QUIDEL 2018 ANALYST DAY

Tuesday, April 3rd, 2018



Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. These statements are not guarantees of future performance. Many possible events or factors could affect our future results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, our reliance on sales of our influenza diagnostics tests; fluctuations in our operating results resulting from seasonality, the timing of the onset, length and severity of cold and flu seasons, government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses; volatility in our stock price, our ability to develop new technologies, products and markets; our reliance on a limited number of key distributors; our protection of our intellectual property and other intellectual property risks, including but not limited to, infringement litigation; our need for additional funds to finance our operations; the financial soundness of our customers and suppliers; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA") and other regulatory agencies, or loss of previously received approvals; changes in laws, regulations or government policies; claims, litigation and other proceedings; compliance with laws and other government regulations; third-party reimbursement policies and potential cost constraints; the reimbursement system currently in place and future changes to that system; our ability to meet demand for our products; interruptions in our supply of raw materials; changes in sales levels as it relates to the absorption of our fixed costs; the quantity of our product in our distributors' inventory or distribution channels; changes in the buying patterns of our distributors; product defects; business risks not covered by insurance; interruption to our computer systems; data corruption, cyber-based attacks, security breaches or other privacy violations; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into US markets; tax rates; the acquisition of the Triage and BC-BNP business, including the ability to achieve anticipated financial results or realize anticipated synergies and operational improvements, and our ability to successfully and timely integrate the acquired business into our operations; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; our significant debt service requirements and ability to generate sufficient cash flow to service our debt; limitations and covenants in our senior credit facility; our inability to settle conversions of our convertible senior notes in cash; the effect on our operating results from the trigger of the conditional conversion feature of our convertible senior notes; our ability to incur significant additional indebtedness; volatility and disruption in the domestic, international and global capital and credit markets; dilution resulting from future sales of our equity; provisions in our charter documents, Delaware law and the indenture governing our convertible senior notes that might delay or impede stockholder actions with respect to business combinations; and our policy to not pay cash dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although some forward-looking statements are expressed differently. Forward-looking statements in this presentation include, among others, statements concerning: our outlook for the business, including, among others, projections about our revenue, revenue profile, gross margins, free cash flow, indebtedness, capital expenditures, expenses, including research and development ("R&D") and sales and marketing ("S&M"), adjusted EBITDA, taxes, market opportunities, geographic expansion, and development, manufacturing and commercial activities; our strategy, guiding principles goals and objectives; our anticipated synergies from the acquisition of the Triage and BC-BNP business, anticipated yield improvement for the acquired business, and transition of the Triage and BC-BNP business; our merger and acquisition ("M&A") strategy. The risks described in our annual report on Form 10-K and subsequent Form 10-Qs and other reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this presentation. We undertake no obligation to update these forward-looking statements, except as required by law.

- **Projections:** Pro forma, projected and estimated numbers are used in this presentation solely for illustrative purposes to reflect the combination of the legacy Quidel business with the Triage and BC-BNP assay business acquired from Alere, Inc. ("Alere") in October 2017. The pro forma numbers are not necessarily indicative of the combined results of operations or financial position that might have been achieved for the periods or dates indicated, they include various adjustments, assumptions and estimates and may not be indicative of the results that may be expected for the combined company. The projections and estimates were based on numerous variables and assumptions, which are inherently uncertain, including factors related to general economic and competitive conditions. Accordingly, actual results could differ materially from those set forth in the projected or estimated numbers. Inclusion of such projected and estimated numbers in this presentation should not be regarded as a representation that such results will be achieved. See "Forward-Looking Statements" above.
- **Non-GAAP Financial Measures**: This presentation contains adjusted EBITDA, which is a non-GAAP financial measure. Such non-GAAP financial measures are presented as supplemental financial measurements in the evaluation of our business. We believe the presentation of these financial measures helps investors to assess our operating performance from period to period and enhances understanding of our financial performance and highlights operational trends. Such measurements may not be comparable to those of other companies in our industry, which limits their usefulness as comparative metrics. Such metrics are not required by or calculated in accordance with generally accepted accounting principles ("GAAP") and should not be considered as substitutes for net income or any other measure of financial performance reported in accordance with GAAP or as a measure of operating cash flow or liquidity. You can find a description and other important information regarding adjusted EBITDA in the financial section of this presentation, and a reconciliation of the most directly comparable GAAP financial measure.

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Today's Agenda

1	*The IVD Market and How We Compete*	*Doug Bryant*
2	*Deeper Dive Strategy Discussion*	*Bill Ferenczy*
3	*R&D Development*	*Werner Kroll*
4	*North American Commercial Update*	*Ed Russell*
5	*International Business Review*	*Ratan Borkar*
6	*Integration Update*	*Karen Gibson*
7	*Finance and M&A*	*Randy Steward*
8	*Q&A Session*	*Mgmt. Team*
9	*Reception*	

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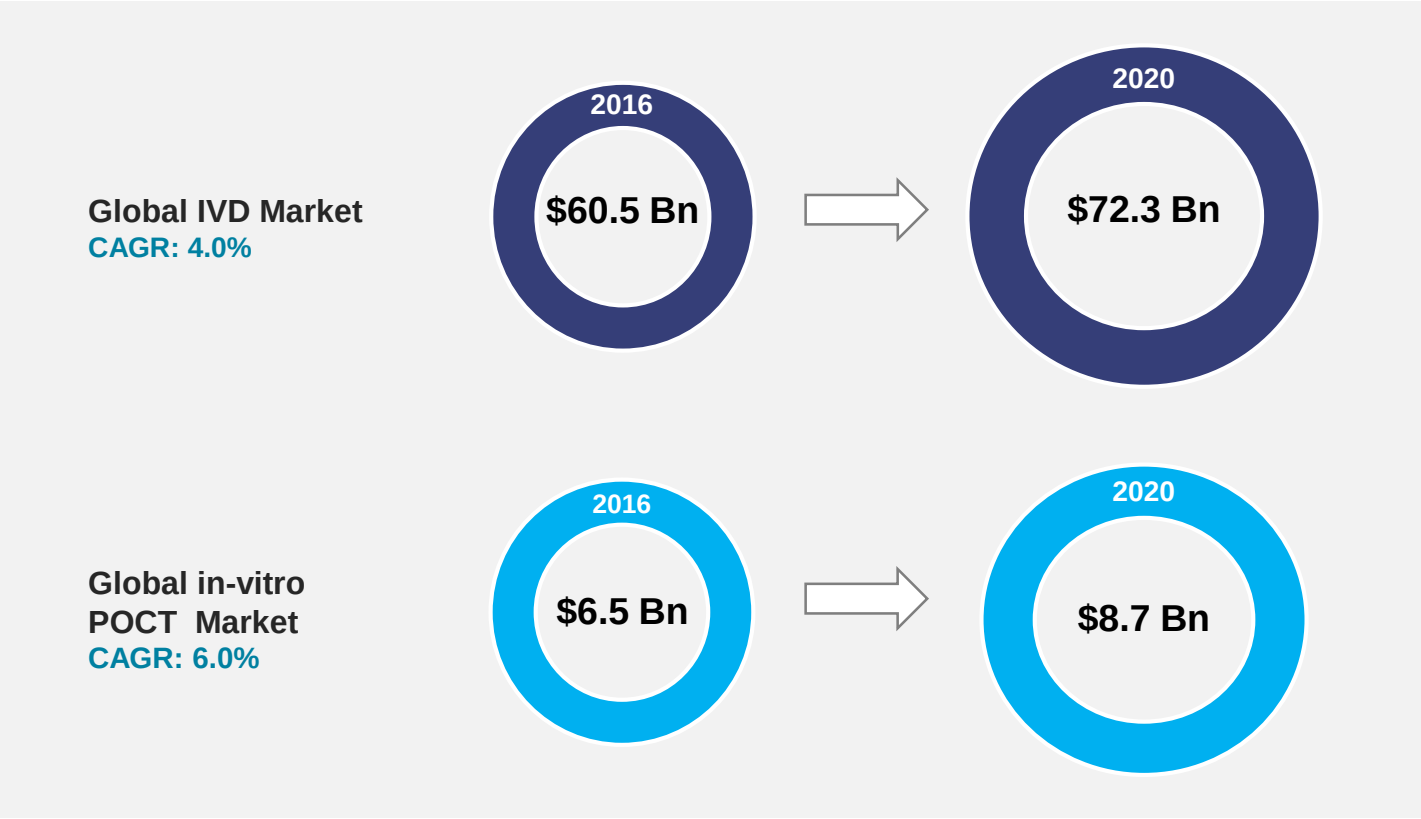
THE IVD MARKET AND HOW WE COMPETE

Doug Bryant,
President & CEO



QUIDEL

POC Testing is Expected to Continue to Drive Growth of Overall IVD Spend



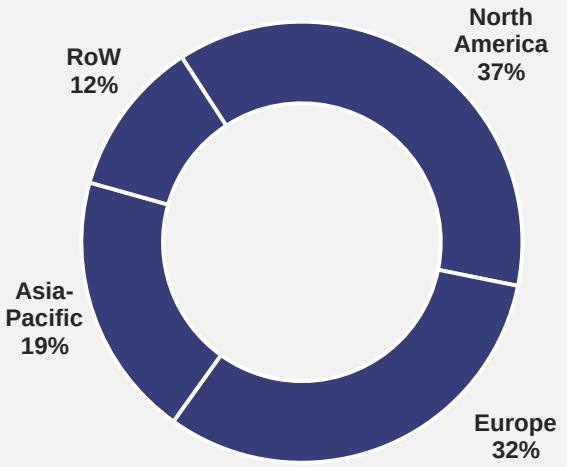
Source: Meddevicetracker 2016,WHO, Deloitte, Quidel Analysis
Global POCT Market excludes professional and home-based glucose testing

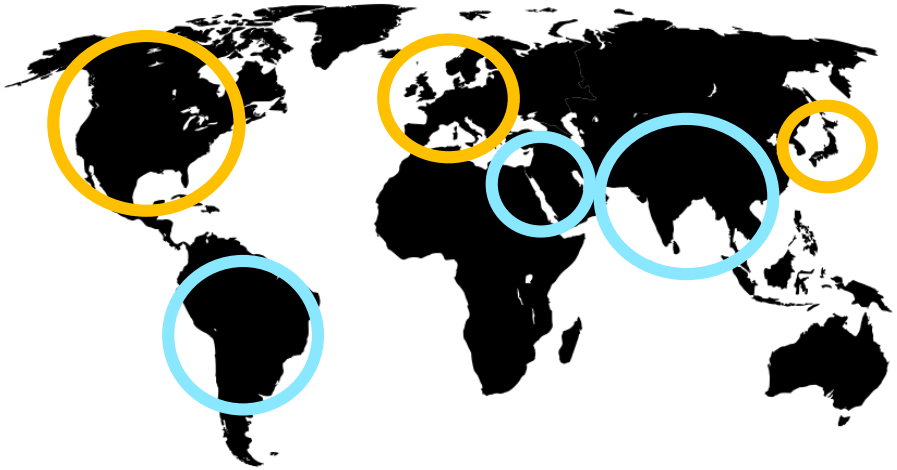
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Global Test Volume Largely Driven by Traditional Markets, though Emerging Markets represent Key Growth Opportunities for the IVD Market

IVD Diagnostics Market Outlook

Percentage of Global Sales





Traditional IVD test markets to experience slower growth rate than emerging markets

- 75% of the global IVD market is driven by traditional IVD market leaders (North America, Europe, and Japan)

Growth expected in emerging markets from 10% in 2016 to 14% 2021

Key Drivers:

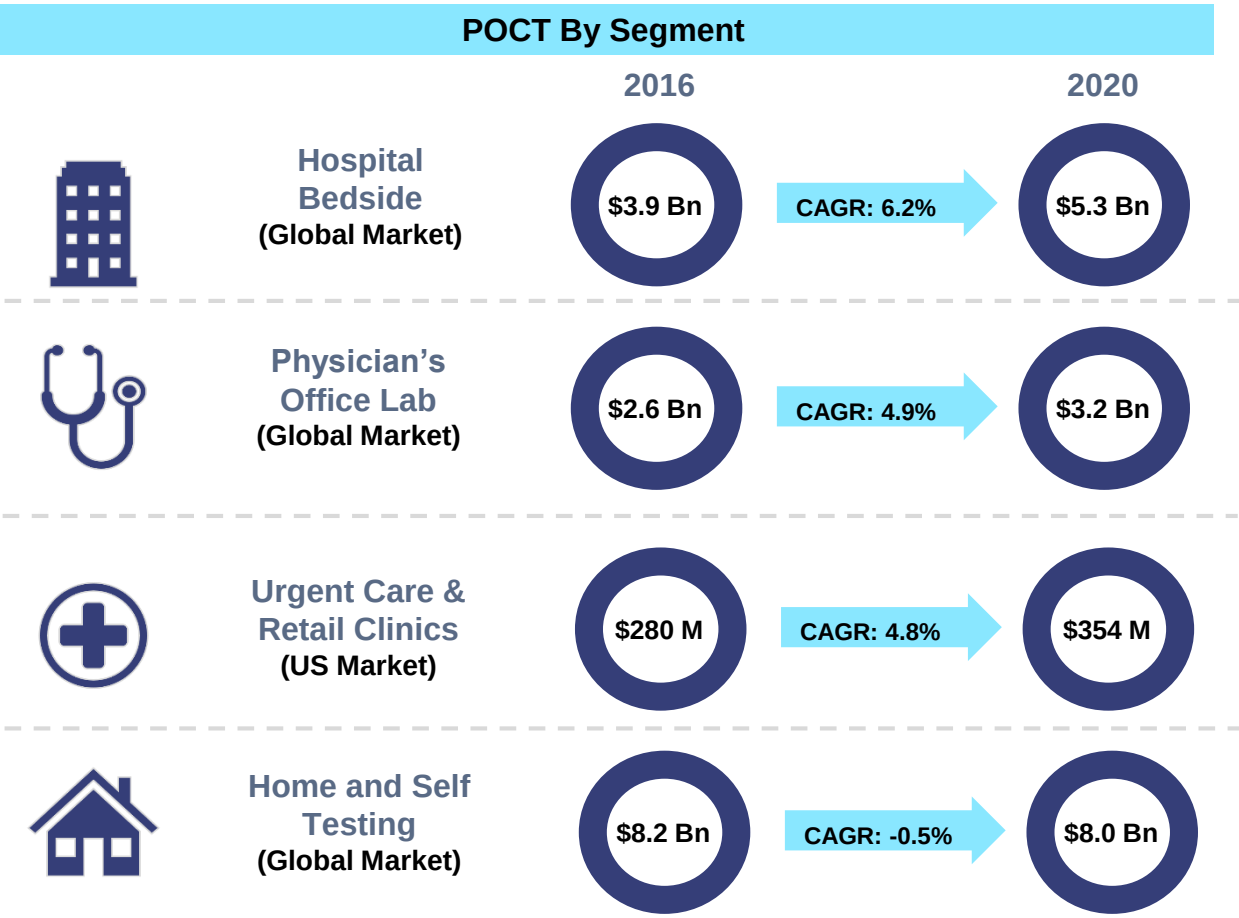
- Healthcare privatization
- Increased insurance initiatives
- Growing middle class

Source: Kalorama 08/16, Meddevicetracker 2016, Quidel Analysis

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Increased Pressure for Healthcare Decentralization creating Growing Sub-segments where Diagnostic Testing Occurs

- Decentralization of care continues in response to high costs associated with traditional settings
- Approximately 30% of patients seeking treatment in traditional hospital ED settings could potentially receive care at alternative, decentralized sites
- Increased development of urgent care clinics in the US, projected growth from 10,000 sites in 2014 to >12,000 by 2019
- Point-of-care rapid test kit sales for the worldwide POL market growing annually at 6.6% (CAGR 2015-2020)

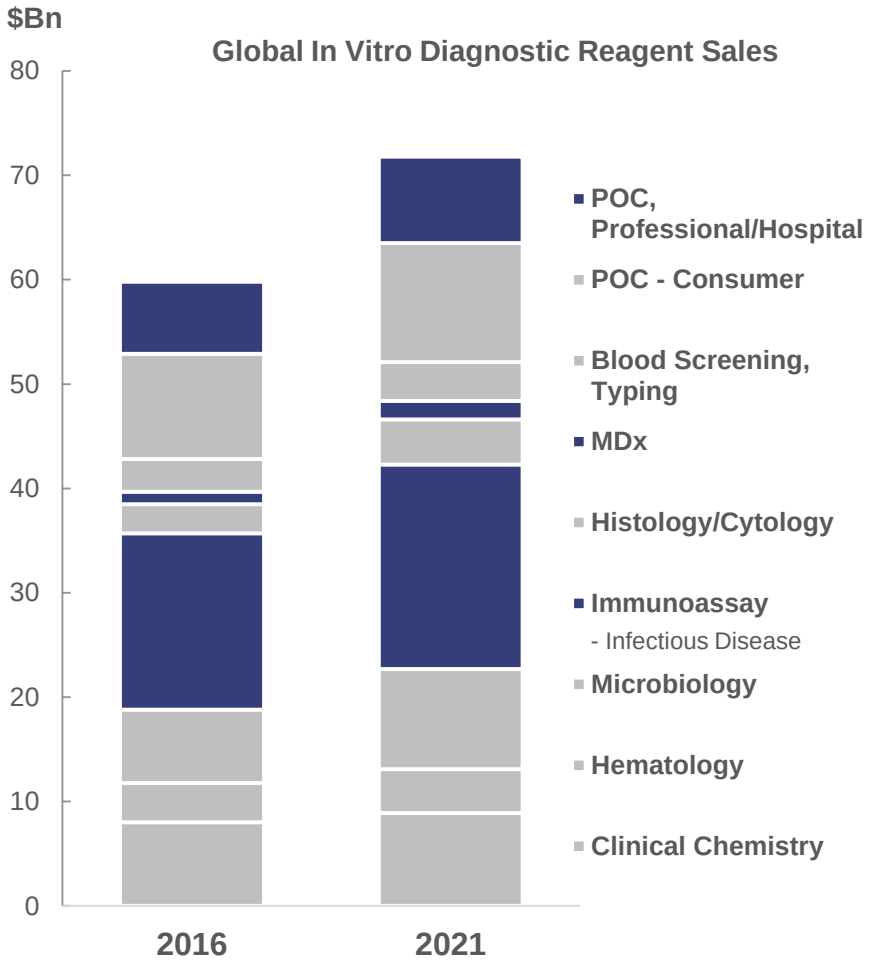


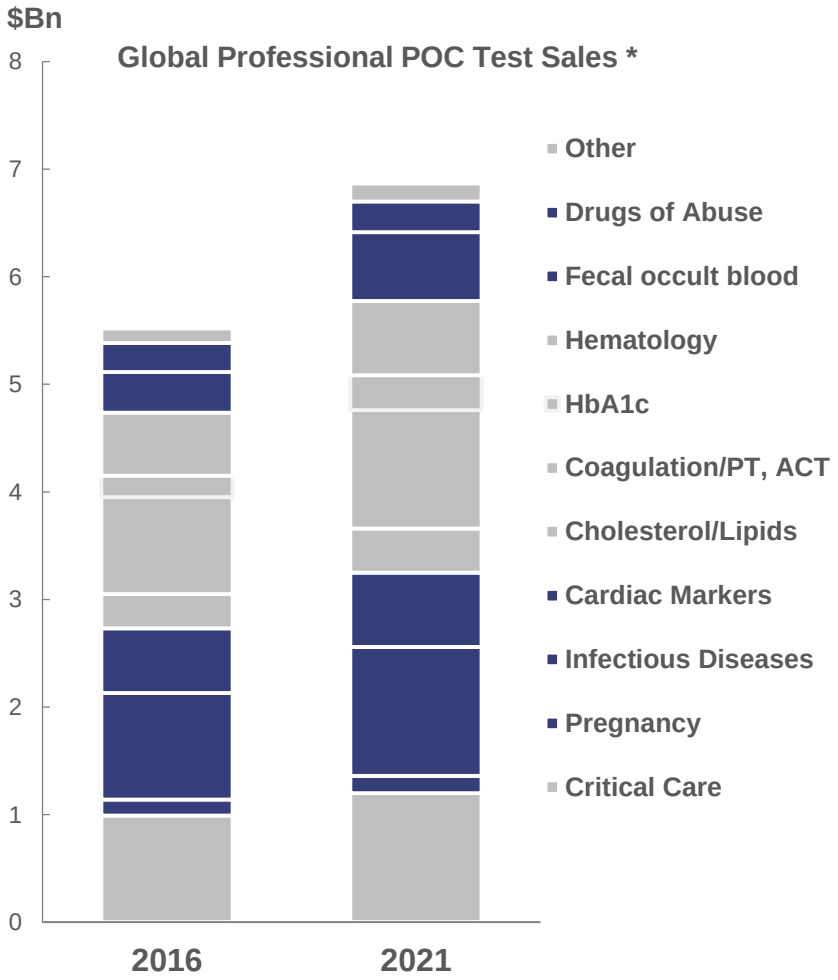
Source: Meddevicetracker 2016, Deloitte Analysis, Giles 2015, Kalorama Retail Clinics 2017, Quidel Analysis
Segments include glucose testing

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Where We Play…







Source: Kalorama 08/16, Quidel Analysis
POCT Worldwide 'Other' category includes TSH, PSA, FSH, cancer, etc

* Does not include "New Market" category as defined by Quidel on subsequent slides

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Our Strategic Intent



Build a broader-based diagnostic company that delivers revenue and margin more consistently. Use existing resources to fortify price and volume in our core businesses, while using our capabilities to attack the limitations of our competitors, and to forge ahead to create new markets.

