wi-Fi, and cellular broadband to allow instant communication of test results to the necessary recipients.

IMPROVED PATIENT OUTCOMES AND MATERIAL COST REDUCTIONS

- Real-time data and decision support at the time of impact or injury
  - The Decision Support application gives real-time results and medical advice and instruction on patient laboratory values and how to stabilize, triage, and treat patients.
  - Upon communication of results, Theranos provides decision support for targeted interventions needed under specific conditions. This system enables doctors to make more informed decisions in complex scenarios and can facilitate the administration of basic care by untrained providers.

- Enabling significant cost savings
  - Theranos estimates fully loaded cost savings of 80% or more to USASOC by eliminating costs attributed to delayed triage and stabilization, prolonged hospital bed time, purchase of equipment and reagents, transportation of patients for testing in the field, laboratory personnel, and additional overhead expenses.

PROJECT SCOPE

- Military applications
  - Medevac: the ability to test and triage wounded soldiers at the time of impact and during evacuation (e.g. in a helicopter), and avoid delayed care due to unavailable medical information while the solider is in transit.
  - Genetic testing: real-time identification from small samples via DNA analysis at the point of service.
  - Telecommunications: device is equipped with software and hardware that enables live communication with offsite medical personnel, allowing the most qualified doctors and surgeons to assist in the stabilization, triage and initiation of treatment at the point-of-service. Theranos field systems' rugged, modular design with integrated communications capability and GPS enable full operability in the field.
  - Role 1-4: brings quick and accurate diagnostic capabilities to the field, performing basic health screenings for minor and severe illnesses (e.g. influenza), and sophisticated testing in real-time for infections, injuries, and more rapid transfusions. In addition, Theranos can collect longitudinal data to assist in infectious disease containment and identification of toxins and other infectious agents on the front-line as well as in more chronic disease management.
- Environmental Testing
  - Theranos hopes to work with USASOC to further develop environmental testing capabilities and looks forward to receiving guidance on any specifications needed to do so.
- IT Security
  - Theranos believes that interoperability with the USASOC system will not be difficult from either a connectivity or data interface standpoint based on feedback from previous interactions with DoD. Theranos will certainly integrate at the discretion of USASOC.
- Confidentiality
  - Given the disruptive and proprietary aspects of Theranos' technology, confidentiality is of the utmost importance. All details and procedures incorporated in this project must be strictly limited to USASOC and Theranos personnel on a need to know basis.

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redefining healthcare

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