

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 8-K**

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 28, 2007

**OraSure Technologies, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-16537**  
(Commission  
File Number)

**36-4370966**  
(I.R.S. Employer  
Identification No.)

**220 East First Street**  
**Bethlehem, Pennsylvania**  
(Address of Principal Executive Offices)

**18015-1360**  
(Zip Code)

Registrant's telephone number, including area code: 610-882-1820

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01 – Regulation FD Disclosure.**

On November 28, 2007, OraSure Technologies, Inc. (the “Company”) will host an Analyst Day meeting in New York, New York, at the NASDAQ MarketSite at Times Square. At the meeting the Company’s senior executive team will make presentations to analysts using slides containing the information attached to this Current Report on Form 8-K as Exhibit 99.1. The fact that these presentation materials are being furnished should not be deemed an admission as to the materiality of any information contained therein. The information contained in the slides is summary information that is intended to be considered in the context of the Company’s Securities and Exchange Commission filings and other public announcements that the Company has made or may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report.

This information shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 – Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Slide show presentation to be used by OraSure Technologies, Inc. on November 28, 2007

**Signatures**

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

Date: November 28, 2007

By: /s/ Jack E. Jerrett  
Jack E. Jerrett  
Senior Vice President, General Counsel  
and Secretary

**Exhibit Index**

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<u>Exhibit Number</u>	<u>Description</u>
99.1	Slide show presentation to be used by OraSure Technologies, Inc. on November 28, 2007



OraQuick *ADVANCE*® Histofreezer® OraSure® Intercept®

# OraSure Technologies, Inc.

***NASDAQ ANALYST DAY  
November 28, 2007***



# Forward-Looking Statements

These slides and the associated presentation contain certain forward-looking statements, including statements with respect to revenues, earnings, technology, new products, product performance, markets, regulatory filings and approvals, and business plans. Factors affecting these statements include, but are not limited to, the ability to develop new technology, technology changes, ability to fund research and development, required regulatory approvals, product performance and market acceptance of products. Please see the Company's SEC filings, including its registration statements, and the Company's most recent Form 10-K and Form 10-Q, for a more detailed description of specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements. The Company undertakes no duty to update these statements.



# AGENDA

## **Analyst Day**

**Wednesday, November 28, 2007**

11:30 – 11:35 am	Introduction – Doug Michels, President & CEO
11:35 – 12:30 pm	Stephen R. Lee, Ph.D. – EVP & Chief Science Officer
12:30 – 12:45 pm	Lunch
12:45 – 1:30 pm	Sue Sutton-Jones – SVP of Regulatory Affairs & Quality Assurance
1:30 – 2:00 pm	Joseph E. Zack – EVP, Marketing and Sales
2:00 – 2:15 pm	Break
2:15 – 2:45 pm	P. Michael Formica – EVP Operations
2:45 – 3:00 pm	Wrap-up



# **Research & Development Overview**

**Stephen R. Lee Ph.D.**

**Chief Science Officer**



## In Process Research & Development

- Develop and commercialize OraQuick® HCV
- Develop oral fluid substance abuse test (SAT) applications for high throughput laboratory systems
- Extend the shelf life of OraQuick® ADVANCE™ HIV Test
- Clinical and Regulatory Studies for OraQuick® HIV OTC
- Label expansion of OTC cryosurgery indications



# Hepatitis C Virus Infection Statistics (United States)

- New infections per year                      30,000 – 40,000
- Persons infected (1.6%)                      4.1 million
- Chronic infection                              3.2 million
- More than half of HCV cases are currently undiagnosed
- Persons with HIV co-infection              ~225,000
- Growing healthcare burden
  - 50% of chronically infected individuals develop progressive liver disease
  - HCV infection is the leading cause of all liver transplants
  - 10,000 deaths/year attributable to complications of HCV infection

**Sources: Armstrong GL et al. (2006) Ann. Intern. Med. 144:705-714  
Scott JD & Gretch DR (2007) JAMA 297:724-732**



## Risk Factors Associated With Acquiring Hepatitis C Virus

- ◆ Past or present injection drug use
- ◆ Transfusion, transplant from infectious donor
- ◆ Infected sex partner(s)
- ◆ Birth to an infected mother
- ◆ Occupational blood exposure (needle sticks)
- ◆ Tattooing/body piercing
- ◆ Renal dialysis



## Rationale for the Utility of a Rapid, Point-of-Care (POC) Test to Aid in Identification of HCV Infection

- Clear unmet need for increased diagnosis of Hepatitis C as recognized by many Public Health entities including CDC.
- Deployment of a rapid POC test will enable increased testing for HCV, particularly in accessing those populations at greatest risk.
- HCV testing in many public health settings is limited due to the requirement to draw blood for laboratory based testing.
- As with HIV, POC testing for HCV will be particularly applicable in settings where the target population is transient, or where return adherence for results is low.
- Current and future improvements in therapy mean that increased diagnosis will be a critical factor in reducing overall morbidity and mortality.



# A Simple Test Procedure Utilizing All Sample Types

## COLLECT

## TEST

Oral Fluid



Venipuncture Whole Blood



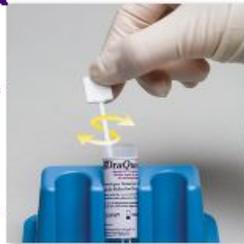
Plasma & Serum



Fingerstick Whole Blood



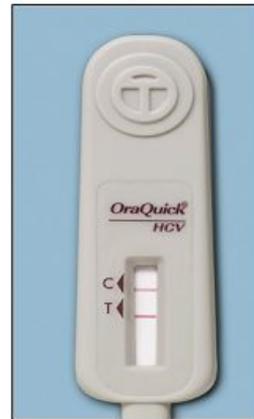
MIX





# Prototype OraQuick<sup>®</sup> HCV Test- Interpretation

- **Non-reactive:** Single line appears at the C (control) triangle
  - A negative result indicates the absence of target antibodies in the sample.
  
- **Reactive for anti-HCV:**
  - **Two lines appear**
    - One at the C (control) triangle and the other at the T (test) triangle
    - Indicates the presence of target antibodies in the sample.





## Sensitivity of the Prototype OraQuick<sup>®</sup> HCV Test in Known Infected Individuals

<b>Specimen Type</b>	<b>N*</b>	<b>No. Reactive by OraQuick<sup>®</sup></b>	<b>Sensitivity (%)</b>
Chronic HCV Infection	47	47	100%
Intra-venous Drug Users	93	93	100%
HCV (RIBA) Positive Plasma Donors	466	466	100%
HIV/HCV Coinfected Patients	33	33	100%



# Comparison of HCV Seroconversion Sensitivity of OraQuick<sup>®</sup> HCV Prototype with EIA

Number of Panels Tested	Number Giving Concordant Results	Number Detected Earlier by HCV 3.0 EIA	Number Detected Earlier by OraQuick <sup>®</sup>	Average Time To Detection by HCV EIA (Days)	Average Time To Detection by HCV OraQuick <sup>®</sup> (Days)	Differential Sensitivity (Avg. Days Detected Earlier by OraQuick <sup>®</sup> )
22	12	0	10	50.7	47.5	3.2 (1.4 to 5.1)*



## Sensitivity in Known HCV Positive Subjects Tested Using Oral Fluid and Whole Blood

No. of HCV Positive Subjects	No. Detected by HCV EIA	No. Detected by OraQuick® HCV (Whole Blood)	No. Detected by OraQuick® HCV (Oral Fluid)
92	92 (100%)	92 (100%)	92 (100%)