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Quidel's 3 Main Objectives in Support of Our Strategic Intent



Cultivate organic growth from Legacy QDEL and Triage and BNP Businesses

Near-to-Mid Term



Fully integrate the Triage and BNP Businesses, and realize synergies;

Pay down debt

Near-to-Mid Term

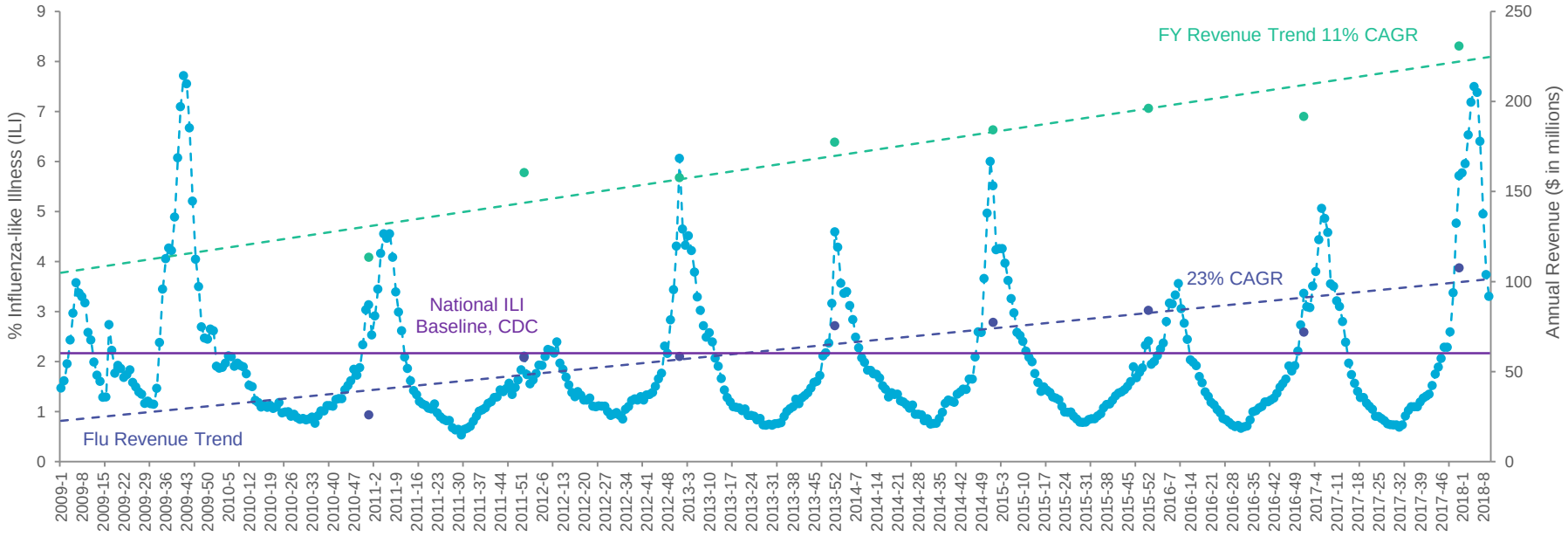


Grow revenues to FY $1B through M&A and new product introductions

Longer Term

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…and Flu, although Volatile, continues to Drive Growth for the Legacy Business as well as the New Quidel.

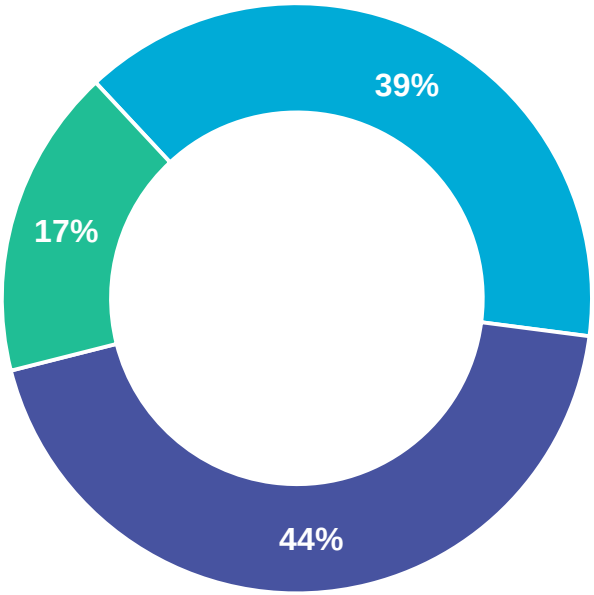


Although ILI varies with each season, **Quidel's revenues have grown at a 11% rate,** largely driven by growth in **Influenza sales.**

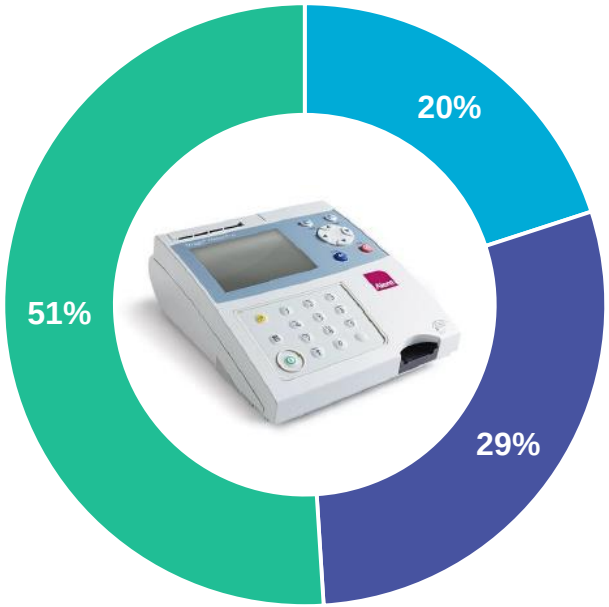
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Complementary Product Lines like Triage and Beckman BNP will Mitigate some of Quidel's Flu Volatility, Reducing Flu Exposure in half, while Creating Scale, providing a Stable Revenue Base, and Introducing us to a New Set of Customers.

2017 Revenue Profile



2018 Anticipated Revenue Profile



Influenza Non-Flu (ex-Cardiac) Cardiac

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Quidel – Building on a History of Innovation

2009 - Present

Acquired Triage and BNP Businesses from Alere	Submitted over 30 510(k) packages to the FDA	Over 25 FDA clearances and expanded product claims, 4 CLIA waiver designations
Launched Sofia 2 platform, 3 FDA-cleared assays	Launched Solana instrumented MDx platform	Launched Sofia platform and 4 FDA-cleared assays
Launched 2 first generation molecular systems (AmpliVue & Lyra)	Launched Virena wireless system	Acquired DHI ($45 million annual direct business)

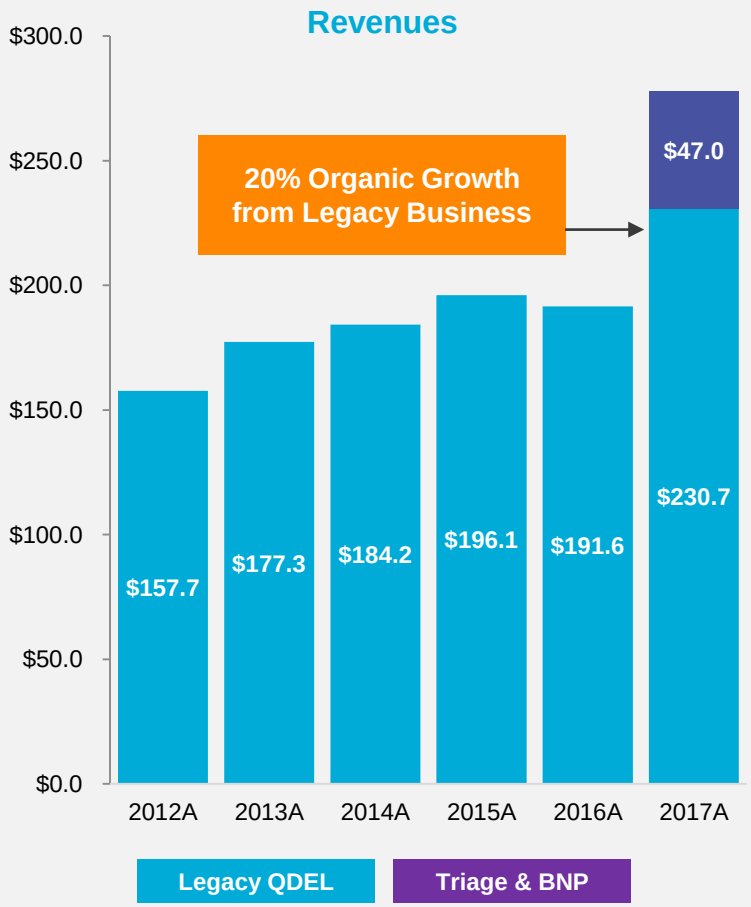
Acquired BioHelix (proprietary HDA technology)	Acquired Immutopics direct bone health business	Acquired RPS POC direct Eye Care businesses	Acquired ViroMed, CellPro direct Virology businesses

1989 - 2009

Launched QuickVue Influenza A/B rapid diagnostic assay	First company to receive CLIA waiver for Flu, Strep and H. pylori tests

1979 - 1989

Company founded	Primarily a provider of Strep A and Pregnancy rapid diagnostics



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Our Focus for 2018







Integration of the Triage and BNP Businesses

- Unlocking synergies
- Leveraging our new sales territories and stronger sales channels in North America
- Strengthening our International Presence

Paying down Debt

Positioning the company for added M&A in the medium to longer term

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A DEEPER DIVE STRATEGY DISCUSSION

Bill Ferenczy,
Vice President
Strategy



QUIDEL

Evolution of Quidel Strategy



1979
Quidel Founded



1985
Strep A

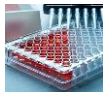


1999
Flu A/B

1970 | **1980** | **1990** | **2000** | **2009**



1984
QV HCG



1989
Acquired Bone Health and Complement

CLIA waivers for Strep A, Flu A+B



Cellular Assays



Molecular Diagnostics



Digital Immunoassays



Cardiology Toxicology



Eye Health

Broader-based diagnostic company that delivers revenue and margin more consistently. Use existing resources to fortify price and volume in core businesses, capabilities to attack the limitations of competitors, and to forge ahead to create new markets

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Charting a Course for the New Quidel



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Customer Driven Approach

A Traditional View



Reference Labs



Hospitals



Clinics



Home

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Our Customer Driven Approach

A More Granular Analysis is Needed



Research	Reference Labs	Hospitals	Clinics	Home
Pharma CRO Univ.	LabCorp Quest ARUP Etc.	Large Hospital Lab	Free-Standing ER	OTC and Self-Testing
	Public Health	Small Hospital Lab	Urgent Care Center	
	IDN Core Lab	Micro Hospital Lab	Physician Office	
			Public Health Clinic	
			Retail Clinic	
			Pharmacy	

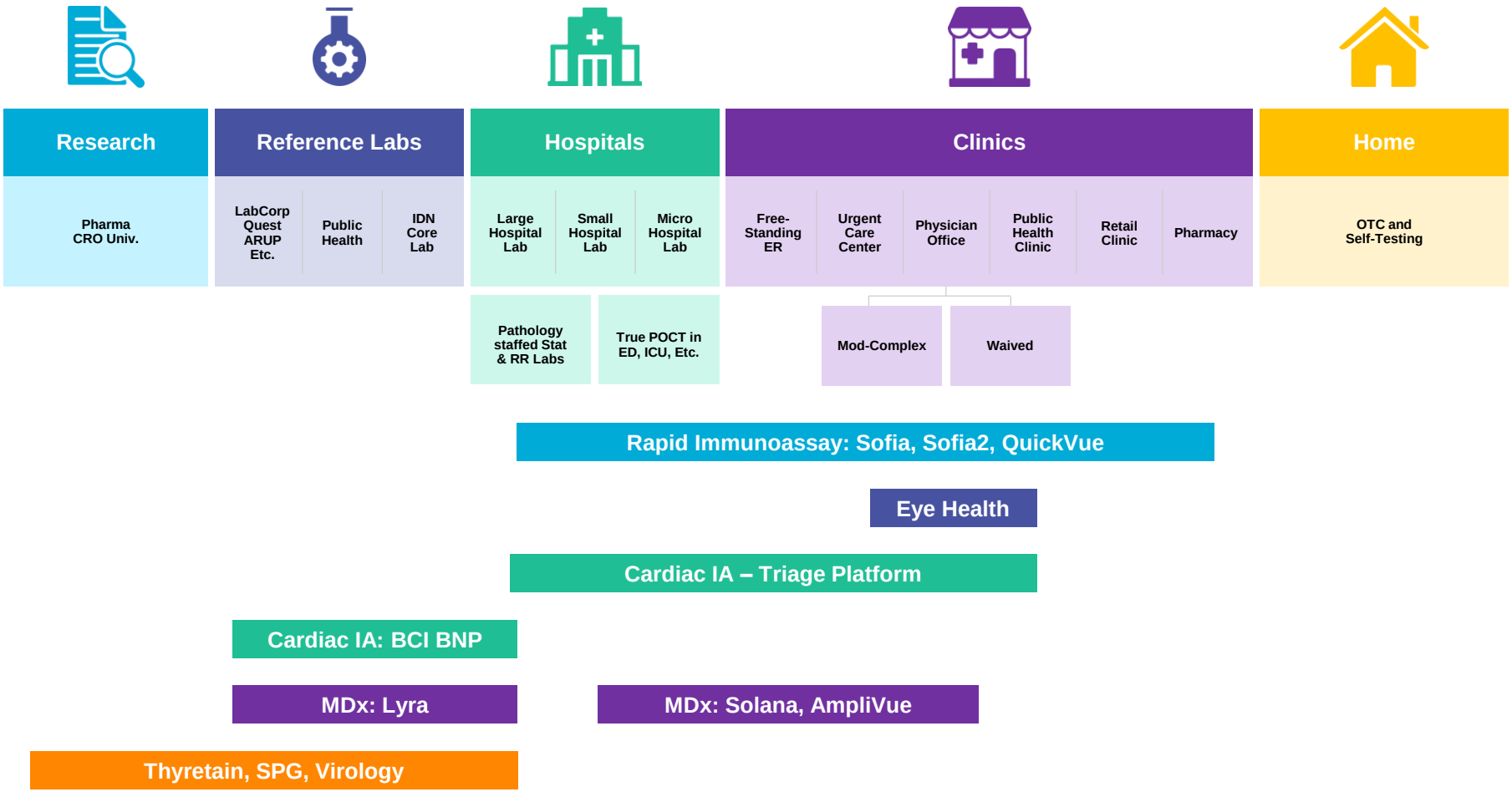
Hospitals	Clinics
Pathology Staffed Stat & RR Labs	Mod-Complex
True POCT in ED, ICU, Etc.	Waived

Many different customer segments, each a unique combination of

Patient types and level of acuity	Patient workflow	Inpatient/ outpatient mix	Reimbursement	Patient and test volumes	Staffing and CLIA status	Turn-around time & throughput requirements

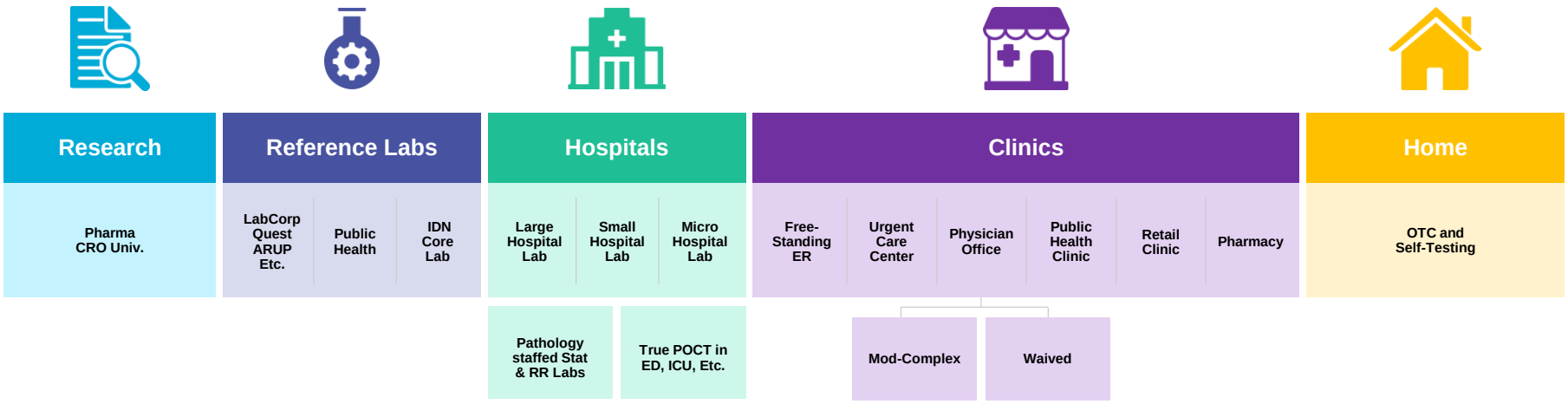
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Where We Play Today



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Competitive Environment



"Big Box Country"

- High volume, automation, robotics
- Heavy capital investment
- Large menu, "bundling"
- Focus on throughput and test cost
- Centralized purchasing
- "Efficient laboratory testing"
- Dominated by large Dx companies

"Land of Opportunity"

- Low volume per site
- Need for low cost instruments
- Selective menu, varies by site
- Focus on turn-around time, clinical impact
- Higher influence from end-users, clinicians
- "Effective laboratory medicine"
- Room to play and grow with right products

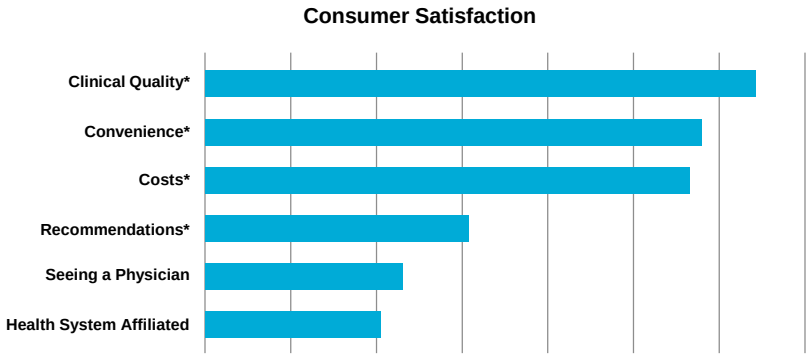
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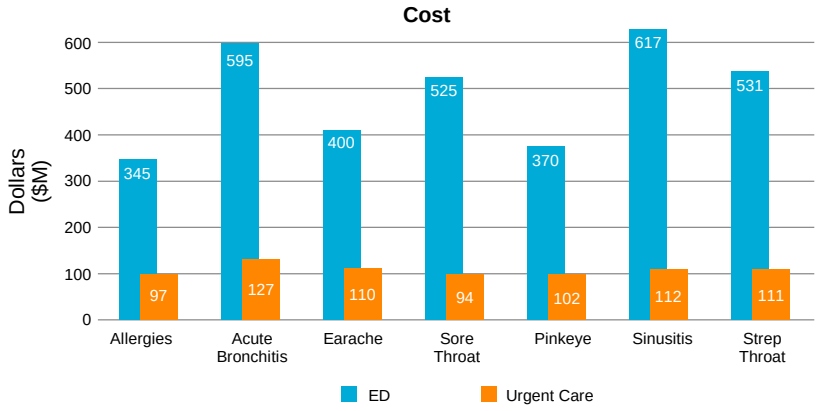
Favorable Market Trends for POCT

Research	Reference Labs	Hospitals	Clinics	Home
Pharma CRO Univ.	LabCorp Quest ARUP Etc. Public Health IDN Core Lab	Large Hospital Lab Small Hospital Lab Micro Hospital Lab	Free-Standing ER Urgent Care Center Physician Office Public Health Clinic Retail Clinic Pharmacy	OTC and Self-Testing
		Pathology staffed Stat & RR Labs True POCT in ED, ICU, Etc.	Mod-Complex Waived	

Patient Care



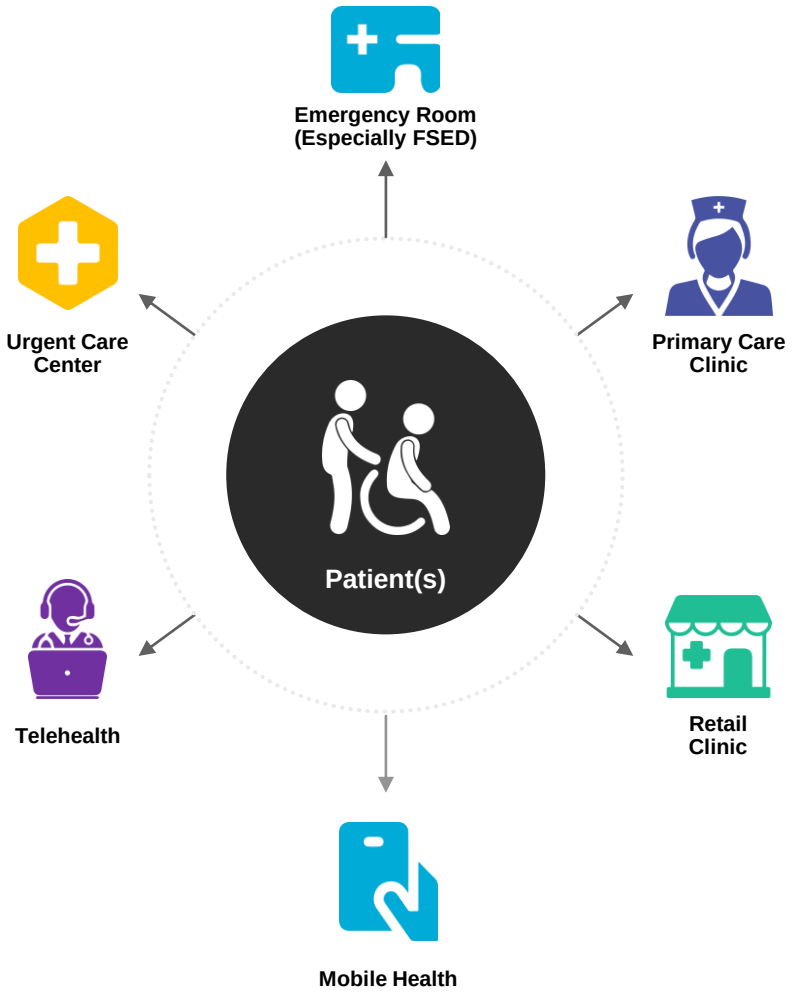
*Composite scores
Source: UCP survey of 1,427 urgent care patients



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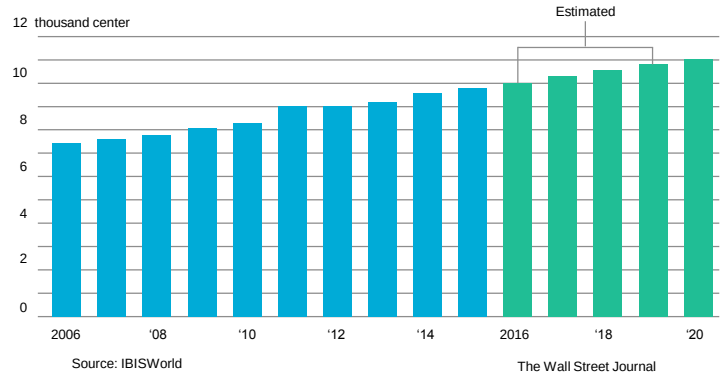
Decentralization Creating More Opportunities for POCT

Multiple Channels for Primary Care Delivery



Surge in Urgent Care – Nearly 11,000 Locations

Rising demand for high-quality, non-critical care is fueling growth of urgent-care centers. Forecasts are for numbers to grow further as the population ages and more people have health insurance.



