Can Theranos Disrupt the Clinical Lab Testing Market: An Objective Look at Advantages, Liabilities and Challenges that must be addressed

Robert Boorstein, MD, PhD
Founder and Director
ClasGroup
1) Understand the opportunities that Theranos sees in the clinical laboratory market.
2) Understand the advantages that Theranos claims will support its ability to take advantage of these opportunities.
3) Critically access the ability of Theranos to achieve stated goals. Why Theranos
Pretest

1. With regard to my knowledge of the Theranos business model, I consider myself
   A. Very familiar
   B. Somewhat familiar
   C. Slightly familiar
   D. Not at all familiar

2. I view the threat of Theranos to my business to be
   A. Very significant
   B. Somewhat significant
   C. Slightly significant
   D. I do not view Theranos as a threat.
Theranos claims to revolutionize the industry

Promotion versus reality
theranos
the blood tests that need just a tiny sample.

Walgreens partners with Theranos to provide lab services

Theranos is working to shape the future of lab testing. Now, for the first time, their high-complexity CLIA-certified laboratory can perform your tests quickly and accurately using tiny samples.¹

Learn more at Theranos.com
Para información en español haga clic aquí
Theranos makes broad highly publicized claims

- Faster
- Less Intrusive—uses fingerstick samples
- Widely available through partnership with Walgreens
- Cheaper (and transparently so) with insurance coverage or self pay.
- Uses revolutionary technology
One tiny drop will change the world.

Theranos gives you precise results in a matter of hours, equipping you with actionable information when you need it. We can help you make fast diagnoses, start triage and treatment quickly, and help you help your patients with the confidence of knowing.
A new kind of patient care.

With Theranos, you can offer your patients advanced, cutting-edge healthcare. From a friendlier blood draw, to fast results, to convenient lab options, you can now give your patients the kind of care you want to provide.
We're committed to making lab testing more accessible to everyone. That means pricing our tests at dramatically low rates. We can accept major insurance carriers as well as Medicare and Medicaid. And if you’re uninsured, we offer you the same discounted prices we offer everyone else. Because a test should cost the same, no matter who you are.
A few drops is all it takes.

Theranos' patented technology can analyze samples as small as 1/1,000 the size of the typical blood draw. Our tests are certified in our CLIA laboratory and cover a full range from blood, urine, and other samples. It’s fast, easy, and the highest level of quality.

Fast results. Fast answers.

Our proprietary infrastructure allows us to perform our test analyses with unprecedented speed. So we can have results to you and your doctor in a matter of hours, not days. Which means a fast diagnosis to support better, more informed treatment.

High levels of precision.

By systematically controlling and standardizing our micro-processes, we offer tests with high levels of precision. We’ve also automated our pre- and post-analytic processes, minimizing human processing — the cause of the majority of lab-test errors.
Theranos claims have received massive attention in multiple media sectors.

- Traditional print
- Digital media
- IT/Silicon Valley Media outlets
- Financial Press
- Clinical Laboratory Trade Publications
Elizabeth Holmes: The Breakthrough of Instant Diagnosis

A Stanford dropout is bidding to make tests more accurate, less painful—and at a fraction...
Creative Disruption? She’s 29 and Set to Reboot Lab Medicine

Elizabeth Holmes plans to revolutionize testing by using tiny blood draws and offering near-instantaneous results.