Preliminary Performance Data from the OraQuick® HCV Prototype in Oral Fluid Samples Paired with Blood, Plasma & Serum: Low Risk Individuals (n=419)

		HCV ELISA	
		+	-
Prototype OraQuick® HCV Assay	+	3 <sup>a</sup>	1 <sup>b</sup>
	-	0	415

a: RIBA 3.0 positive  
b: RIBA 3.0 indeterminate

**Specificity= 99.8% (95% CIs: 98.7-100%)**

**Subjects gave concordant results when tested with all 5 specimen types (serum, plasma, FS blood, VB, oral fluid)**



# HCV Prototype: Additional Study Findings

- Verified use of multiple anti-coagulants (EDTA, citrate, heparin): No interference noted
- Tested with worldwide genotype panel: Detected all major genotypes and subtypes
- Tested specimens with potential interfering serology (HAV, HBV, HIV, HTLV, HSV, Syphilis, Toxoplasmosis, CMV etc): No cross-reactivity



# OraQuick<sup>®</sup> Rapid HCV Test Timeline

- ❖ Preclinical development completed and prototype design complete
- ❖ Technology transfer complete and prototype produced at scale in manufacturing facility
- ❖ Clinical study protocols complete and study sites selected
  - Planned trials support CLIA waiver and submission for CE mark
- ❖ Clinical studies expected to start end of this year and continue through Q1 '08
- ❖ US regulatory filings are targeted for middle of next year



## Rationale for Developing High Throughput Automated Assays with Oral Fluid

- Market adoption of oral fluid testing is increasing
- Microplate systems are more labor intensive than current fully automated systems
- Microplate systems do not perform random access testing, but test in “batch” mode
- Medium and large sized reference labs all use automated systems for urine testing
- Offering oral fluid applications on fully automated systems will combine the convenience of an oral fluid sample with the increased efficiencies of full automation



# Roche-OraSure Collaboration Combining Proven Expertise

## OraSure Value

- Oral fluid market leader
- Extensive device development expertise
- Assay/ Applications experience with oral fluid
- Ref. Lab partner network

## Roche Value

- Leadership in DOA testing market
- Extensive assay development expertise
- Automated systems experience
- Large scale manufacturing capabilities



# The Intended Result for Both Organizations

- Generation of world class oral fluid assays
- Faster time to market by combining expertise
- Maintain leadership positions in the WW DOA testing market
- Maintain differentiation from competition
- Ongoing collaboration in collection devices and assays – menu expansion



# High Throughput SAT Assays- Initial Launch Menu

- Cocaine
- Opiates
- THC (Marijuana)
- Amphetamines/Methamphetamines
- Phencyclidine (PCP)

**Required panel of drugs to be tested according to guidelines from National Institute of Drug Abuse**



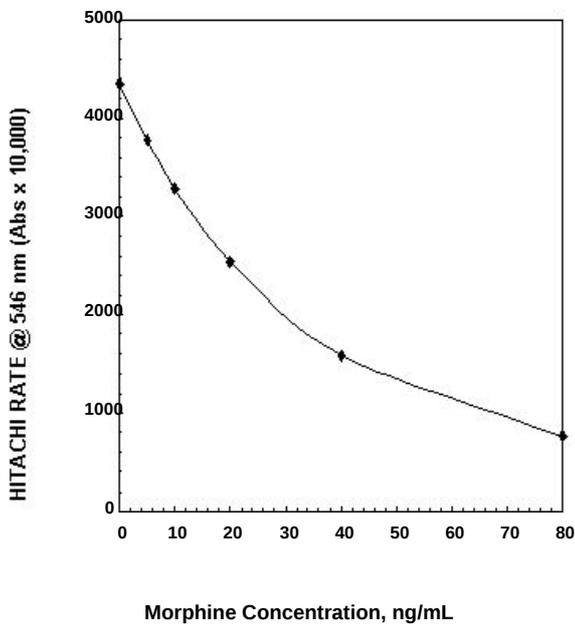
# Progress with High-Throughput Oral Fluid Assays

- Prototype tests for most of the assays designated for the initial launch menu have been developed
- Initial performance shows good clinical correlation with existing confirmatory algorithms and excellent precision
- Performance data on these prototypes was presented at the 2007 Society for Forensic Toxicologists (SOFT) meeting



# Dose Response Curve and Cutoff for High Throughput Oral Fluid Opiate Assay

## Opiates Assay Calibration Curve on Roche/Hitachi 917



## Oral Fluid Cutoff Concentrations

Cutoff	Dynamic Range	LDL
ng/mL	ng/mL	ng/mL
10	0-80	0.5

\*Oral fluid cutoff concentrations are for sample diluted by diluent in the Intercept® Oral Specimen Collection Device.

LDL, or analytical sensitivity, is defined as the lowest drug concentration that can be distinguished from zero calibrator with 95% confidence (2SD) and determined by running 21 replicates of 0 calibrator and calculating the mean and standard deviation (S.D.) of 21 results.

**Source:** Hoch D et al. Society of Forensic Toxicologists 2007



# Accuracy of the High Throughput Opiate Assay

## Specificity in low prevalence population:

		OTI EIA Assay (10 ng/mL)	
		+	-
Opiates Assay (10 ng/mL)	+	0	0
	-	0	200

A total of 200 individual clinical samples from a low risk population that screened negative with the OraSure Technologies, Inc ( OTI ) Micro-Plate assays ere tested in the semi-quantitative mode with Opiates automated assay.

## Sensitivity in high prevalence population:

		LC/MS/MS (10 ng/mL)	
		+	-
Opiate assay (10 ng/mL)	+	115	35*
	-	2	331

Sensitivity =  $115 / (115 + 2) = 98.3\%$

Specificity =  $331 / (331 + 35) = 90.4\%$

\*Of the 35 false positive results, 16 (46%) had total opiates greater than 10 ng/mL. (any combination).



# Precision of the High Throughput Opiate Assay

## Opiate Assay Within Run Precision, n=21

Levels tested (ng/mL)	Within Run Mean (ng/mL)	Precision (% CV)	Recovery (%)
5.0	5.3	3.4	107
7.5	7.7	2.6	103
10.0	10.3	2.3	103
12.5	12.6	1.5	101
40.0	41.0	1.5	102