Source: IBISWorld

The Wall Street Journal

600 Free-standing Emergency Departments



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Quidel Strategy Overview



Design and develop innovative platforms, assays and informatics that satisfy unmet needs in true POCT settings



Leverage these products to penetrate and grow business in POCT and other decentralized market segments



Exploit selected opportunities in other segments by leveraging:

- POCT platform capabilities and large base of placements to expedite introduction and uptake of novel biomarkers
- SPG/Cell-based technologies to deliver innovative tests for non-POCT settings

Supplement, Enhance and Expand via licensing, M&A

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POCT Guided Innovation

A Clear Definition of POCT is Critical

Widely used, but ambiguous term

Many people equate POCT with:

- Any testing not performed in large central labs
- Any testing performed on a POCT-style platform

Our definition provides clarity:

- Test performed near patient
- Can be run by non-lab personnel
- Actionable results
- Results available while patient waits



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POCT Guided Innovation

Enables Three Sustainable Positions

Design for POCT:

- Rapid results
- Simple (“Waivable”)
- Small footprint/portable
- Low cost instrument
- Low total cost/patient result at low volume
- Room temp stability
- Data capture for connectivity/surveillance
- Test menu with urgent and other actionable assays
  - Infectious disease
  - Cardiology
  - Inflammation
  - Toxicology
  - Neurological
  - Gastrointestinal

1. Penetrate/Grow POCT Business

Hospital ER, ICU and OR
Free standing ERs, Urgent Care
Physician, STD, Retail Clinics; Pharmacies
Mobile health, home testing, Etc.

2. Penetrate Other Decentralized Sites

Small Hospitals, Mod-complex POLs

Lower volume settings where total cost/patient test competitive with central lab analyzers

3. Novel Biomarkers

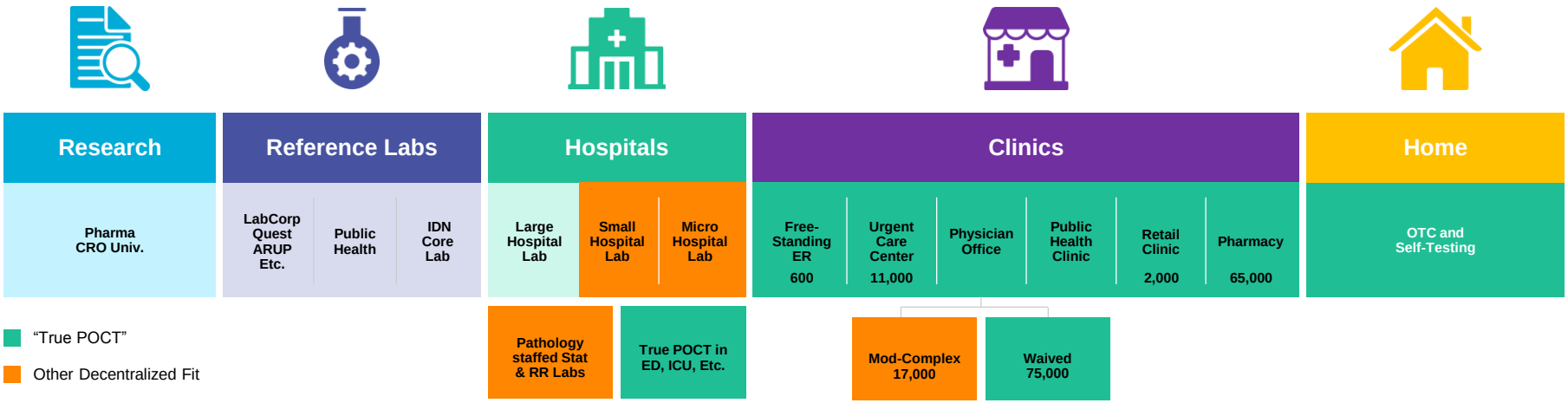
Established base of instruments provides a large number of potential customers for novel test

Low cost platform facilitates acquisition and speeds uptake in other settings

Potential to collaborate with wide range of partners developing new biomarkers

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Where We Will Win



Rapid Immunoassay: Sofia, Sofia2, QuickVue

Cardiac IA – Triage Platform

Eye Health

MDx: Savanna

Novel Biomarker

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Continued Immunoassay Innovation and Menu Expansion

2018 → **>2023**



Sofia/QuickVue

Grow/Leverage Instrument Base		Near Term Assays		Sofia2 "Enhanced" Assays
Flu A+B	RSV	Lyme WB	Vitamin D (Europe)	Strep 98
Strep	Lyme (serum)	Sofia2 Legionella & Strep pneumo (Europe)		Respiratory Virus Panel
		QV Adeno (pink eye)	C. Difficile	

Integration/ Account Management		Defend and Grow		
Solidify base	D-Dimer	Continued Growth OUS	Launch hsTnI in Europe	Defend US base
BNP in POL	Intl. Growth			

Other Potential Sofia and/or Triage Assays	
Eye Health	Cardiorenal/AKI
PCT	Syphilis/ Other STD
Toxicology	TBI
Dengue	Fungal Infection
PIGF	TB Serology
Bacterial/Viral Differentiation	

Next Generation IA System
Cardiac, toxicology, infectious disease, inflammation, other key acute conditions
High Sensitivity
Multiplexing
Shorter TATs
Design Synergy with Savanna



Triage MeterPro

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Savanna Will Drive MDx POCT Penetration and Growth

2018 — **2020** — **>2023**

Savanna



Finalize Cartridge and Instrument Development

Sample to Results	30 – 45 Minute TAT
Multiplex Up to 12 Targets	
Low Cost Instrument/ Disposable	Room Temperature Stability

Assay Development

STD Panel		HSV/VZV/ Syphilis
Respiratory Virus Panel	Vaginitis	HIV VL

Clinical Studies for Initial Savanna Assays

Launch
Europe Late 2019
US: 2020

Other Potential Savanna Assays

- GI Panel(s)
- C Difficile
- MRSA, VanA, Carba-R
- Group B Strep
- HCV
- Transplant
- TB
- Blood Stream Infection

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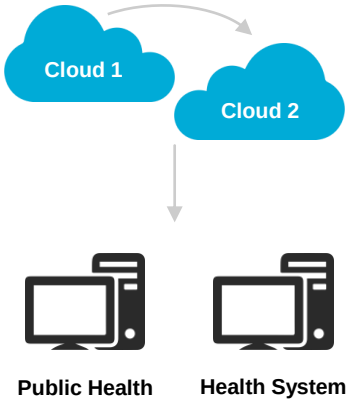
Placements Power Virena



7000 Connected Analyzers



Daily Data Upload
(Now >1 million results/month in peak season)



Cloud-Based Data Management

Simple, **secure** and HIPAA compliant

De-identified data **automatically transmitted** via a secure, cellular network

Data securely stored and available anytime, from anywhere, for **authorized users**

De-identified data may be shared with federal, state and local health organizations to **support public and private** health partnerships

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Virena Powers Placements and Test Utilization

Virena Ecosystem Creates Value for Multiple Stakeholders



Public Health

- Real-time disease surveillance
- Incidence and prevalence data
- Power public awareness and action plans

Clinicians

- Prevalence data
- Pre-test probability to enable increased diagnostic certainty

Health Systems/Providers

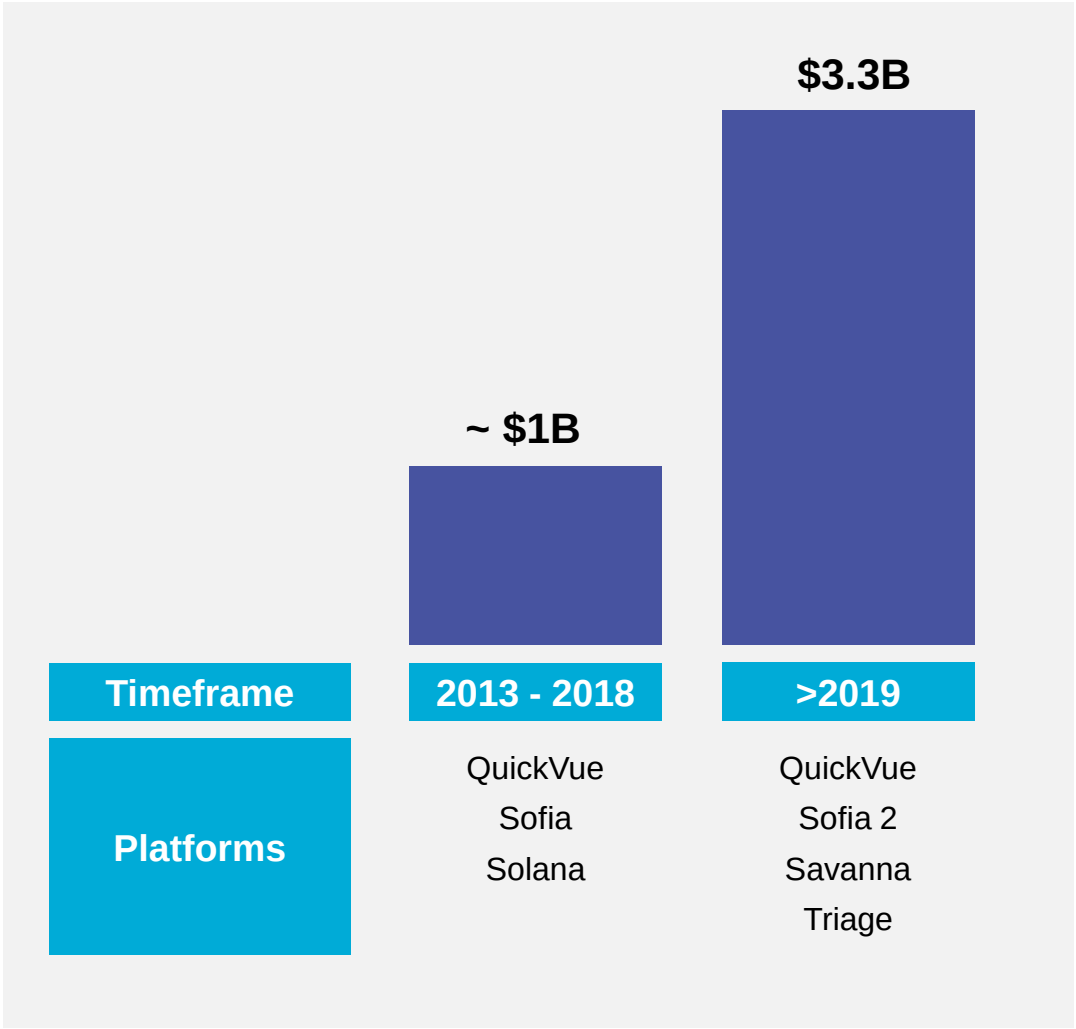
- Management of remote analyzers; quality control
- Forecasting/resource planning
- Prevalence data to support reimbursement

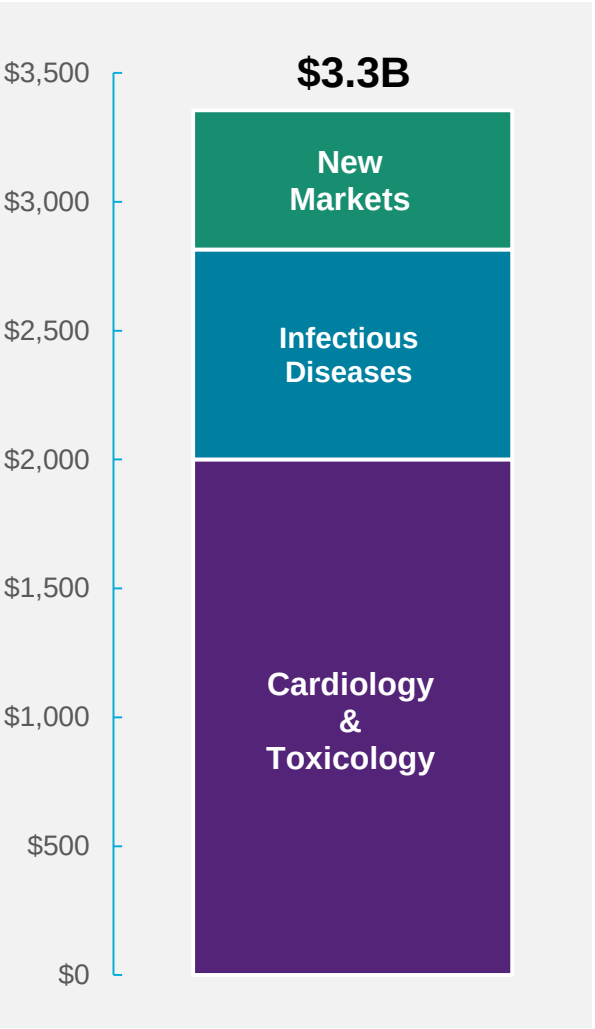
Quidel

- Monitor real-time usage
- Forecast seasonal demand
- Quality control
- Geotargeting

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A Much Larger Addressable Market for the New Quidel





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Summary

POCT-guided design and development of innovative platforms, assays and informatics

Penetrate and grow Quidel business in targeted market segments

- True POCT settings
- Other decentralized and low volume sites

Exploit selected opportunities in other market segments

A focused approach that best leverages Quidel's legacy and recently acquired assets for success in an addressable market estimated at $3.3B

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PRODUCT DEVELOPMENT UPDATE

Werner Kroll,
Senior Vice President
R&D



QUIDEL

Innovative Product Developments Combined with Systematic Evolutionary Improvements of Successful Product Lines – From Sample to Cloud

1984	1998	2011	2017	2022
QuickVue	**Triage**	**Sofia**	**Sofia 2**	**NGI**
• Original product concept • Lateral flow immunoassay • Fast, visual read results • CLIA waived	• High sensitivity assay • Quantitation • Assay documentation • Fast results	• Instrument read lateral flow • Improved objective results • Documentation of assay results • Higher sensitivity through fluorescent readout • Normalization	• Multiplexed immunoassays • Improved sensitivity • Analyte quantitation • Built-in communication and barcode reader	• Improved sensitivity and robustness • Assay modularity • Scalability of many small manufacturing lots

NGI: The Next Generation Immunoassay platform for the next decade

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Savanna Molecular Platform*: Targeting CLIA Waived Sample-In Result-Out Simplicity

Mini panels are the sweet spot for Savanna assays in the continuum from one parameter assays to arrays to NGS based broad panels



System Builds on Proven Robust Technologies

- 4 color PCR multiplexing
- Magnetic bead based nucleic acid isolation
- Peltier technology with light fiber optical readout

Simplicity and Speed (15–50 minutes TAT)

- Allows use in CLIA waived setting

Instrument Modularity

80/20 Assay Concept

- Provide actionable cost conscious results for majority of samples – direct remaining samples to reflex testing

Scalable Assay Manufacturing Concept

*in development

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2017 Focus of Savanna Project on Development of Solutions for Developed Markets

Mini panels are the sweet spot for Savanna assays in the continuum from one parameter assays to Array or NGS based broad panels



Develop critical mass of target sized mini panels (4 to 8 analytes) at time of launch of Savanna platform

- STD panel
- Pharyngitis panel
- Respiratory panel
- HSV / VZV / Syphilis panel
- Vaginitis panel

Provide differentiating therapeutically actionable clinical results

Provide CLIA waived solution that solve the needs in simplicity, hands-on time, turn around time

Address limitations of single parameters as delivered by current systems

Addresses and implements move from fee for service medicine to value based diagnostics

Address reimbursement issues created by large array panels or NGS based assays

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Strep 98*: Next Generation Sofia2 Lateral Flow Strep A Assay with Performance Not Requiring Culture Backup

Addressing the entire clinical Process Line

Quidel already providing complete strep A solution from RADT to confirmatory Solana molecular assay

Reducing time to “confirmed” results from days or hours to minutes

Target to improve Sofia Strep A+ assay performance from excellent 93.7% sensitivity and 94.4% specificity to CLIA waived a 98.2% sensitivity and 97.2% specificity no culture backup performance of Solana GAS

Reduce risk for potential complications in missed positive children while still maximizing antibiotic stewardship and reducing unnecessary use of antibiotics

Sofia Strep A+	
Sensitivity	93.7%
Specificity	94.4%

No culture confirmation required

Solana Gas - Mod. Complex	
Sensitivity	98.2%
Specificity	97.2%

Sofia Strep 98*	
Sensitivity	9x%
Specificity	9x%

Sample Preparation → **Sample Enrichment** → **Background Reduction** → **Image Analysis** → **Statistical Data Handling**

* in development

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Sofia 2 Whole Blood Lyme Assay Racing toward Simplicity in an Overly Complicated World

Simplify user workflow and improve patient experience

While choosing a system that is simple we ensured by the introduction of bidirectional flow concept that we provide still more or the same information as current assays.

When designing and developing the whole blood Lyme assay we shifted our focus beyond the underlying technology to also include the user experience.



Current Workflow

- Blood draw from patient with syringe and needle
- Sample sent to lab
- Sample centrifuged for plasma separation
- Assay run on big box instrument
- Patient contacted for follow up
- Result communicated to physician

Sofia 2 Enabled Workflow

- Obtain finger prick sample from patient
- Run Sofia 2 Lyme assay-
  Obtain result in 15 minutes
- Initiate follow up activities while patient still present

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RVP4: Respiratory Virus Panel on Sofia 2

New lateral flow multiplex technology allows cost conscious simultaneous detection of panel of most prevalent respiratory viruses

Differential diagnosis assay for patients presenting with ILI symptoms

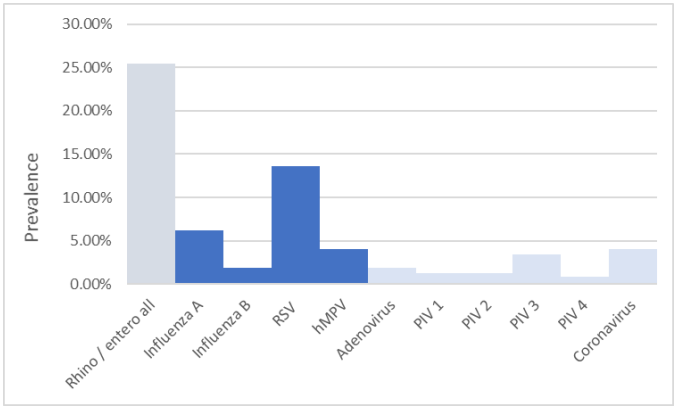
Expand the use of current products into broader actionable panels

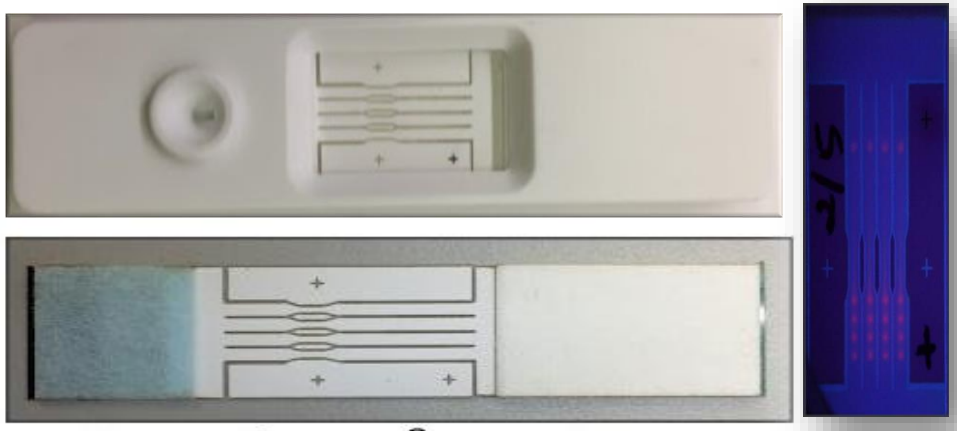
Covers FluA, FluB, RSV and hMPV on one Sofia 2 cartridge

Prevalence during Flu season is comparable for Flu, RSV and hMPV

- Efficient algorithm for sequential reflex testing not meaningful
- Infections caused by all 4 viruses impact same target groups (elderly and children)

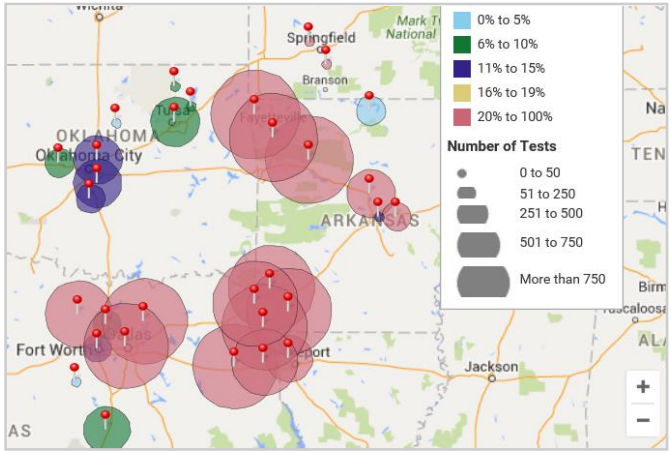
Flu, RSV and hMPV results are actionable and have different treatments mandating differential diagnosis

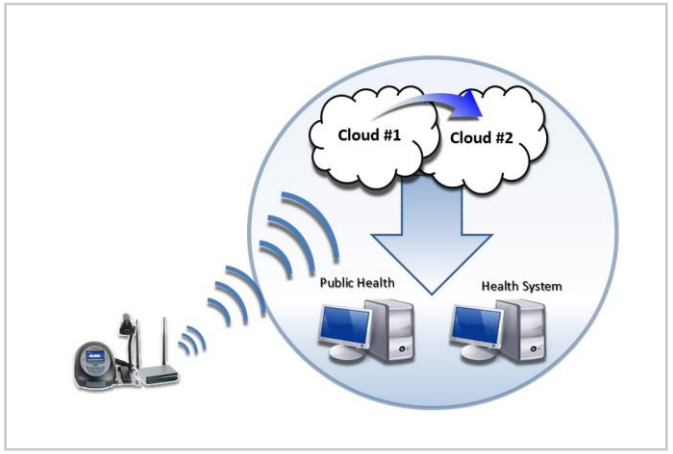




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Virena Data Management and Surveillance Tool





Real-Time Data Management

- Remotely Manage Instrument Usage, Support Operator Training Initiatives, and Monitor QC Compliance

Real-Time Infectious Disease Mapping

- Respond rapidly to emerging infectious disease trending in your area
- Aid in diagnostic accuracy
- Efficiently manage staffing needs

Simple, Secure and Compliant

- Data is de-identified and shared with federal, state and local health organizations in near real-time
- All data is shared with authorized users at myvirena.com
- Transmits data on a secure cellular, 4G LTE network, connection to existing networks is not required

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BREAK



QUIDEL

NORTH AMERICAN COMMERCIAL UPDATE

Ed Russell,
SVP North America
Commercial Operations



QUIDEL

US Commercial Update

1 Overview of Acquired Alere Assets

2 Points of Commercial Leverage and Lift

3 Integration Execution

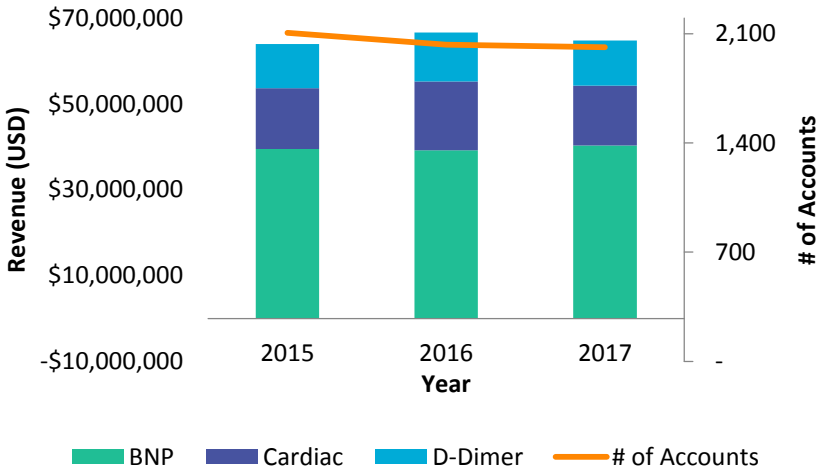
4 Trends of Influenza Accounts

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Acquired Assets in US

Triage MeterPro

2015 – 2017 CAGR = 0.4%



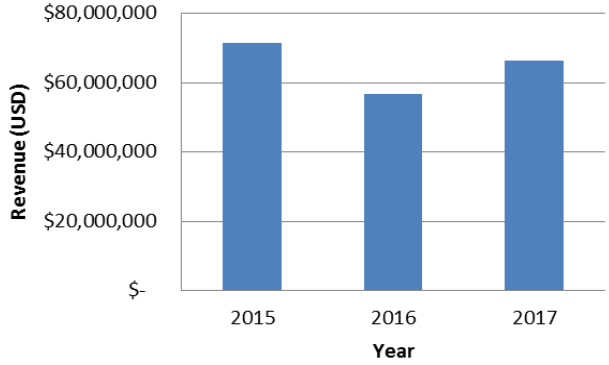
2015 to 2017 Revenue CAGR 0.4%

- Hospital growth flat
- POL growth at ~4%

- **6,450** Triage instruments across ~2,100 accounts
- **60%** of accounts purchasing one assay
- **~14** Headcount transitioned to Quidel (Tech Support, Marketing, FAS)
- Very limited commercial focus from Alere in past **~2 yrs**

Beckman BNP

2015 – 2017 CAGR = -3%



2015 to 2017 CAGR at -3%, but 2018 YTD indicates staying at 2017 levels.

