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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 8-K

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**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 18, 2014**

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### **PDI, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-24249**  
(Commission  
File Number)

**22-2919486**  
(IRS Employer  
Identification No.)

**Morris Corporate Center 1, Building A**  
**300 Interpace Parkway,**  
**Parsippany, NJ 07054**  
(Address of principal executive offices and zip Code)

**(862) 207-7800**  
Registrant's telephone number, including area code:

**Not Applicable**  
(Former name or former address, if changed since last report)

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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))
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#### **Item 7.01. Regulation FD Disclosure.**

PDI, Inc. (the "Company") is furnishing a Corporate Presentation dated November 2014 (the "Corporate Presentation"), attached as Exhibit 99.1 hereto, which the Company may use from time to time in presentations to investors and other stakeholders. The Corporate Presentation will also be available on the Company's investor relations webpage at <http://www.pdi-inc.com>.

The information contained herein and in the accompanying exhibit shall not be deemed filed for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

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

(d) *Exhibits.*

99.1 Corporate Presentation dated November 2014 (furnished and not filed for purposes of Item 7.01)

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### SIGNATURES

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

**PDI, INC.**

By: /s/ Graham G. Miao  
Graham G. Miao  
Executive Vice President, Chief Financial Officer and  
Treasurer

Date: November 18, 2014

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### EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Corporate Presentation dated November 2014 (furnished and not filed for purposes of Item 7.01)

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# Investor Presentation

November 2014

## FORWARD-LOOKING STATEMENTS

This presentation and accompanying narrative contain forward-looking statements regarding future events and financial performance. These statements involve a number of risks and uncertainties and are based on numerous assumptions involving judgments with respect to future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond PDI's control. Some of the important factors that could cause actual results to differ materially from those indicated by the forward-looking statements are changes in outsourcing trends or a reduction in promotional, marketing or sales expenditures in the pharmaceutical, biotechnology and life sciences industries, the early termination of a significant services contract or the loss of one or more of our significant customers or a material reduction in service revenues from these customers. Other factors that could cause actual results to differ materially from those indicated by the forward-looking statements include payers not providing reimbursement and/or our inability to negotiate reasonable reimbursement rates, gaining market acceptance of our tests, establishment of acceptable billing procedures, our ability to successfully implement our business model and manage the size of our operations, competition in the molecular diagnostics industry, changes in the regulatory oversight of laboratory tests as well as changes in laws and healthcare regulations applicable to us or our industry and the other risk factors detailed from time to time in PDI's periodic filings with the Securities and Exchange Commission including without limitation, PDI's Annual Report on Form 10-K for the year ended December 31, 2013, and PDI's subsequently filed quarterly reports on Form 10-Q and current reports on Form 8-K. Because of these and other risks, uncertainties and assumptions, undue reliance should not be placed on these forward-looking statements. In addition, these statements speak only as of the date of this presentation and, except as may be required by law, PDI undertakes no obligation to revise or update publicly any forward-looking statements for any reason.



# PDI Overview

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- **Strong core commercialization business**
  - Top 3 leader in US over twenty five years in business
  - Current \$120 million in revenue
  - 1,000 Sales Reps in the field
- **New Molecular Diagnostics Business**
  - Solid foundation with recent acquisitions (Asuragen assets and RedPath)
  - Current \$12 million in revenue
  - By 4Q 2015: 4-5 tests expected to be commercialized in GI and endocrine with combined market potential of >\$2.5 billion



# PDI's Commercialization Services

## Unparalleled Infrastructure to Reach Physicians



**Personal CSO**  
Effective Live Sales Calls and Multi-Channel Integration

**Physician Panel of 466,000**  
Active Panel of Physicians

**Rep to HCP Communication**  
Software Platform for Reps and Physicians to communicate

**Flexible and efficient solutions**



# PDI's Commercialization Services

## Multi-Channel Platform



Source: Group DCA





# Our Mission

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**Leading Commercialization Company  
of Molecular Diagnostics Tests  
for Optimal Patient Care**





# Interpace Diagnostics Advantage

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## Diagnostic Commercialization Experience