Eric J. Topol, MD, Elizabeth Holmes | Disclosures
November 18, 2013

Cover Story

Theranos: The biggest biotech you’ve never heard of

Firm sees stealth as a competitive advantage while it works to bring a revolutionary medical device to market

SUBSCRIBER CONTENT: Aug 30, 2013, 3:00am PDT

THIS WOMAN INVENTED A WAY TO RUN 30 LAB TESTS ON ONLY ONE DROP OF BLOOD
Selected Media Citations 2015

Source: www.Theranos.com, 4/21/2015

CBS This Morning: Blood, Sweat & No Fear
TIME 100: The Most Influential People in the World in 2015
USA Today: Arizona health law could boost Theranos' bio-tech prospects
The Arizona Republic: Patients can soon get lab tests without doctors' orders
The New York Times: The Healing Power of Your Own Medical Records
Fortune: 9 of the most inspiring acts of leadership
Inc.: How Elizabeth Holmes Became America's New Entrepreneurial Icon
Glamour: Career Advice From Theranos Founder Elizabeth Holmes
Fox Business: Theranos, Cleveland Clinic CEO's on innovation partnership
The Arizona Republic: Tech company Theranos pushes consumer lab-testing bill
Fast Company: Most Innovative Companies 2015
Inc.: Elizabeth Holmes Is a Beacon for Female Entrepreneurs
8th Annual Crunchies Awards: Best Health Startup
Brand Channel: Breakthrough Branding: Theranos, with Walgreens, Revolutionizes Healthcare
Clinton Foundation: Health Matters
Stanford Graduate School of Business: View From the Top
ABC15: Score big savings on your lab tests with Theranos
Elizabeth Holmes, 30, is the youngest woman to become a self-made billionaire—and she’s done so four times over. In 2003, as a Stanford undergrad, she founded Theranos, a Palo Alto company that’s disrupting the business of blood testing, replacing the services provided by giants like Laboratory Corp. of America and Quest Diagnostics. “What we’re about is the belief that access to affordable and real-time health information is a basic human right, and it’s a civil right,” she says.

Theranos has raised approximately $400 million, with a recent round valuing it at $9 billion—more than the market caps of any of her rivals. Holmes holds 50% of the stock, putting her net worth at $4.5 billion. With just a drop of blood Theranos can do the same tests that used to require vials of it, at lower cost. “It’s one of those white-whale type of approaches, where if this were to become mainstream, then the entire diagnostic testing market would turn over,” says Mike Cherny, the diagnostics analyst at International [Strategy & Investment](http://www.forbes.com/international/).
Publication in Forbes raises profile in financial community

Market value of $9 billion comparable to that of Labcorp and Quest

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Sources: Laboratory Economics, Yahoo finance, as of 4/21/2015.
Theranos looks more like a high tech Unicorn than a biotech lab startup

Recent lab IPO’s

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<td>Exact</td>
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Well known Unicorn companies

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<th>Company</th>
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Sources: Fortune, Yahoo finance, as of 4/21/2015.
Unique features of Theranos rise to prominence

Lack of peer reviewed publications
### Unique features of Theranos rise to prominence

A large patent estate with broad claims

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<tr>
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<td>Rapid measurement of formatted blood component separation rate from small sample volumes</td>
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<td>0719,382</td>
<td>Finger warmer</td>
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<td>8,883,516</td>
<td>Systems and methods of fluid sample processing</td>
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<td>8,862,793</td>
<td>Methods and systems for network connectivity</td>
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<tr>
<td>8,862,448</td>
<td>Integrated bio-data capture and analysis system</td>
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<td>8,558,774</td>
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<td>7,988,127</td>
<td>Calibration of fluidic devices</td>
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<td>7,904,617</td>
<td>Bodily fluid analyzers, and system including same and method for programming same</td>
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<td>7,895,594</td>
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<tr>
<td>7,291,497</td>
<td>Medical device for analyte monitoring and drug delivery</td>
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A subset of patents describes methods, systems and devices for analyzing broad categories of samples.

United States Patent
Holmes

Systems and methods for multi-analysis

Abstract

Systems and methods are provided for sample processing. A device may be provided, capable of receiving the sample, and performing one or more of a sample preparation, sample assay, and detection step. The device may be capable of performing multiple assays. The device may comprise one or more modules that may be capable of performing one or more of a sample preparation, sample assay, and detection step. The device may be capable of performing the steps using a small volume of sample.
A smaller subset of patents describes methods, systems and devices for measurement of specific analytes.

