

Message

**From:** Danise Yam [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=DYAM]  
**Sent:** 4/29/2009 6:23:59 PM  
**To:** Carolyn Balkenhol [/o=theranos organization/ou=first administrative group/cn=recipients/cn=cbalkenhol]  
**Subject:** RE: Need an invoice for Schering-Plough

Danise Yam  
Corporate Controller  
Theranos, Inc  
3200 Hillview Ave  
Palo Alto, CA 94304

Tel:  
Fax:

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**From:** Carolyn Balkenhol  
**Sent:** Wednesday, April 29, 2009 10:57 AM  
**To:** Danise Yam  
**Subject:** Need an invoice for Schering-Plough

The PDF is what they currently have (and which has been approved already). I think we need to send an updated version with corrected dates, which I have attached. The invoice date is still 4/15 (which is what was sent to S-P and approved at that point). I have only modified the expiration of the terms and the start date.

Please prepare an invoice and send back to me.

Thanks,  
Carolyn

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**From:** Elizabeth Holmes  
**Sent:** Wednesday, April 29, 2009 10:51 AM  
**To:** Carolyn Balkenhol  
**Subject:** FW: Follow up

Elizabeth Holmes  
President and Chief Executive Officer  
Theranos, Inc.

Tel:  
Fax:

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Theranos, Inc., 3200 Hillview Avenue, Palo Alto, CA, 94304  
650-838-9292 www.theranos.com

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**From:** Elizabeth Holmes  
**Sent:** Wednesday, April 15, 2009 1:22 PM  
**To:** james.mcleod@spcorp.com; Cullen, Constance  
**Subject:** Follow up

Dear Jim,

In follow up to our discussions with Connie, we have cemented a comprehensive validation program on one of our multiplexed cytokine panels. I have attached the invoice and program overview to this email. This invoice should work in lieu of a contract as this analysis will be done at Theranos and the scope is restricted to validation.

We did of course work through the validation program with Connie in great detail. We will present the results of the validation by your visit in May. We can then use that visit to discuss the data and the best ways to create value in ongoing programs given the ability to collect higher integrity data, faster.

Talk to you soon,  
Elizabeth.

Elizabeth Holmes  
President and CEO  
Theranos, Inc.

Tel:  
Fax:

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650-838-9292 www.theranos.com



Theranos, Inc  
 3200 Hillview Avenue  
 Palo Alto, California 94304  
 Tel: (650) 838-9292  
 Fax: (650) 838-9165

Invoice #	SP09001
Invoice date	April 29, 2009

Purchase Order #	
Agreement Date	

Bill To: Schering-Plough Research Institute  
 1011 Morris Avenue  
 Mail Location U-13-3000  
 Union, New Jersey 07083

Attn: Jim McLeod  
 Early Clinical Research and Experimental Medicine

Quantity	Description	Rate	Amount
	Data delivery, client infrastructure and 24x7 customer care support		included
	Distribution, trial definition/project management, services configuration/software customization (TheranOS), analytics, and Schering-Plough-specific secure back-end database and server infrastructure		included
	Set up and infrastructure, Real-time and multiplexed analysis - 2,790 multiplexed cartridges (CRP, IL-6, TNF-α) at \$100 per cartridge (\$33 per analyte including time, technicians, readers, and other materials)	(Laboratory discount pricing)	\$279,000
	Use of Theranos Systems is governed by Theranos Terms of Service, attached to this invoice.		
<b>PAYMENT DUE UPON RECEIPT. Late payments shall incur interest at the rate of 1.5% per month until paid in full. All such interest shall be due and payable on demand.</b>		Subtotal	\$279,000
		Sales Tax	0.00
		Total	\$279,000
		Prepayment	0.00
		Balance Due	\$279,000

**Wire Transfer Instruction**

Bank: Comerica Bank, 226 Airport Parkway, Suite 100 San Jose, CA 95110  
 Swift code: \_\_\_\_\_ Routing Number: \_\_\_\_\_ Account Number: \_\_\_\_\_

All costs described herein are in U.S. currency. Payments made to THERANOS will be made in U.S. currency.

**These payment terms expire May 1, 2009, if this agreement is not executed in full by that date.**



**KEY PROJECT OBJECTIVE**

Comprehensive validation of the Theranos cytokine panel under FDA/ICH guidelines, according to attached Full Validation Protocol. Project 'success' criteria include analysis of blinded samples provided by Schering-Plough.

