



**Q3 2018 Earnings Call • November 1, 2018**

Kevin Hrusovsky, Chairman – CEO; charts  
Joe Driscoll, CFO; script

This presentation contains “forward-looking” statements that are based on our beliefs and assumptions and on information available to us as of the date of this presentation. Forward-looking statements include all statements that are not historical facts. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The risks and uncertainties that we face are described in our most recent filings with the Securities and Exchange Commission. Except as required by law, we assume no obligation to update these forward-looking statements, even if new information becomes available in the future.

This presentation will also include certain financial measures that were not prepared in accordance with U.S. GAAP. The information required by the SEC pursuant to Regulation G, including reconciliation of the non-GAAP financial measures to the most directly comparable GAAP financial measures, can be found in our earnings release issued previously today, which is on our website.

1. Highlights
2. Goals and Priorities
3. Neurology
4. Financial Recap
5. Q&A

## BUSINESS

- Instrument and kit momentum strong, new products, pubs, studies, menu and industry events/awareness
- Share growth in Pharma and Academic continue to grow
- Break through with NF-L (Neuro Filament Light) as an MS treatment monitor. FDA meeting standing room only
- Pubs accelerating: 40 Q3 pubs., >290 total pubs with >150 Neuro
- Simoa planar instrument launch for Onco w/10 plex assay potentially 1H '19. Test bed assessment start by YE '18
- Commercial expansion ongoing, +60HC from YE (50%)
- Regained IVD rights; bioMerieux contract termination

## FINANCIALS

- Q3 Revenue \$10.6M, +85% vs. PY Q3, +61% excluding 1 time bioMerieux license revenue (\$1.3M)
- YTD Revenue \$26.8M, +64%, +56% excluding 1 time
- High margin mix accelerating, Consumables growth +100%
- Q3 GM: 52.8%, +820bp, + 140bp adjusting for 1 time revenue YTD GM: +400bp, +130bp adjusted
- Record level instrument utilization: Neurology is leader but Onco growth +200%: Annualized +\$60K vs. \$50K target for HD1
- Product revenue growth: + 83% Pharma, +79% Academic
- Instrument growth accelerating in 2H after 3 years flat growth

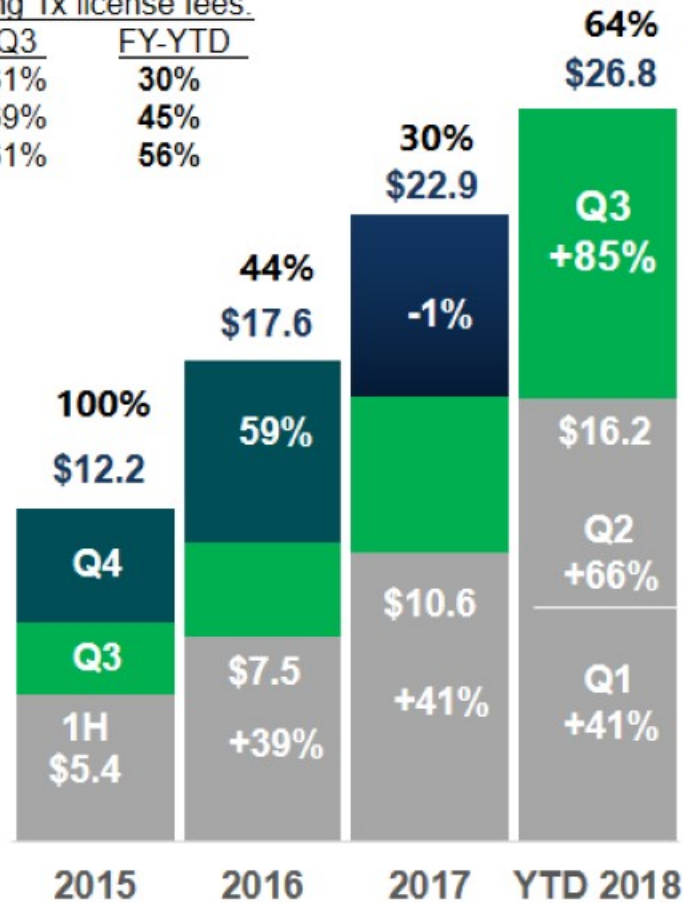
# Sequential Quarter and Year to Date Growth Continues to Accelerate

(\$ in millions)

## Total QTRX Revenue Growth

Excluding 1x license fees:

	Q3	FY-YTD
2016	31%	30%
2017	69%	45%
2018	61%	56%



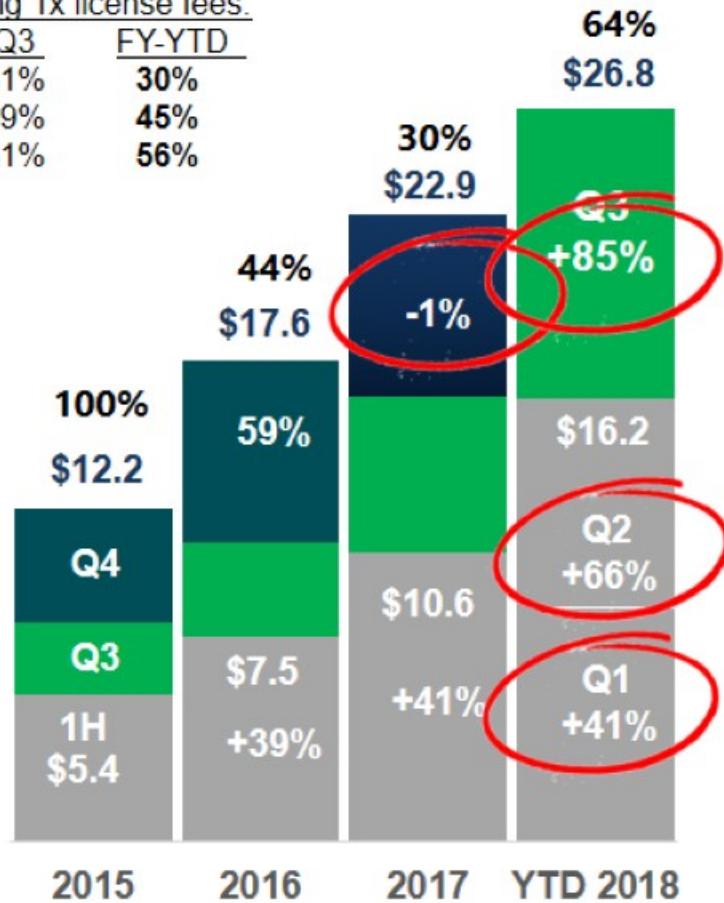
# Sequential Quarter and Year to Date Growth Continues to Accelerate

(\$ in millions)

## Total QTRX Revenue Growth

Excluding 1x license fees:

	Q3	FY-YTD
2016	31%	30%
2017	69%	45%
2018	61%	56%



GM:

47%

44%

44%

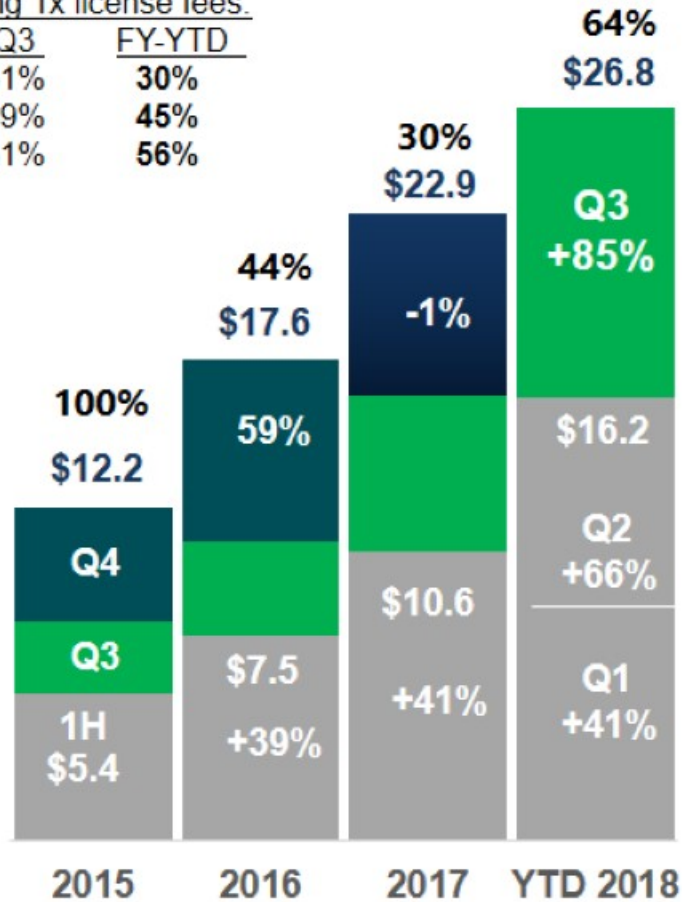
48%

# Sequential Quarter and Year to Date Growth Continues to Accelerate

## Total QTRX Revenue Growth

Excluding 1x license fees:

	Q3	FY-YTD
2016	31%	30%
2017	69%	45%
2018	61%	56%



GM: 47% 2015, 44% 2016, 44% 2017, 48% YTD 2018

(\$ in millions)