**Source:** Hoch D et al. Society of Forensic Toxicologists 2007



# Dose Response Curve and Cutoff for High Throughput Oral Fluid Amphetamines and Methamphetamines Assay

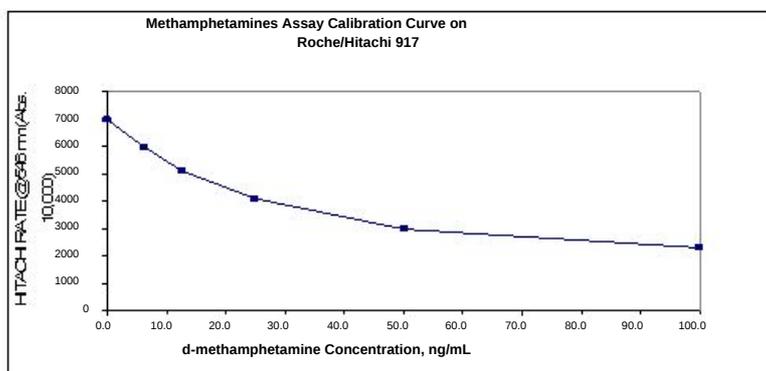
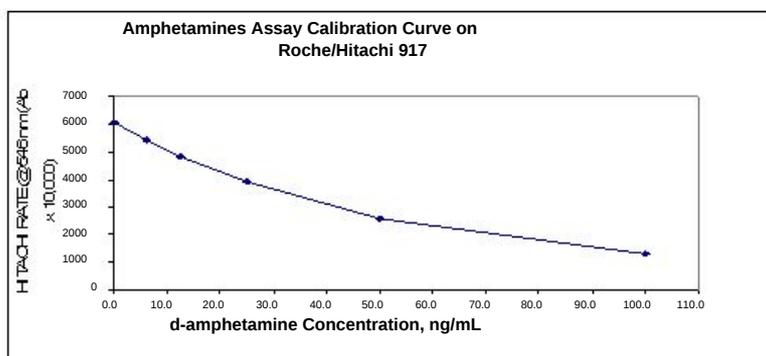
## Oral Fluid Cutoff Concentrations

	AMP ng/mL	Methamp ng/mL
Cutoff	40	40
Dynamic Range	0-100	0-100
LDL	0.6	1.0

\*Oral fluid cutoff concentrations are for sample diluted by diluent in the Intercept® Oral Specimen Collection Device.

LDL, or analytical sensitivity, is defined as the lowest drug concentration that can be distinguished from zero calibrator with 95% confidence (2SD) and determined by running 21 replicates of 0 calibrator and calculating the mean and standard deviation (S.D.) of 21 results.

## Calibration Curves



Source: Mountain L, et al. Society of Forensic Toxicologists 2007



# Precision of Amphetamines and Methamphetamines Assay

## Amphetamines Assay Within Run Precision, n=21

Levels tested (ng/mL)	Within Run Mean (ng/mL)	Precision (% CV)	Recovery (%)
12.5	12.9	2.8	104
30.0	30.1	1.7	100
40.0	40.9	1.3	102
50.0	52.2	1.3	104

## Methamphetamines Assay Within Run Precision, n=21

Levels tested (ng/mL)	Within Run Mean (ng/mL)	Precision (% CV)	Recovery (%)
12.5	12.7	3.2	101
30.0	30.2	1.8	101
40.0	41.4	1.3	104
50.0	53.9	3.7	108

**Source:** Mountain L, et al. Society of Forensic Toxicologists 2007



# Specificity of Amphetamines and Methamphetamines Assay

A total of 200 individual clinical samples from a low risk population that screened negative with the OraSure Technologies, Inc ( OTI ) Micro-Plate assays were tested in the semi-quantitative mode with Amphetamines and Methamphetamines automated assays.

		OTI EIA AMP Assay (100 ng/mL)				OTI EIA Methamp Assay (40 ng/mL)	
		+	-			+	-
AMP Assay (40 ng/mL)	+	0	1	Methamp Assay (40 ng/mL)	+	0	0
	-	0	199		-	0	200

**Source:** Mountain L, et al. Society of Forensic Toxicologists 2007



# Sensitivity of Amphetamines and Methamphetamines Assay

A total of 49 clinical samples from a drug prevalent population were tested in the semi-quantitative mode with the automated Amphetamine and Methamphetamine/MDMA assays. All samples were also tested for the presence of d-amphetamine, d-methamphetamine, MDA, MDMA, and MDEA with LC/MS/MS. The LC/MS/MS result is considered positive if any of these drugs are present at concentrations  $\geq$  40 ng/mL.

		LC/MS/MS (40 ng/mL)				LC/MS/MS (40 ng/mL)	
		+	-			+	-
AMP assay (40 ng/mL)	+	31	0	Methamp assay (40 ng/mL)	+	49	0
	-	18*	0		-	0	0

\*The 18 samples that gave negative results on the amphetamines assay had concentrations of methamphetamine  $\geq$  40 ng/mL.

**Source:** Mountain L, et al. Society of Forensic Toxicologists 2007



# Dose Response and Cutoff for High Throughput Oral Fluid Cocaine Assay

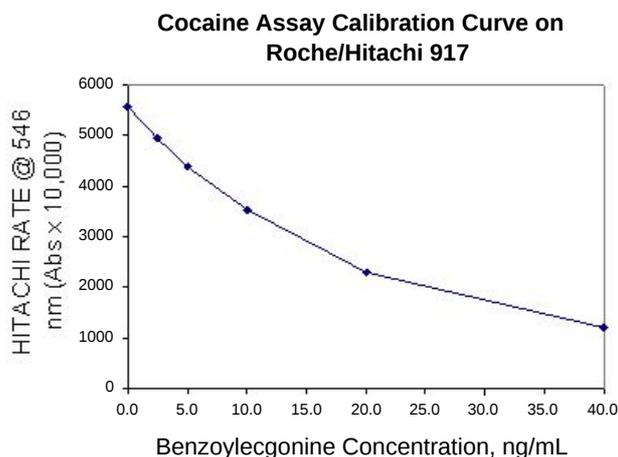
## Oral Fluid Cutoff Concentrations

Cutoff	Dynamic Range	LDL
ng/mL	ng/mL	ng/mL
3	0-40	03

\*Oral fluid cutoff concentrations are for sample diluted by diluent in the Intercept® Oral Specimen Collection Device.

LDL, or analytical sensitivity, is defined as the lowest drug concentration that can be distinguished from zero calibrator with 95% confidence (2SD) and determined by running 21 replicates of 0 calibrator and calculating the mean and standard deviation (S.D.) of 21 results.

## Calibration Curves



**Source:** Zhao J., et al. Society of Forensic Toxicologists 2007



# Precision of the Cocaine Assay

## Cocaine Assay Within Run Precision, n=21

Levels tested (ng/mL)	Within Run Mean (ng/mL)	Precision (% CV)	Recovery (%)
2.25	2.5	2.6	112
3	3.2	2.8	105
3.75	3.9	2.9	103
5	5.0	2.1	100
6.25	6.2	1.8	99
30	30.6	1.0	102

**Source:** Zhao J., et al. Society of Forensic Toxicologists 2007



# Accuracy of the Cocaine High Throughput Assay

•A total of 560 clinical sample pools from a drug prevalent population were tested in the semi-quantitative mode with the automated cocaine assay. All samples were also tested for the presence of benzoylecgonine with LC/MS/MS.

		LC/MS/MS (2 ng/mL)	
		+	-
Cocaine assay (3 ng/mL)	+	377	4*
	-	2**	177

$$\text{Sensitivity} = 377 / (377 + 2) = 99.5\%$$

$$\text{Specificity} = 177 / (177 + 4) = 97.8\%$$

\* 2 of the 4 discrepant samples that had tested positive on the automated assay contained trace amounts of benzoylecgonine.

\*\* The 2 false negatives gave values of 1.41 and 2.56 ng/mL on the automated assay.