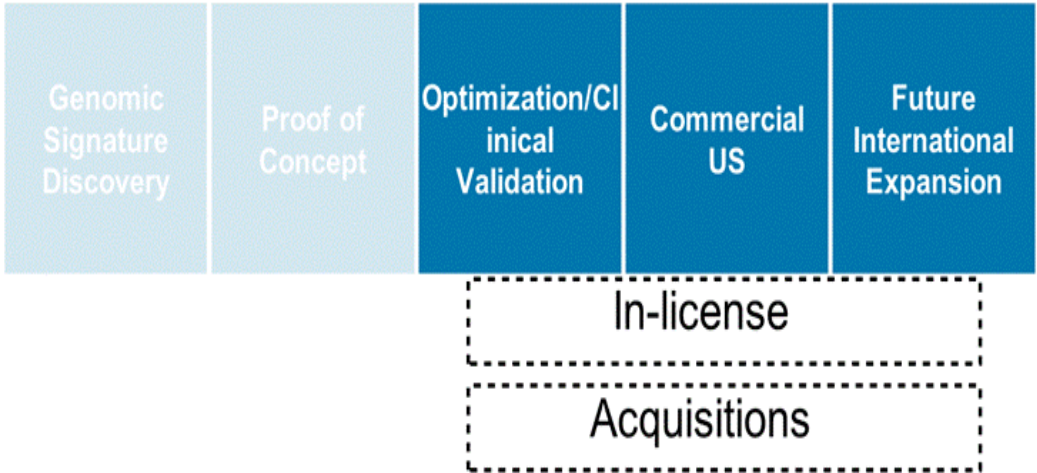
Tapping into the power of PDI's Commercial expertise and infrastructure

- **Broad commercial capabilities** to physicians (Highly Trained Sales Reps, Expansive Digital Communications, Optimized Mobile Access)
- **Extensive back office infrastructure** (Recruiting & Hiring, Training, Compliance, Territory Alignment, Analytics, CRM/SFA, Sales Operations)



# Our Philosophy

Targeting products that are nearing or ready commercialization



# Key Milestones Accomplished

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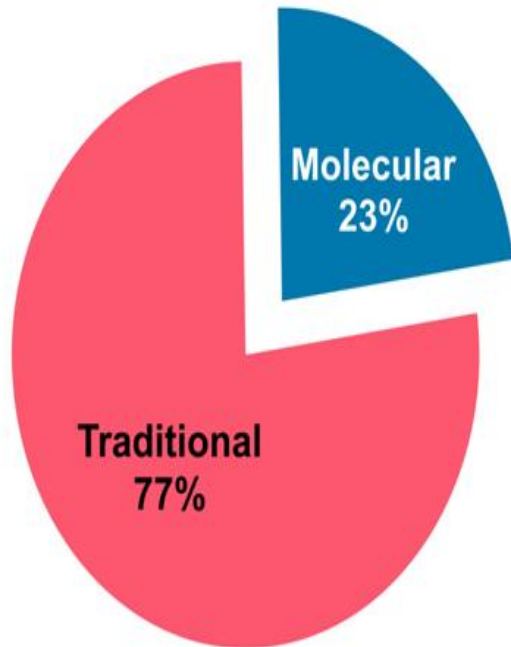
- AUGUST 2013: Exclusive Option to Acquire Thyroid cancer diagnostic
- AUGUST 2014: Acquired Asuragen Thyroid and Pancreas Assets
- AUGUST 2014: Announced molecular diagnostics leader to the board of directors (Heiner Dreisman former CEO of Roche Diagnostics)
- AUGUST 2014: Acquired turn-key CLIA certified and CAP accredited commercial laboratory New Haven CT
- OCTOBER 2014: Announced acquisition of RedPath Integrated Pathology and GI assets



# 2013 Total Diagnostics Market \$62B

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## Molecular Diagnostics \$14B



“Molecular diagnostics is the fastest growing segment of clinical testing today”



Source: Leomics Associates



# Specialty Molecular Test Developers

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## A Growing Field

1. Most Developers of Lab Developed Tests (LTDs) are science driven with limited commercial capabilities
2. Fast-growing diagnostics field is in early stages of rapid growth
3. The future of personalized medicine is quickly gaining momentum