**United States Patent**

Dayel, et al.

March 24, 2015

**8,984,932**

**Rapid measurement of formed blood component sedimentation rate from small sample volumes**

**Abstract**

Devices and methods are described for measuring formed blood component sedimentation rate. Some of the methods may use (1) centrifugal techniques for separating red blood cells from plasma and (2) video and/or still imaging capability. Both may be used alone or in combination to accelerate formed blood component sedimentation and to measure its rate. In one example, the method may advantageously enable rapid measurement of sedimentation rate using small blood sample volumes. Automated image analysis can be used to determine both sedimentation rate and hematocrit. Automated techniques may be used to compensate for effects of hematocrit on uncorrected sedimentation rate data.
Most of the patents submitted are unrelated to the current Theranos business model

- Point of care devices
- Wearable and ingestable devices
- Systems for data analysis, transmission and decision making.
Unique features of the Theranos rise to prominence

Intense secrecy regarding technical operations
Stealth Research
Is Biomedical Innovation Happening Outside the Peer-Reviewed Literature?
John P. A. Ioannidis, MD, DSc

Information about Theranos, a privately held biotechnology company that has developed novel approaches for laboratory diagnostic testing, has appeared in The Wall Street Journal, Business Insider, San Francisco Business Times, Fortune, Forbes, Medscape, and Silicon Valley Business Journal—but not in the peer-reviewed biomedical literature. As of January 5, 2015, a search in PubMed using Theranos as a search term identified affiliations for only 2 unrelated articles coauthored by Theranos Inc employees, although these 2 reports do not offer insights about their company.

Conversely, according to the non-peer-reviewed sources mentioned above, Theranos is “revolutionizing the blood test” and this “is a golden idea”: “the company can run hundreds of tests on a drop of blood far more quickly than could be done with whole vials in the past—and it costs a lot less.” The company is estimated to be worth $9 billion. Test results are “near-instantaneous.”

Moreover, the company has teamed with Walgreens pharmacies in Palo Alto and Arizona to create “Theranos Wellness Centers.” A footnote in the respective Walgreens webpage mentions that the laboratories are Clinical Laboratory Improvement Act–certified. According to the same sources, Theranos has operated in stealth mode for more than a decade, not publishing anything in the literature while preparing to change the entire health system: “One closely guarded secret is... how exactly the technology behind its blood test works.”
Publication of key findings adds value to new companies

Invitae Analytic Validation Summary

Executive Summary

Analytic validity of the Invitae genetic test has been demonstrated in studies. Two of these studies utilize well-known reference samples and examine a broad set of genes and broad classes of DNA variation. A third study utilizes clinical samples from two major academic medical centers and focuses on BRCA1 and BRCA2. In all cases, independent data on these individuals from traditional diagnostic technologies (such as Sanger sequencing) is available as a “gold standard” for comparison.

Results from 718 individuals tested in these three studies are summarized in this document. Over this combined set, in direct comparison with the “gold-standard” data, 100% analytic sensitivity and 100% analytic specificity has been observed for all pathogenic DNA variations within the analytic range of the Invitae test. This enables the detection and confirmation of pathogenic variations in individuals using an orthogonal technology. Furthermore, Invitae’s current standard testing procedures utilize both gap-filling and confirmation on patient samples to further ensure completeness and accuracy.