YTD'18 Revenue



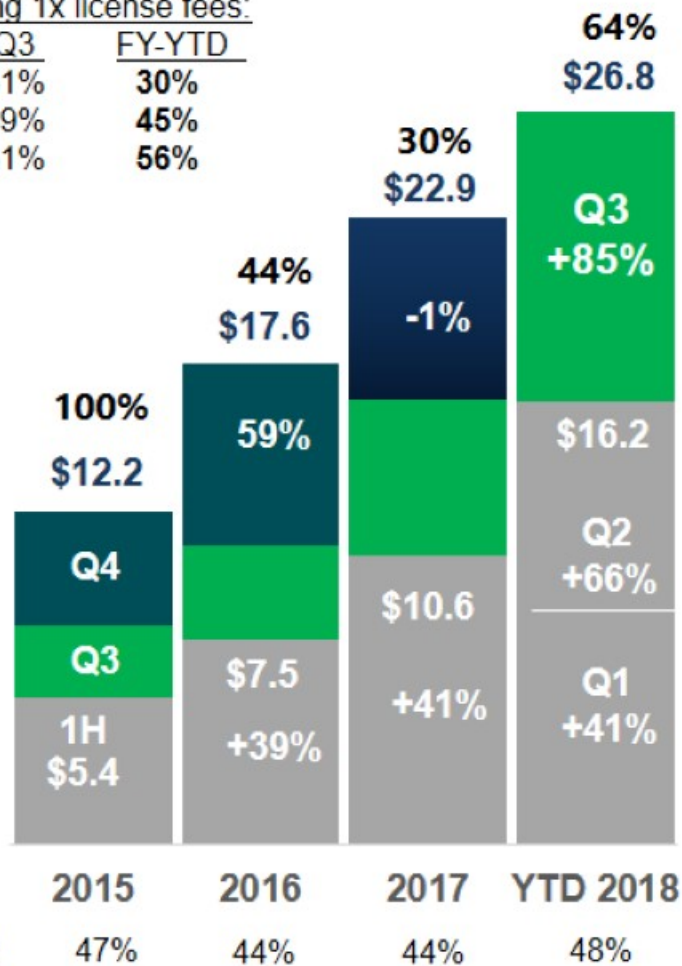
Sales in millions

# Sequential Quarter and Year to Date Growth Continues to Accelerate

## Total QTRX Revenue Growth

Excluding 1x license fees:

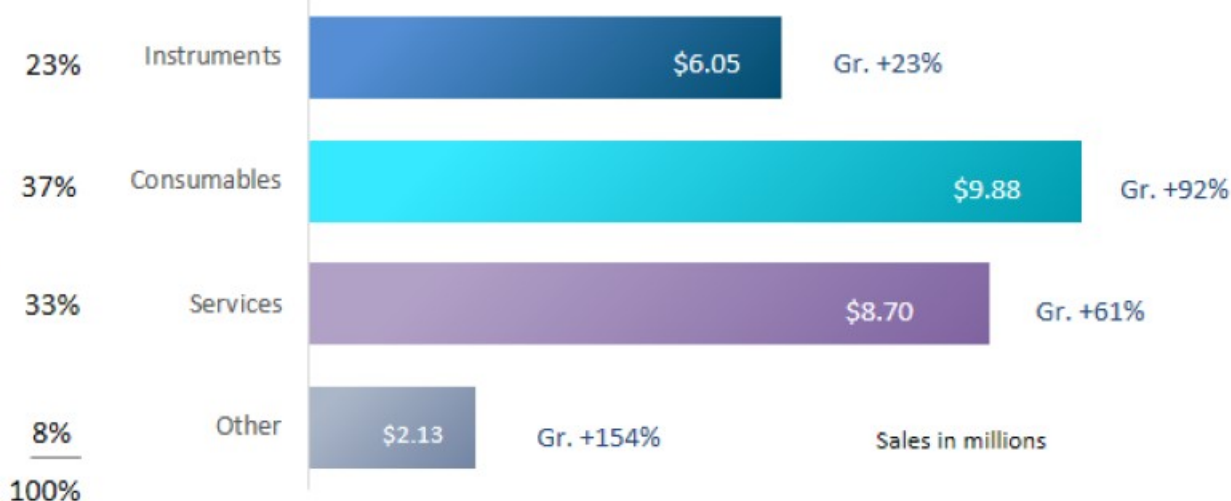
	Q3	FY-YTD
2016	31%	30%
2017	69%	45%
2018	61%	56%



(\$ in millions)