**PDI Commercial Expertise Aligned with Specialty Molecular Diagnostics Market Dynamics**



# Our Market Focus

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GI

*PathFinderTG*<sup>®</sup>  
Integrated pancreatic oncology assay

Endocrine

 **ThyGenX**<sup>™</sup>  
THYROID ONCOGENE PANEL

currently  miRInform<sup>®</sup> Thyroid

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## Current In-Market Test Opportunity

Pancreatic Cysts  
**\$350M**

Thyroid Cysts  
**\$350M**



Source: Company estimates



# Two State-of-the-Art CLIA Labs

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## Endocrine Center of Excellence

### New Haven

- Located near Yale University
- Medical Director  
Henry Rinder, MD
- Access to top scientific talent
- miRNA and endocrine focus
- NextGen Sequencing

## Gastrointestinal Center of Excellence

### Pittsburgh

- Located near University of  
Pittsburgh
- Chief Scientific Officer  
Syd Finckelstein, MD
- Access to top scientific talent
- Complex molecular testing  
capabilities GI focused



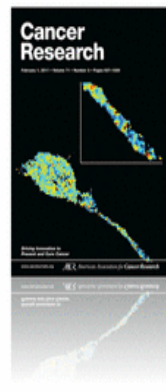




# PathFinderTG<sup>®</sup> is Clinically Validated

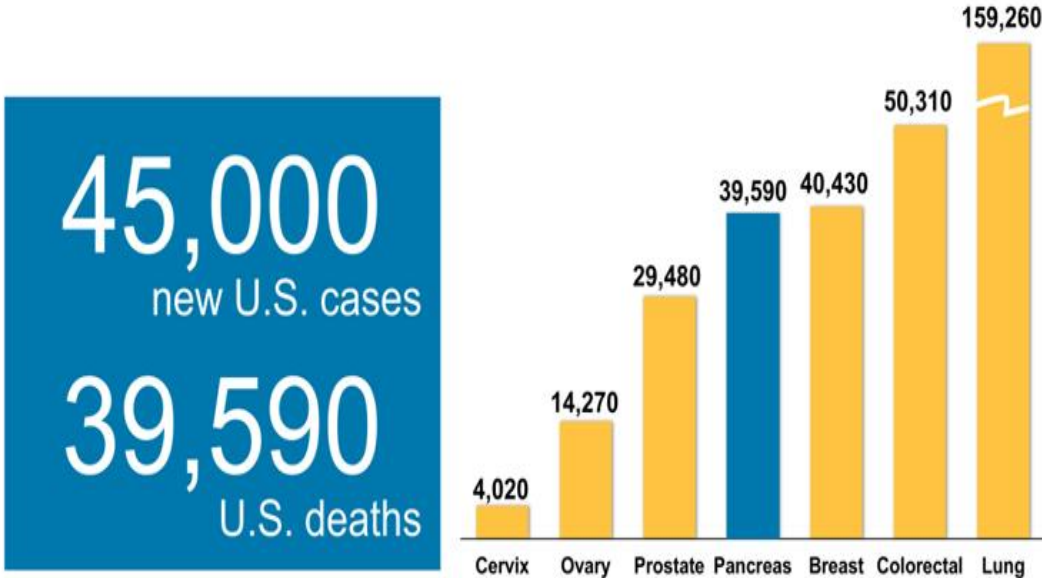
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- **Over 20,000 clinical cases analyzed**
- **Over 200 peer-reviewed articles**
  - Over 20 distinct clinical applications



# Pancreatic Cancer:

## The Fourth Leading U.S. Cancer Killer



Source: ACS Cancer Facts & Figures 2014; all figures annual



# 120,000 Pancreatic Cysts Annually

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- **The clinical dilemma:**

- GE manage patients using endoscopic ultrasonography (EUS) and perform fine needle aspiration of cyst.
- Cyst fluid tested for CEA, amylase, and cytology (1<sup>st</sup> line tests)
- These measures can't accurately risk-stratify patients.

