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**From:** Susan DiGiaino[/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SDIGIAIMO]  
**Sent:** Mon 11/24/2008 3:15:05 PM (UTC)  
**Subject:** FW: Next Steps/Action Items  
[Next Steps Action Items SD Week of November 23 2008.doc](#)

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**From:** Susan DiGiaino  
**Sent:** Saturday, November 22, 2008 6:12 PM  
**To:** Elizabeth Holmes  
**Subject:** Next Steps/Action Items

Hi there – I have updated our next steps/action items document and will continue to work on it over the weekend. I believe I have included most of the projects we are working on and proposed next steps and follow up.

I believe for all we need to start thinking about our modeling capabilities and how we can customize for a specific compound specifically for example, Cytofab – a compound that is already in Phase II of where we could make a huge impact – also a bigger push looking at research hospitals/institutions this is a completely different business model but can be very lucrative for us.

I hope to meet with you and Marc or at least have a TC on specific strategies for next year and beyond. I have not been to CA since February 2008 and I believe it would be advantageous for me to come out early next year. It would also be good to know what we are all working on going forward.

Also, can you confirm with Kelley my business cards as I still do not have them.

Best Regards,  
Susan

**Susan**

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## Next Steps/Action Items Week of November 23rd, 2008

### Tier I - Key Accounts

1. **PICR – Angiogenesis Validation (VEGF, VEGFR2, PLGF)**
  - Alastair is re-running “sloppy” samples as the CV was high for the Theranos system as per our conversation with Andrew Hughes.
  - Scheduling TC with Caroline in regards to upcoming studies, grant approval process and opportunities for 2009.
  - “live” validation is still ongoing
  
2. **PICR-Apoptosis**
  - Study to be completed by end of December 2008, on target to complete.
  - Schedule TC with Alastair once study is completed to review feedback and discuss future opportunities
  
3. **BMS – GLP-1 Validation**
  - Final revisions of SOW, Terms of Services, and Invoice Document sent to BMS week of November 11<sup>th</sup>, 2008.
  - Andrea to finalize, internal process for signature may take a week.
  - Follow up with Andrea via VM and e-mail on November 20<sup>th</sup> and 21<sup>st</sup> regarding finalizing documents so we can finalize a study start time – ideal 1<sup>st</sup> week of December.
  - Left Paul Rhyne e-mail and VM regarding MB116 project, follow up again week of November 24<sup>th</sup>, draft invoice.
  - Follow up with Donna on Phase IV, Pharmacovigilance contacts.
  
4. **Novartis- ACZ885 Pediatric Validation Study**
  - Study ongoing
  - Phase III follow on study to start early next year – adding more sites and Italy site to add an additional 100 patients
  - Working with Stefan to compile data we already have to present to John Varaklis and Emmanuele –send out week of November 24<sup>th</sup>
  - Follow up with sites and feedback on technology has been positive thus far
  
5. **Novartis-Reclast**
  - Trial has been delayed until end of 2<sup>nd</sup> quarter 2009.
  - Next meeting planned for 1<sup>st</sup> week of December.
  - Christina having meeting with the cardiovascular team
  - Schedule larger presentation and draft SOW to present to Christine prior to meeting in December.

**6. Pfizer**

- Elizabeth following up with Dr. Aidan Power
- Susan following up with Dr. Scott Fountain – Senior Director Translational Science Pfizer – located in CA

**7. Centocor**

- Contract signed and assay development has been initiated

**8. Eli-Lilly Protein C Validation**

- Need more data to move discussions forward specifically wanting 510 (k) approval on sepsis cartridge, already have contract with Biosite
- There is a need for a POC system as stated by their head of clinical research
- Potential to work with key medical institution that works with Lilly as a way to showcase our systems

**9. AstraZeneca – CytoFab**

- Awaiting Phase II results from latest study, should come in by end of this year.
- Scheduling meeting for late January with key decision makers for the Cytofab team including Dr. Paul Newell.
- Interested in data from the Recentin as well as apoptosis studies.

**10. AstraZeneca – AZD2171**

- Study is ongoing – enrollment is slow but we expect to enroll enough patients (6) by end of year to provide the data Andrew Hughes is looking for.
- Schedule follow up meeting with Dr. DeBono – investigator for study and well known though leader in oncology about additional studies/opportunities, new cost structure – target early 2009
- Scheduling larger meeting for end of January discussing our modeling capabilities around Recentin, make sure to include Glen Clack and Nick Botwood – Medical Director for Recentin..

**11. AstraZeneca – Respiratory/Inflammation**

- Left VM and e-mail for Harsukh in regards to upcoming study in China 500-600 subjects, Asthma/COPD markers, drafting SOW
- Sent on November 20<sup>th</sup> potential assays of interest discussed with Seth, looked at a similar disease map
- Elizabeth to send additional information around modeling
- Scheduling meeting early in January 2009 to discuss our modeling capabilities

- Following up with Harsukh on initial evaluation “in-house” on non-GLP samples to be performed early next year.

#### **12. AstraZeneca – Obesity/Diabetes**

- Scheduling TC with Dr. Bjorn Carlsson for week of December 8<sup>th</sup>, 2008 to discuss a path forward

#### **13. GSK Metabolic-Follow up Study for AXOR**

- Corresponded with Becky on current AXOR study, they will have data by early February and will then make a decision on next steps, they are still working on the protocol for the follow on study and once the synopsis is complete she will send.