**Source:** Zhao J., et al. Society of Forensic Toxicologists 2007



# High-Throughput Oral Fluid Assays High level Milestones

- Conduct alpha studies with prototype assays at customer sites
- Complete feasibility and finalize design
- Develop calibrators and controls
- Conduct technology transfer
- Complete 510K testing
- Inventory build and launch



# OraQuick<sup>®</sup> HIV Shelf Life Improvement - Current Status

- Product modifications to support longer shelf life have already been implemented and verified
- Proposed modifications do not require additional clinical trials
- Currently conducting real-time validation/stability studies using GMP material
- These studies utilize 3 production lots containing all proposed modifications
- Real-time stability testing to continue throughout the year
  - Just successfully passed 6 month time point
- Target for shelf life is >12 months (dependent upon generating real time stability data)



# Strategy for Shelf Life Extension

- Shelf life extension will occur in unregulated markets upon successful completion of stability testing and process validation
- Shelf life in US and EU will be extended after approval of the appropriate regulatory submissions.
- Additional submissions will be made in certain geographies where required
- Our goal is to extend product shelf life in all geographies in 2008



# Questions and Answers



# **Regulatory Affairs/ Quality Assurance/ Clinical Trials Overview**

**Sue Sutton-Jones**

**SVP, RA/QA**



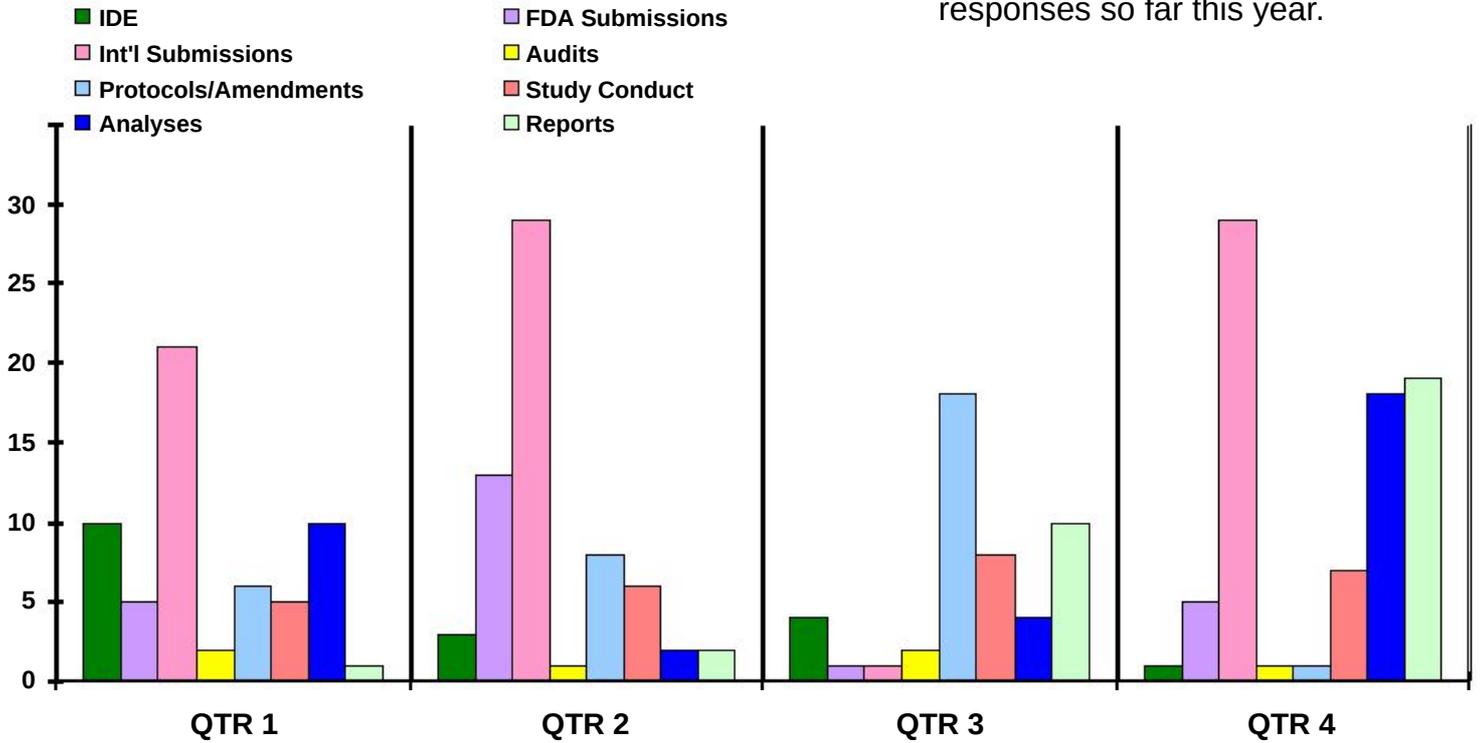
# Key Role in Bringing Products to Market

- RA/CA/QA play a role in the product lifecycle from conception through to obsolescence of the product.
  - Strategy
  - Negotiation
  - Organization
  - Subject Matter Experts
  - Archivists
  - Business Partners
  - Looked on by many regulators as the “conscience of a Company”, our credibility is the credibility of the Company



# RA/QA/CA Submission Activities 2007

Over 200 submissions and responses so far this year.





# Some of Our International Activities

## ❖ CE Mark Achieved for OraQuick

## ❖ Dossiers/Documentation

- Individual EU countries
- Argentina
- Brazil
- Ecuador
- Guatemala
- Israel
- Russia
- Vietnam
- Thailand
- South Korea
- China
- Mexico
- Philippines
- Indonesia
- UAE
- Validations in multiple African Countries



# **OraQuick® *ADVANCE* HIV-1/2 Antibody Test** **OVER-THE-COUNTER APPLICATION**



# Regulatory Update for HIV OTC

## □ Panel track submission

- ❖ Premarket approval is required (PMA)
- ❖ The PMA will be reviewed by the Center for Biologic Evaluation and Research (CBER). We expect the PMA will also be presented to an FDA advisory panel for review and comment.



# Clinical Study Considerations

- In designing the proposed program, OraSure gave special consideration to a number of topics:
  - All protocols must be able to demonstrate that the product meets the criteria defined at the March 10, 2006 BPAC meeting;
  - The population expected to use the OTC product;
  - Creation of easy to read and understand instructions for use;
  - User friendly packaging and presentation of the product;
- **3 Phased Approach to Clinical Studies**
  - **Label Comprehension and Reading Contrived Devices**
    - Where the subject does not self test
  - **Observed Use**
    - Subject observed performing the test.
  - **Unobserved Use**
    - Subject performs tests in uncontrolled environment



# Label Comprehension

## Label Comprehension Study

### ✓ Status - completed

- Performed after refining labeling and instructions through pre-testing
- Tests target population understanding of the instruction materials
- Subjects do not conduct a test with an actual device



# Reading Contrived Devices

- ◆ The purpose of the study is to demonstrate that individuals from the target population are able to accurately interpret various test result.
- ◆ In this study, subjects selected from the target population are given contrived devices to read and interpret the results
- ◆ The subjects in this study do not test themselves and the devices used are “dummy” devices that are not infectious.



## Observed Use

- The subjects will be selected according to the demographics of the end users identified for this product.
- Subjects will be given the test kit and provided with a setting in which to take the test on their own.
- Subjects will be observed ( through glass) while performing the test and their test result will be compared to the result from a trained professional.
- This study is observed so that the actual use of the test kit by a “consumer” can be documented prior to allowing subjects to take the kit in a setting of their choice.
- Subjects will be interviewed about their experience with the test after they have completed running and interpreting their own test.