Pancreatic cysts:

**only  
2-5%**  
chance of  
cancer

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- **The result:**

- 80% of all surgeries are for benign disease → wasted healthcare resources.
- Pancreatic cancers go undetected.

Pancreatic cysts:

**80%**  
surgeries are  
benign

# First-Line Tests & Current Guidelines

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Sendai guidelines 2012 and ACG guidelines 2007 strongly favor surgical resection because of the inability of first-line tests to predict biological behavior and aggressiveness.

***PathFinderTG*<sup>®</sup> technology helps physicians  
reduce unnecessary surgeries and more  
accurately detect cancer risk**



**Highly  
Accurate  
Test  
Results**

## Multi-faceted robust platform

1. 147 DNA mutation markers
2. CEA & Amylase biomarkers
3. DNA quantification
4. Loss of heterozygosity
5. Cytology results

# PathFinderTG<sup>®</sup>

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## An established track record

1. The first and only molecular test for the diagnosis and prognosis of Pancreatic cancer from cysts
2. Better than first-line testing for cancer risk stratification
3. Robust clinical database
4. Recent peer review publication in *Endoscopy* (492 sample size)





# Endoscopy

Performance of all patients (n=492)	<i>PathfinderTG</i> <sup>®</sup> Pancreas	Sendai Guidelines	P Value
<b>Specificity</b>	<b>90.6%</b>	<b>46.2%</b>	<b>&lt;0.0001</b>
PPV	57.9%	20.8%	<0.0001
NPV	97.2%	97.0%	0.88
<b>Sensitivity</b>	<b>83.3%</b>	<b>90.9%</b>	<b>0.17</b>

**Substantial improvement over current guidelines**



Source: Integrated molecular pathology accurately determines the malignant potential of pancreatic cysts, *Endoscopy*, 10/2014

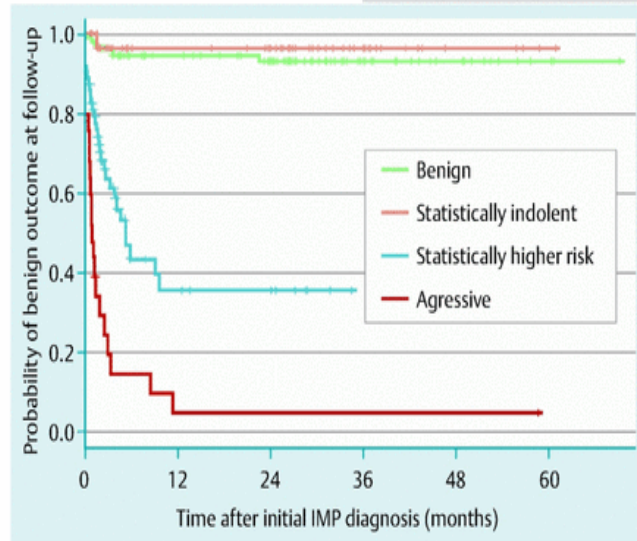


# PathFinderTG<sup>®</sup> Pancreatic Cysts

## Clinical Validity and Utility

79% of patients who met Sendai guidelines for surgery actually had benign outcomes and surgery could have been avoided.

97% probability of benign outcome at a median 3 years follow up



PFTG provides an effective strategy of risk stratification of malignancy for optimal patient care

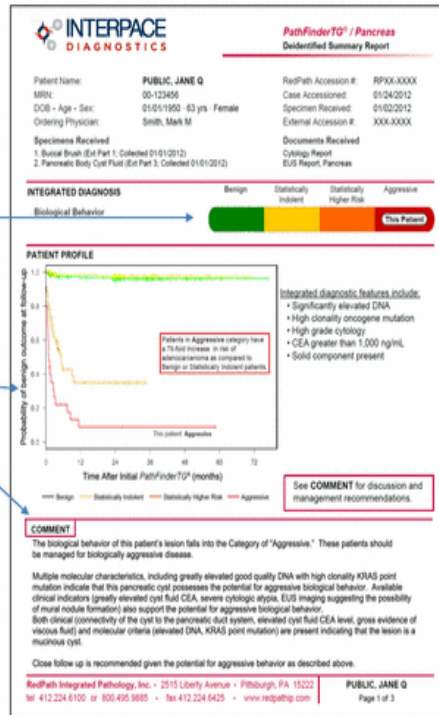


Source: Integrated molecular pathology accurately determines the malignant potential of pancreatic cysts, *Endoscopy*, 10/2014