Clinical utility and cost of non-invasive prenatal testing with cfDNA analysis in high-risk women based on a US population

Ken Song1, Thomas J. Muncy1, and Aaron B. Caughey3

1Ansa Diagnostics, Inc., San Jose, CA, USA and 2Ochsner Health & Science University, Portland, OR, USA

An empirical estimate of carrier frequencies for 400+ causal Mendelian variants: results from an ethnically diverse clinical sample of 23,453 individuals

Gabriel A. Lazzarin, MS1, Imran S. Haque, PhD3, Shilvani Narareth, MS1, Kevin Iori, BS1, A. Scott Patterson, MA1, Jessica L. Jacobson, MD1, John R. Marshall, MD1, William K. Seltzer, PhD, FACMG1, Pasquale Patrizio, MD4, Eric A. Evans, PhD1, and Balaji S. Srinivasan, PhD1,5,6

Purpose: Recent developments in genomics have led to expanded carrier screening panels capable of assessing hundreds of causal mutations for genetic disease. This new technology enables simultaneous measurement of carrier frequencies for many diseases. As the resultant rank-ordering of carrier frequencies impacts the design and prioritization of screening programs, the accuracy of this ranking is a public health concern.

Methods: A total of 23,453 individuals from many obstetric, genetics, and infertility clinics were referred for routine reproductive disease carrier screening. Multiple carrier screening was performed and results were aggregated for this study.

Results: Twenty-four percent of individuals were identified as carriers for at least one of 108 disorders, and 3.2% were carriers for multiple disorders. We report tabulations of carrier frequency by self-identified ethnicity and disease.

Conclusion: To our knowledge, this study of a large, ethnically diverse clinical sample provides the most accurate measurements to date of carrier frequencies for hundreds of recessive alleles. The study also yields information on the clinical considerations associated with routine use of expanded panels and provides support for a pan-ethnic screening paradigm that minimizes the use of “rare” categories by the physician, as recommended by recent guidelines.


Key Words: carrier frequency; carrier screening; genetic testing; pan-ethnic; recessive disease
Even trade publications were supportive of the Theranos approach.

**Inside the Diagnostics Industry**

**Theranos Aims to Transform the Medical Diagnostic Industry**

After years of speculation, Theranos (Palo Alto, Calif.) last fall unveiled its revolutionary plan to reshape the future of laboratory testing. With a laser-sharp focus on lowering testing costs (always 50 percent or below Medicare reimbursement rates) and standardizing quality, the company’s plans potentially hold benefits for stakeholders across the health care industry.

Patients benefit from the convenience of Theranos draw centers in Walgreens pharmacies and from the company’s proprietary and patented infrastructure for processing microsamples (one-one thousandth the size of a typical blood draw). The company believes its quick return of precise results will provide enhanced efficiency and informative, longitudinal value for physicians and pathologists. Theranos also poses a disruptive threat to the laboratory industry through a transformative emphasis on transparency reflected in the company’s commitment to both price transparency (all price prices are on the company’s Web site) and publication of margin of error variation for aiding interpretation of test results.

The company’s goal of deploying a national network of accessible testing centers is becoming a reality with the expansion of its Walgreens-based Wellness Centers to the Phoenix area in mid-November 2013, following the opening of the first center in Palo Alto in September 2013. Elizabeth Holmes, Theranos’s founder and CEO, recently spoke to DTET about the unique infrastructure powering the company’s pioneering vision.

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**Diagnostic Testing & Emerging Technologies**

"With new customer paradigms, laboratories need to evaluate where they will fit in."

—Robert Boorstein, M.D., Ph.D.

"It is a national footprint with a robust information management system," says Robert Boorstein, M.D., Ph.D., director of the laboratory consulting firm Cla Group (New York). "Doctors are already used to ordering prescriptions online and patients are used to going there to pick up their prescriptions ... Spreading out demand will affect labor costs and be much more efficient than standalone draw stations."

Boorstein predicts much like Amazon is changing the retail model through use of technology and new distribution methods, laboratories need to think outside of the box for wholly new models.

"With new customer paradigms, laboratories need to evaluate where they will fit in," says Boorstein. "It is hard to envision the logic of freestanding draw centers at some point. Why would you need separate facilities if draws can be done at drug stores up to 24 hours a day?"
Ignoring Lab Industry, Theranos Goes Its Way

Unknown to the wider clinical laboratory industry, this emerging laboratory test firm has disruptive plans.