**PROJECT PARAMETERS**

Project	Schering-Plough - 001
Cartridge Analytes	Multiplexed Cartridge: CRP, IL-6, TNF- $\alpha$
Sample Types	Archived Samples – Plasma, whole blood
Sites (Number) – Location	(1) – Theranos
Number of Blinded Samples for Validation	30 (minimum 5mL per blinded sample)
Number of Cartridges	2,790
Number of Readers	10
Localization/Languages for Translation	None (English Only)
Touch Screen Interface Questions/Customization	None
Data Infrastructure	Configure a secure Schering-Plough-specific data infrastructure
Expected Start Date	May 1, 2009
Expected End Date	TBD
Total Duration of Services	TBD (the "Term")

## Theranos<sup>TM</sup> System Full Validation Protocol: (hs)CRP, IL-6, TNF-a multiplex

### **References/Background**

- ICH Q2 (R1) "Validation of Analytical Procedures"
- FDA CDER "Bioanalytical Method Validation"
- Binodh DeSilva et al. Recommendations for the Bioanalytical Method Validation of Ligand-binding Assays to Support Pharmacokinetic Assessments of Macromolecules. *J. Pharmaceutical Research*, Vol. 20:1885-1900 (2003)
- Previous programs for development of diagnostic systems undergoing regulatory approval

### **Generally recommended parameters for investigation**

1. Calibration Curve
2. Accuracy
3. Precision
4. Specificity
5. Quantitation limit
6. Linearity
7. Range
8. Stability

### **Reference methods**

Proposed reference method for each assay --TNF-alpha, IL-6 and CRP (both high and low sensitivity) -- is R&D Systems kits. Performance specifications are included in the Cartridge Inserts in each Cartridge box.

### **Proposed analysis**

Detailed analysis protocols will be sent prior to evaluation initiation.

The calibration curve (1) can be assessed using 8 points (one blank, one zero spike and 6 spikes at levels, including LOQ's) in triplicate on each instrument. This can be done over three days (not necessarily consecutive) to generate data on reliability.

For accuracy (2), precision (3), and specificity (4), we recommend using 10 instruments and 120 cartridges per instrument. 20 cartridges will be run at each of the LLOQ, medium range and ULOQ levels for each sample type (plasma & whole blood). This will yield a strong dataset for statistical analysis of accuracy, precision and specificity.

For quantitation limit (5) verification, one can run 6 levels of spiked plasma around the stated limits of quantitation. We propose testing three levels above and three below the LLOQ and ULOQ, respectively, in triplicate on each instrument.

For linearity (6), we recommend using plasma and spiked analytes and testing 5 levels in triplicate on each instrument.

For range (7), we recommend testing 6 points around the claimed LLOQ and ULOQ to gauge response at the boundaries of the assay(s). This will also be done in triplicate on all instruments.

For stability (8), we test under 2-8°C conditions, for time points 0, 1, 2, and 3 months and run tests in triplicate at each of the LLOQ, mid-range and ULOQ levels of the assay(s). We recommend using plasma for these experiments as it can be stored for the duration of testing.

**NOTE:** The aforementioned numbers assume statistical significance for three analytes as each cartridge is multiplexed. The processing requirement is for each sample tested to contain a mix of all three analytes to be measured, in known quantities. Such samples may include archived clinical samples, spiked samples, or may be purchased. Each cartridge requires ~20uL of sample.

**Summary of runs per instrument to achieve statistical significance**

Calibration Curve	Accuracy/Precision					
	In plasma			In whole blood		
In plasma	At Mid-range	At LLOQ	At ULOQ	At Mid-range	At LLOQ	At ULOQ
8 point calibration						
72	20	20	20	20	20	20

  

Linearity	Range around Limits		Stability (3months)		
	In plasma		In plasma		
In plasma	at LLOQ	at ULOQ	At Mid-range	At LLOQ	At ULOQ
15	18	18	12	12	12

**Estimated schedule**

Standard Theranos instrument run-time will be accelerated for this program. Total number of cartridges provided will be 2,790 of the TNF-alpha, IL-6, CRP multiplex. Up to 10 additional instruments will be shipped. The total expected runtime (not including sample load, reference testing and the stability duration) is around 1 month. The total human capital commitment will only be 5 days over the entire program duration as it only takes up to 10 minutes to prepare and load a sample on a single instrument, after which the instruments run on their own.



## ThERANOS, INC. TERMS OF SERVICE

This agreement is entered into by and between Theranos, Inc. ("ThERANOS") and Schering-Plough ("COMPANY"), effective as of date of execution.