Revenue primarily driven by Beckman **winning and retaining** large analyzer placements

780 accounts

Historically, there was **limited interaction** between Alere and Beckman Commercial Teams

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Commercial Leverage and Lift

Common Call Points Drive Sales Rep Efficiency

- **Acute** : Core Hospital Labs, EDs, IDNs
- **POL** : Urgent Care, Family Practices, Free Standing EDs, Community Health Centers
- **Government** : VA System, DOD, Public Health

Minimal Incremental Sales Headcount

Legacy Quidel built-out US sales infrastructure 2014-2015 in prep for organic/inorganic scaling

- **Average Quidel Rep Territory pre-Alere ~ $2.5M** (ex DHI, Eye Health, Research)
- **Average Quidel Rep Territory post-Alere ~$3.5M** (ex Beckman BNP)

Substantive Cross Selling Opportunities

- Established Triage and Beckman BNP accounts (Hospital Core Labs, IDNs, VA) providing efficient and more leveraged access for legacy Quidel products
- Pulling Triage into historically strong segments of Quidel – Urgent Care, POL, Community Health
- Q2 initiating cross selling program targeting acute accounts based on gaps in Triage, molecular, and immunoassay

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Integration Execution

Intense Sales Training Program

- Two comprehensive in-person training sessions (Oct 2017 & Feb 2018); augmented by required e-learning program (Brainshark)
- All Reps Certified on Product, Positioning, Competition and Disease States

2018 Sales Compensation Plan Driving Triage

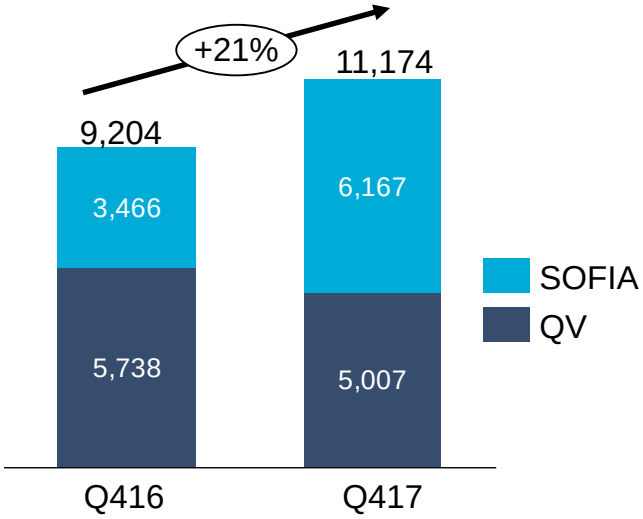
- Triage in ‘Strategic Bucket’
- ‘Add an Assay’ Program launching Q2 to leverage existing Triage installed base

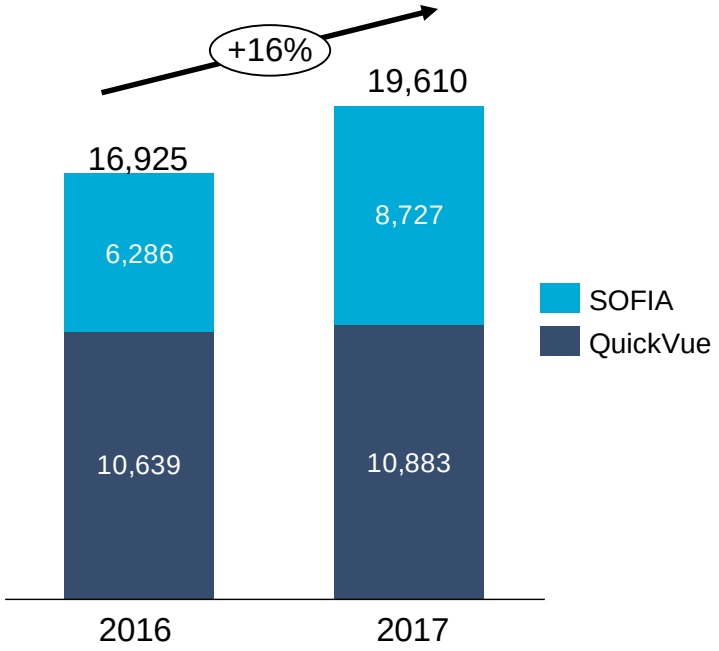
Working Well with Beckman Commercial Team

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Influenza

Distinct Ordering Account - QuickVue & Sofia Influenza





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INTERNATIONAL BUSINESS REVIEW

Ratan Borkar,
SVP International
Commercial Operations



QUIDEL

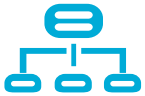
Discussion Overview



Overview of international business



Profile of the Triage business acquired



Go-to-market (GTM) strategy for the acquired business



Progress made since Day 1

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International Market Dynamics

- Physician office testing in some countries
- Call point is mainly hospitals
- Flu testing is the standard of care in a few markets; limited Strep A market

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International Market Dynamics



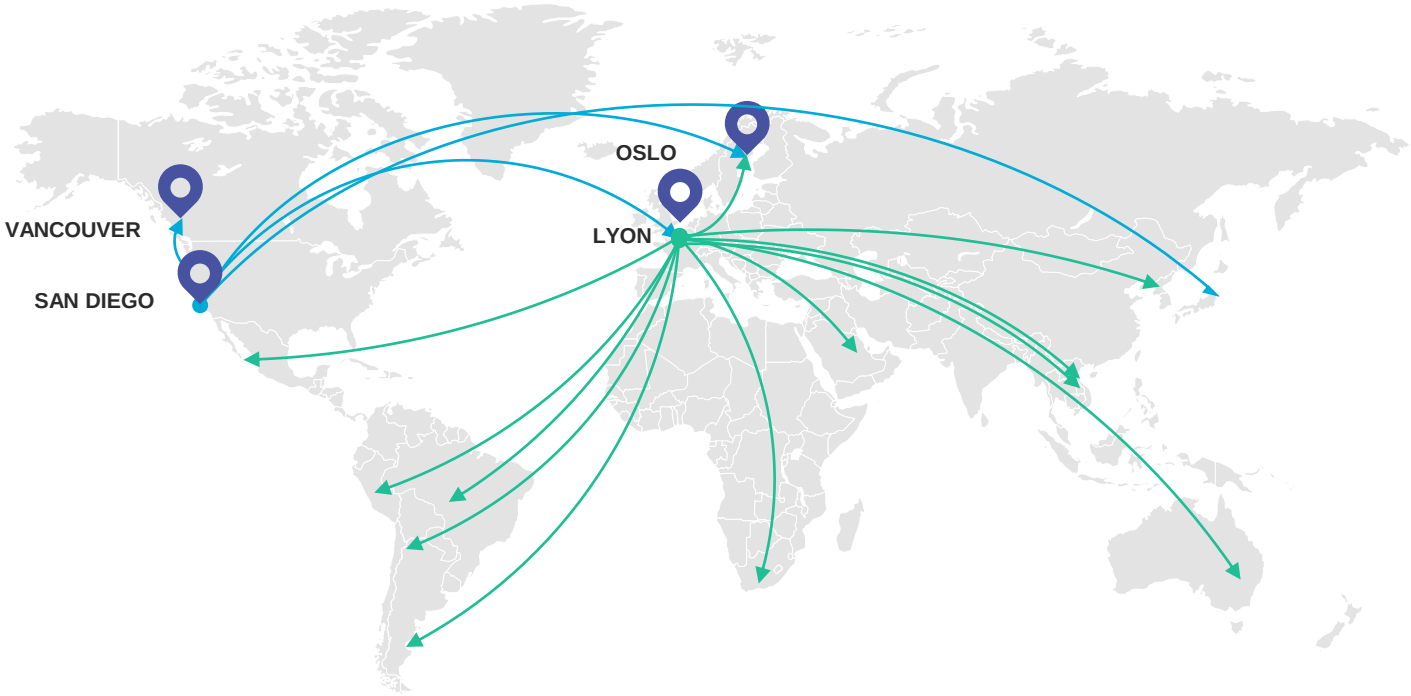
Intense competition from low cost manufacturers (FDA not barrier to entry)



Reimbursement varies

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Prior to 2012 We Had a Handful of Distributors

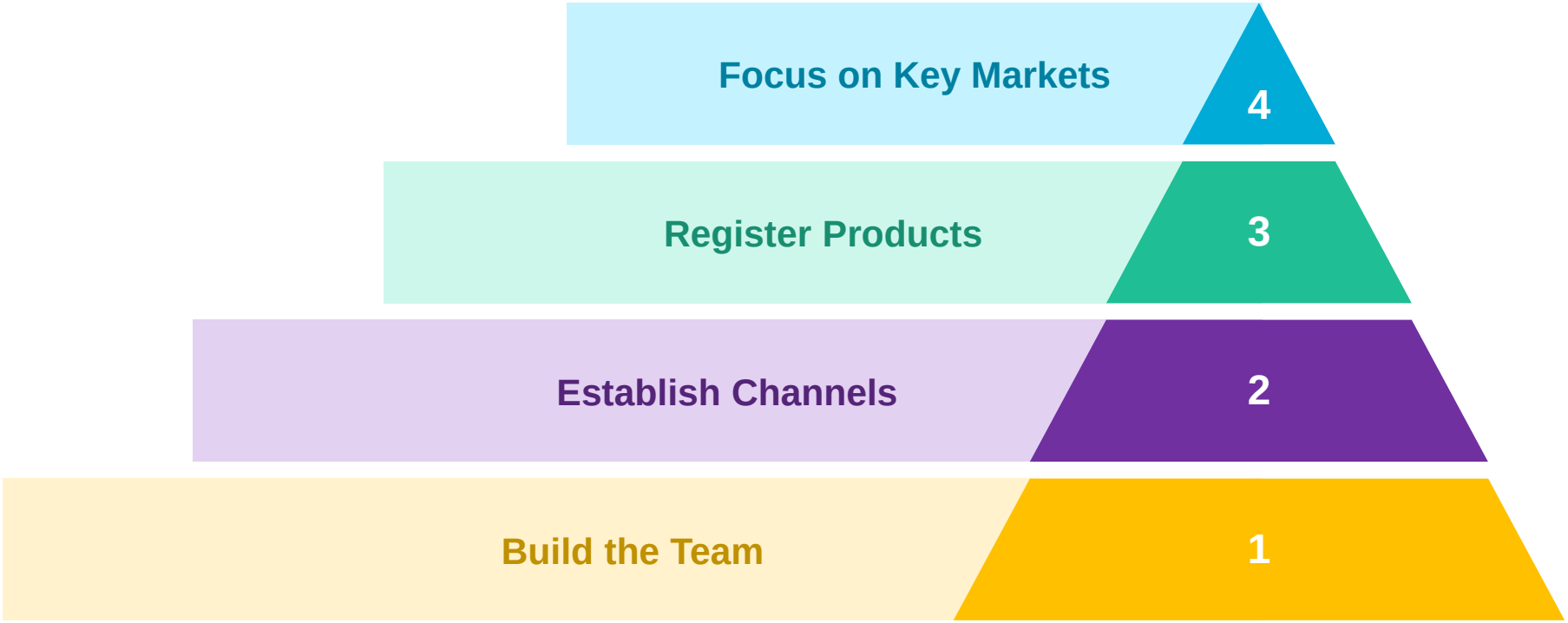


Direct Shipments

Biomerieux

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Commercial Strategy



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The Triage acquisition was transformational for the international business

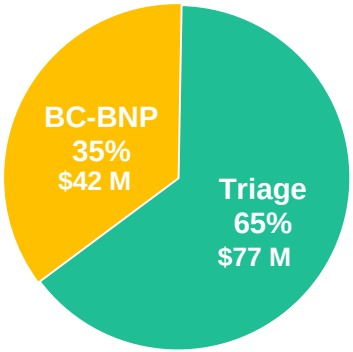
Quidel Int'l Sales

$33 M*



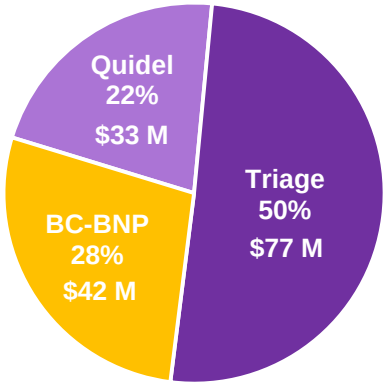
Triage + BC-BNP Int'l Sales

$120 M



Combined Entity Int'l Sales (Pro forma)

$153 M



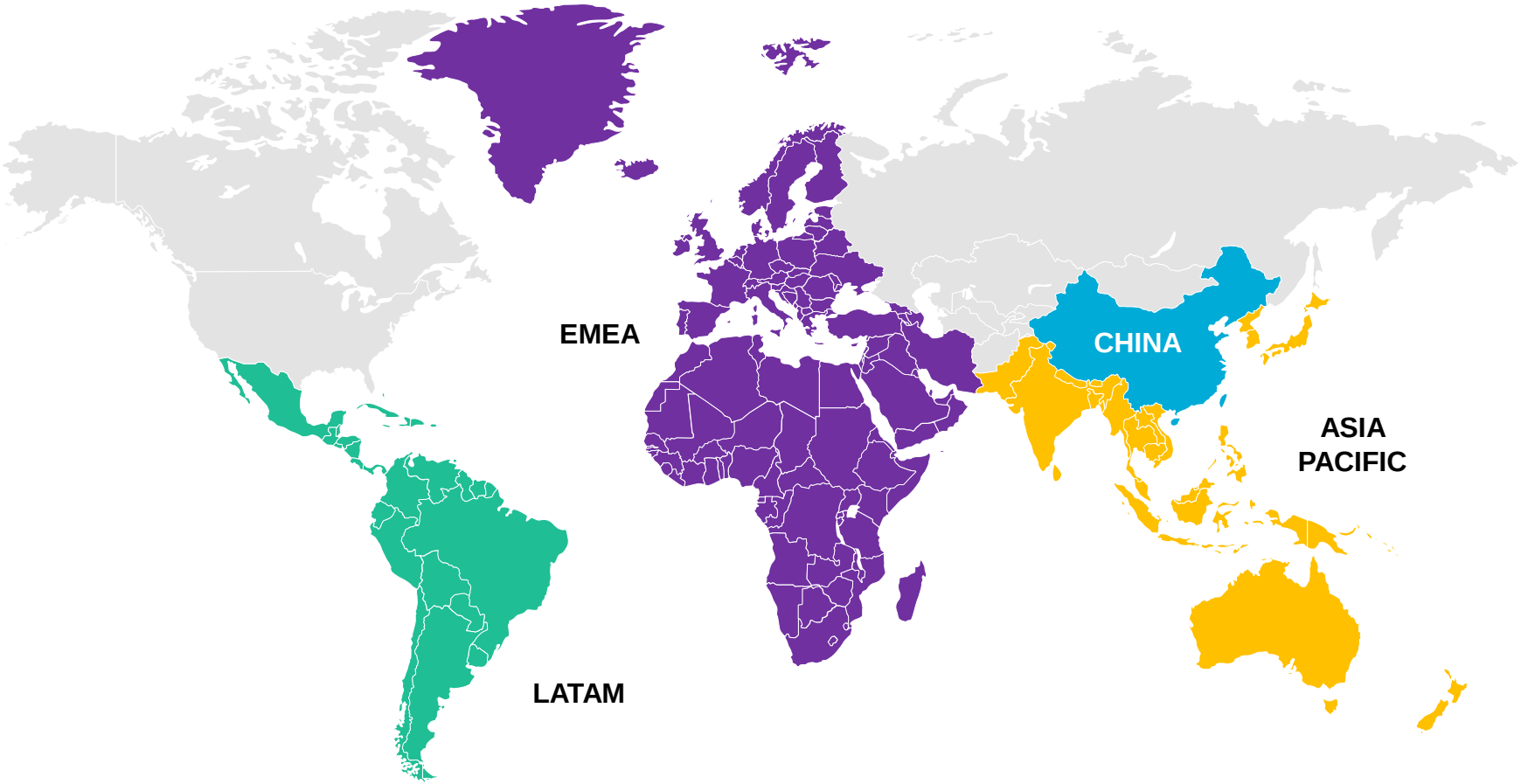
Key Observations

- **Scale of international business has increased significantly (5x)** with the acquisition of the Triage and BC-BNP product portfolio
- Triage and BC-BNP product portfolio will provide Quidel with **greater diversification and geographic footprint,** and will increase its penetration of the point-of-care market
- This will allow Quidel to **have critical mass in key countries to build a commercial presence** to redefine its go-to-market strategy

Note: All revenues correspond to FY '16
*Includes sales for 'Specialty Products' group

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2018 International Commercial Structure



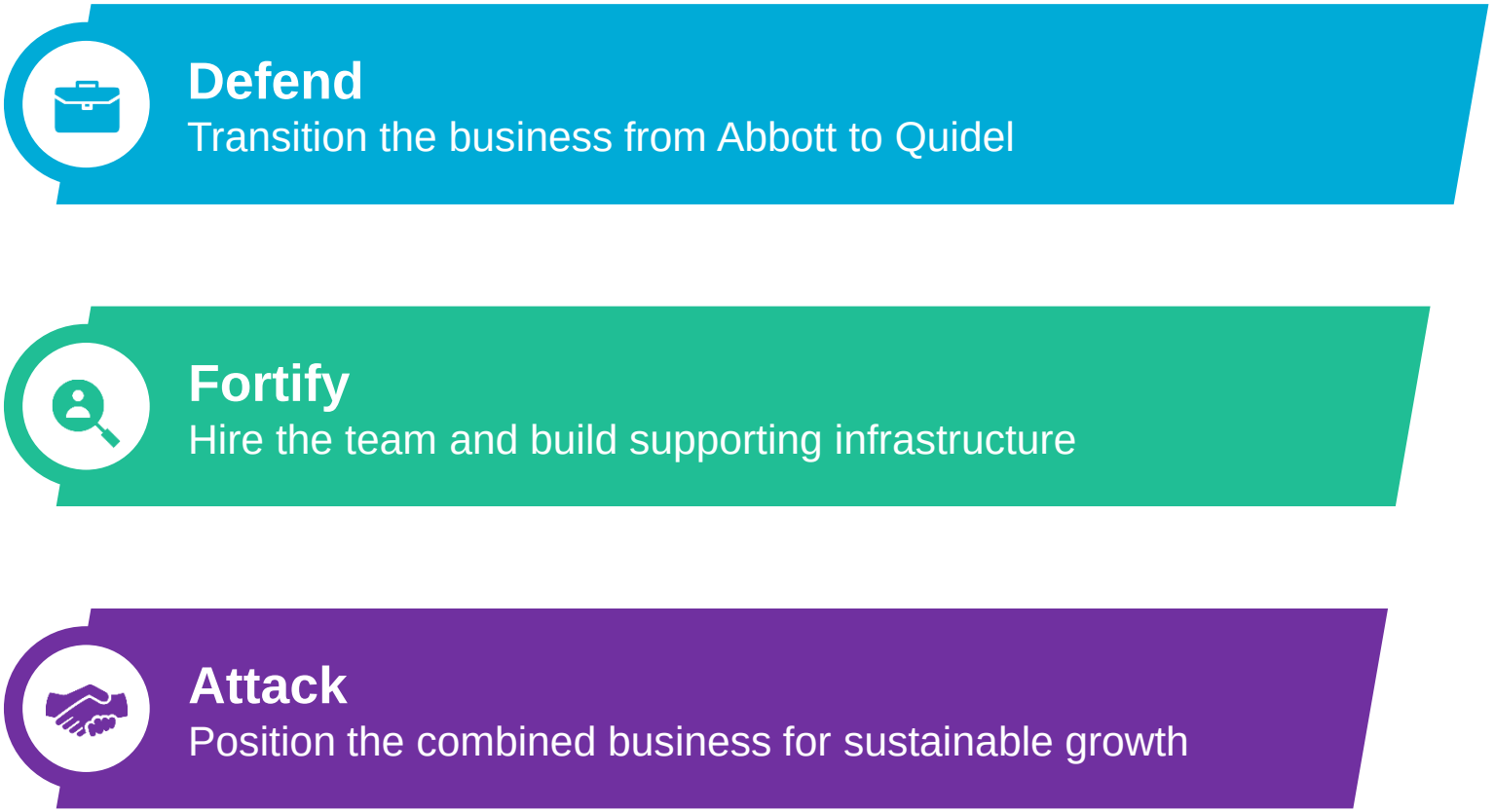
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Concurrently We Are Building Back Office Functions