## Unobserved Use

- Subjects will be screened per the protocol and a sample taken to determine their HIV status.
- Subjects will be given the test kit and asked to take the test and report back to the clinical study site within a week. (Subjects will provide contact information prior to being given a test kit to leave the clinical site so that we may conduct follow up.)
- Subjects will report their HIV test results, which will be compared to the professional determination of their status.
- Questions about their experience performing the test will be asked during an interview conducted when they return with their result.



## Referral to Care and Resource Answer Center

- ❖ For the referral and resource program we will at minimum include the key points of the CDC Guidelines for HIV Counseling.
- ❖ For the observed and unobserved phases, the counseling system will have functional capabilities intended for launch.
  - ✓ 1-800# number access.
  - ✓ According to standard CDC recommended guidelines.
  - ✓ Call agents, methods, as intended launch.
  - ✓ Will not be operating on full intended commercial scale.



# OTC Milestones

<b>Task</b>	<b>Status</b>
<b>Robust Comprehension</b>	Complete
<b>Reading Contrived Devices</b>	Complete
<b>Observed User Study</b>	Protocol written and to be submitted to FDA by end Q4 2007 Study to be executed in 2008
<b>Unobserved User Study</b>	Protocol written and to be submitted to FDA by end Q1 2008 Study to be executed in 2008
<b>Referral to Care and Resource Answer System</b>	Complete
<b>FDA Submission</b>	2008



# OraQuick<sup>®</sup> HCV Test

→ Clinical Study Update



# HCV Regulatory Update

- Submission reviewed by Center for Devices and Radiological Health (CDRH)
  
- PMA for a rapid test for HCV
  
- 180 day review time estimated
  
- Clinical trials are straightforward and uncomplicated.



# HCV Rapid Test Human Subject Clinical Trial

## ➤ Population

- Thousands of subjects with signs and symptoms of Hepatitis, or at high HCV infection risk
- Hundreds of asymptomatic subjects

## ➤ Inclusion / exclusion criteria

- Either gender, ≥ 2 yrs of age, informed consent
- No subjects <2 yrs, therapy for HCV infection

## ➤ Test via comparator methods

- (FDA approved EIA, RIBA)



# CLIA Waiver Trial

- ❖ Trial to establish appropriate device characteristics for CLIA-waiver
- ❖ Minimum of 3 U.S. centers
- ❖ (consistent with point-of-care testing)
- ❖ Patients consistent with expected use
- ❖ Test via comparator method (FDA approved EIA, RIBA) blinded from operator
- ❖ OraQuick<sup>®</sup> testing by operator



# Studies Required for FDA Approval of the HCV Rapid Test

<b>Task</b>	<b>Status</b>
<i>Feasibility</i>	Complete
<i>Seroconversion</i>	Complete
<i>Unrelated medical conditions</i>	Complete
<i>Genotypes</i>	Complete
<i>Food and Beverage</i>	Complete
<i>Interfering substances</i>	Complete
<i>Anticoagulants</i>	Complete
<i>Clinical performance in human subjects</i>	Q4 2007 to begin
<i>FDA, CLIA, CE Mark Submissions</i>	2008



# **2007 Cryosurgical Device Clinical Study**



## Cryosurgical Clinical / Regulatory Efforts

- Clinical Study to expand the claims for an over the counter cryosurgical system were begun in Q3.
- The last subject will exit the study the end of this month.
- We are targeting to submit the 510k in Q1 2008.
- This will increase our offerings for an over the counter cryosurgical product to three applications.



# Questions and Answers



# **Sales & Marketing Overview**

**Joseph E. Zack**

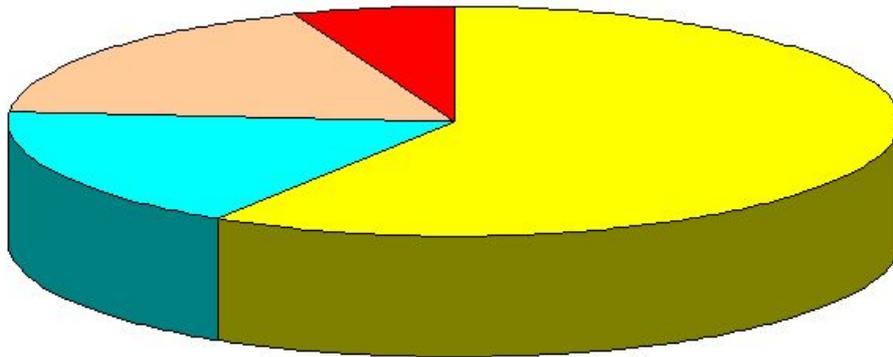
**EVP – Sales & Marketing**



# U.S. Market Potential: HIV Tests \*

17 Million Potential Tests for OraQuick®

## Diverse Customer Base Potential



■ Hospitals

■ Public Health

■ MD Offices

■ Government Programs

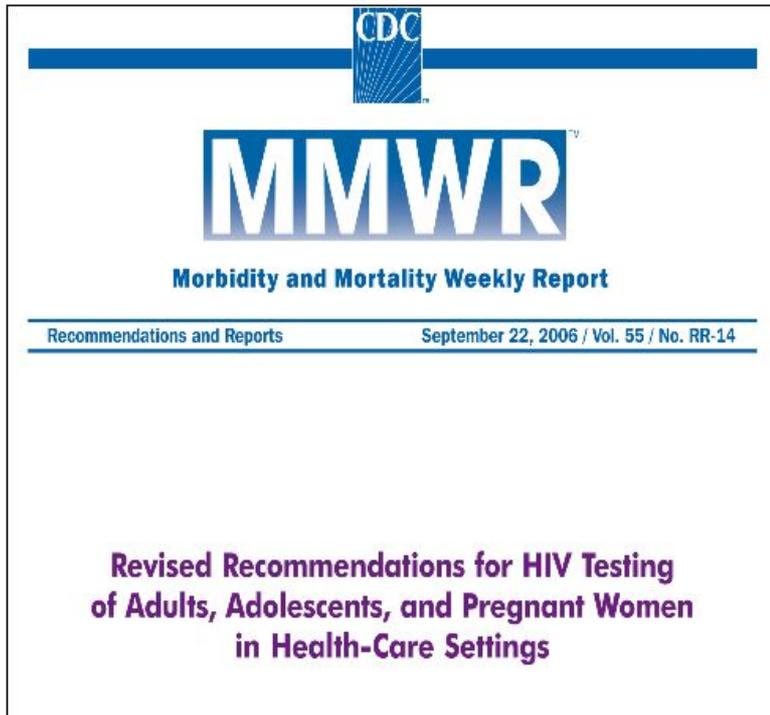
\* Excludes OTC market and impact of CDC guideline changes and new program announcement.

Source: Company Estimates based on Industry Reports.