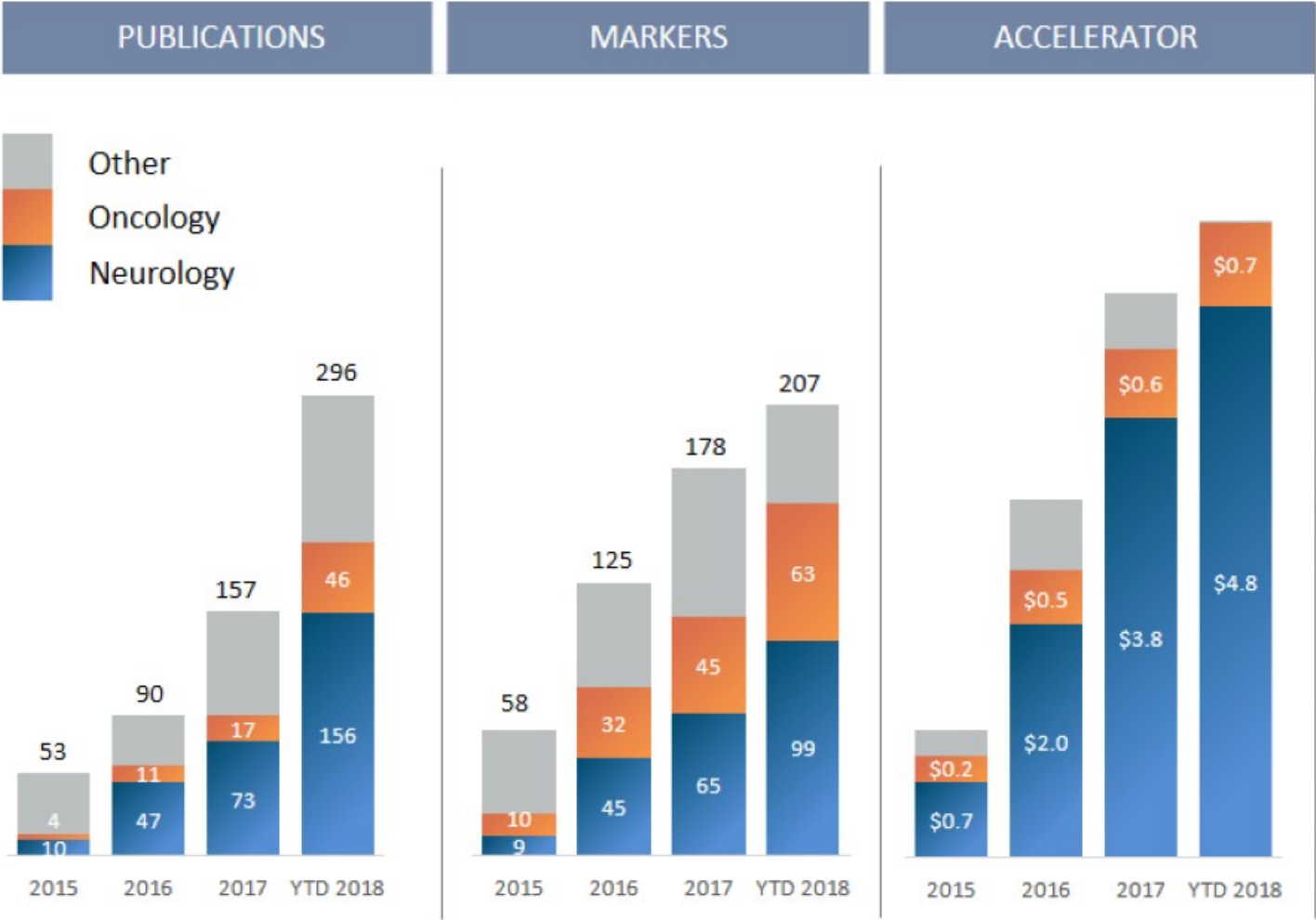
YTD'18 Revenue

Q3'18 Revenue

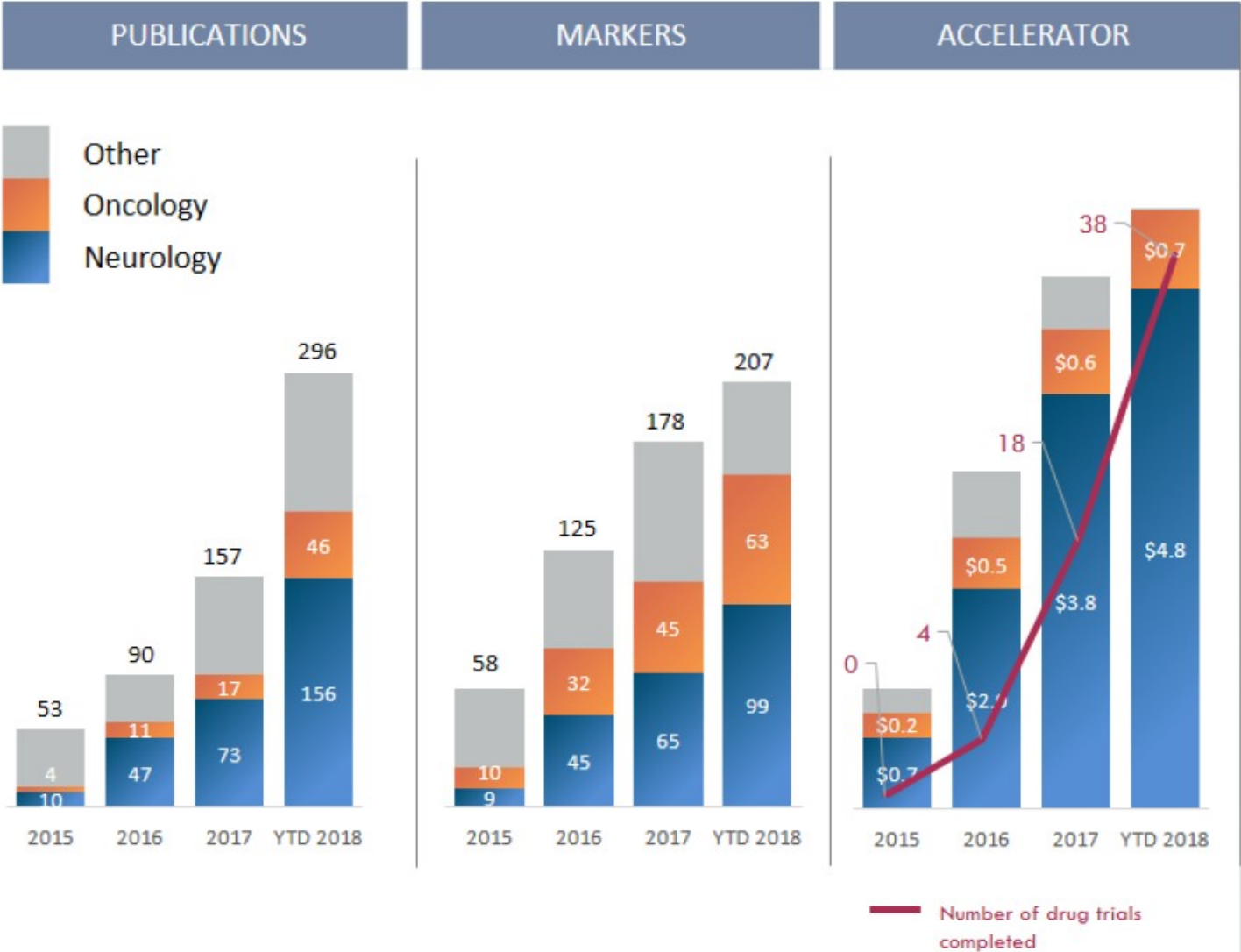




# Scientific Research is Driving Brand Awareness, Performance and Utilization

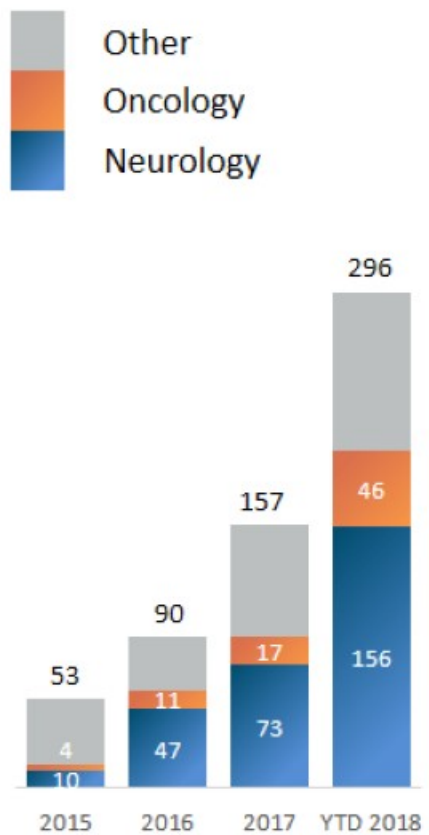


# Scientific Research is Driving Brand Awareness, Performance and Utilization

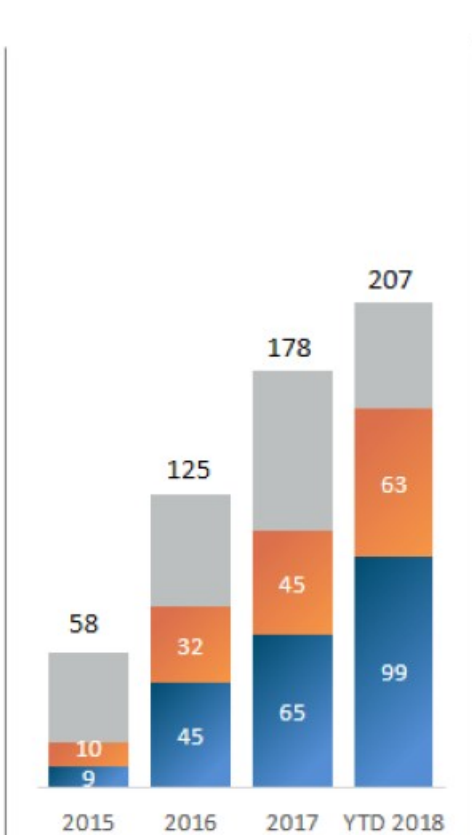


# Scientific Research is Driving Brand Awareness, Performance and Utilization

## PUBLICATIONS



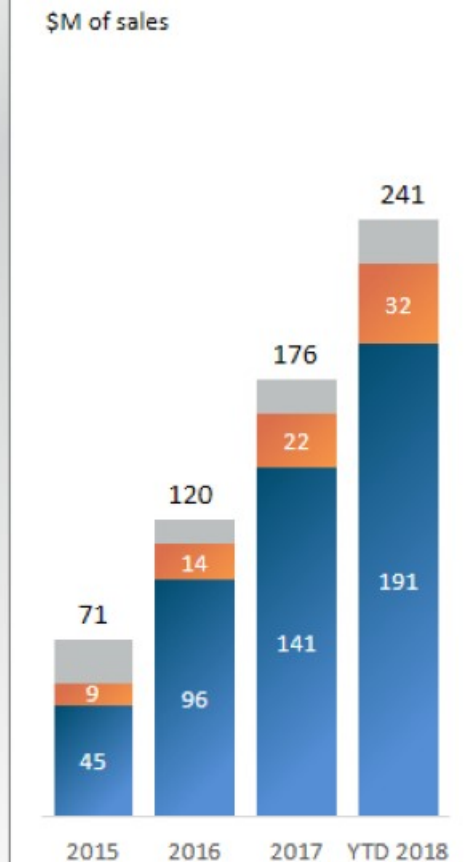
## MARKERS



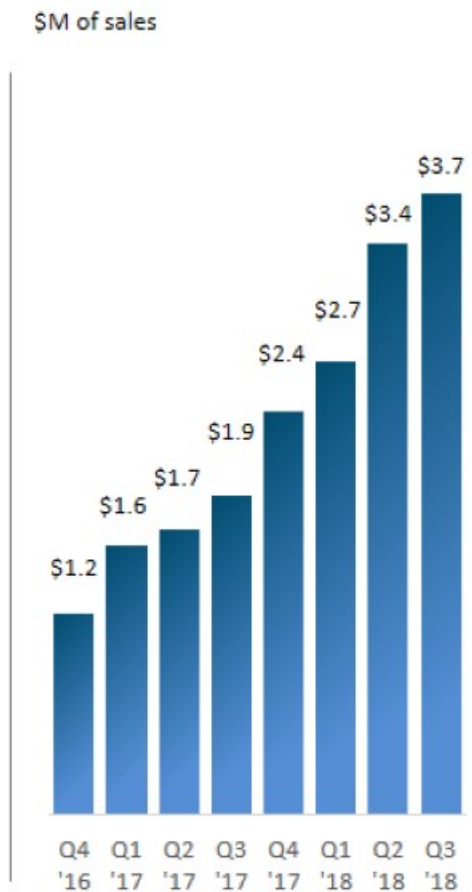
## ACCELERATOR



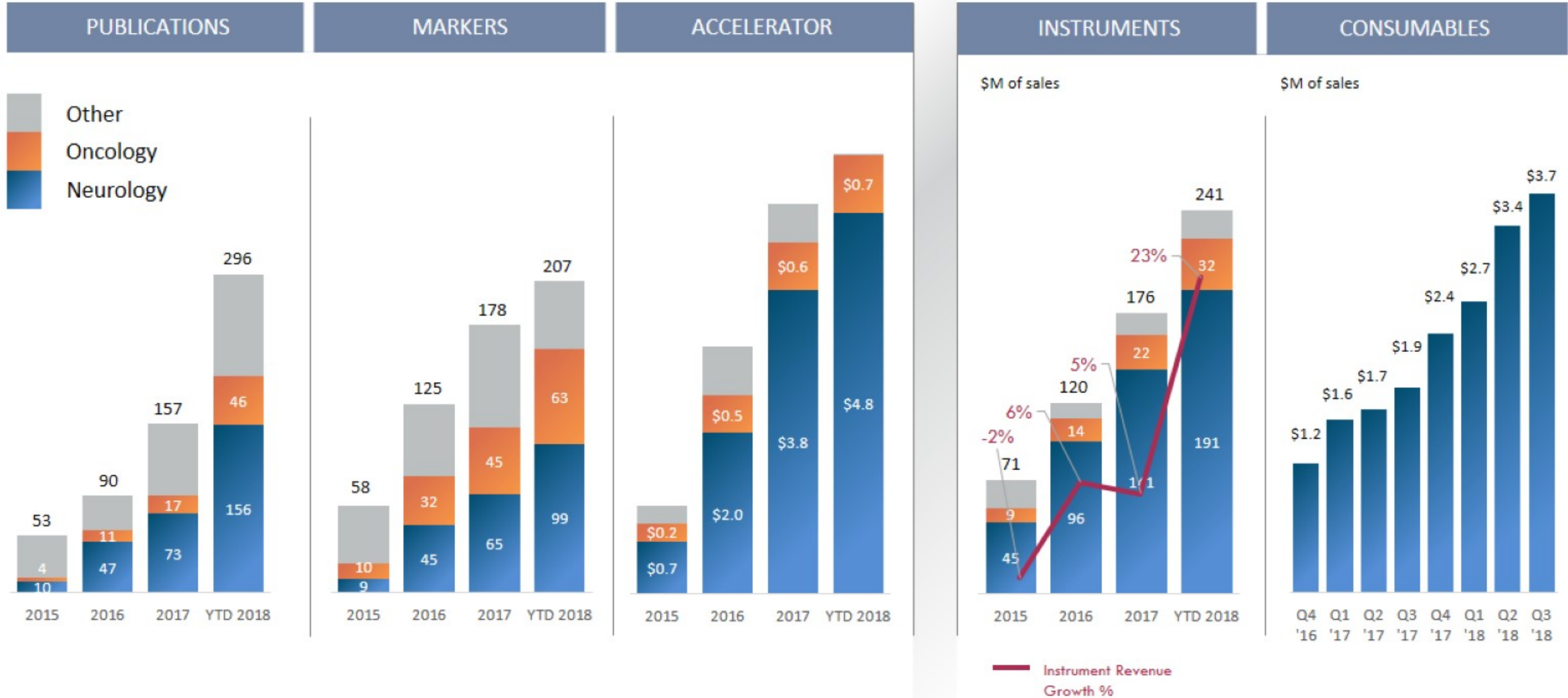
## INSTRUMENTS



## CONSUMABLES

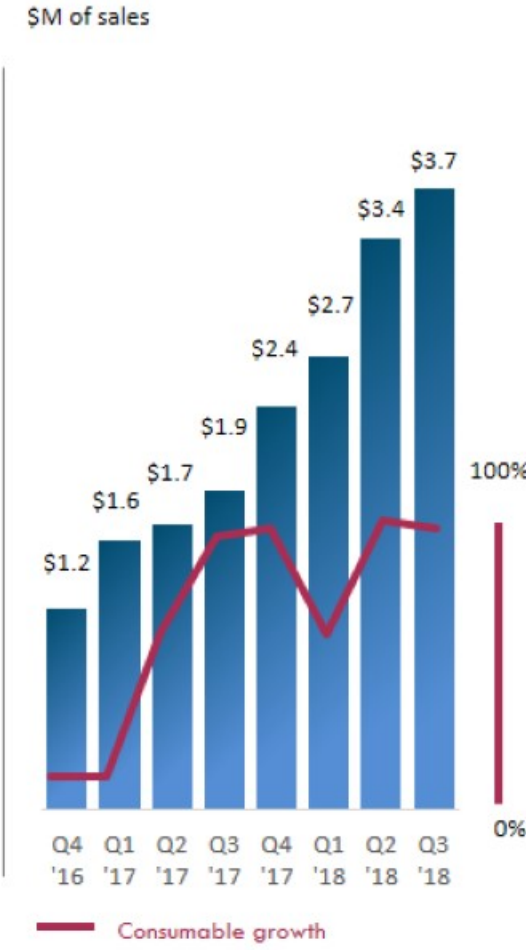