- ERP systems are being built to support Order to Cash
- 3PL proposals are being received for shipping and logistics for Europe, China and India
- Shared Services for Europe being built in Ireland
- Building China Operations

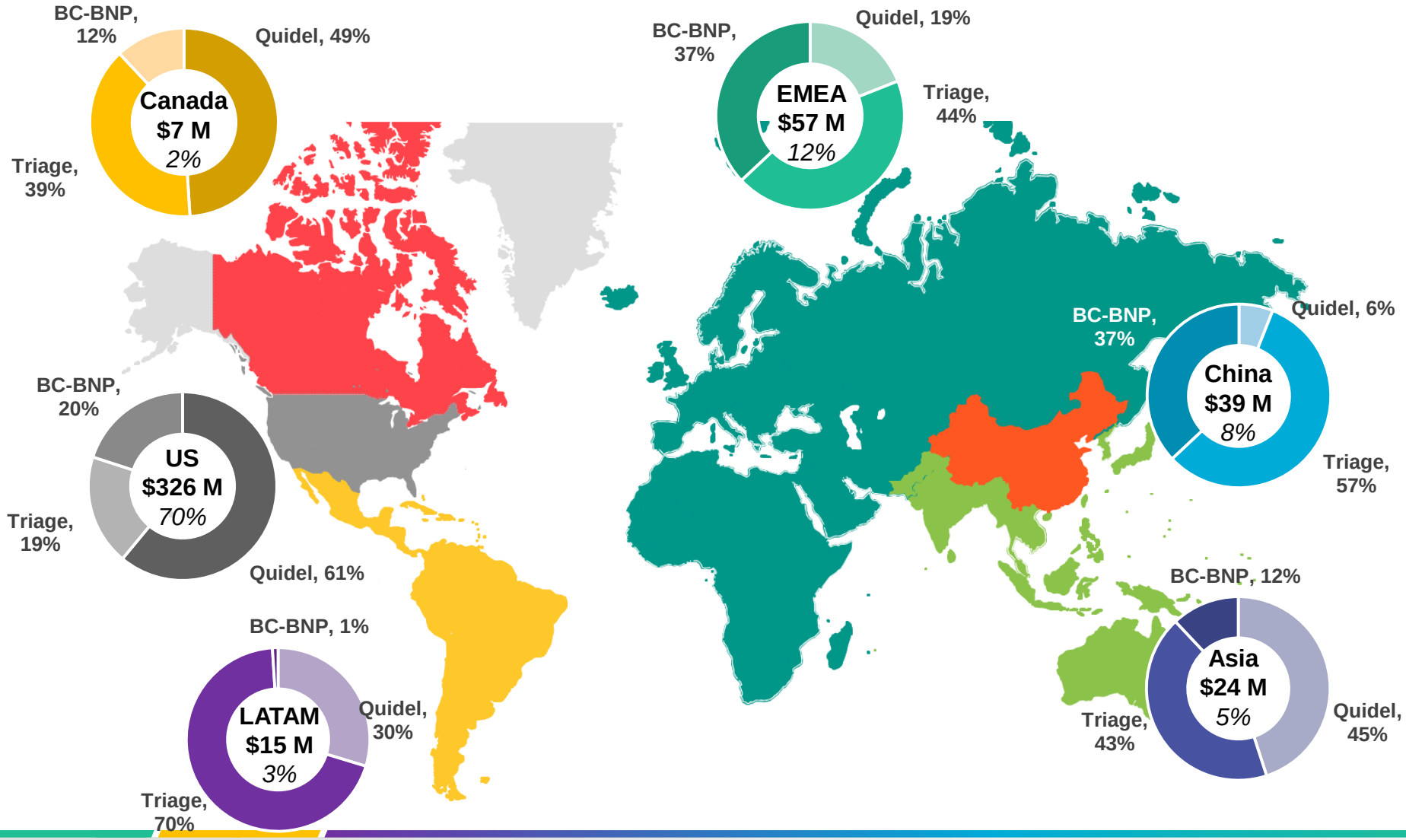
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2018 Top 3 Priorities



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Geographical footprint of the new Quidel



Note: All revenues correspond to pro-forma FY '17.

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TRIAGE & BNP INTEGRATION UPDATE

Karen Gibson,
Vice President
IS & Integration



QUIDEL

Everyone LOVES This Deal….





"We have been waiting for management to put its cash balance to use on an asset that diversified the business and it seems it found an asset which does just that, and does it at a valuation and accretion that seems almost hard to believe."

"..we are fans of the bold move"

Analysts

"..congrats on inking a truly stupendous acquisition that seems (to us anyway) the rare trifecta of perfect fit, good terms, and positive market reception... the wait was long but worth it."

"Home-run, guys. Home-freaking-run!"

Shareholders

"So exciting, how can I help?!"

"We are now a talent magnet in SD"

Quidel Employees

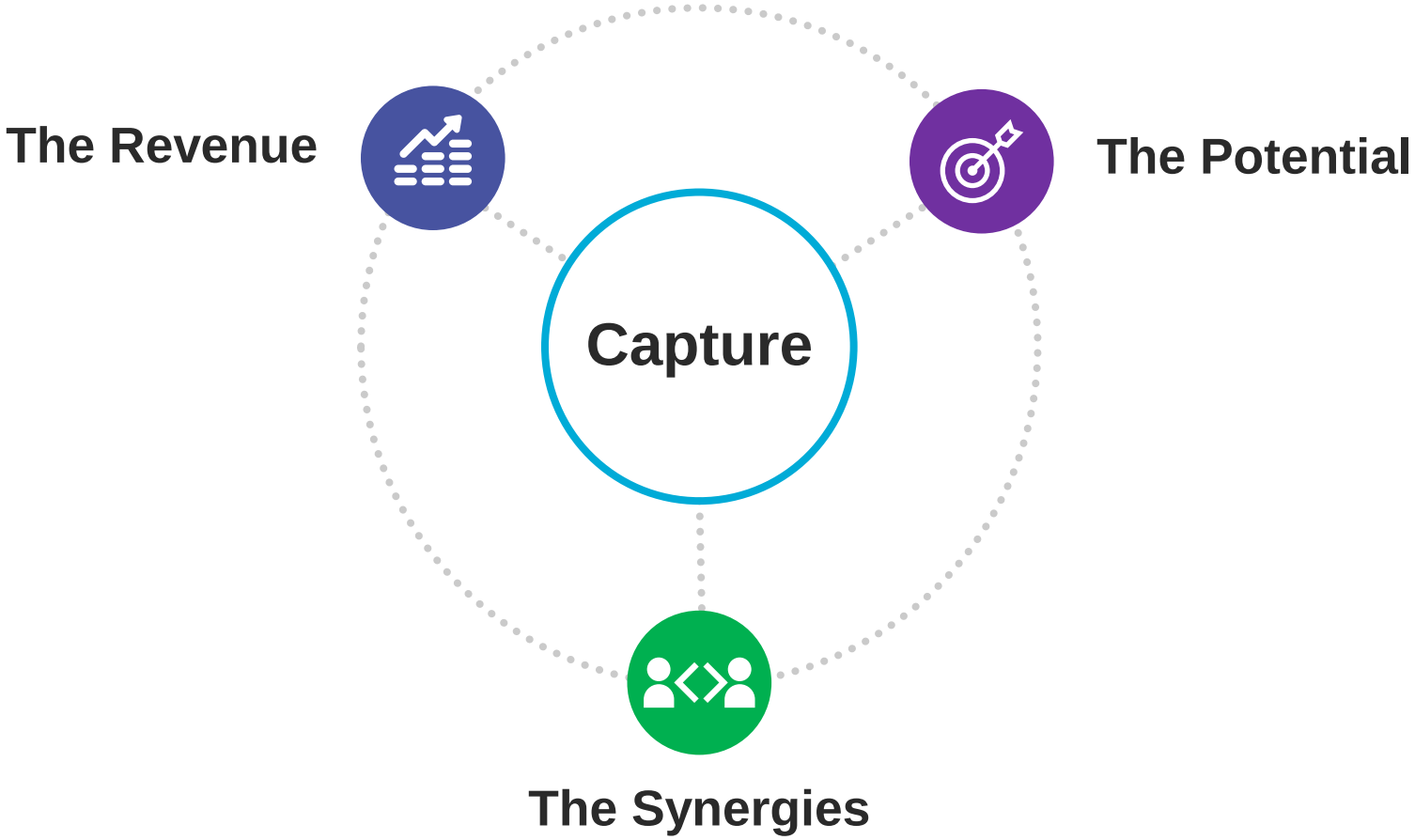
"So happy we are going back to a San Diego company!"

"We will have the best softball team in the league!"

Triage Employees

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How Do You Realize Deal Success?



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Integration Team Structure



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Integration Progress

First 90 Days



Transitioned **472** US employees from Abbott



Assumed **all US customer contracts**; Sales and Marketing



Began taking orders and collecting cash from US customers and **24 direct export markets** (53% of Revenue) - leveraging Abbott distribution capabilities under Transition Services Agreements



Hired **36 Sales/Marketing employees** **in China, Germany, Italy, and Ireland**

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Integration Progress

First 90 Days



Completed Sale/Leaseback of Summers Ridge Facility-**$149M**

Segregated San Diego Summers Ridge Science Park Campus–**Co-located Quidel employees** into Buildings C and D

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Integration Progress

First 180 Days

- **Restructured North American Sales** to incorporate Triage and BNP
- Developed **Global ERP** transition plan
- Hired an additional **19 employees in Austria, China, Germany, and Ireland**
- Initiated EMEA ERP team; Contracted with **DHL 3PL** for EMEA
- Selected Business Office in **Galway, Ireland;** Renovations are underway with completion at **end of April**
- Selected Business Office in **Shanghai, China**; Opening in **August**

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INTEGRATION SYNERGIES

Capturing the Synergies



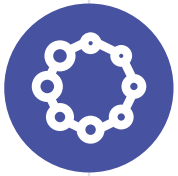
QUIDEL

Synergy Categories



Supply Chain Harmonization

Leverage suppliers across the combined enterprise



Yield Improvement

Improve manufacturing yields via minimizing process variation, defects, and rework



Productivity

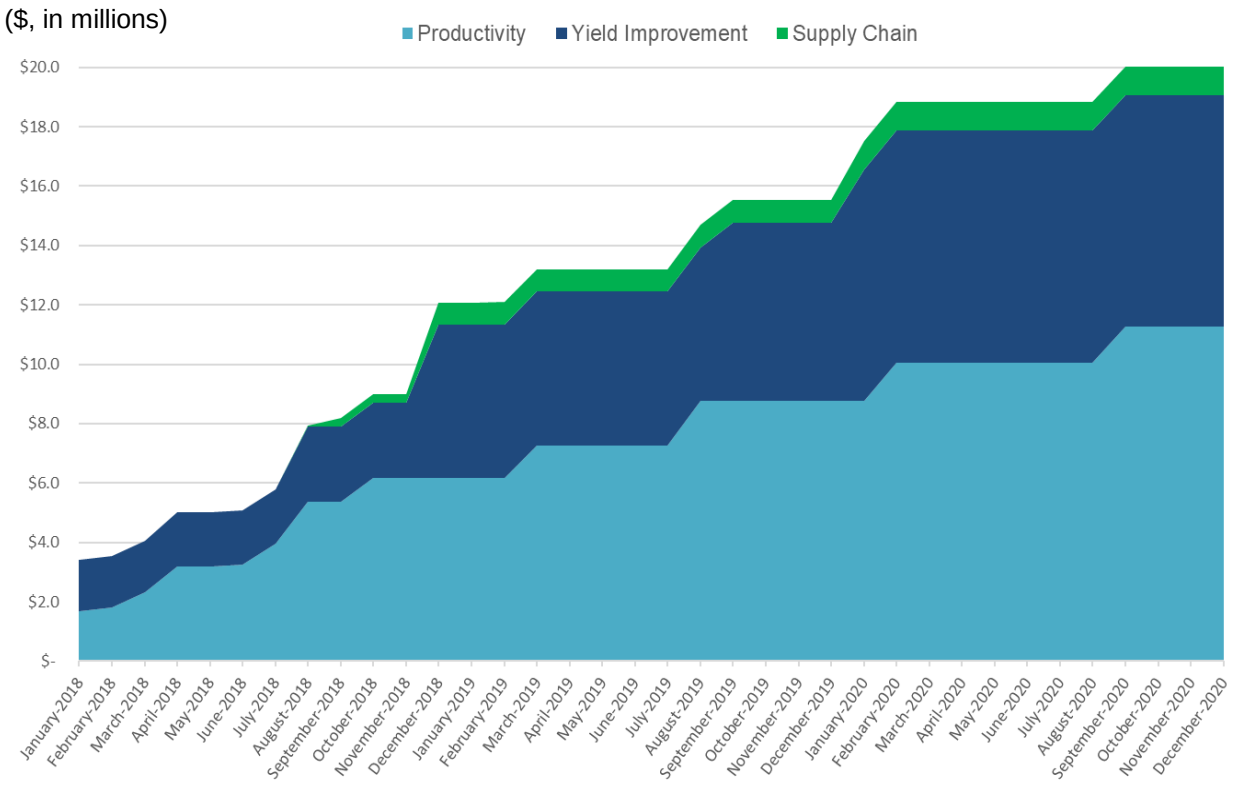
- Eliminate redundant roles within the combined organization
- Improve or automate processes to require less manual effort

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Synergy Plan

Annualized Run Rate Plan	
12/18	$10.8M
12/19	$15.5M
12/20	$20.0M

Annualized Run Rate Synergy Plan



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Yield Improvement

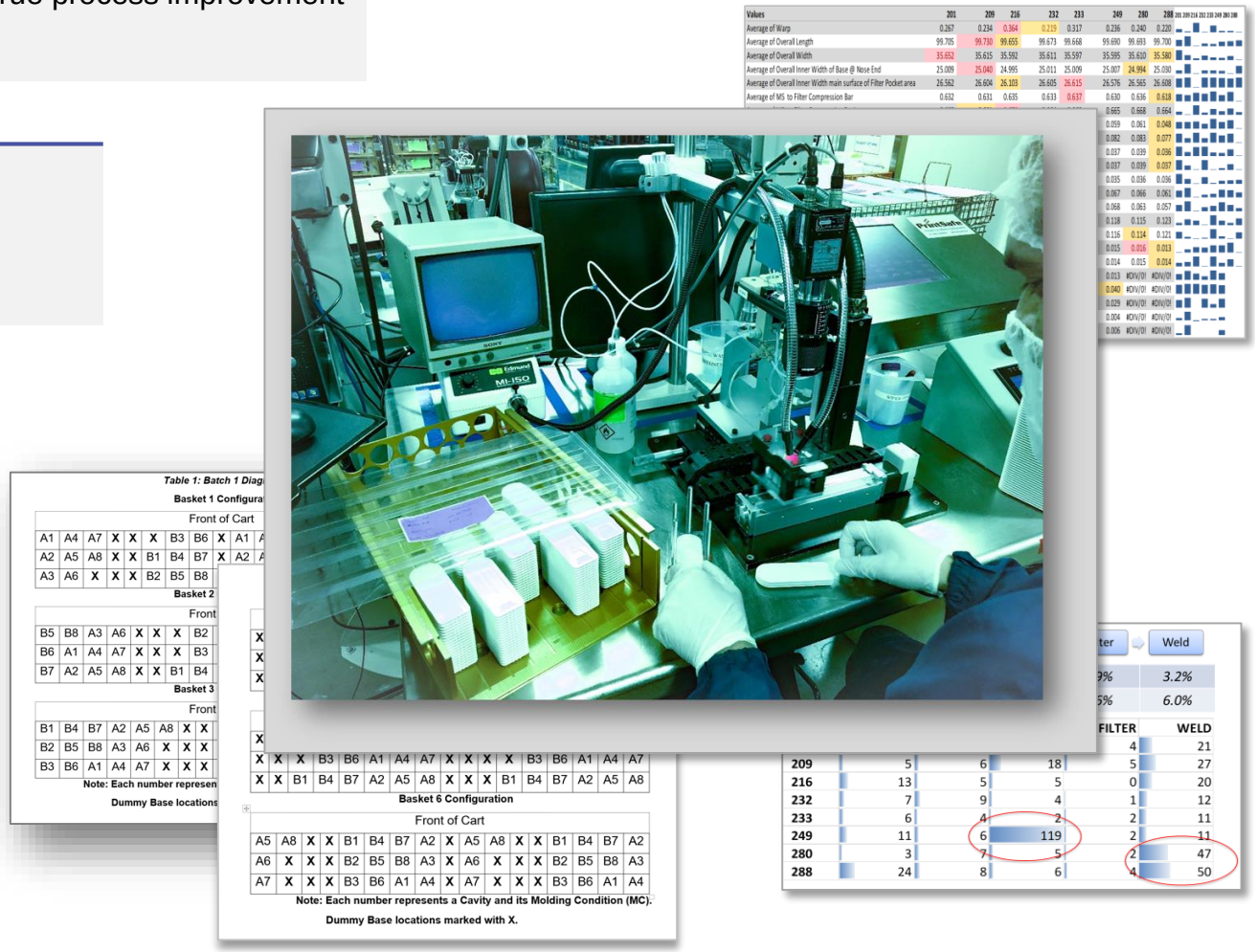
Systematic, data-driven initiative

to focus on key bottlenecks and true process improvement opportunities…

12 projects identified –

6 currently in process…

$7M annualized opportunity when fully realized…



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Line 5 Automation

Manufacturing is one of our Core Competencies …



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BUILDING THE GLOBAL BUSINESS

Capturing the Potential



QUIDEL

Building the Global Business

Converting Triage business to Quidel control requires balancing several factors



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Quidel/Abbott Transition Service Agreements (TSA)

Operating TSA

	Sales & Marketing	Order To Cash	Warehousing & Logistics	Financial Reporting & Settlement
Types of Services Performed	• Sales • Marketing • Management of Contracts and Tenders	• Customer Service • Order Processing • Invoicing • Collections • Tech Support	• Warehousing • Transportation • Product Importation • Registration • S&OP Planning	• Reporting of sales,A/R, inventory, A/R, returns, allowances • Monthly Settlement

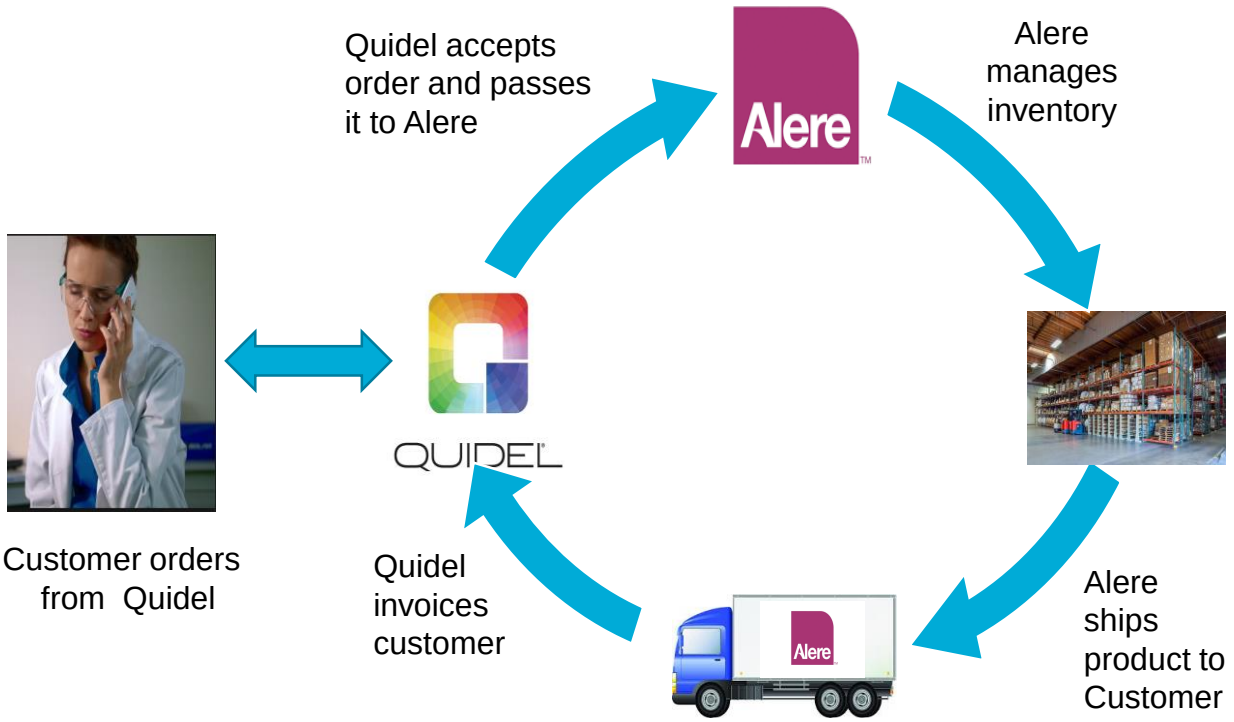
General TSA/ Reverse TSA	• Access to Alere/Abbott IT systems • Regulatory /Packaging/ Product Registration	• Shared facilities spaces • Charges are net of Reverse TSAs

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Day 30 – US Operating Model

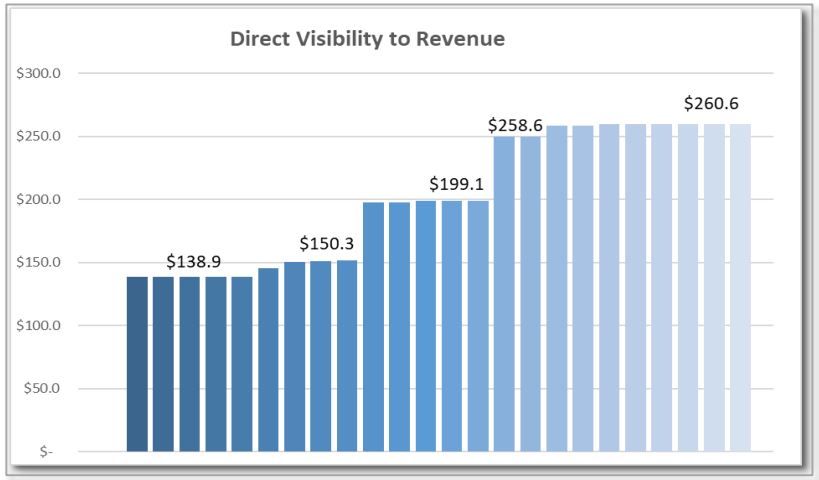
Day 30

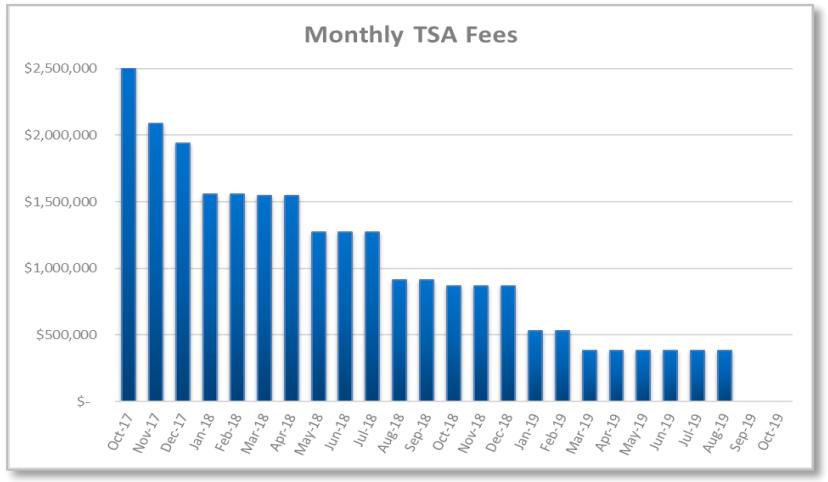
- Implemented for US and 3rd party export customers (in 25 countries)
- Quidel manages customer relationship
- Quidel owns financial transaction with customer
- Utilizes Alere's warehouse and logistics (cold chain)