## Clinically Meaningful and Actionable Results

- PFTG Diagnosis
- Patient management recommendations
  - Based on patient outcome data
  - Provided by board certified pathologists



Example Report: PFTG Pancreas

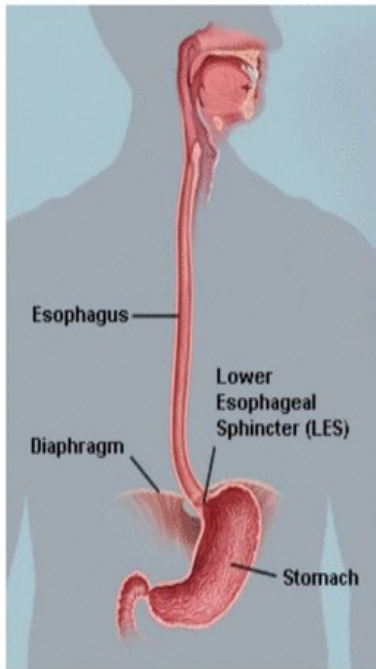
## Market Accelerators

- Publication of pivotal registry trial in *Endoscopy*
- Double sales force by early 2015
- Deploy established PDI commercial infrastructure
  - Managed Care Access/Reimbursement
  - Multi-channel marketing
  - Medical education
  - Patient advocacy



# What is Barrett's Esophagus?

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- Gastroesophageal reflux very common (10-20% US adults)
- 6% progress to Barrett's Esophagus (**~3.3 million adults**)
- Barrett's Esophagus precedes esophageal cancer infrequently (1-3%)
- Ablation (Barrx) has emerged as a treatment and prevention strategy
- A high unmet medical need exists for a molecular diagnostic test to aid in cancer risk assessment

# Barrett's Esophagus

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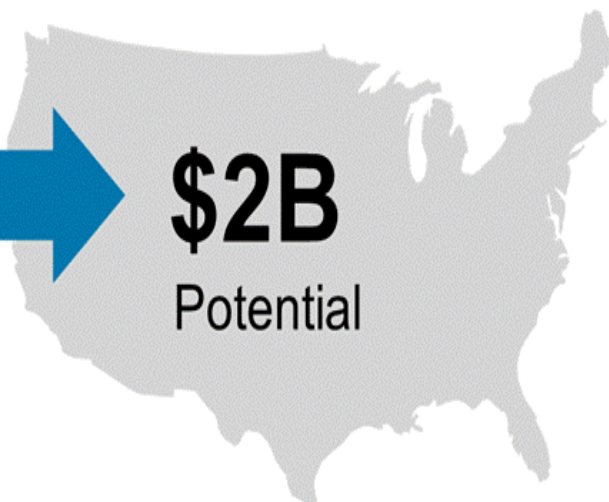
**~3.3M**