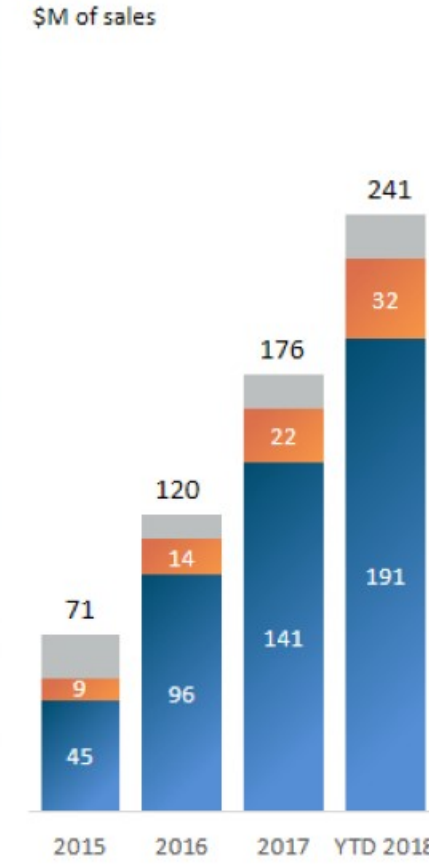
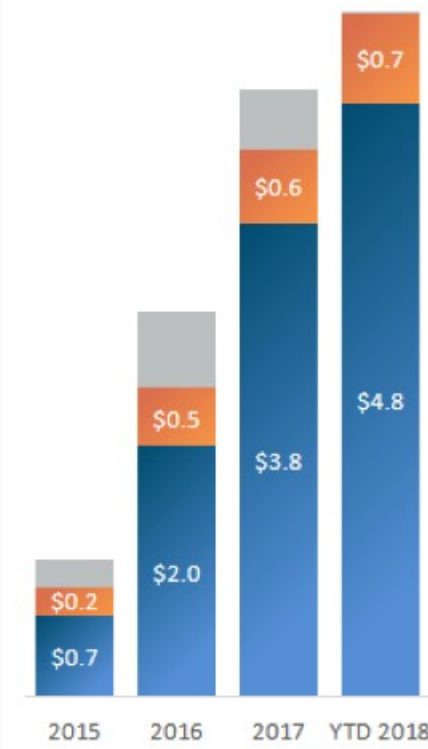
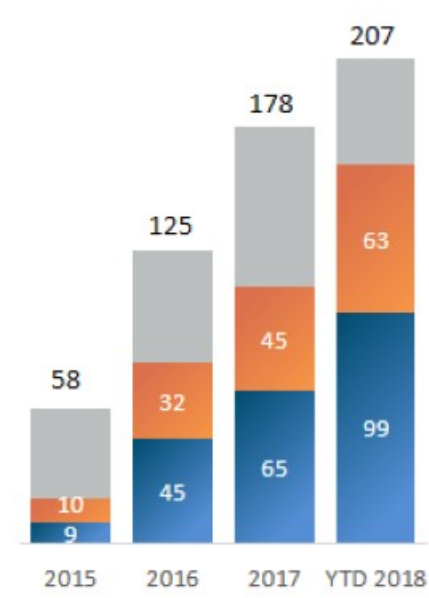
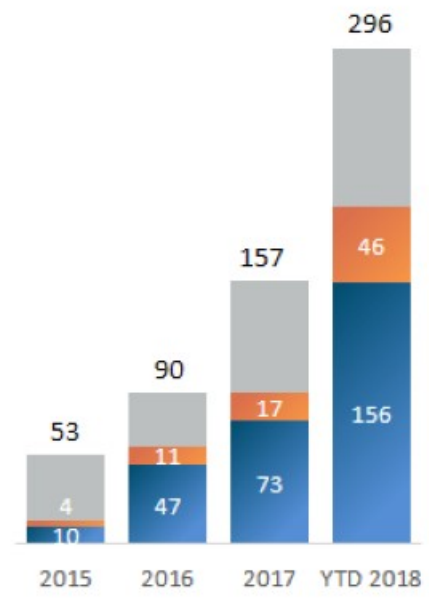


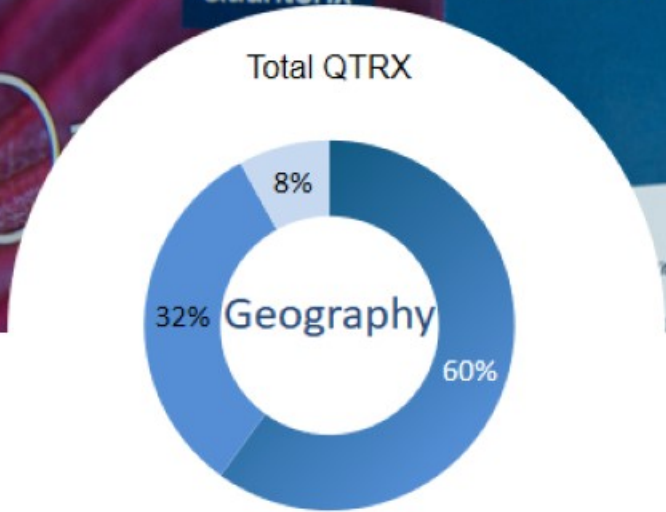
# Scientific Research is Driving Brand Awareness, Performance and Utilization



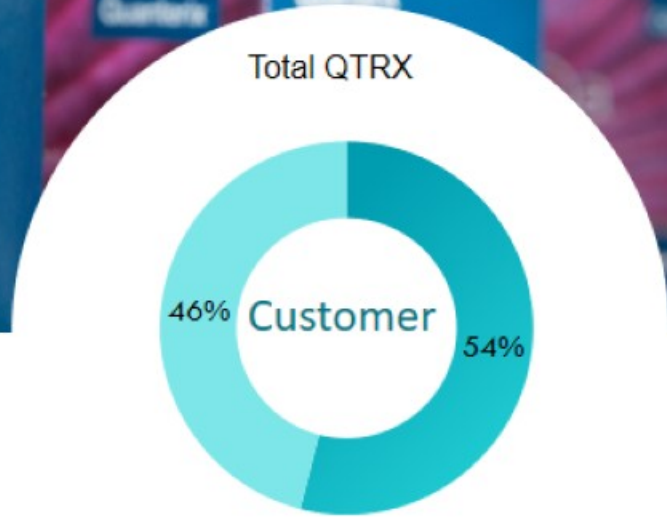
# Scientific Research is Driving Brand Awareness, Performance and Utilization

PUBLICATIONS      MARKERS      ACCELERATOR      INSTRUMENTS      CONSUMABLES

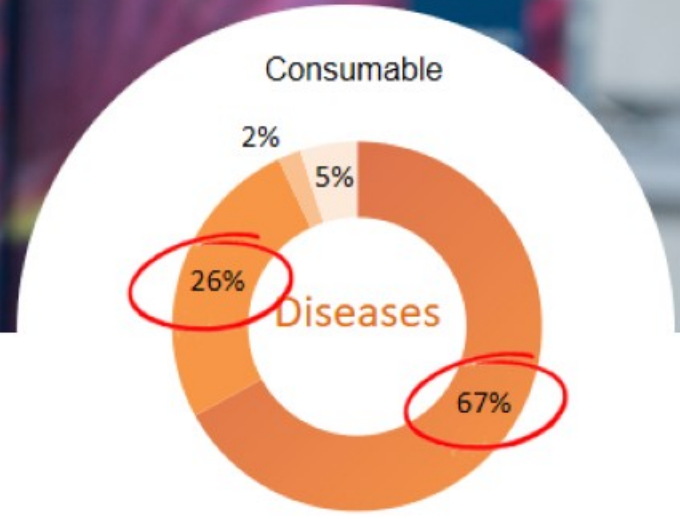




	<u>Growth</u>
NA	+68%
Europe	+72%
Asia	+18%



	<u>Growth</u>
Pharma/Biotech CRO	+62%
Academia	+54%



	<u>Growth</u>
Neurology	+80%
Oncology	+148%
Cardiology	+274%
ID	+46%
<b>} 94%</b>	