CEO SUMMARY: With each passing month, Theranos pulls open the curtain a bit more on its business structure and its market growth plans. Its clinical lab tests are now offered in Walgreens pharmacies in Palo Alto, California, and Phoenix, Arizona. Recent news coverage in Fortune and USA Today disclosed that company officials—based on stock sales to date—value the company at $9 billion. That’s more than the market value of the shares of Quest Diagnostics or LabCorp.

My Visit to Walgreens For Theranos Lab Tests

Secretive lab test company is getting profiled by national the press, but is it delivering to patients?

CEO SUMMARY: One of the biggest unknowns in the lab testing industry today is Theranos, the lab testing company based in Palo Alto, California. It says its proprietary technology is poised to transform the lab testing experience for patients and physicians. It says it can perform hundreds of lab tests, using a finger stick collection with a micro-specimen and return results in four hours. Here is the actual experience of your Dark Report editor, who had Theranos perform lab tests for him and his physician.

By Robert L. Michel
What I had envisioned.
- Seamless electronic ordering of lab tests
- Rapid friction free blood draws and payment (like Starbucks or Uber).
- Rapid delivery of results.
- Efficient use of personnel and space.

Obstacles to delivery
- Central lab testing, not point of service.
- Difficulties with finger stick collections.
- High labor costs/low utilization.
- Regulatory barriers.
- No real leap in information management
- Payment/reimbursement
Current Operation of the Theranos model

Theory vs. Reality
What is the current operational model?

- Specimens are collected at draw stations within 40 Walgreens in Phoenix area in Arizona.
- Largely, but not entirely, collected with fingersticks
- Specimens shipped to CLIA laboratory in Palo Alto
  - Limited services in California
  - Arizona laboratory not clearly operational, yet
- Results available in 1-3 days on Theranos website.
Does the current operational model disrupt existing laboratory services?

- Availability of draw stations.
- Utilization of finger sticks.
- Turnaround time.
- Price transparency.
- User experience.
Availability of draw stations in Arizona

**Theranos**

**Sonoma-Quest**
Is the micro-sample a new and compelling standard?

the lab test, reinvented.

MICRO-SAMPLE
No more huge vials to fill. At Theranos, we only need a few drops.

NANOTAINER™
0.508 in
Our nanotainer™ tube is smaller than a dime.
Is the micro-sample a new and compelling standard?

The claim

```
A few drops is all it takes.
```

Theranos’ patented technology can analyze samples as small as 1/1,000 the size of the typical blood draw. Our tests are certified in our CLIA laboratory and cover a full range from blood, urine, and other samples. It’s fast, easy, and the highest level of quality.

The reality

- No published data on the use by Theranos of fingersticks vs traditional phlebotomy.
- Published anecdotal reports (Dark Report, Laboratory Economics) report frequent use of traditional phlebotomy.
Is the micro-sample a new and compelling standard?

the Theranos counter was quick. All my 7 tests and panels qualified for the finger prick method (I had called their customer support to verify this beforehand). Theranos has their own waiting room and blood draw room. It was a relaxing environment. A large screen TV showed tropical fish swimming to the sound of soothing music. The technician explained the process, a heat pad was applied to my left hand and middle finger, and a device executed a painless prick to the tip of my middle finger. The technician gently squeezed my finger to extract a small amount of blood. The process was quick, painless, and much easier than a traditional blood draw.

I am aware that Theranos is a new technology and that not all tests are offered through them, however, there should be more education for doctors sending their patients here—none of the tests I was having done were able to be done via a finger stick, all had to be done via a traditional blood draw.
Is the micro-sample a new and compelling standard?

- Limited documentation that fingersticks are actually predominant or preferred method.
- Lack of commitment to fingersticks in advertising to physicians office collections.
- Inherent limitations of finger sticks.
  - Sample storage and transport
  - Sample availability for repeat and sendout specimens.
  - Requirement for duplicate collections for failed sticks or tests requiring traditional samples

No new infrastructure needed.