1. **ThERANOS SYSTEM.** THE "ThERANOS SYSTEM" is the system comprising the T.OS, Reader(s), Cartridges, Assays (each as defined in this Article 1) and any other components developed by or for ThERANOS facilitating the operation of any of the foregoing, alone or in any combination. As used in this Invoice: (a) "Assay" means any method used for the detection of an analyte (e.g. a biomarker) or multiplexed set of analytes and/or measuring their concentration in a matrix, including, without limitation, human blood (b) "Cartridge" means ThERANOS' analytical chips containing biological fluid processing technology and assays to measure, among other matters, the concentration of specific analytes, including biomarkers in a biological fluid sample; (c) "Reader" means ThERANOS' device capable of running Cartridges, extracting data from a Cartridge or other analytical device, transmitting data to a database hosted by ThERANOS, communicating with authorized parties and providing analytical information; and (d) "T.OS" means ThERANOS proprietary ambulatory bioinformatics communication system, database, analytical engine, algorithms and methodologies, and related statistical and other analysis methods, data repositories and technologies.

### 2. **SERVICES**

2.1. In purchasing the Systems and Services, COMPANY agrees to these Terms of Service.

### 3. **PAYMENT TERMS**

3.1. Payment is due upon receipt of this Invoice.

3.2. The agreement and payment terms herein expire May 1, 2009 if not executed in full by that date.

3.3. **Late Payments.** Late payments shall incur interest at the rate of 1.5% per month until paid in full. All such interest shall be due and payable on demand.

3.4. **Expense Disbursements and Pass-through Costs.** ThERANOS charges for third-party expense disbursements and other costs incurred in connection with the performance of the Services. These costs include, but are not limited to, ThERANOS personnel travel and lodging (including travel to all IMs or IM sites and services related activities), shipping, telecommunications, data transmission, printing, additional touch-screen customizations, any incidental expenses, and the associated administrative fees incurred to provide or in support of the Services outlined in this Invoice.

### 4. **ACCESS TO SOFTWARE AND USE OF THE T.OS**

4.1. ThERANOS hereby grants to COMPANY a non-exclusive, non-transferable, non-sub licensable license to use, in accordance with, and solely for the purposes specified in, this Invoiced and only for the term of the Project: (a) Software installed on Readers, for use by COMPANY employees and COMPANY contractors who are obligated in writing by confidentiality obligation at least as protective of ThERANOS and its Confidential Information as this Invoice ("COMPANY Contractors") and (b) Software related to the T.OS which may be accessed through the Readers or at a designated website or IP address, disc, programs or other designated location ("Client Accessible Software"). "Software" means computer programs, object code and related materials, in machine readable or printed form, including any updates or upgrades thereto.

4.2. ThERANOS and its licensors shall at all times retain sole and exclusive ownership of all Software and, as between the parties, all Software is Confidential Information of ThERANOS. COMPANY shall use commercially reasonable efforts to prevent unauthorized access to, or use of, the Software, and notify ThERANOS promptly of any such unauthorized use. COMPANY shall not: (a) allow access to the Client Accessible Software by more than the number of concurrent users indicated in the Invoice, (b) disassemble, decompile or otherwise reverse engineer the Software, (c) modify, copy, sell, rent, transfer, reproduce or distribute the Software, except as specifically provided in the Invoice, (d) use the Software



to provide processing services to third parties or otherwise use the Software on a "service bureau" basis, or (e) create Internet "links" to or from the Software, or "frame" or "mirror" any of COMPANY's content which forms part of the Software. COMPANY shall at all times comply with terms and conditions applicable to third party software provided with the Software. THERANOS reserves all rights in the Software not expressly granted herein.

**5. THERANOS PROPERTY**

5.1. As between COMPANY and THERANOS, all Inventions and improvements developed in connection with or as a result of the Services, during the term of this Invoice and thereafter, whether by COMPANY or THERANOS, or by the parties jointly, directed to: (a) any part or the whole of the THERANOS System or any improvements thereto, including, without limitation, the T.OS analytical engine and the algorithms therein; or (b) the generation of assay (s) used in conjunction with the THERANOS System, shall be the sole and exclusive property of THERANOS. COMPANY shall promptly disclose to THERANOS in writing any Inventions described in the preceding sentence, and COMPANY hereby assigns to THERANOS any right, title or interest it may have in such Inventions.

**6. INDEMNIFICATION**

COMPANY will indemnify and hold harmless THERANOS and its respective employees, officers, directors, independent contractors, stockholders and agents against and from any third party claim arising out of or in connection with: (a) the conduct of a Project or the use of the results of a Project; (b) COMPANY's breach of this Invoice, negligence or intentional misconduct; or (c) the development, manufacture, use, sale, offer for sale, marketing or testing of any product or service by or under the authority of COMPANY (including any personal injury or property damage related thereto). COMPANY shall be promptly notified of any such claim and THERANOS shall cooperate with COMPANY in the defense of such claim.

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives as of this day and year.

**THERANOS, INC.**

**SCHERING-PLOUGH ("COMPANY")**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

**Please sign and date two (2) originals and send both to THERANOS for signature via traceable mail (e.g., UPS or FedEx). One executed original will be returned to COMPANY.**