# CDC Revised Recommendations

## Background Rationale for Revision



- Advocate Routine Voluntary HIV screening 13-64 yrs
- De-stigmatize HIV testing process
- Emphasize cost effectiveness of testing in all ranges of prevalence
- Promote opt-out testing models
- Increase diagnosis of HIV
- Decrease time for testing procedure
- Known positives reduce unsafe practices
- Bottom line....early detection reduces transmission



## CDC Initiative

### CDC Opportunity

- CDC redirected \$45 million in funding to expand HIV testing
- Program goal is to test 1.0 million persons for HIV
- 23 jurisdictions awarded approximately \$35 million
- Individual grant size: \$600K - \$6MM
- Program will be for 3 years



# Grant Recipients

## The 23 Jurisdictions

California

Chicago

Connecticut

District of Columbia

Florida

Georgia

Houston

LA County

Louisiana

Maryland

Massachusetts

Michigan

Missouri

New Jersey

New York City

New York State

North Carolina

Ohio

Pennsylvania

Philadelphia

South Carolina

Tennessee

Virginia



## CDC Initiative Status

- ❖ Working with each of the jurisdictions closely
- ❖ Tracking implementation
- ❖ Bulk of Revenues expected in 2008



# Demand for Prevention in U.S.

## Prevention initiatives within U.S. Hospitals

- 20% of pregnant women don't know their status
- Vertical transmission accounts for 100% of all pediatric infections – 98% could have been prevented<sup>1</sup>
- 1 million needle stick injuries annually; 16,000 result in HIV exposure<sup>2</sup>
- More than 55% of patients tested in the ER are discharged prior to receiving their HIV test results<sup>3</sup>
- Only 10% of patients referred out to hospital clinics from ER Departments actually undergo testing<sup>4</sup>
- Conversely, when rapid testing was performed, 99.3% of patients received their results; 80% of them entered into care.

1. Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women, MMWR, Vol. 50/No. RR-19, November 9, 2001.

2. American Nurses Association, Needlestick Injury, <http://www.nursingworld.org>, 2002.

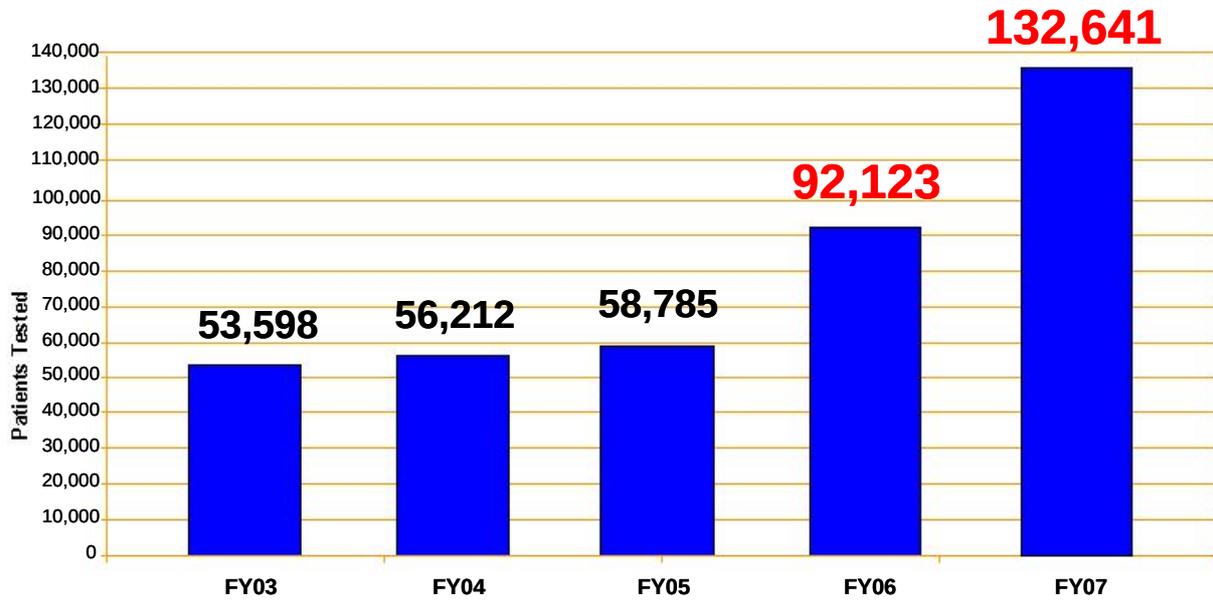
3. CDC, 2002.

4. *Only 10% of Patients Referred Out to Hospital Clinics from ER Departments Actually Undergo Testing*, Dr. Roger Lewis, Harbor UCLA Medical Center, Reuters Health, 2001.



# HIV Testing Expansion Initiative New York City Health and Hospitals Corp Impact on HIV Prevention

## Continued Increase in HIV Testing



CDC, Dr. Bernie Branson  
PACHA Meeting, October 15-16, 2007  
FY03 - FY05 Outpatient Only  
FY06-07 Outpatient, Inpatient and ED

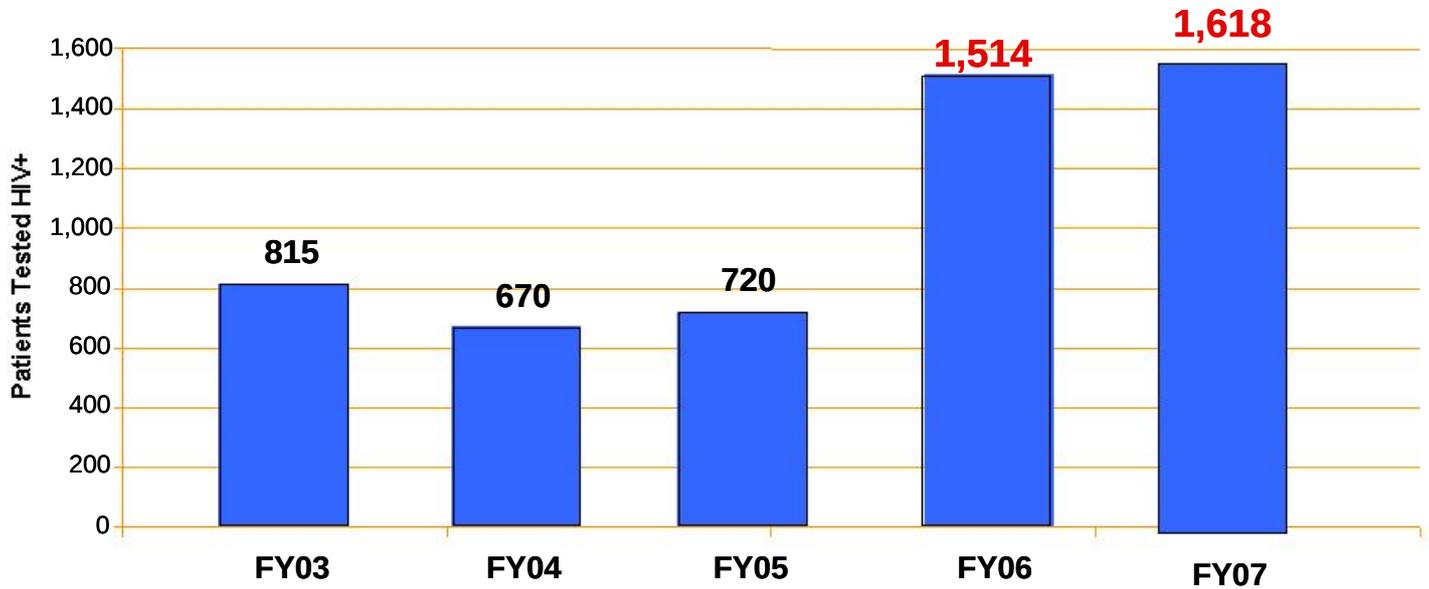


# HIV Testing Expansion Initiative

## New York City Health and Hospitals Corp

### Impact on HIV Prevention

Number of HIV-Positive Persons Identified More than Doubled



CDC, Dr. Bernie Branson  
PACHA Meeting, October 15-16, 2007  
FY03 - FY04 Outpatient Only  
FY05 Outpatient and ED Pilot Sites Only  
FY06-07 Outpatient, Inpatient and ED