You can draw samples in your office using your standard venipuncture draw method.
Small specimens in your smallest collection containers are all we need.
Does Theranos provide more rapid Turnaround time than traditional competitors?

Source: https://theranos.com/our-technology, 4/22/2015
Does Theranos provide more rapid Turnaround time than traditional competitors?

How important is turnaround time anyway?
Does Theranos provide more rapid Turnaround time than traditional competitors?

- No published data on turnaround time.
- Anecdotal reports suggest 2-3 day turnaround times are typical, less than industry standard of 1 day.
- Remote central lab processing (Palo Alto) makes Turnaround times less than 1 day impossible or prohibitively
- True rapid turnaround time (0-4 hours) would require a totally different testing model, i.e. point of service devices in draw locations.
Has Theranos changed standards for pricing and price transparency?

Theranos is committed to making lab testing more accessible to everyone. That means pricing their tests at dramatically low rates. Theranos can accept major insurance carriers as well as Medicare and Medicaid. And if you're uninsured, they offer you the same discounted prices they offer everyone else. Because a test should cost the same, no matter who you are.
Has Theranos changed standards for pricing and price transparency?

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<tr>
<td>Cardiac IQ™ Lipoprotein Fractionation, Ion Mobility</td>
<td>83704</td>
<td>$50.00</td>
</tr>
<tr>
<td>Complete Blood Count w/Differential and Platelet Count (CBC)</td>
<td>85025</td>
<td>$20.00</td>
</tr>
<tr>
<td>Comprehensive Metabolic Panel</td>
<td>80053</td>
<td>$29.00</td>
</tr>
<tr>
<td>Creatinine</td>
<td>82565</td>
<td>$16.00</td>
</tr>
<tr>
<td>C-Reactive Protein (CRP)</td>
<td>80140</td>
<td>$27.00</td>
</tr>
<tr>
<td>Estradiol</td>
<td>82670</td>
<td>$90.00</td>
</tr>
<tr>
<td>Ferritin</td>
<td>82728</td>
<td>$40.00</td>
</tr>
<tr>
<td>Glucose, Gestational Tolerance, 1 Hour</td>
<td>82950</td>
<td>$16.00</td>
</tr>
</tbody>
</table>

Source: Laboratory Economics from Arizona and California Medicaid programs and Theranos
Has Theranos changed standards for pricing and price transparency?

- Theranos leads the industry in publishing clear accurate pricing.
- Theranos pricing conveys significant competitive advantage for self pay patients.
- Theranos pricing *may* be attractive for patients with high co-pays or deductibles.
- **Unknown:** Will Theranos price schedules become the industry norm?
Does the current operational model disrupt existing laboratory services?

1. Availability of draw station
2. Utilization of finger sticks.
3. Turnaround time.
5. User experience.

1. Similar locations, expanded hours.
2. No evidence of significant benefit or standard utilization
3. Less than commercial competitors. Not meeting advertised claims.
4. Pricing model attractive to self-pay patients and may impact industry pricing.
5. Driving patient ordering and reporting.
Is Theranos fundamentally changing the user experience?

A totally new experience.

Over the next few months, we’ll be introducing groundbreaking new spaces that transform the way you think about lab tests. Our Theranos Wellness Centers are designed to make your experience as easy and comfortable as possible. You can make an appointment or walk in at your leisure with your doctor’s order form. Then enjoy our friendly new process. Everything is designed with your wellness in mind.

Unrivaled convenience.

With Theranos, you can give your sample in your doctor’s office, or bring your doctor’s lab order to any of our convenient Theranos Wellness Centers. No more trekking to an out-of-the-way laboratory. No more dealing with your health on someone else’s terms. With our extended hours – including nights and weekends – it’s easy to fit your tests into your busy schedule.
Is Theranos fundamentally changing the user experience?