REVENUE GROWTH

GM IMPROVEMENT

NEW PRODUCTS

COMMERCIALIZATION & EXPANSION

VALIDATION

## REVENUE GROWTH

### METRIC

### STATUS

FY +40% min:

AHEAD

+64% YTD

By YE, \$40k to \$50k consumables:

AHEAD

\$62k Annualized

By YE, Instrument +20%:

AHEAD

New target > 25% FY



GM IMPROVEMENT

METRIC

STATUS

By YE, +300 bps:

ON TARGET

+820 bps Q3, +400 bps YTD  
Excluding one time adj:  
+140 bp Q3, +130bp YTD

## NEW PRODUCTS

### METRIC

**SR-X** By YE, 50 SR-X 1-6 plex:

**SP-X** Develop Simoa benchtop for 6+ plex:

**ASSAYS** By YE, 25 new assays:

**SERVICE** Open CLIA Lab for pharma services:

### STATUS

AHEAD

>55 booked YTD; New target 70

AHEAD

Q4 early access with 10 plex

AHEAD

28 YTD; New target 40 new assays

AHEAD

Aushon acquisition

## COMMERCIALIZATION & EXPANSION

### METRIC

### STATUS

By YE, add 20 HC:

ON TARGET

+25 Commercial HC YTD (total now 75);  
new SSR selling model focused  
on accelerating drug approvals

Consolidate dx license rights:

AHEAD

DONE!

## VALIDATION

### METRIC

**PUBS** By YE, 275+

**PENETRATION** By YE, 100% top pharma

850 Phase 1, 2, 3 trials

35+ instruments in CRO's

One IVD or LDT Deal

### STATUS

**AHEAD**

290+, 50%+ showing disease progression utility;  
139+ pubs YTD, many showing drug trial utility

**ON TARGET**

23/25 top pharma

**AHEAD**

800 Phase 1, 2, 3 trials

**ON TARGET**

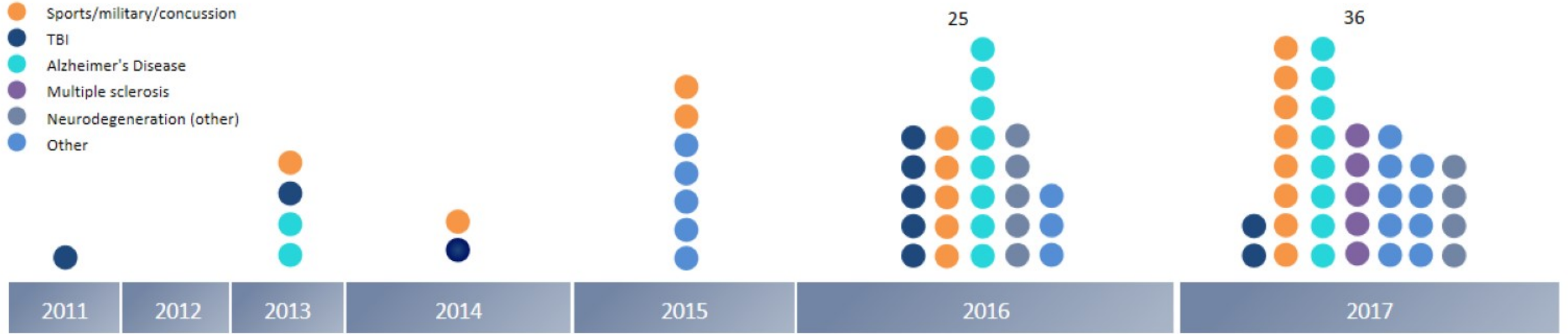
32 instruments in CRO labs

**ON TARGET**

Discussions ongoing

# A Growing Presence in Neurology Publications is Catalyzing Disruption

- Sports/military/concussion
- TBI
- Alzheimer's Disease
- Multiple sclerosis
- Neurodegeneration (other)
- Other



Year	2011	2012	2013	2014	2015	2016	2017	
Publications	1	0	3	2	6	25	36	
Key Publications				JAMA Neurol. 2014;71(6):684-692. Tau 28 concussed Hockey players AUC 0.91 Tau predicts return-to-play following concussion	JAMA Neurol. 2015; Aug 3 Tau (chronic) 70 ex-deployed military personnel Tau predicts TBI history, and long-term symptoms	Neurol Neuroinflammation 2016; Aug 2 NF-L 12 patients, longitudinal study NF-L reflects MS progression	J Neurotrauma Neurol. 2016; Oct 1 NF-L 19 collegiate players (TCU) NF-L reflects extent of football hit exposure over a season	JAMA Neurol 2017; May 1 NF-L 570 patients & HCs cross-sectional Plasma NF-L exhibits high diagnostic accuracy for Alzheimer's disease (AUC 0.87)
Institutions							UNIVERSITY OF GOTHENBURG University of Basel NYU	