OraQuick<sup>®</sup> *ADVANCE*<sup>™</sup>

## Impact on HIV Prevention

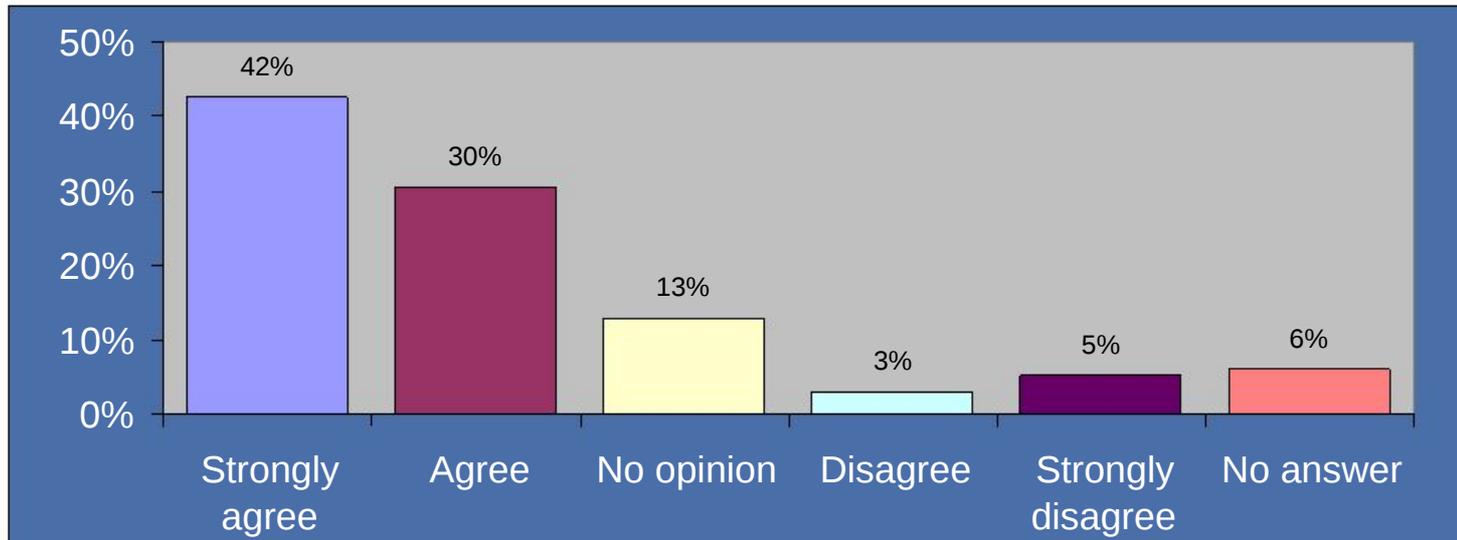
### Cook County Hospital

- OraQuick testing in the ED (2002)
  - 62% accept HIV testing
  - 98% receive test results
  - 3,802 patients screened
  - 93 (2.4%) new HIV positive
  - 80% entered HIV care
- Test Performance
  - Sensitivity 100%
  - Specificity 99.94%
- 42% of patients tested had never been screened for HIV
- 42% of positive patients had no risk factors that would prompt their physician to screen them for HIV
- 34% identified as MSM
- 10% identified as IDU
- 3% identified as having a partner who was an IDU



# What do patients think? Impact on HIV Prevention

“The ER is a good place to perform HIV testing”



- Preliminary data, 680 pts - GWU Hospital ED

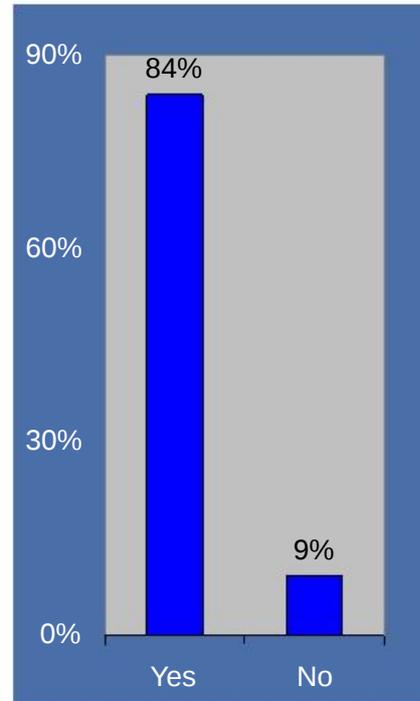


# What do patients think? Impact on HIV Prevention

Would you  
recommend to a friend  
to get an HIV test if  
they went to the ER?

- Preliminary data, 680  
pts

*GWU Hospital ED*





# Social Marketing Program

## City Initiatives

### Objective

- ➔ Collaborate with local constituencies to ensure residents know their HIV status
  - Washington DC
  - Philadelphia

**COMING TOGETHER TO**





## DC – Results to Date\*

- **DC Data\***
- At the end of 2006, HAA (HIV/AIDS Administration) saw a 75% percent increase in overall HIV screening in the District, yielding a 3.5% positivity rate.
- As of September 30, 2006, more than 16,700 residents tested with 580 preliminary positive results (approx. 3.47% rate).
- Over 550 persons trained to offer HIV screening in public health and hospital settings.
- In 2005, HAA averaged approximately 27,000 HIV tests per year, since then they have increased testing to approximately 96,000 tests per year

\*Come Together DC – Get Screened for HIV Progress Report. Obtained from CDC Application for grant opportunity CDC-PS07-768



# Philadelphia

## City-wide rapid HIV testing initiative

- State Senator Hughes, PA Secretary Johnson, PHL Commissioner Paris, AACO Director Cella