#### **14. GSK Oncology – UK/US**

- Elizabeth to follow up directly with Walter in regards to our modeling capabilities
- Walter works with Pazopanib – design program around
- Discuss potential evaluation at GSK
- Susan following up with Dr. Richard Wooster – Senior Director, biomarker development, cancer metabolism in Collegeville – works for VP Dr. Barbara Weber

#### **15. Celgene**

- Elizabeth finalizing agreement with Randall
- Left VM and sent e-mail to Garret Hampton – head of biomarker group in San Diego- interested in meeting in 1<sup>st</sup> quarter of 2009 – Pharmacodynamics key area

#### **16. Eisai**

- Interested in a PAR assay – timelines needed – study start September 2009
- Evaluation with current apoptosis panel and potential inflammatory panel to be performed at MD Anderson January/February 2009 – will need to amend protocol/IRB approval
- Elizabeth to confirm budget and timeframe
- Andrew to contact Susan week of November 24<sup>th</sup> about upper managements comments and feedback on his suggested project
- Cartridge would be used in combination with other PD assays most probably apoptosis and/or inflammation in future studies
- Development would need to start ASAP

#### **17. Mayo Clinic**

- Evaluation of the Therasys System performed in the endocrinology and metabolism unit by Dr. Vella (key investigator for Daiichi-Sankyo he also worked with Suku)
  - i. GLP-1 Active and c-peptide analyzed
    - 1. 1 patient – 6 time-points,
      - a. 7:30am (2 samples run in duplicate) Result: 2.0pM, 2.1pM
      - b. 8:00am: 1.8pM
      - c. 8:30am: .7pM
      - d. 9:00am: (GLP-1 infused) .2pM
      - e. 9:30am: 113
      - f. 10:00am: 103
- Results need to be confirmed and compiled by Stefan including Raw data and sent to Dr. Vella – will send to Susan first
- Dr. Vella was impressed with the results and was what he wanted to see and more based on the wide dynamic range and sensitivity of the assay
- Interested in performing study and publishing data on GLP-1 total and active starting February 2009
- Preparing Invoice for 2600 cartridges and 6 readers over 2 weeks
  - i. Send to Jeanette Larson – study lead nurse, will send to administration for review with Terms of services document
- Development of GLP-1 total assay – upcoming Daiichi-Sankyo study will involve this analyte- need to recoup costs here – Dr. Vella stated that if all goes well in his study he will publish data and share with others at the Mayo Clinic, technology has potential to replace current assay systems.
- Dr. Vella is on his honeymoon for 3 weeks returning 2<sup>nd</sup> week in December, will discuss Daiichi-Sankyo study then – doesn't have specifics he needs to speak to Suku, will start end of 1<sup>st</sup> quarter next year

#### 18. Daiichi-Sankyo Metabolism/Sepsis

- Working with Dr. Vella to identify specifics around upcoming study – 1<sup>st</sup> Quarter 2009
- Call Suku to discuss development costs around GLP-1 total
- Follow up with Abdel week of November 24<sup>th</sup>
- Confirm if we have supplied them the information they have requested as far as technical information from vendors

#### 19. Sanofi-Aventis

- Elizabeth to review Apidra proposal and send to Susan week ending November 28<sup>th</sup>
- Schedule TC with Michelle and Dr. Noah Rosenberg to discuss potential project – December 2008
  - i. Identify key thought leader of whom he regards as the best in his field
- Susan scheduling TC with Dr. Andre DeGenio as well as head of oncology programs Dr. Nabbibou

## **Tier II Accounts**

### **1. Novartis Oncology**

- Working with Michael Shi- head of biomarker oncology group to identify project, interested in angiogenesis and apoptosis markers – how to get into his heads ASAP
- Left VM and e-mail to RAD001 lead to identify potential synergies – prepare proposal around modeling for RAD001 and provide to John Hohneker as well as Dr. Rashan Hasad.

### **2. Novartis – Institute for Biomedical Sciences – Cambridge, MA**

- Scheduling meeting Humphrey – head of biomarker group oncology for 1<sup>st</sup> week of December – goal is to schedule an initial evaluation – they pay for cartridge/reader costs.

### **3. Millennium**

- Send to Hadi Apoptosis comparison data (Theranos vs. ELISA ) week of November 24<sup>th</sup> – Elizabeth to review data from Ian
- Schedule follow up TC with Hadi in December 2008 to discuss a path forward and project specifics
- Susan to identify with Julie other teams within different areas as well as those additional individuals in our meeting to have follow up calls with

### **4. BMS – Antibody development/Phase IV Ixebepilone/Dasatinib**

- Elizabeth finalizing agreement with Andrea

### **5. UCB Pharma Inflammation**

- Re-organization has occurred, Richard to contact me beginning of January 2009 to discuss potential synergies.

### **6. Amgen-Inflammation**

- Elizabeth following up with Scott Patterson – Medical Sciences Director and head of their biomarker initiative

### **7. Merck/Serono - Bone**

- Elizabeth following up to move project forward or identify other opportunities.

### **8. Merck/Serono – Fertility**

- Elizabeth following up.

## **Tier III Accounts**

## **9. Wyeth**

- Call scheduled for week of December 1st with Dr. Ole Vesterquist – VP translational medicine, biomarker development
- Key oncology research director, Dr. Allen Lee in Cambridge, contact to set up meeting, left VM Friday, November 21<sup>st</sup>, 2008.

## **10. Solvay Pharmaceuticals**

- Interest from John Brennan head of clinical development, met with back in the Summer of 2007, Medical Director for obesity is also interested in meeting
- Interested in metabolic, neuroscience, experience with vaccines (titer levels, influenza vaccine) as well as hormone replacement men and women
- Scheduling meeting for early to mid January 2009.

## **11. Schering-Plough**

- Elizabeth connecting with Jim Mcleod and moving specific project forward

Interest and follow up from the following companies:

Gilead Sciences  
BayerHealthcare  
Takeda  
Schering-AG  
Genzyme  
HGSI  
Medimmune