HEAD HEALTH CHALLENGE  
2X Winner

GOOD MORNING AMERICA

"Concussion"  
Starring Will Smith & Alec Baldwin

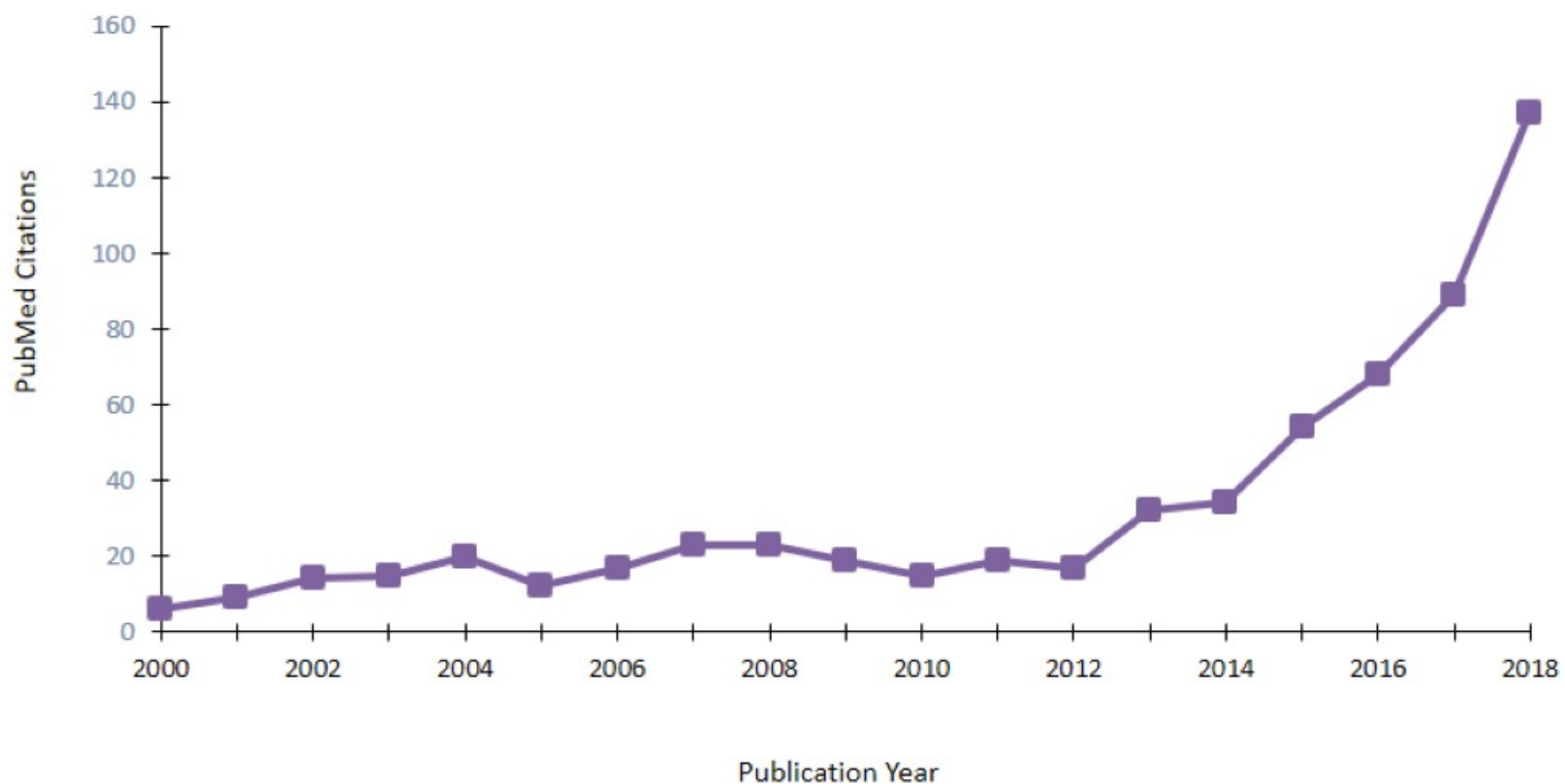
Genentech  
Biogen  
Pfizer

UBC  
Bloomberg

Lilly  
SANOFI

# Neurofilament Light in Research Studies for MS and Other Neurological Conditions Accelerating Rapidly

## RESEARCH PUBLICATIONS ON NFL



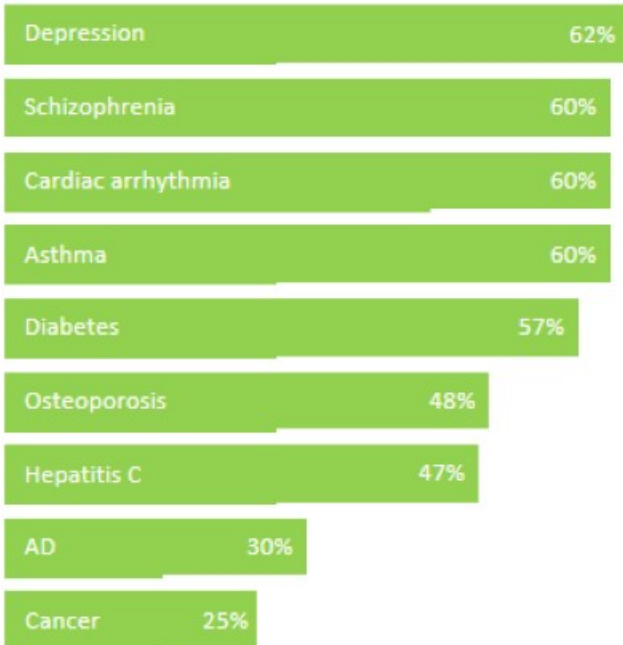
	CAGR
2003-2018 YTD	16%
2013-2018 YTD	34%

## DRUG PERFORMANCE

### TOXICITY

Adverse drug events are a substantial cause of Death in USA

### EFFICACY

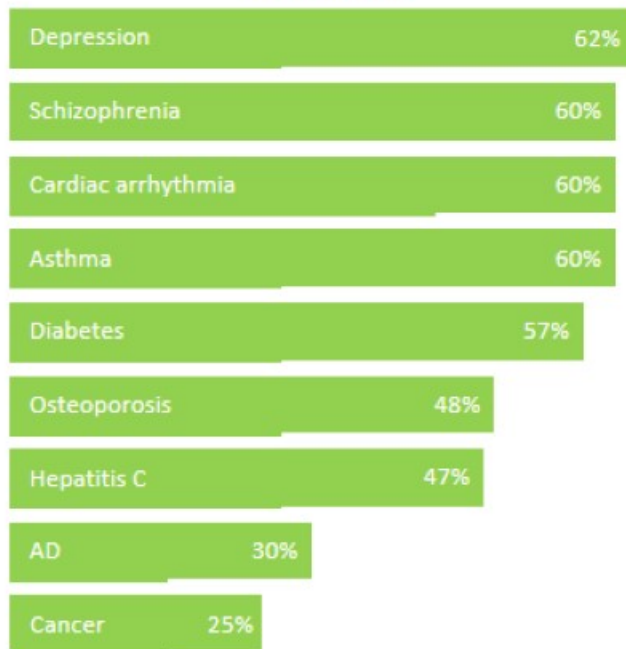


## DRUG PERFORMANCE

### TOXICITY

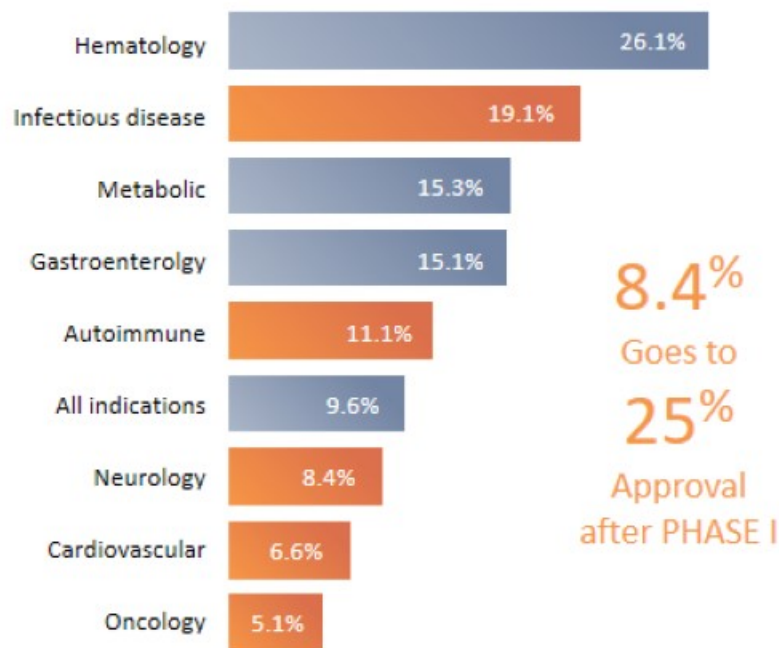
Adverse drug events are a substantial cause of Death in USA

### EFFICACY



## PROBABILITY OF DRUG APPROVAL

300%  
increase if biomarkers  
are used



8.4%  
Goes to  
25%  
Approval  
after PHASE I

Probability of phase III approval  
after Phase 1 approval

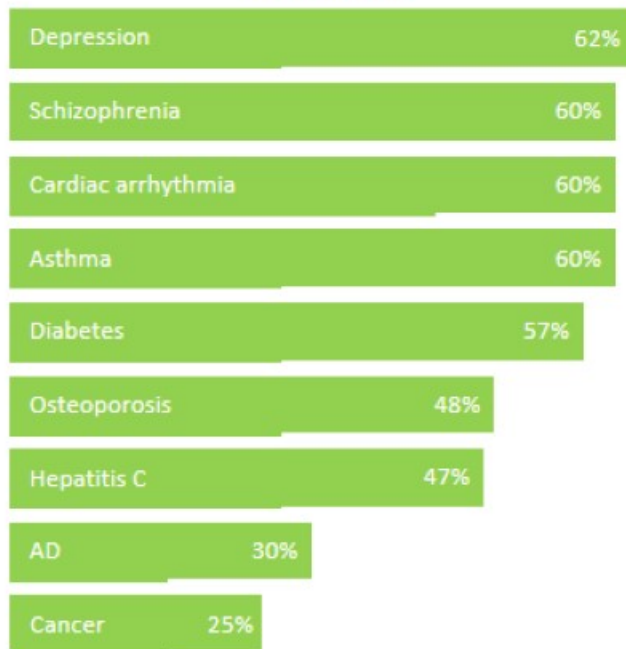


## DRUG PERFORMANCE

### TOXICITY

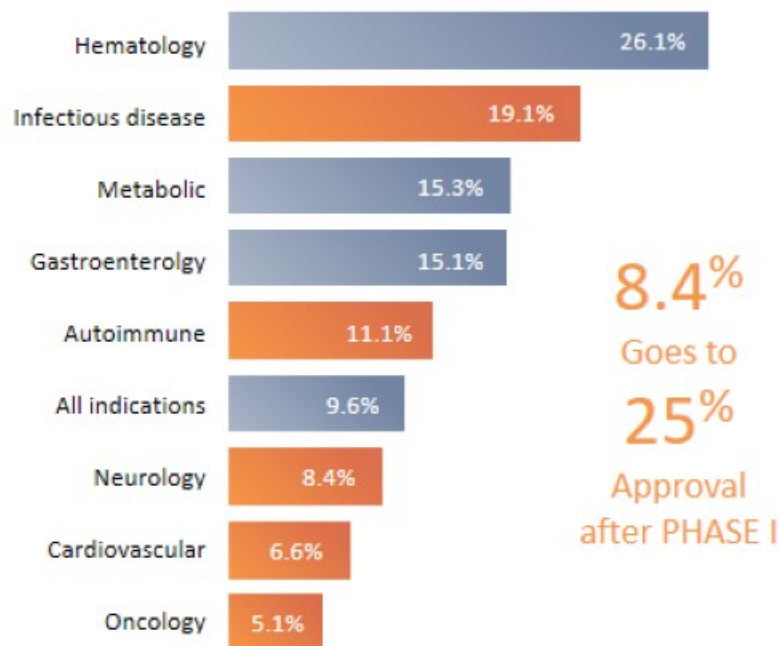
Adverse drug events are a substantial cause of Death in USA

### EFFICACY



## PROBABILITY OF DRUG APPROVAL

300% increase if biomarkers are used



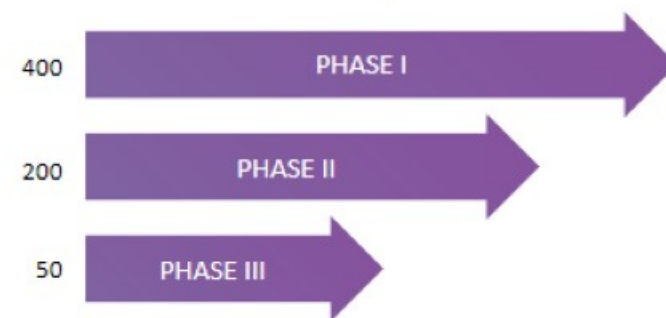
8.4% Goes to 25% Approval after PHASE I

Probability of phase III approval after Phase 1 approval

## VALIDATION OF SIMOA IMPACT



650 clinical trials with Simoa at single CRO



MYRIAD RBM.

## Early Alzheimer's Disease: Developing Drugs for Treatment Guidance for Industry

*Additional copies are available from:*

*Office of Communications, Division of Drug Information  
Center for Drug Evaluation and Research  
Food and Drug Administration*

*10901 New Hampshire Ave., Hillendale Bldg., 4th Floor  
Silver Spring, MD 20993-0002*

*Phone: 855-543-3784 or 301-796-3490; Fax: 301-431-4353; Email: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)  
<http://www.fda.gov/Drugs/Guidance/Compliance/RegulatoryInformation/Guidance/default.htm>*

*and/or*

*Office of Communication, Outreach, and Development  
Center for Biologics Evaluation and Research  
Food and Drug Administration*

*10901 New Hampshire Ave., Bldg 71, rm. 3129  
Silver Spring, MD 20993-0002*

*Phone: 301-833-4708 or 240-462-8010; Email: [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov)  
<https://www.fda.gov/BiologicsBloodVaccines/Guidance/Compliance/RegulatoryInformation/Guidance/default.htm>*

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)

February 2018  
Clinical/Medical

Revision 1

### FDA INITIATIVE...

FDA recognizes the criticality of ID'ing pre-clinical patients for drug trials using biomarkers.