## \$1.5 million state grant

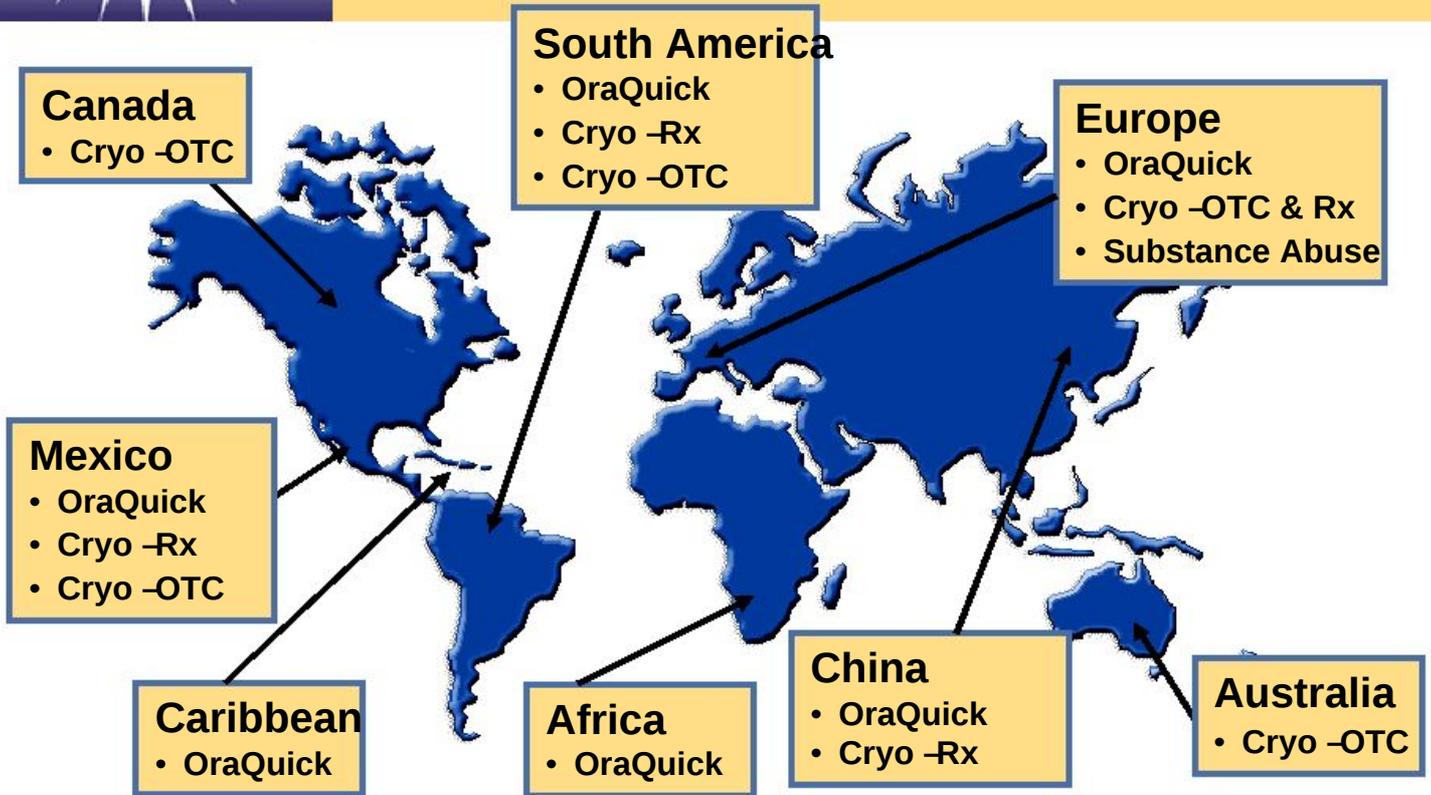
- Largest amount awarded to HIV/AIDS program in State history

Focus on traditionally underserved populations

Support recently released CDC guidelines



# Global Expansion





# Questions and Answers



# **Operations Overview**

**P. Michael Formica**

**EVP - Operations**



# Bethlehem Buildings

Tech III Headquarters  
(48,000 ft<sup>2</sup>)



(Acquired in 2006)

North Building (32,000 ft<sup>2</sup>)



(Acquired in 1997)

South Building (37,000 ft<sup>2</sup>)



(Acquired in 2006)

**Total: 117,000 ft<sup>2</sup>**



# Space Allocation

**Total** 117,000 sq ft

❖ Manufacturing	50,500 sq ft
❖ Clean Rooms	15,500 sq ft
❖ Warehouse	11,000 sq ft
❖ Office Space	40,000 sq ft



# Facility/Capacity Long Range Plan

## ❖ Joint Analysis with Facility Planning Consultants

- 2008 – 2011
- Facilities and Infrastructure Analysis
- Production Line/ Production Process Capacity Analysis
- Review of Off-Shore Manufacturing Strategy



# OraQuick Capacity Plan

- Based on Multiple Production Lines
  - Semi-Automated Assembly Lines
  - Automation Assembly Lines
- Off-Shore Production Capacity



# Tech III Building (48,000 sq ft)

- Ⓜ Corporate Headquarters
- Ⓜ Finance & Accounting
- Ⓜ Operations Department
- Ⓜ Oral Fluid Collection Manufacturing
- Ⓜ Assay Formulations
- Ⓜ OraQuick Assembly
- Ⓜ Control Warehouse (Shipping & Receiving)





## North Building (32,000 sq ft)



- Assay Formulations
- Assay Assembly
- OraQuick Device Assembly
- QC Laboratory
- Vial Filling
- QED
- Micro-plate Coating/ Pouching



## South Building (37,000 sq ft)



- ◆ Sales & Marketing
- ◆ Research & Development Laboratory
- ◆ Research & Development Staff
- ◆ Regulatory & Quality Assurance & Clinical Trials
- ◆ IT/ MIS Staff

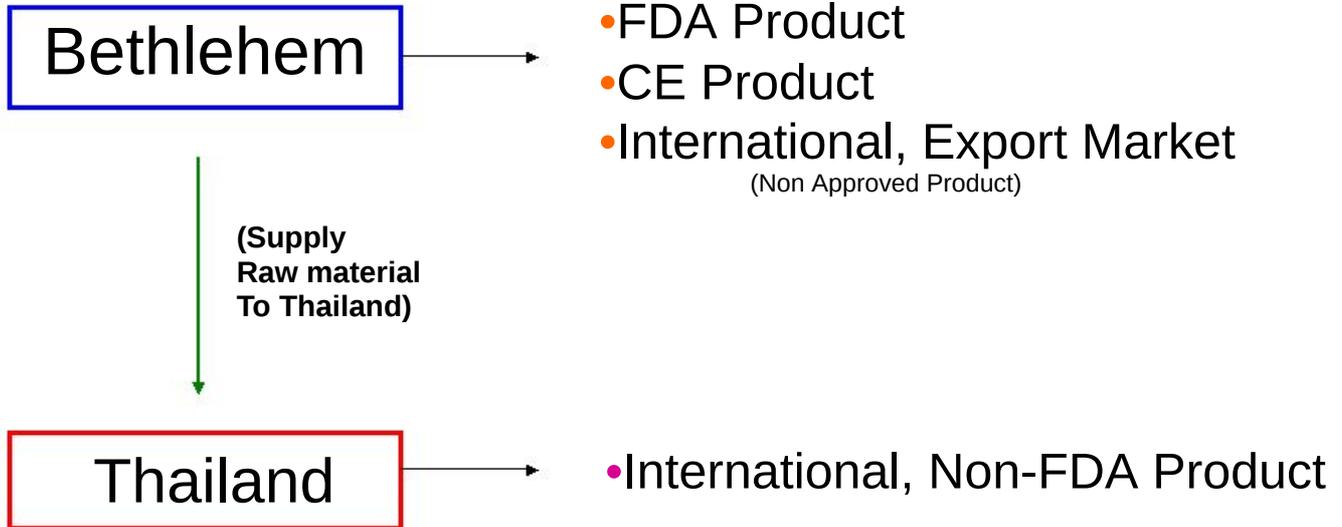


# Aerial View of Tech III Campus





# OraQuick International Supply Chain





# SAP Installation Update

## ❖ **Modules Installed:**

- ✓ FICO – Finance & Controlling
- ✓ MM – Materials Management
- ✓ PP – Production Planning
- ✓ QM – Quality Management
- ✓ SD – Sales & Distribution
- ✓ WM – Warehouse Management

## ❖ **Present Focus**

- Utilize System Capabilities to Improve Processes



# Summary

- ❖ Facility Planning Driven by Strategic Analysis
- ❖ Facilities & Infrastructure in place for growth
- ❖ Facilities Expansion Possible if Needed



# Questions and Answers



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# OraSure Technologies, Inc.

Thank You