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Building the Quidel Global Footprint





Estimated Date	Cumulative Revenue	Countries
10/17	$0.0M	Deal Close – All countries under Abbott TSA
11/17	$138.0M	US & 3rd party exports (25 countries)
4/18	$145.6M	Alere Subsidiaries: Taiwan, S. Korea, Malaysia
6/18	$150.3M	Alere Subsidiaries: Argentina, Colombia
8/18	$197.9M	Alere International Network: EMEA (49 Countries)
10/18	$199.1M	Alere Subsidiaries: Japan
1/19	$250.1M	China
4/19	$260.0M	Subsidiaries: Brazil, India, Australia
8/19	$260.0M	Migrate US Distribution to Quidel

Revenue estimates are FY2016

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EMEA Shared Service Center



Merchant's Square

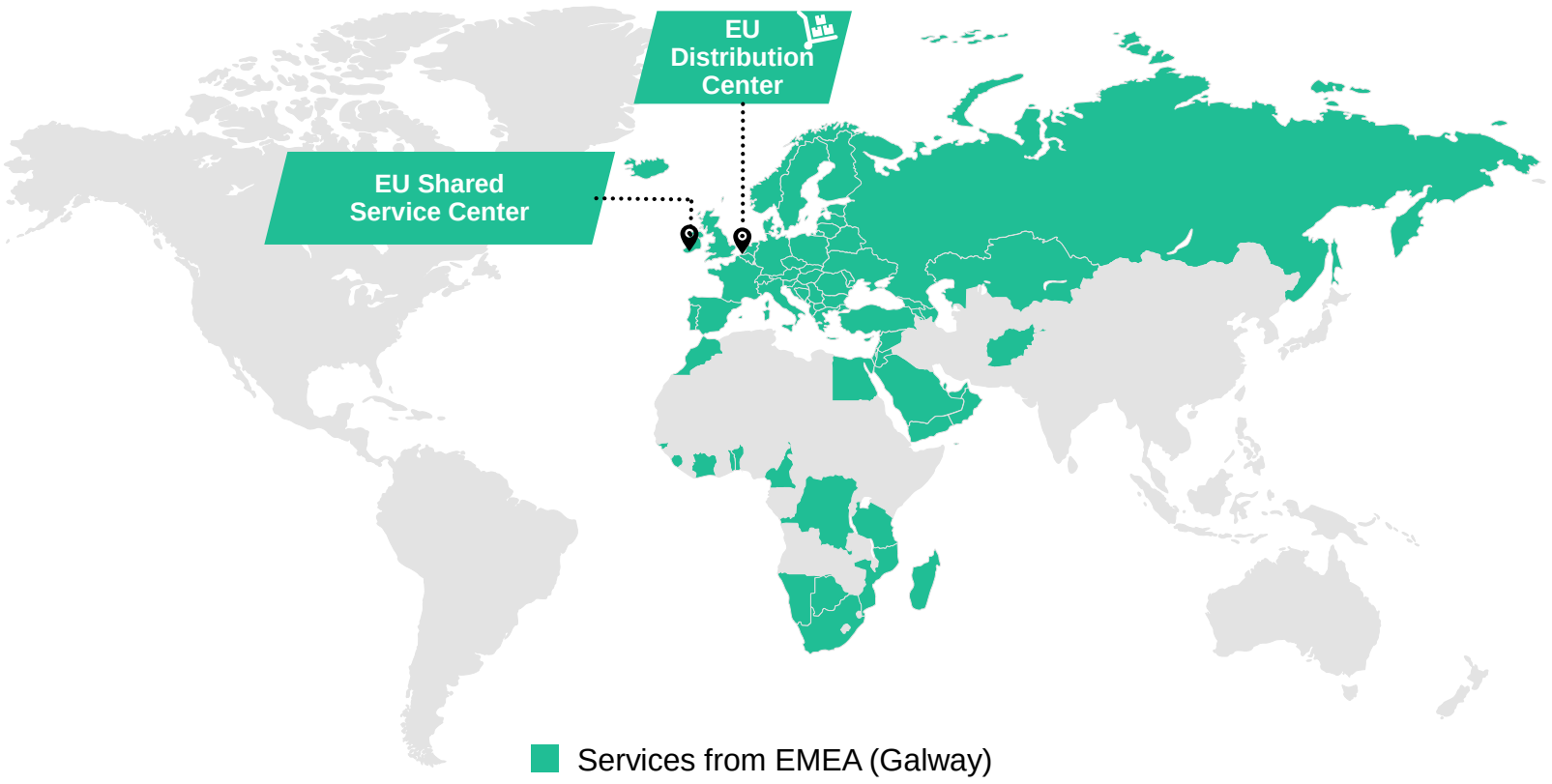
EMEA Shared Service Center will be in Galway, Ireland

DHL 3PL Distribution Center will be in Nijmegen, NL

Finance, Customer Service, Technical Support, HR, IT Legal – ~30 in 2018

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EMEA Shared Service Center



49 Countries	~2770 Customers	~58 Distributors	~$50M in Revenue

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China Regional Office



Business office in Shanghai, China

Finance, Customer Service, HR, IT, Technical Support, Legal, Regulatory, Sales and Marketing

Supporting full China team of 42 employees

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Global Order-to-Cash System



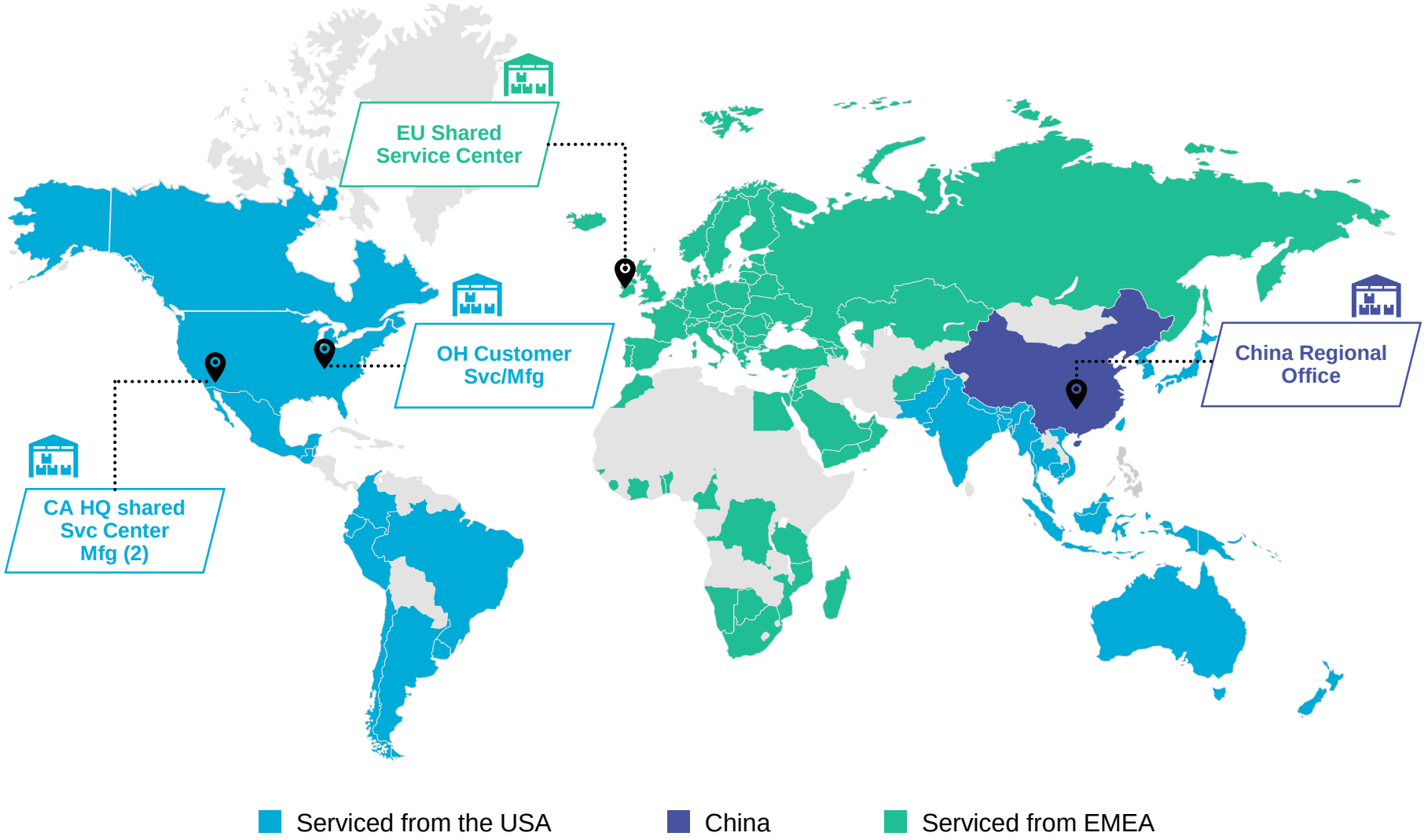
Next generation of Infor LN (Quidel current ERP system)

Leverages Infor software in the cloud - less upfront cost to Quidel, Speed of implementation, Security expertise, and Global reach

At completion, we will have consistent customer facing processes and global inventory visibility

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Complete Global Business Infrastructure



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FINANCIAL UPDATE

Randy Steward,
Chief Financial Officer



QUIDEL

2017 Pro-forma Results

2017 Pro Forma Results						
	Legacy		Triage/BNP		Total	
	$	%	$	%	$	%
Revenue	230,713	100%	237,865	100%	468,577	100%
Total COS	89,599	39%	107,622	45%	197,221	42%
Gross Profit	141,114	61%	130,243	55%	271,356	58%
R&D	30,300	13%	16,656	7%	46,956	10%
S&M	56,532	25%	52,064	22%	108,596	23%
G&A	28,705	12%	786	0%	29,491	6%
Acquisition & Integration Costs	16,506	7%	-	0%	16,506	4%
Total Operating Expenses	132,043	57%	69,507	29%	201,549	43%
Operating Income	9,071	4%	60,736	26%	69,807	15%
Depreciation/Amortization	24,014		26,109		50,123	
Stock Comp Expense	9,061		-		9,061	
Business Development	16,506		-		16,506	
FMV Markup	-		10,950		10,950	
EBITDA	58,653	25%	97,795	41%	156,447	33%

Note: Information per 8-KA filing, plus actual Q4 results

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Growth Drivers of the Business

Quidel's Revenue Structure (FY17)

Cardiac Immunoassay

- Triage
- Triage Tox.
- Beckman BNP

Triage $135M (PF2017)	BC BNP $103M (PF2017)

$238M

4-5% growth

Rapid Immunoassay

- Sofia
- QuickVue
- Eye Health

Sofia $82M	QV $81M	Eye Hlth. $3M

$165M

10%+ growth, Flu-dependent

Specialized Diagnostic Solutions

- Virology + Thyroid
- Specialty
- Other

Virol. $38M	Splty. $11M	Other $2M

$52M

Low growth

Molecular Diagnostic Solutions

- Lyra
- AmpliVue
- Solana

AV $3M	Lyra $3M	Sola. $7M

$14M

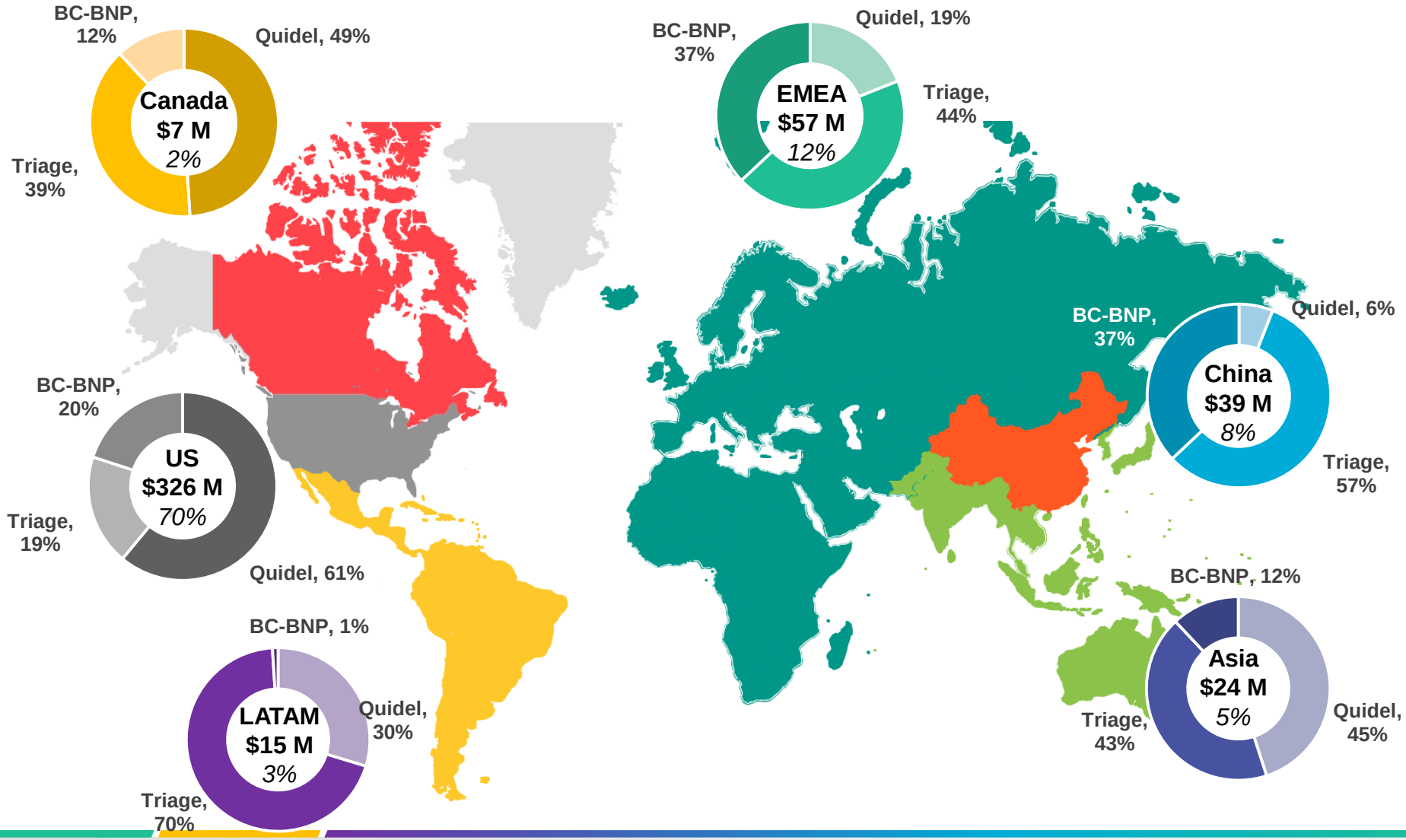
High growth off small base

Anticipated Long-term Growth Profile

 Internal company data. All numbers rounded. Pro-forma Cardiac Immunoassay revenues from 2017.

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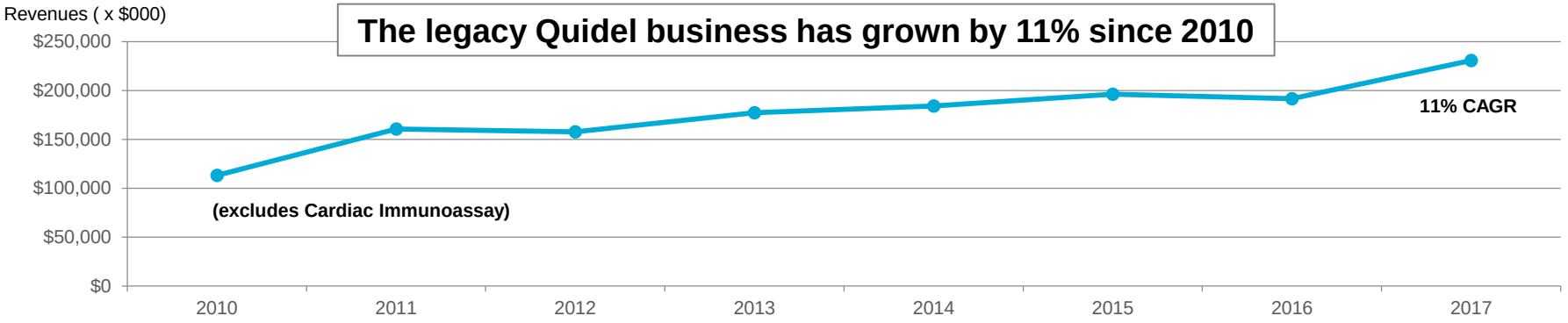
Geographical Footprint of the New Quidel

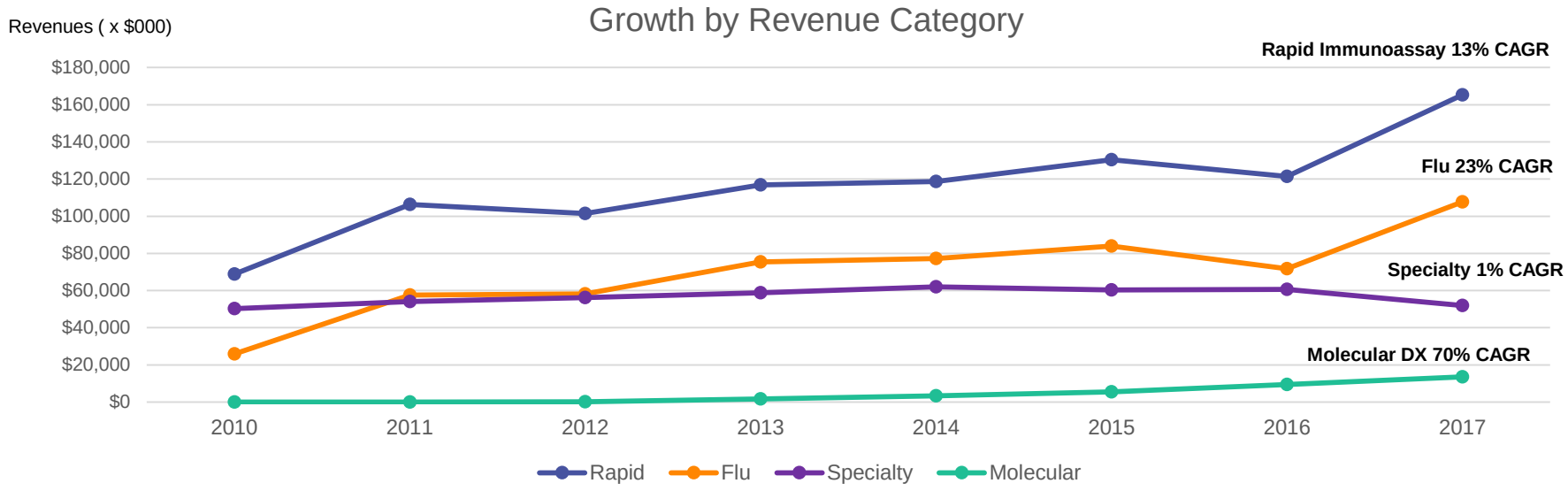


Note: All revenues correspond to pro-forma FY '17.

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Revenue Graphs: Growth Drivers

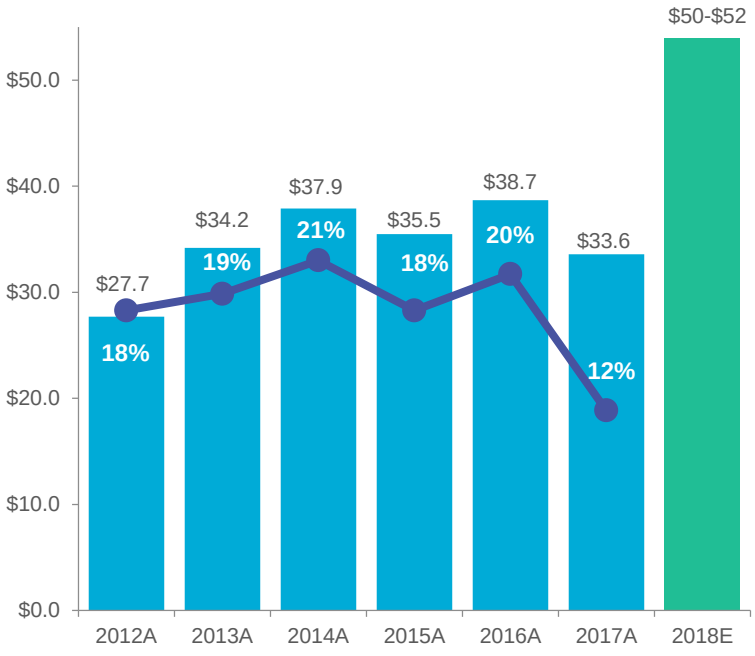




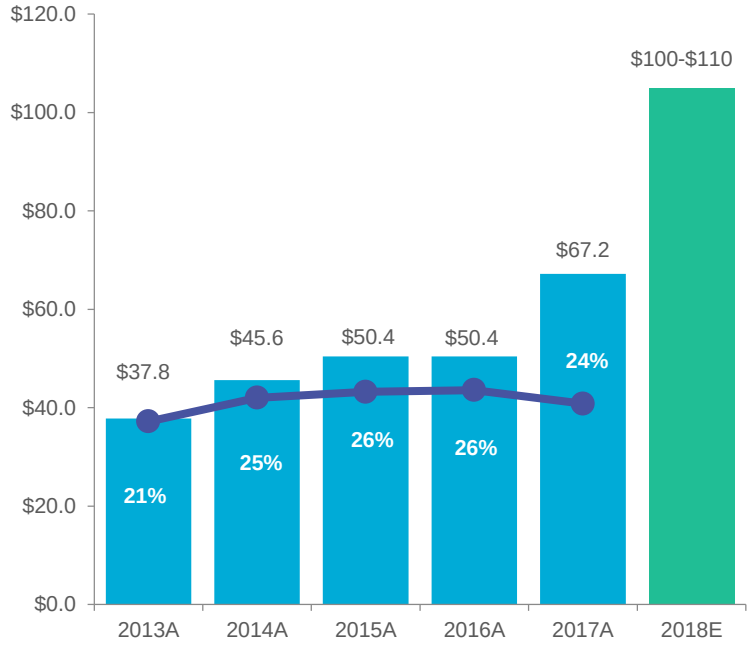
Internal Company data. Growth rates from FY2010-2017, except Molecular (2013-2017).
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We Continue to Monitor our Expenses Diligently and Manage the Business Prudently as We Remain Dedicated to Growing the Top and Bottom Line.