### WHAT IT MEANS FOR QTRX...

Encourages biopharma to identify/incorporate promising biomarkers in trial design

## Early Alzheimer's Disease: Developing Drugs for Treatment Guidance for Industry

*Contains Nonbinding Recommendations  
Draft - Not for Implementation*

### 1 Breakthrough Devices Program 2 Draft Guidance for Industry and 3 Food and Drug Administration Staff


4 *DRAFT GUIDANCE*

5 This draft guidance document is being distributed for comment purposes only.  
6 Document issued on October 25, 2017.

7 You should submit comments and suggestions regarding this draft document within 60 days of  
8 publication in the *Federal Register* of the notice announcing the availability of the draft guidance.  
9 Submit electronic comments to <https://www.regulations.gov>. Submit written comments to  
10 Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm.  
11 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of  
12 availability that publishes in the *Federal Register*.

13 For questions about this document regarding CDRI-regulated devices, contact the Office of  
14 Device Evaluation (ODE) at 301-796-5550 or [BreakthroughDevicesProgram@fda.hhs.gov](mailto:BreakthroughDevicesProgram@fda.hhs.gov). For  
15 questions about this document regarding CBER-regulated devices, contact the Office of  
16 Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

17 When final, this guidance will supersede "Expedited Access for Premarket  
18 Approval and De Novo Medical Devices Intended for Unmet Medical Need for  
19 Life Threatening or Irreversibly Debilitating Diseases or Conditions," issued  
20 on April 13, 2015.

21  **U.S. FOOD & DRUG**  
22 **ADMINISTRATION**  
23 U.S. Department of Health and Human Services  
24 Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

### FDA INITIATIVE...

→ FDA recognizes the criticality of ID'ing pre-clinical patients for drug trials using biomarkers.

→ FDA to expedite development, assessment, and review of medical devices addressing treatment or diagnosis of life-threatening or irreversibly debilitating conditions.

### WHAT IT MEANS FOR QTRX...

Encourages biopharma to identify/incorporate promising biomarkers in trial design

Expedited review of IVD tests; more probable Class II path. Example: Banyan TBI test (6 mo to clearance).

## Early Alzheimer's Disease: Developing Drugs for Treatment Guidance for Industry

*Contains Nonbinding Recommendations  
Draft - Not for Implementation*

### Breakthrough Devices Program Draft Guidance for Industry and Food and Drug Administration Staff

 **FEDERAL REGISTER**  
The Daily Journal of the United States Government

### Program for Parallel Review of Medical Devices

A Notice by the Centers for Medicare & Medicaid Services and the Food and Drug Administration on 10/24/2016

Leroy A. Richardson,  
Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Center for Disease Control and  
Prevention.  
FF Doc. 2016-23069; Fd-42 30-21-16, 0143 and  
BILLING CODE 4120-19-P

DEPARTMENT OF HEALTH AND  
HUMAN SERVICES

Centers for Medicare & Medicaid  
Services

(CMS-3160-R4)

Food and Drug Administration

(Docket No. FDA-2016-41-0306)

Program for Parallel Review of Medical  
Devices

AGENCY: Food and Drug Administration;  
Centers for Medicare & Medicaid  
Services, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug  
Administration (FDA) and the Centers  
for Medicare & Medicaid Services (CMS)  
(the Agencies) are informing the public  
that the Parallel Review of medical  
devices pilot program will be fully  
implemented and extended indefinitely.  
The Agencies are soliciting nominations  
from manufacturers of innovative  
medical devices to participate in the  
"Program for Parallel Review of Medical  
Devices." The Parallel Review program  
is a collaborative effort that is intended  
to reduce the time between FDA  
marketing approval or FDA's granting of  
a de novo request and Medicare  
coverage decisions through CMS's  
National Coverage Determination (NCD).

### FDA INITIATIVE...

FDA recognizes the criticality of ID'ing pre-clinical patients for drug trials using biomarkers.

FDA to expedite development, assessment, and review of medical devices addressing treatment or diagnosis of life-threatening or irreversibly debilitating conditions.

FDA teaming up with CMS to provide parallel review of medical device approval and Medicare coverage.

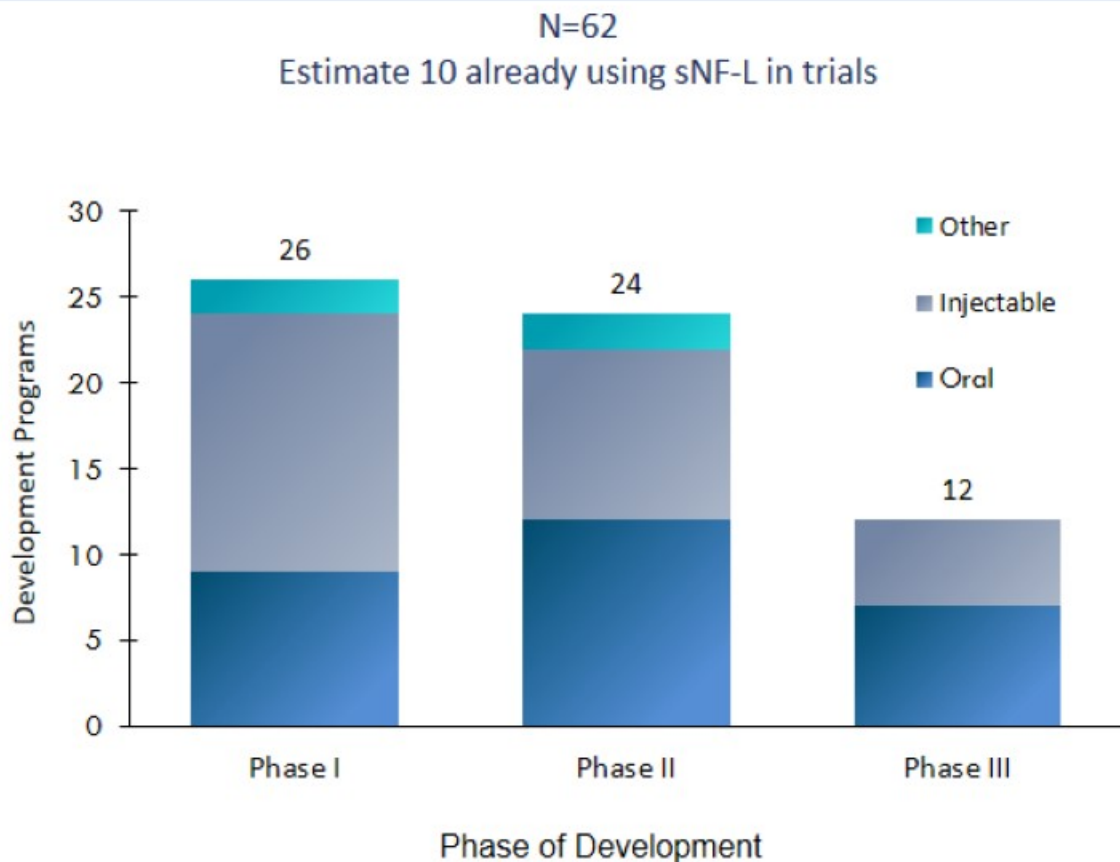
### WHAT IT MEANS FOR QTRX...

Encourages biopharma to identify/incorporate promising biomarkers in trial design

Expedited review of IVD tests; more probable Class II path. Example: Banyan TBI test (6 mo to clearance).

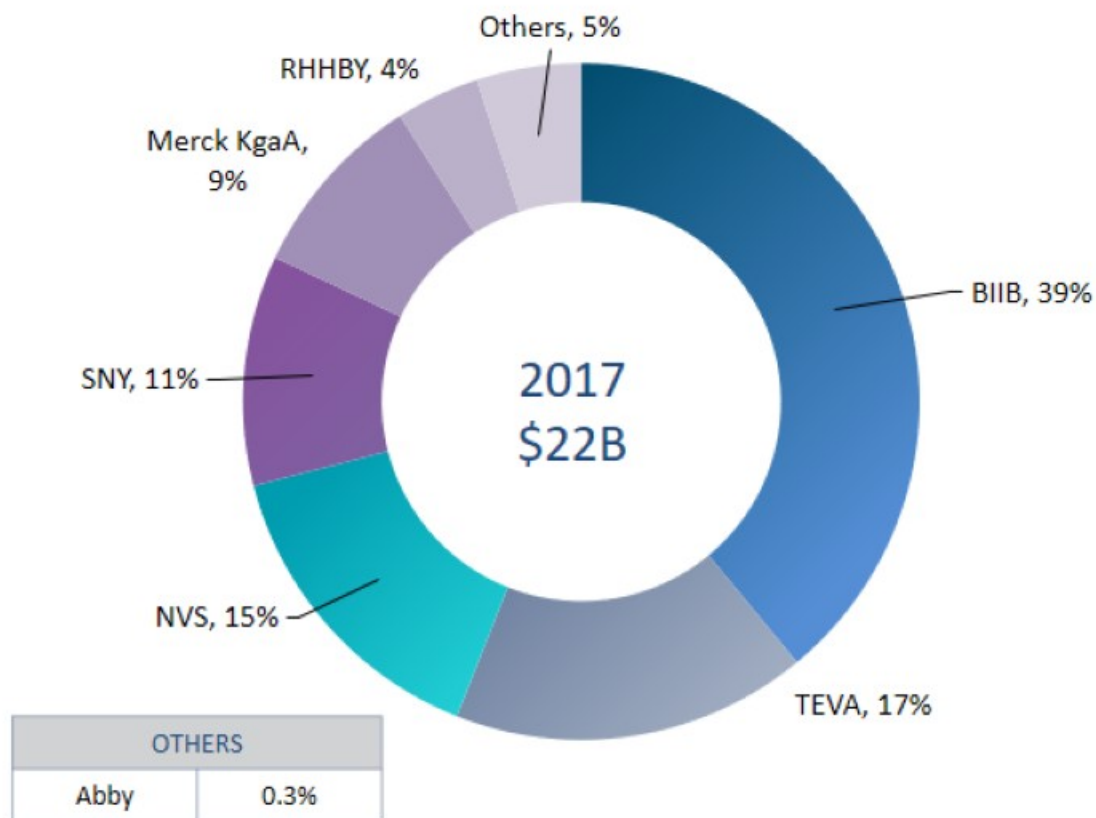
Potential to secure reimbursement determination simultaneous with FDA clearance