Direct ordering of lab tests  Patient access to results
Does the current operational model disrupt existing laboratory services?

1. Similar locations, expanded hours.
2. No evidence of significant benefit or standard utilization.
3. Less than commercial competitors. Not meeting advertised claims.
4. Pricing model attractive to self-pay patients and may impact industry pricing.
5. Driving patient ordering and reporting.

1. Availability of draw stations
2. Utilization of finger sticks
3. Result turnaround time
4. Price transparency
5. User Experience
Where does Theranos go from here?
Where Does Theranos go from here?

- Expansion of current model.
- Patient directed testing
- Point of service diagnostics using current Walgreens distribution.
- Growth of true point of care and wearable technologies.
- FDA oversight
Expansion of the current model

- Stated goal is presence in all 50 states in “substantial” portion of 8200 Walgreens locations
- Limited growth on the Arizona footprint
  - Expansion from 20-40 sites in last year confined to Phoenix Metro area.
  - Phoenix area CLIA lab still in development
  - Newark CA area CLIA lab in development (additional site or replacement).
Limits to Expansion of the Model

- To compete for routine laboratory business nationally with a small number of CLIA sites because of the cost and time limitations of sample transport.
- Development of regional CLIA sites would require each site to validate each assay as an LDT.
- Potentially prohibitive cost of logistics for low cost, low margin samples.
- Potentially prohibitive cost of dedicated low productivity phlebotomy staff.
Growth Potential of Patient Directed ordering

- Theranos presumably believes this is significant growth area.
- How large is the dollar value of patient directed ordering?
  - Low cost tests (cholesterol, INR, HbA1C, cholesterol)
  - No insurance coverage.
  - Variable state regulations.
- Competition from (reluctant) competitors
- Competition from direct to consumer waived tests.
Evolution of the current model to testing performed on site at Walgreens

- 4 hour turnaround time can only be provided doing on site testing.
- Much of patent estate is geared to “point of care” technologies.
- Would satisfy needs of impulse based consumers.
FDA obstacles to migration of current model

- Manufacture of Point of service devices would require FDA approvals either as In Vitro Diagnostics, or as “waived” tests.
  - Use of devices as Theranos devices as IVD’s would require licensure of every site as a laboratory.
  - Use of devices as “waived tests” would require appropriate licensure and oversight of testing personnel.
- Approval for essentially all tests would have to be in place before putting devices into use.
Development of ingestable and wearable devices and communications technologies

- A major point of focus in Theranos patents
- Would require different pathways of FDA approval, regulatory oversight, ordering and billing.
- A highly competitive field
Has Theronos revolutionized the industry?

Promotion versus reality
Has Theranos Revolutionized the Industry?

- Central lab instrumentation
- Point of care instrumentation
- Use of microtainers
- Price transparency and low pricing
- Patient empowerment
- Self pay provision of services
- Order entry/Results reporting/EMR interfaces
1. With regard to my knowledge of the Theranos business model, I consider myself
   A. Very familiar
   B. Somewhat familiar
   C. Slightly familiar
   D. Not at all familiar

2. I view the threat of Theranos to my business to be
   A. Very significant
   B. Somewhat significant
   C. Slightly significant
   D. I do not view Theranos as a threat.
Silicon valley and Innovation in Laboratory Medicine

Natural Partners
Silicon Valley meets Laboratory Medicine

Necessary inputs
- Clinical and Medical Expertise.
- IT expertise
- Engineering Expertise
- Skilled Technical Workforce
- Access to Venture Capital

Successful Ventures
- Ariosa
- Invitae
- Counsyl
What to look for in a groundbreaking venture?

- Clear aims and understanding of target market
- Desire to capture major share of the market
- Pricing transparency
- Reduced cost compared with competitors
- Use of Social Media
- Bypass traditional “key opinion leaders”
- Success marked by rapid obvious growth
Questions? Comments?

Thank you