Annual Investment: R&D
(in $ million, percentage of sales in white)



Annual Investment: S&M
(in $ million, percentage of sales in white)



Internal Company estimates for full year 2018.

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To Date, We Have Significantly Reduced our Debt Structure

Current Debt	Transaction Date October 6, 2017	March 31, 2018	Actions
Convertible Bond Debt	$167 million	$97 million	Re-paid $70 million through convertible bond exchange.
Term Loan Debt	$245 million	$143 million	Paid $100 million from $149 million sale/leaseback of Summers Ridge facility.
Revolver Debt	$10 million	-	Paid $10 million from $149 million sale/leaseback of Summers Ridge facility.
Total Debt	**$422 million**	**$240 million**	
Leverage Ratio	4.0X	< 2.5X	

Time Period	Target Leverage Ratio		
December 2018	< 1.5X		
December 2019	< 1.0X		

Internal Company estimates for 2018, 2019.
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Our Future Look for Maximizing Shareholder Value

- Achieve high-single digits in annual revenue growth through new product introductions
- Invest in the development and commercialization of new products driving gross margins to 65%
- Leverage operational efficiency driving EBITDA margins to 35%
- Maximize cash flow from the core business
- Pay down debt and pursue outside opportunities that add $150-$250 million in annualized revenue within five years



Internal Company estimates. Actual results could differ.

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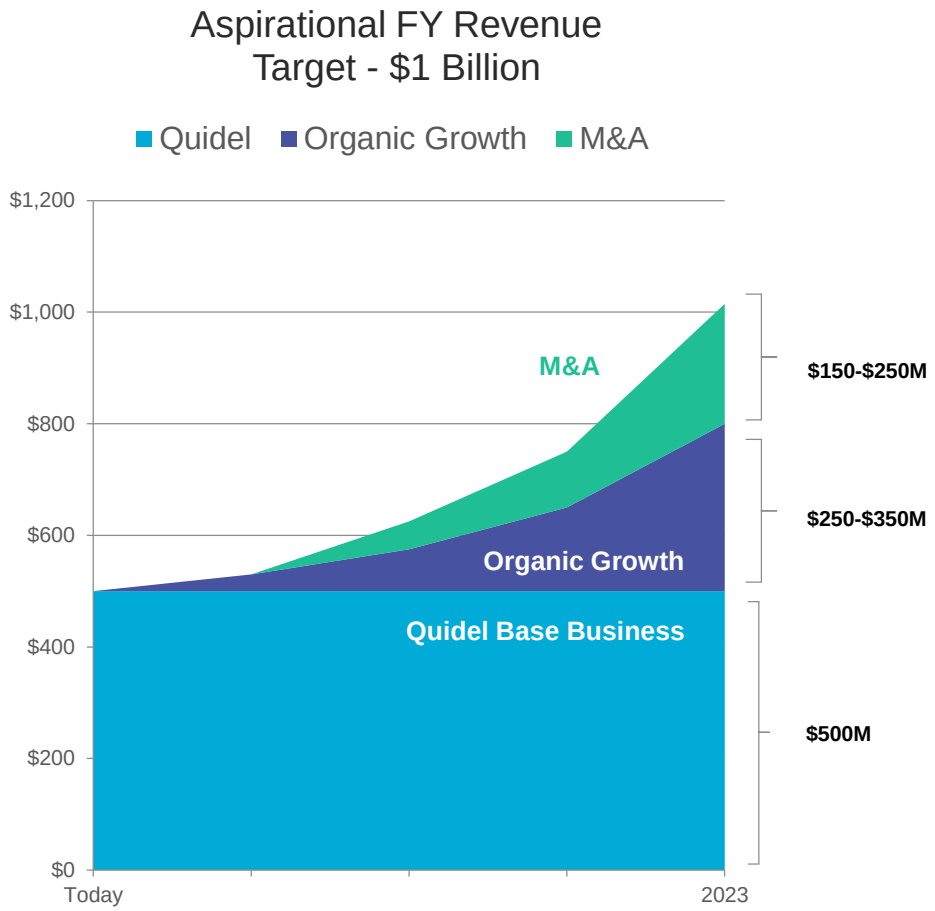
Revenue Growth is Critical to Maximizing Shareholder Value

Organic Growth Assumptions

- Market expansion for Sofia, Solana
- Development of new products on existing platforms
- Launch of Savanna

M&A Target Criteria

- Adds an incremental $150-250M by 2023
- Meets existing company margin profile
- Complements current commercial structure



Aspirational revenue targets. Actual performance could vary considerably based on multiple factors.

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Our M&A Strategy

Use cash on hand to pay down debt and pursue inorganic opportunities to diversify and augment the non-respiratory part of the business

What we're looking for…



Targets range from tuck-ins up to equal size



New technology that accelerates the advancement of in-house MDx abilities



Products that reduce the seasonality, volatility of flu season



Firms that can leverage our international market presence



Accretive within 12-24 months

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Our Goals for 2018



Grow legacy QDEL business by 10% or greater



Establish Baseline Cardiac Revenue of $250 million



Integrate at least 95% of Triage & BNP Businesses



Unlock $10 million in annual run-rate synergies



EBITDA at 32% or greater for Full Year 2018



Achieve leverage ratio equal to or under 1.5X by end of year

Internal Company estimates. Actual results could differ.

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We are Expecting Strong Financial Performance in 2018

	2018	LT Growth
Revenue	Up to $520M	+7%
Gross Margin	58% - 60%	+10%
EBITDA	32% - 34%	+15%
Free Cash Flow	$45M - $55M	+15%



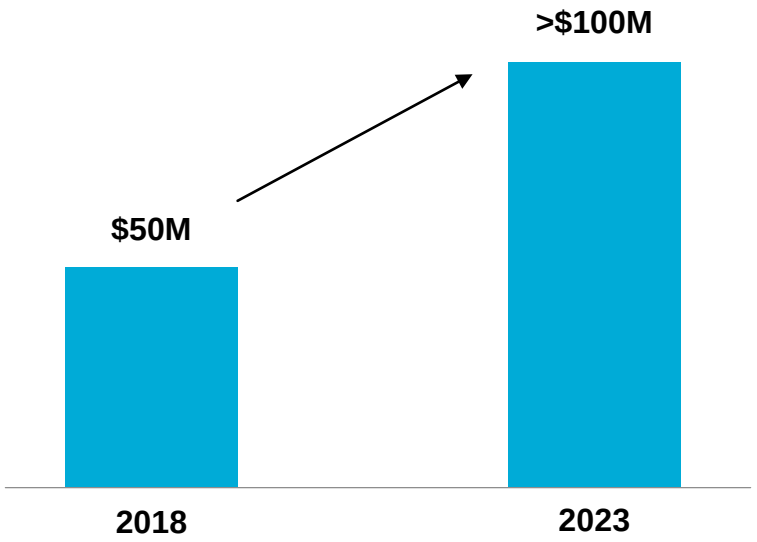
Internal Company estimates. Actual results could differ.

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Free Cash Flow

- **Infrastructure investments and productivity improvements**
- **Ongoing manufacturing maintenance**
- **Instrument purchases**
- **Cash taxes estimated at the tax provision dollars**
- **Ongoing Abbott annual payments of $48M**

15% FCF CAGR



CapEx	$30M	→	$40M
Annual Abbott Payment	$48M	→	$40M

94 Free cash flow = operating cash minus CapEx/Abbott consideration payments.

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Financial Appendix

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Since 2010, We've Committed over $850 million in Capital to Acquire New Capabilities and Technologies in Pursuit of Outside Opportunities that Complement Growth and Diversify Revenue

Recent Capital Structure History		
Target/Action	**Time Period**	**Rationale**
Diagnostic Hybrids, Inc. (DHI)	2010	Paid approx. $130 million for $45 million annual revenue cell culture business, direct to customers, approx. 75% of revenues are non-flu. Added ViroMed and CellPro businesses through acquisition.
Share Issuance	2011	Raised $60 million by issuing 4.6 million shares at $13.15/share.
BioHelix, Inc.	2013	Paid net consideration of $18.5 million for proprietary isothermal molecular HDA technology in infectious disease.
AnDiaTec GmbH	2013	Paid approx. $7.3 million for MDx presence in EU.
Convertible Notes Offering	Dec 2014	Raised $172.5 million, 3.25% coupon, due 2020.
Share Repurchases	2015 – 2016	Opportunistic repurchases of approx. 2.5 million shares.
Bond Repurchase	2016	Approx. $4.5 million in one-time opportunistic purchase
Immutopics, Inc.	March 2016	Paid approx. $5.5 million for $2 million + annual revenue Bone Health business at 70%+ gross margin with manufacturing synergies.
InflammaDry and AdenoPlus	May 2017	Paid approx. $14 million for $4-5 million annual revenue POC CLIA-waived Eye Health products, anticipating double digit annual growth with 70% GM.
Alere Triage and Beckman BNP Assets	September 2017	Total consideration of up to $680 million, which includes $400 million purchase price for Alere Triage assets and San Diego facilities, $40 million in contingent consideration for EEA BNP business, and $240 million in deferred consideration for ROW BNP business.
Sale/Leaseback of Summers Ridge facility	Jan 2018	Raised $149 million from sale of Triage manufacturing facility. Used proceeds to pay down $110 million in debt.
Convertible Bond Exchange	Jan 2018	Used stock to buy back approx. $40% of bonds, pay down $68 million in debt.

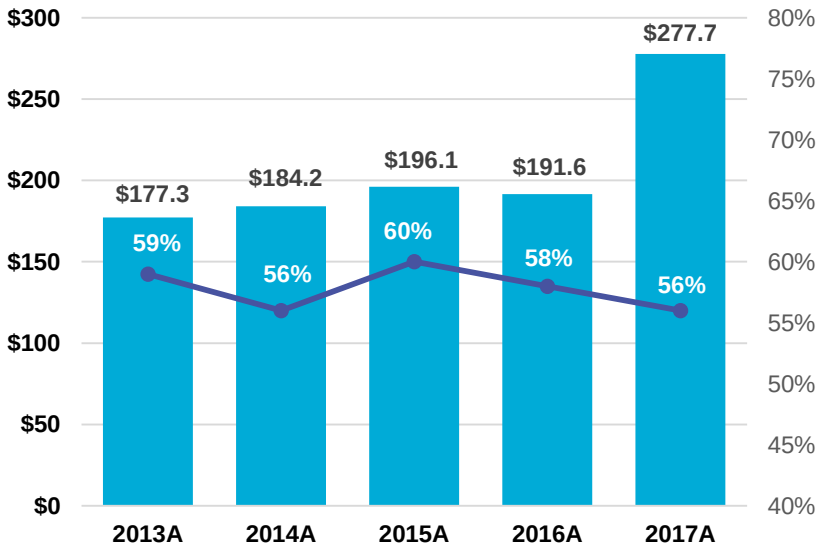
Represent Strategic Acquisitions

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Quidel Financial Overview

Revenue

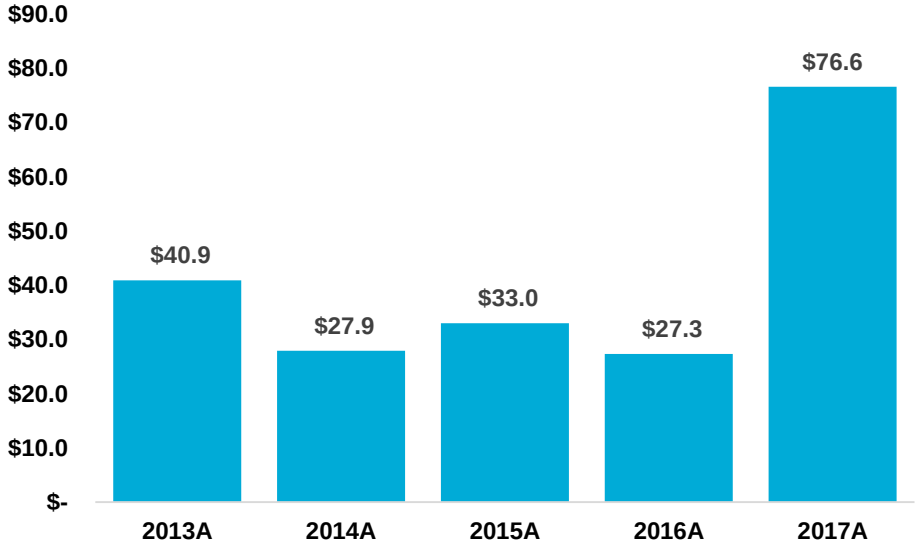
(in $ million, percent gross margin in white)



12 months ended December 31

Adjusted EBITDA(1)

(adjusted, in $ million)



Balance Sheet as of December 31, 2017

(in millions)

Cash and Cash Equivalents	$36.1
Total Assets	$935.3
Long-term Debt and Lease Obligation	$381.1
Stockholder's Equity	$227.1

Adjusted EBITDA excludes interest, depreciation, amortization, stock compensation, business acquisition costs, asset impairment and restructuring charges.

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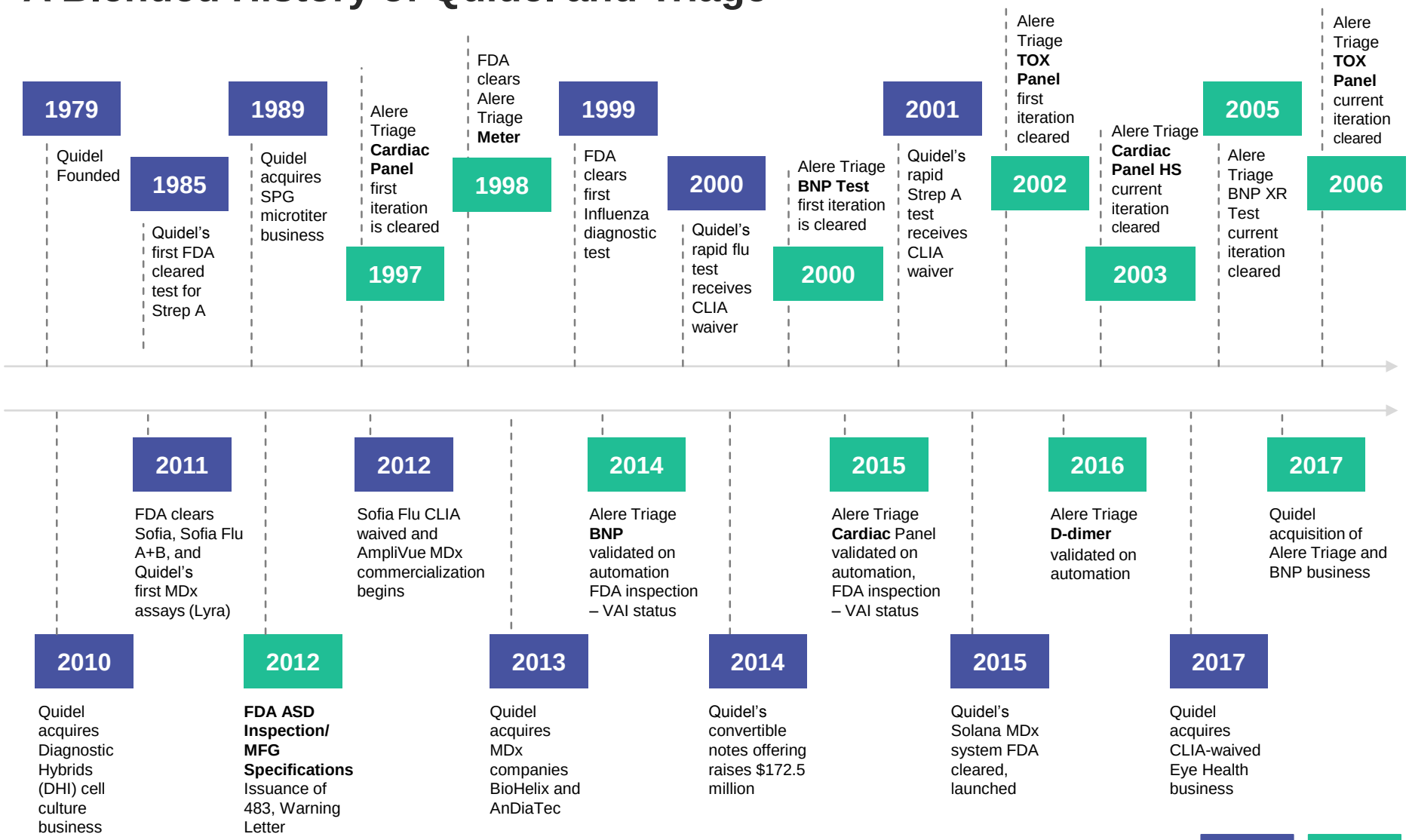
Q&A



APPENDIX



A Blended History of Quidel and Triage



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The New Quidel Serves the Diagnostic Needs of Customers Across the Globe

5

Manufacturing and R&D facilities

1,200

Employees Worldwide

25

Projects Supported By 90 R&D Employees

100

Sales Representatives in the U.S. and Canada

75

Employees Focused on International Commercial

90+

Countries Covered by our International Commercial Team

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Our Guiding Principles

Quidel develops, manufactures, and sells diagnostic solutions across a broad continuum. Our primary markets are in the physician office lab (POL), hospitals, and clinical and reference labs globally.

We grow by introducing products to the market that have at least two of the following attributes:

- **Improved Accuracy**
- **Lower Cost**
- **Faster Turn Around Time**
- **Easier to Use**
  - More Efficient Workflow
  - Better Data Handling

We protect our brand in the marketplace through:

- Superior Performance
- Reliable Supply
- Customer Service
- Commitment to Quality
- High Compliance
- Innovation and Automation

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Our Core Values Are a Competitive Advantage

We thrive as an organization by being:

Customer Driven

Committed to the customer – both internal and external. Keys to customer satisfaction are: Frequency of Contact and Impeccable Follow up.

Focused on Execution

Execution means things done well, at speed. Speed requires focus – on the two or three things that matter.

New Product Oriented

To be successful and relevant in our industry, we must be new product oriented. These products must deliver on at least two of the attributes that are emerging as important to healthcare: accuracy, time to result, ease of use, and cost.

Determined

While planning and process are important structural elements that help us get things done, it is tenacity and the ability to handle change that will enable us to prevail over time. Motivation matters.

Optimistic

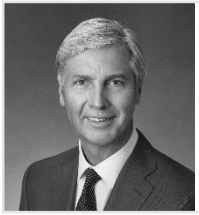
We are never, ever deterred by the disappointments that inevitably arise when trying to achieve great things. We take the difficulties we face when doing challenging work and turn them into opportunities to succeed where others have failed.

Team Players

We are motivated and driven to succeed, as individuals; yet, we recognize that only when the Team achieves its objectives will we be ultimately successful. Respect for others is a key part of good teamwork and allowing others to “take the shot” is another important aspect.

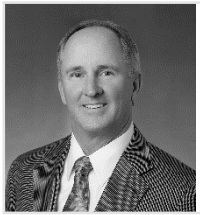
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Quidel's Management Team has a Long History of Achievement in Diagnostics, as well as a Broad Range of Skills in the Sector



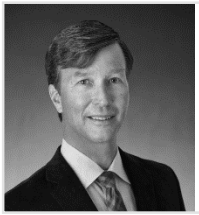
Douglas C. Bryant, President and Chief Executive Officer

Served as Executive Vice President and Chief Operating Officer, Luminex Corporation; Vice President of Abbott Vascular for Asia/Japan; Vice President of Abbott Molecular Global Commercial Operations; and Vice President of Abbott Diagnostics Global Commercial Operations. Vice President, Diagnostic Operations, Europe, Middle East, and Africa; and Vice President, Diagnostic Operations, Asia Pacific. Mr. Bryant holds a B.A. in Economics from the University of California at Davis.



Randall J. Steward, Chief Financial Officer

Served as Chief Financial Officer for Navilyst Medical, Inc., Chief Operating Officer for SeQual Technologies, Inc., Executive Vice President and CFO for Spectrum Brands. Mr. Steward holds a B.B.A. in Accounting from Southern Methodist University. Mr. Steward is also a Certified Public Accountant and a member of AICPA.



Michael D. Abney, Jr., Senior Vice President, Distribution

Served as Vice President, Channel and Distribution for ConvaTec; previously Vice President, Supplier Management, PSS Inc. and McKesson Medical Surgical, and Vice President of Operations at PSS. Mr. Abney received his BA in Finance from the University of Florida in 1989.

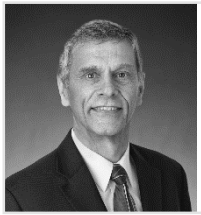
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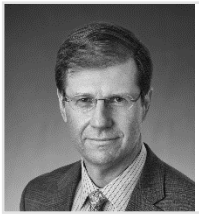
Robert J. Bujarski, J.D., Senior Vice President, Business Development and General Counsel

Served as General Counsel and Vice President since 2005, previously was an associate attorney with Gibson, Dunn & Crutcher LLP. Mr. Bujarski received his B.A. degree in 1991 from the University of Arizona and his law degree in 2001 from the University of Arizona.



Werner Kroll, Ph.D., Senior Vice President, Research and Development

Previously served as Vice President and Global Head of Research and Innovation for Novartis Molecular Diagnostics/ Co-diagnostics. Has also held senior positions at Novartis, Bayer Diagnostics and Bayer Pharmaceuticals, and AGFA. Dr. Kroll received his doctorate in Physiological Chemistry from the University of Marburg.



Ed Russell, Senior Vice President, North America Commercial Operations

Served as Commercial Leader, North American Biosciences at Thermo/Life Technologies. Prior to that, Mr. Russell served as SVP/GM for Life's Global Services & Support business, served as President & GM of Japanese operations, and led the Sales Operations function. Mr. Russell is a graduate of the U.S. Coast Guard Academy and also holds an MBA from the Wharton School of Business, University of Pennsylvania.



Ratan Borkar, Senior Vice President, International Commercial Operations

Served as Vice President, International since 2012 and joined Quidel as Vice President, Business Development in 2009. Previously was an investment banker and served as Vice President, Healthcare Investment Banking at JPMorgan. Mr. Borkar has an MBA from the University of Michigan's Ross School of Business, and received his Bachelor of Commerce from the University of Mumbai.