Adults



**\$2B**

Potential



**~650,000**

Screened Annually

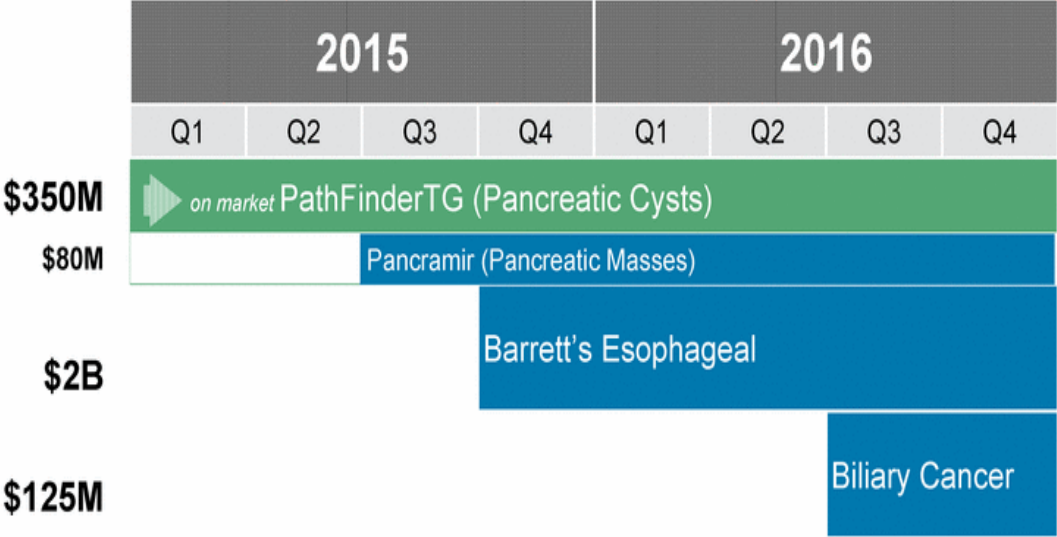
Same platform as *PathfinderTG*<sup>®</sup> Pancreas  
Launch in 4Q2015



Source: Company estimates  
For Investigational Use Only. The performance characteristics of this product have not been established.



# GI Pipeline and Market Potential







# The Endocrine Oncology Market

*ThyGenX*



# Thyroid Nodules

## Common clinical problem

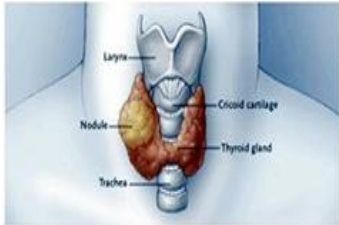
~10-18 m

US Adults have nodules

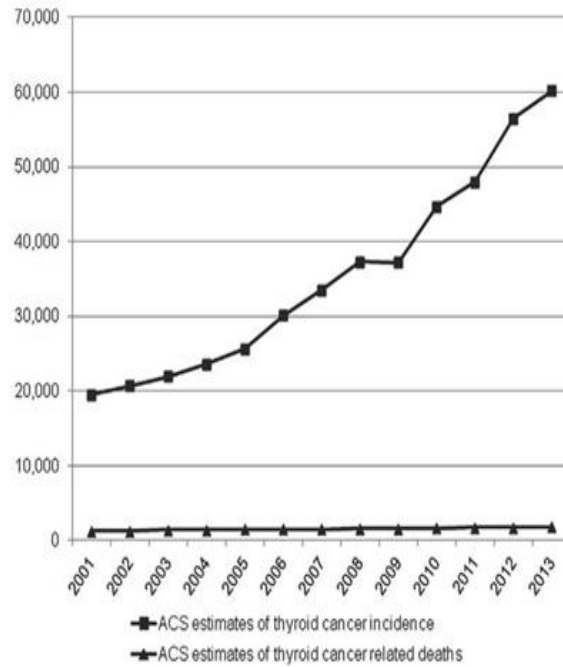
Estimated

525,000

thyroid FNA per year in US and growing



## Thyroid Cancer Incidence\*



\*American Cancer Society



# Thyroid Surgery

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## Is Not Inconsequential; Significant Surgical Risks

- Large incision in sensitive area and potential for significant scarring
- Risk of vocal cord damage, hoarseness, paralysis, and at the extreme, tracheotomy



# Guideline Recommendations

## Molecular Markers/Diagnostic Testing



### 2013 NCCN Guidelines

Molecular Diagnostics recommended testing on some indeterminate cytologies to minimize unnecessary surgeries



### 2014 American Thyroid Association Revised Guidelines

MDx Tests should be considered for suspicion of malignancy or indeterminate. The best markers are (BRAF, RAS, RET/PTC, PAX8/PPARG), a gene expression classifier, and Galectin-2 immunohistochemistry