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Our Innovative New Products are Designed to Meet the Various Needs of the Customer in Any POC Setting

Rapid Immunoassay



FDA–Cleared, CLIA–Waived

Sofia® Immunoassay platform is the next generation, objectively-read system in support of our legacy lateral flow business, designed to deliver more value and a higher **gross margin.**

Sofia captures market share with the first wave of assays (for Respiratory Disease) in physician offices, hospitals and alternate sites.



FDA–Cleared, CLIA–Waived

Sofia® 2, at a fraction of the cost of the original Sofia, can further penetrate the lower-volume and higher-volume segments of the POC testing market.

Sofia 2's integrated wireless options will expand connectivity with the potential to increase overall diagnostic testing.

Cardiac Immunoassay



FDA–Cleared

Triage® MeterPro® is our cost effective, easy to use instrument for cardiovascular and toxicology diagnostic assays. Multiple immunoassays can run on the same platform, with rapid results in about 15-20 minutes

The **MeterPro** instrument can run multiple sample types, such as whole blood, plasma, or urine, with process controls built into the meter, software and test device

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Our Innovative New Products are Designed to Meet the Various Needs of the Customer in Any POC Setting

Molecular





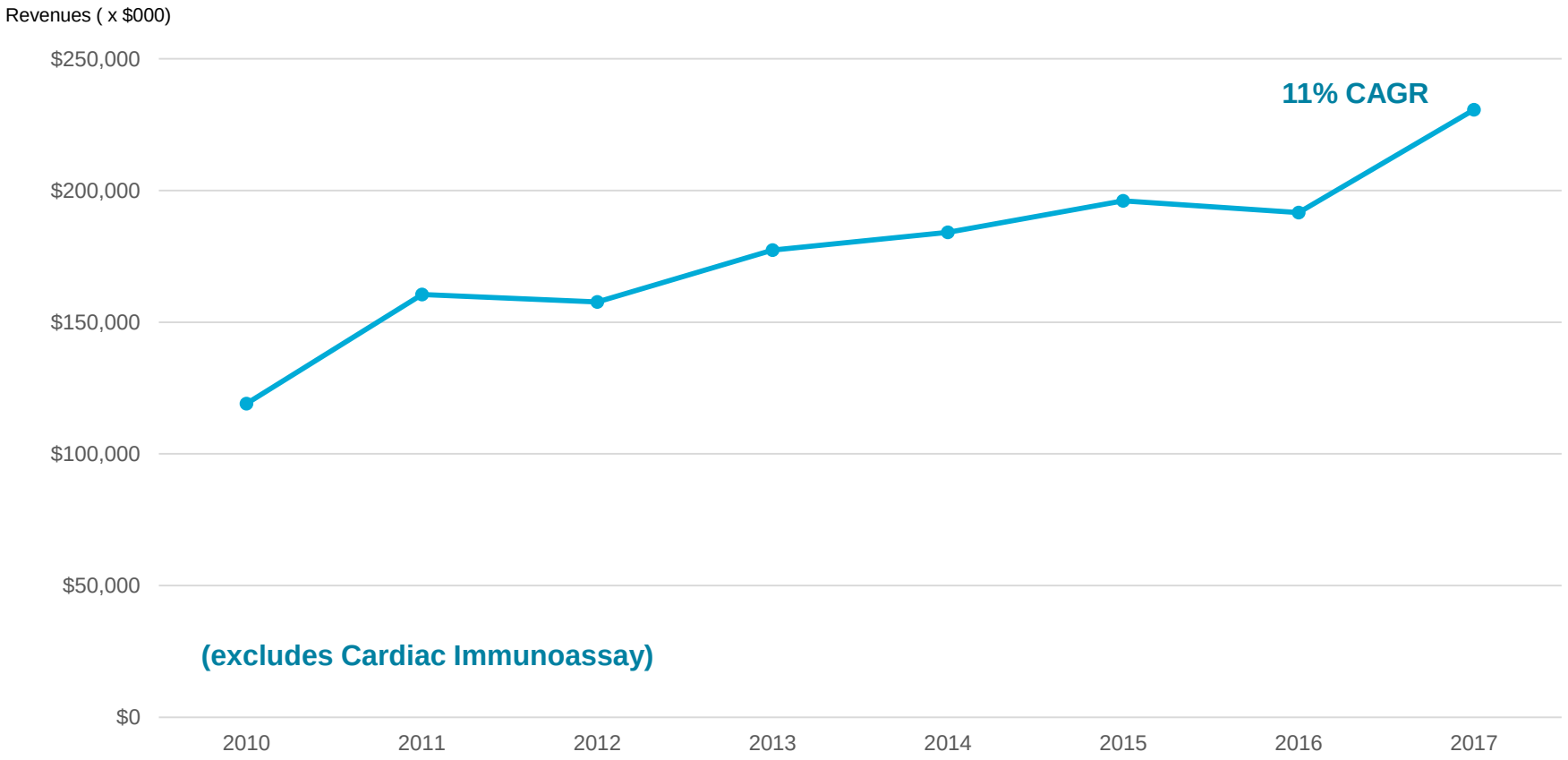




FDA–Cleared, Mod–Complex	FDA–Cleared, Mod–Complex	FDA–Cleared, Highly–Complex	In Development
AmpliVue, a non-instrumented, hand-held disposable molecular device requires no thermocycler or upfront costs. Moderately complex claim provides an easy-to-use entry point into molecular testing for smaller hospitals and lower-volume users wishing to convert from legacy testing methods.	**Solana**, our first instrumented molecular system, extends AmpliVue's proprietary HDA technology to offer a low-cost, medium volume molecular solution that can multiplex, running up to 12 samples at a time in approx. 30 minutes. **Solana** is designed for samples that do not require extraction or quantitation in the mod-complex setting.	**Lyra**, our Real-time molecular PCR assays, are designed to run on a hospital lab's existing thermocycler, and provides a real-time testing solution to higher throughput labs using a hospital's established systems – with no upfront costs. **Lyra** molecular assays can be paired with other **Lyra** assays to create customized multiplex Respiratory Disease panels.	**Savanna** is our low-cost, fully integrated "sample-to-answer" molecular diagnostic system. Target cartridge cost is less than $5 and target instrument cost is $10,000, designed for low-volume and potentially CLIA-waived settings. **Savanna** can run either traditional PCR or HDA assays for samples that do not require extraction.

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Quidel has a History of Solid Revenue Growth



Quidel full year revenues (2010-2017), excludes acquired Cardiac (Triage and Beckman BNP Businesses)

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Our R&D and Regulatory Expertise is What Fuels Growth

Since 2011, Quidel has submitted over 30 510(k) packages resulting in over 25 FDA clearances and expanded product claims, 6 CLIA - waiver designations and numerous product introductions, contributing $95M in annual revenues[1]

FDA-cleared Products since 2011

Sofia® Instrumented Immunoassay	
CLIA - Waived	Sofia Analyzer
CLIA - Waived	Influenza A + B
CLIA - Waived	Group A Strep
CLIA - Waived	RSV
Mod - Complex	hCG
Mod - Complex	Lyme Disease
	Legionella (CE Mark only)
	S. Pneumo (CE Mark only)

Sofia 2® Instrumented Immunoassay	
CLIA - Waived	Sofia 2 Analyzer
CLIA - Waived	Influenza A+B
CLIA - Waived	Group A Strep
CLIA – Waived	RSV
Mod – Complex	Lyme Disease

AmpliVue® HDA Isothermal Molecular	
Mod - Complex	C. difficile
Mod - Complex	Group A Strep
Mod - Complex	Group B Strep
Mod - Complex	Pertussis
Mod - Complex	Trichomonas
Mod - Complex	HSV 1 + 2

Solana® HDA Isothermal Instrumented Molecular	
Mod - Complex	Solana Instrument
Mod - Complex	Influenza A + B
Mod - Complex	Group A Strep
Mod - Complex	Strep Complete (A + C/G)
Mod - Complex	Trichomonas
Mod - Complex	HSV 1+2/VZV
Mod - Complex	RSV + hMPV
Mod - Complex	C. difficile

Lyra® Real-Time PCR Molecular	
Highly - Complex	Influenza A + B
Highly - Complex	RSV + hMPV
Highly - Complex	Adenovirus
Highly - Complex	Parainfluenza 123
Highly - Complex	Strep A + C/G
Highly - Complex	C. difficile
Highly - Complex	HSV 1+ 2/VZV

1. Latest TTM combined revenues for Sofia and Molecular products. Not all FDA submissions and clearances since 2011 are shown.

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Triage products comprise Quidel's Cardiac revenue category

Quidel's Triage system of tests comprises a comprehensive test menu that provides the diagnostic answers to make rapid, cost-effective treatment decisions at the point-of-care (POC). Quidel provides a diverse immunoassay menu in a variety of tests to provide you with diagnostic answers for quantitative BNP, CK-MB, d-dimer, myoglobin, troponin I and qualitative TOX Drug Screen.



The Quidel Triage BNP Test is a rapid, point-of-care fluorescence immunoassay used with the Quidel Triage MeterPro. The test is used to measure B-type natriuretic peptide (BNP) in EDTA anticoagulated whole blood or plasma specimens. The Quidel Triage BNP Test is the first rapid BNP immunoassay indicated for risk stratification for both acute coronary syndrome and heart failure.



The Quidel Triage Troponin I Test is a next generation fluorescence immunoassay, to be used with the point-of-care Quidel Triage MeterPro, for quantitative measurements of next generation Troponin I.



The Quidel Triage Cardiac Panel is a rapid, point of care fluorescence immunoassay used with the Quidel Triage MeterPro. This test is designed to determine the level of creatine kinase MB (CK-MB), myoglobin and troponin I in EDTA anticoagulated whole blood or plasma specimens. This can be used as an aid in the diagnosis of myocardial infarction (injury).



The Quidel Triage Cardio2 Panel is a fluorescence immunoassay, to be used with the portable Quidel Triage MeterPro, for quantitative measurements of next generation Troponin I and B-type Natriuretic Peptide.



The Quidel Triage Cardio3 Panel is a fluorescence immunoassay, to be used with the point-of-care Quidel Triage MeterPro, for quantitative measurements of CK-MB, next generation Troponin I and B-type Natriuretic Peptide.



The Quidel Triage D-Dimer Test is a rapid, quantitative immunoassay to aid in assessing and evaluating patients with suspected disseminated intravascular coagulation (DIC) and thromboembolic events including pulmonary embolism (PE) and deep vein thrombosis (DVT).



The Quidel Triage Profiler SOB Panel is a fluorescence immunoassay that empowers physicians with the ability to distinguish between the many causes of shortness of breath in about 20 minutes. The panel is to be used with the portable Quidel Triage MeterPro, for quantitative measurements of Myoglobin, CK-MB, Troponin I, B-type Natriuretic Peptide and D-dimer.



The Quidel Triage TOX Drug Screen is a fluorescence immunoassay to be used with the Quidel Triage MeterPro for the qualitative determination of the presence of drug and/or the major metabolites above the threshold concentrations of up to 10 distinct drug classes, including assays for acetaminophen/paracetamol, amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, phencyclidine, THC and tricyclic antidepressants in urine.

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What is an Immunoassay?

An immunoassay is a test that relies on biochemistry to measure the presence and/or concentration of an analyte. The analyte can be large proteins, antibodies that a person has produced as a result of an infection or small molecules.

These assays are **highly adaptable** and can be applied to many formats depending on the needs of the end user.

- The principle component of an immunoassay designed to detect a specific analyte, such as influenza nucleoprotein, are the **antibodies that have been carefully selected to ensure the detection** of the analyte at low concentration with high specificity, meaning will not react with similar antigens.
- The second feature of an immunoassay is the **system that is designed to detect the binding of the specific antibody to the target analyte**.
- Originally the signal from an immunoassay resulted from an enzyme acting on a substrate to yield a colored solution with the amount of color in the solution being equivalent to the amount of antigen in the test solution.

More recently the many complex steps of an immunoassay have been compressed into a **simplified format for the end user.**

- The format is dependent on the flowing of the specimen together with the assay components through a nitrocellulose test strip.
- In this format, binding of the antibody to the target antigen is directly observable by the user due to the accumulation of dyed microbeads that will bind to a specific location on the nitrocellulose yielding a colored line that is easily observable by the user (if the target analyte is present in the specimen).

Immunoassays today are designed in many formats **depending on the target analyte and the needs of the end user.**

- They can also be used to detect target analytes in a wide range of sample types including serum, plasma, whole blood, urine, or swabs of nasal passages, throat or urogenital tracts.

Quidel offers a continuum of diagnostic immunoassays including **ELISAs**, visually read rapid lateral flow tests and fluorescent immunoassays that are placed in an analyzer that automatically measures the fluorescent signals, interprets the data, and immediately displays the result on its screen.

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What are Fluorescent Immunoassays?

Fluorescent Immunoassays are simply a different type of immunoassay. The key variable is the biochemical technique used for detecting the binding of the "detection" antibody and the analyte molecule.

The **advantages of a Fluorescent detection system** have been known for many years

- Sensitivity detection of the analyte
- Simplified reagents and simpler assay designs
- Several breakthroughs have occurred over the past few years that have enabled the implementation of a fluorescent based immunoassay system at the point of care.

Modern fluorescent-based immunoassay

- A modern fluorescent-based immunoassay uses as the detection reagent a fluorescent compound which absorbs light or energy (excitation energy) at a specific wavelength and then emits light or energy at a different wavelength
- The difference between the wavelength of the excitation light and the emission light is called the **Stokes shift**. The greater the shift or difference in the wavelength the less interference there will be by having the excitation light detected as partof the emission light.
- Recently a number of technical improvements have occurred that has enabled the implementation of a high sensitivity immunoassay system.
  - Availability of narrow wavelength low cost light sources
  - Newer more stable fluorophores that have very wide Stokes shifts
  - Stable solid state light detectors and microprocessors to process and analyze the data from each test.

When a fluorescent detection system is linked to a lateral flow assay and matched with a powerful yet low cost analyzer like the **Quidel Sofia or Sofia 2**

- The result is improved assay performance, the opportunity for walk away testing along with the elimination of misinterpretation often associated with visually-read point-of-care assays.

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What are Molecular Tests?

Quidel Molecular Tests involve the detection and/or analysis of nucleic acid molecules (DNA/RNA) to provide clinical information. These products extend Quidel's continuum of diagnostic choices from rapid immunoassays to confirmatory nucleic acid testing. Quidel has three development programs which may appeal to those labs just starting out in molecular, to experts that are looking for consistent, high quality results.

Lyra®

Lyra® real-time PCR assays are an open platform solution for high throughput, high quality molecular testing to detect and identify infectious diseases. Lyra PCR assays are focused on optimizing a lab's workflow to make these tests simple and easily implemented with minimal steps, easy refrigerated storage, room temperature procedures and flexible instrumentation.

Lyra assays have been validated on the Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument, Cepheid® SmartCycler® II and Life Technologies QuantStudioTM Dx Real-Time PCR Instrument. Their easy to follow procedures, eight (8) sample allotments in a 96-test kit, and robust stability are compatible with an existing workflow. Quidel wants to help any molecular laboratory use Lyra to expand their existing test menu or bring tests in house. Lyra Direct real-time PCR assays eliminate the need for RNA/DNA purification, allowing for quick simple manual sample processing before the sample is added to the Master Mix.



AmpliVue®

AmpliVue® assays provide access to all of the benefits of lateral flow molecular testing to any size laboratory. AmpliVue uses Quidel's proprietary Helicase Dependent Amplification (HDA). Quidel wants all labs to have access to the improved specificity, better accuracy and faster results, which molecular provides.

Using a small hand-held cartridge which requires no equipment beyond a thermal block with a heated lid, AmpliVue eliminates the barrier of a large capital investment for molecular testing. AmpliVue assays are also considered CLIA moderately complex, which allows for simple training and freeing high complexity staff to work on other assays. Bringing tests in house, reducing turnaround time, reducing hands-on time and simplifying your workflow are just a few logistical benefits of AmpliVue.



Solana®

Solana®, a simplified molecular testing platform, is making molecular diagnostics faster and easier than ever before, without sacrificing performance. Solana combines Quidel's proprietary helicase-dependent amplification (HDA) with fluorescence detection to deliver results you can trust, in an actionable timeframe.



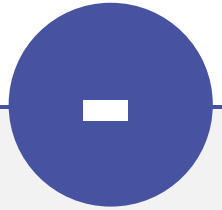
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Why Use Molecular Assays?



Advantages

- High Sensitivity/Specificity
- Earlier detection of infections
- Quantification
- Species differentiation
- Strain identification
- Potential for high throughput
- Impact to patient management



Disadvantages

- Complexity
- Cost
- Extensive training may be required
- May require cross contamination provisions
- Standardization can be complicated

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Molecular Diagnostic Tests Involve a 3-Step Process



Lysis and/or Extraction and concentration of nucleic acids

Sequence specific amplification of target

Can be done by isothermal methods or by PCR

Detection of the amplified target

by fluorescent probes, turbidity, bioluminescence, lateral flow

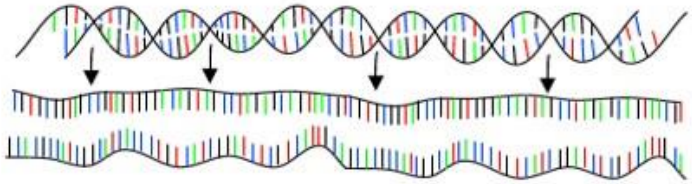
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Polymerase Chain Reaction (PCR): the Grandfather of Amplification

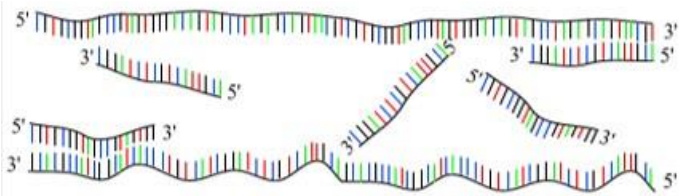
PCR: Polymerase Chain Reaction

30 – 40 cycles of 3 steps

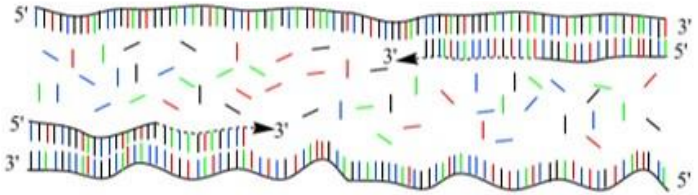
1 **Denaturation**



2 **Annealing**



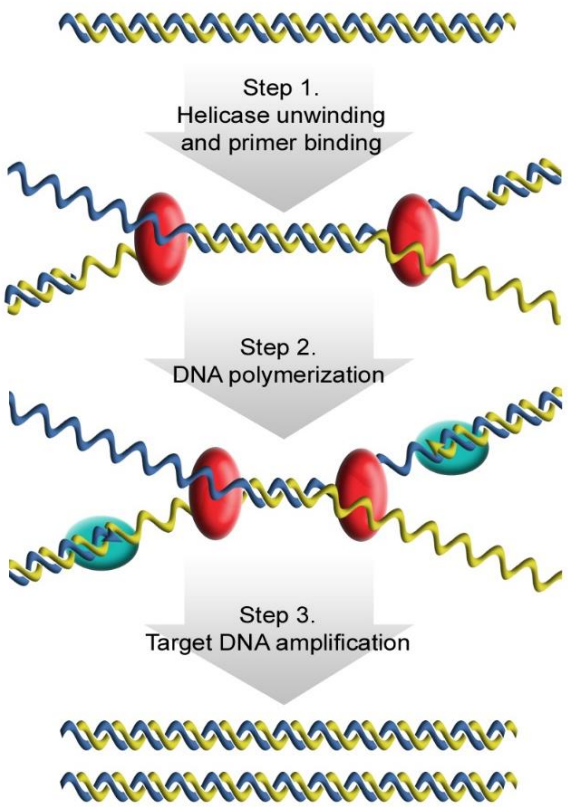
3 **Extension**



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Molecular Diagnostic Isothermal HDA Technology Has Significant Advantages for Point-Of-Care Applications

Mechanism of Helicase-Dependent Amplification (HDA)



- HDA technology is the science behind Quidel's **Solana® and AmpliVue®** molecular products

- Developed in-house by **BioHelix scientists**; more than **12 years of experiences** in HDA

- Comprehensive IP over HDA technology which helps positioning a **unique methodology with royalty-free revenue stream**

- Compared to traditional PCR, isothermal technologies have several **advantages**
  - Lower cost (no thermo-cycling)
  - Faster (potential to compete with immunoassay)
  - Simple workflow

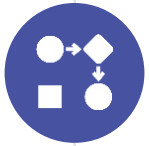
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Some Considerations When Evaluating Molecular Platforms



Performance

Sensitivity & Specificity > Comparison to culture or other MDx?



Workflow

- Hands on time, total number of steps, batching or on-demand
- Space requirements
- Specimen compatibility
- How will QC and data be managed



Throughput

- Anticipated test volume per hour, per day
- Seasonality impact on volume



Turnaround Time

How quickly is the result needed



Cost

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CLIA-Waived Influenza tests

List of Available CLIA-Waived Rapid Flu Tests

Available CLIA-Waived, Antigen-Based Rapid Flu Tests (6)

- Alere BinaxNOW Influenza A&B Card 2 (Reader)
- BD Veritor System for Rapid Detection of Flu A+B (Reader)
- Princeton Biomeditech BioSign Flu A+B (Known Distributors: LifeSign LLC Status Flu A&B, Sekisui Diagnostics LLC OSOM Ultra Flu A&B Test, OraSure QuickFlu Rapid A+B Test, Polymedco Poly Stat Flu A&B Test, LABSCO Advantage Flu A&B, Meridian BioScience ImmunoCard STAT Flu A&B, McKesson Consult Diagnostics Influenza A&B)
- Quidel QuickVue Influenza A+B
- Quidel Sofia Influenza A+B FIA on the Sofia FIA Analyzer (Reader)
- Quidel Sofia Influenza A+B FIA on the Sofia 2 FIA Analyzer (Reader)

Available CLIA-Waived, Nucleic Acid-Based Rapid Flu Tests (7)

- Alere I Flu A/B
- BioMerieux BioFire FilmArray RP EZ
- Cepheid Xpert Flu + RSV Xpress Assay performed on the GeneXpert Xpress System (GXI)
- Cepheid Xpert Xpress Flu Assay performed on the GeneXpert System (GXII and GXIV)
- Mesa Biotech. Inc. Accula Flu A/Flu B Test performed on the Accula Dock
- Roche Cobas Liat Influenza A/B Assay (formally known as Iquum Liat Influenza A/B Assay)
- Roche Cobas Liat Influenza A/B+RSV Assay (formally known as Iquum Liat Influenza A/B+RSV Assay)

Source: FDA website January 2018.

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