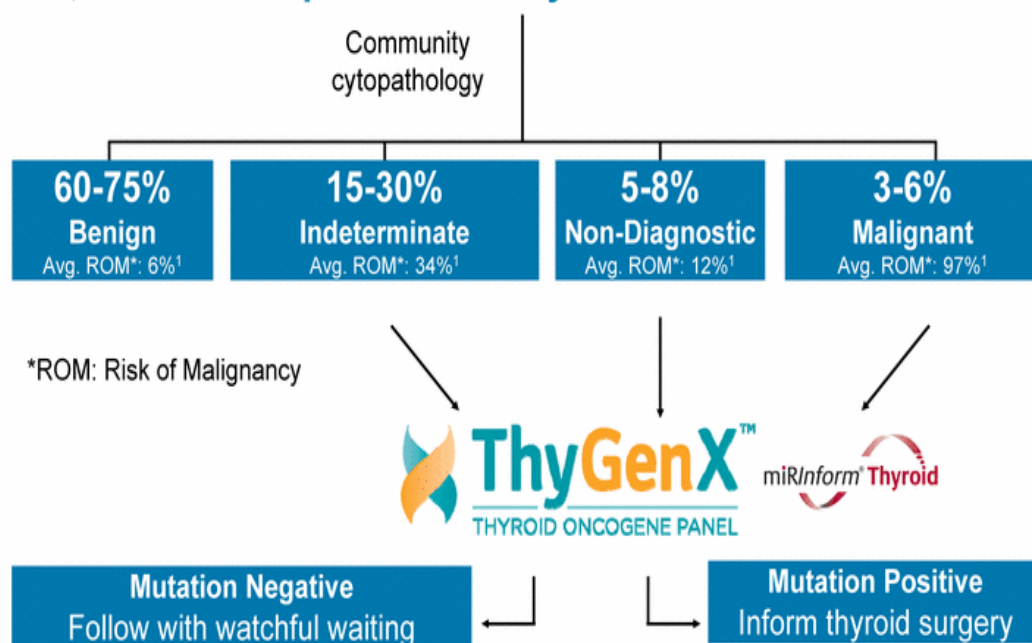


Source: Cooper DS et al. Thyroid. 2009;19(11):1167-1214; National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. V.1.2014; ATA Guidelines on Thyroid Nodules and Differentiated Thyroid Cancer – Highlights, Consensus, and Controversies. ICE/ENDO conference; June 21-24, 2014; Chicago, Illinois.



# miRInform® Pathway for Thyroid Cancer Diagnosis

525,000 FNA Biopsies Annually



<sup>1</sup>Wang CC, Friedman L, Kennedy GC, et al. *Thyroid*. 2011;21:243-251; <sup>2</sup>Nikiforov et al. *JCEM* 2001;



# Improving Thyroid Cancer Diagnosis

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## Use of Molecular Markers

**Molecular diagnostic tests helps the diagnosis of thyroid cancer when cytology is indeterminate**



### CURRENTLY 2 MAIN PLATFORMS:

1. Mutation/Genetic Testing  
“Rules-In” Cancer
  - Highly specific  
(BRAF, KRAS, HRAS, NRAS, RET/PTC1, RET/PTC3, PAX8/PPAR-γ, etc.)
  - ThyGenX (Currently miR*Inform*®)
2. Gene Expression  
“Rules-Out” Cancer
  - Highly sensitive
  - Veracyte Afirma GEC



# Interpace Diagnostic Tests

## Meet or Exceed Thyroid Clinical Guidelines

<p><b>Currently</b></p>  <p>Sanger Sequencing</p>	<p>KRAS, BRAF*, HRAS*, NRAS*, RET/PTC1*, RET/PTC3, PAX8/PPARy* (17 reportable markers)</p>
<p><b>4Q 2014</b></p>  <p>NextGen Sequencing</p>	<p>KRAS, BRAF*, HRAS*, NRAS*, RET/PTC1*, RET/PTC3, PAX8/PPARy*, <b>PIK3CA</b> (47 reportable markers)</p>



# Interpace Diagnostic Tests

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## Thyroid Tests Performance

4Q 2014 (Mutation Assay)



NextGen Sequencing

**Highly specific**  
“Rules-In” Cancer

2H 2015 (miRNA Markers)

**miRNA Classifier**

**Highly sensitive**  
“Rules-Out” Cancer—  
In clinic miRNA Markers

Blinded multi-faceted validation underway



# miR*Inform* + miRNA Classifier (2H2015)

miR*Inform* with miRNA Classifier substantially improves performance over competition

	Veracyte <i>Afirma</i>	miR <i>Inform</i> <sup>®</sup>	miR <i>Inform</i> <sup>®</sup> With Classifier
Characterize Malignancy	No	Yes	Yes
Pathology	Veracyte Performs	Any Pathologist	Any Pathologist
Prominent Results	Likely Benign	Likely Malignant	Benign/Malignant
FNA Samples	2	1	1
PPV	56%	81%	in progress
NPV	95%	64%	in progress



# Thyroid Franchise

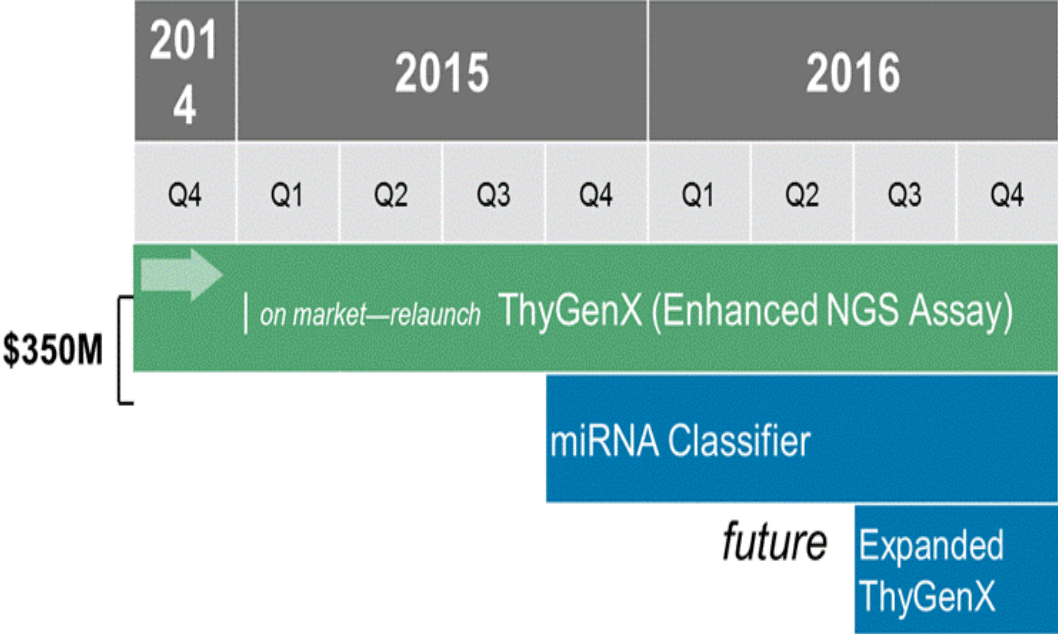
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## Market Accelerators

- Launch ThyGenX 4Q 2014 (Improved NextGen sequencing platform from miRInform®) and launch miRNA Classifier by 2H 2015
- More than double field force by 1Q 2015 and scale with growth
- Deploy established PDI commercial infrastructure
  - Managed Care Access/Reimbursement
  - Multi-channel marketing
  - Medical education
  - Patient advocacy



# Endocrine Pipeline and Market Potential



# Current PDI Commercial Services

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## Core business update

- Strong 2014 momentum leading into 2015
- \$140M new awards in Q4
- Multiple top pharma, mid-size, and small clients across numerous therapeutic categories
- PD One Rep to Physician Software Platform set to grow to 700 Rep subscriptions by 1Q2015



# Financial Update

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## 2014 Expectations

Revenue:	\$121M - \$123M
Operating Loss: (GAAP)	\$(15M) - \$(17M)
Cash (Year End):	\$21M - \$23M



# PDI Value

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1. Molecular Diagnostics commercialization strategy has significant upside potential — substantially higher gross margins and recurring revenue base
2. Core CSO and multi-channel offerings set for positive growth in 2015 and provide solid base for future success
3. PD One Software Platform is poised to differentiate sales rep to physician communication