MULTIPLE SCLEROSIS\* THERAPIES IN DEVELOPMENT



Source: Health Advances commissioned research, 2018

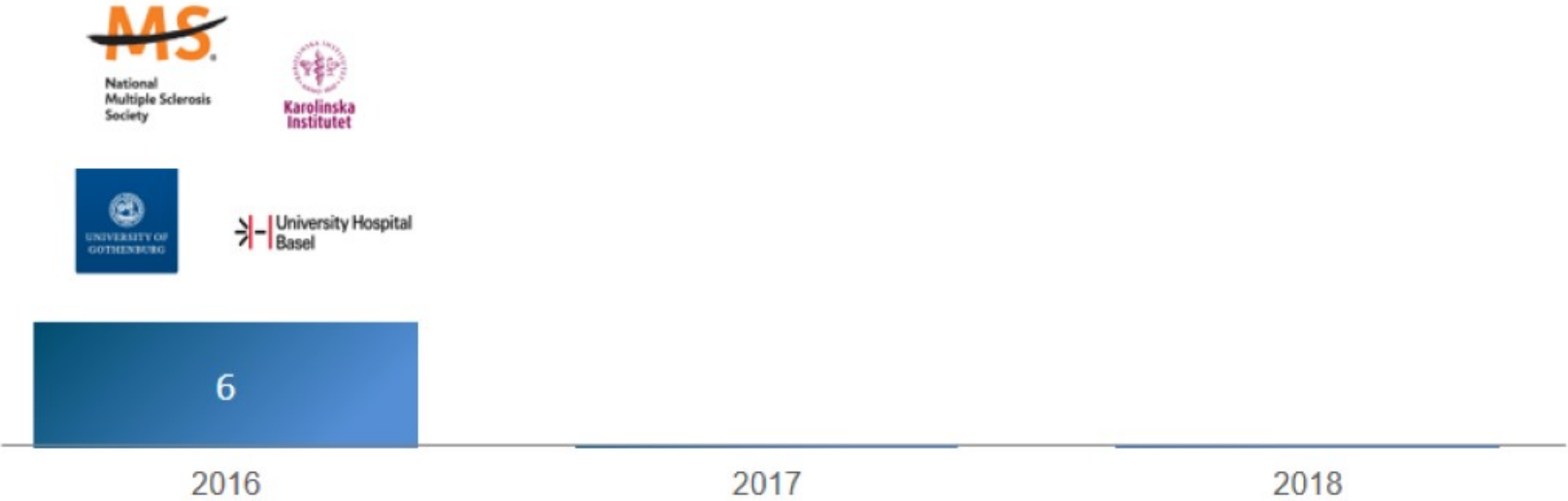
MULTIPLE SCLEROSIS CATEGORY MARKET SHARE BY & SALES



Source: Company data, Cowen and Company

# Serum NFL Research Dramatically Highlighted at European Committee for Treatment and Research in Multiple Sclerosis Annual Meeting – Oct., 2018

## SERUM NFL PUBLICATIONS AT ECTRIMS



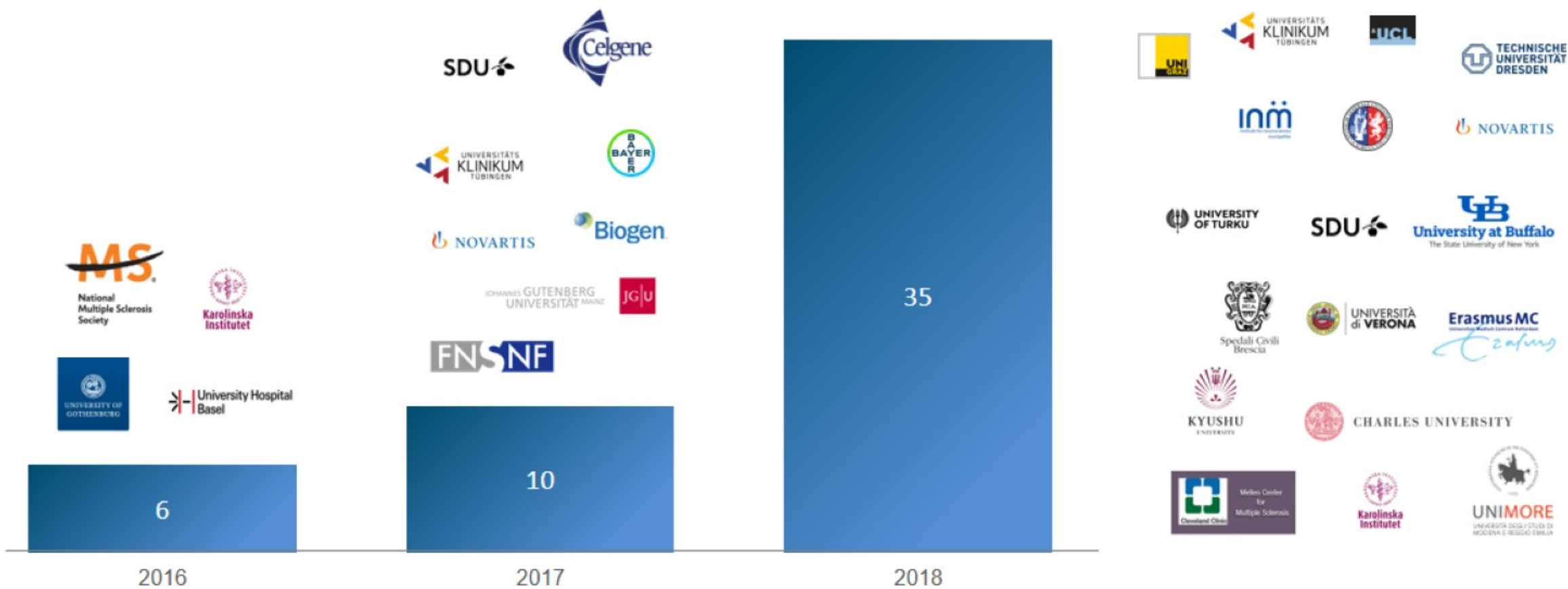
# Serum NFL Research Dramatically Highlighted at European Committee for Treatment and Research in Multiple Sclerosis Annual Meeting – Oct., 2018

## SERUM NFL PUBLICATIONS AT ECTRIMS



# Serum NfL Research Dramatically Highlighted at European Committee for Treatment and Research in Multiple Sclerosis Annual Meeting – Oct., 2018

## SERUM NFL PUBLICATIONS AT ECTRIMS





Potential to move routine patient MS management away from \$3000 MRI's to a simple blood test



NF-L as surrogate for MRI:  
MS patients: 2.5M  
MRI monitoring 1-2X/yr  
4M NF-L tests/year

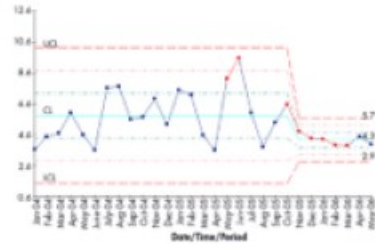
# Why the Wave of Interest in Simoa NfL?

Potential to move routine patient MS management away from \$3000 MRI's to a simple blood test



NF-L as surrogate for MRI:  
MS patients: 2.5M  
MRI monitoring 1-2X/yr  
4M NF-L tests/year

Potential to improve patient quality of life through more accurate and timely precision medicine

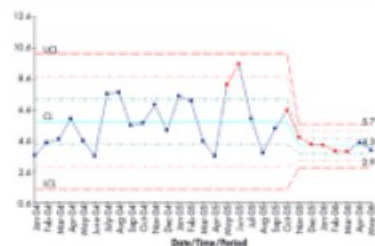


Potential to move routine patient MS management away from \$3000 MRI's to a simple blood test



NF-L as surrogate for MRI:  
MS patients: 2.5M  
MRI monitoring 1-2X/yr  
4M NF-L tests/year

Potential to improve patient quality of life through more accurate and timely precision medicine



Experts and opinion leaders all agree:

“Blood NF-L is a long-term prognostic biomarker of disease evolution and progression.” –Prof Ludwig Kappos, Univ Hosp Basel

“Plasma NF-L is a biomarker of brain lesion activity.”  
–Dr. Gregory Opitck, Receptos/Celgene

“Serum NF-L is a surrogate to quantify effects of neuro-protective drugs in clinical trials .” –Prof Jens Khule, Univ Hosp Basel

“MRI shows the ashes, NF-L shows the match.”  
–Prof David Leppert, Novartis/Unv Basel

Potential to accelerate clinical trials through more rapid end-points

2 years:



- T2 lesions
- brain atrophy
- relapses
- disability progression



6 months:





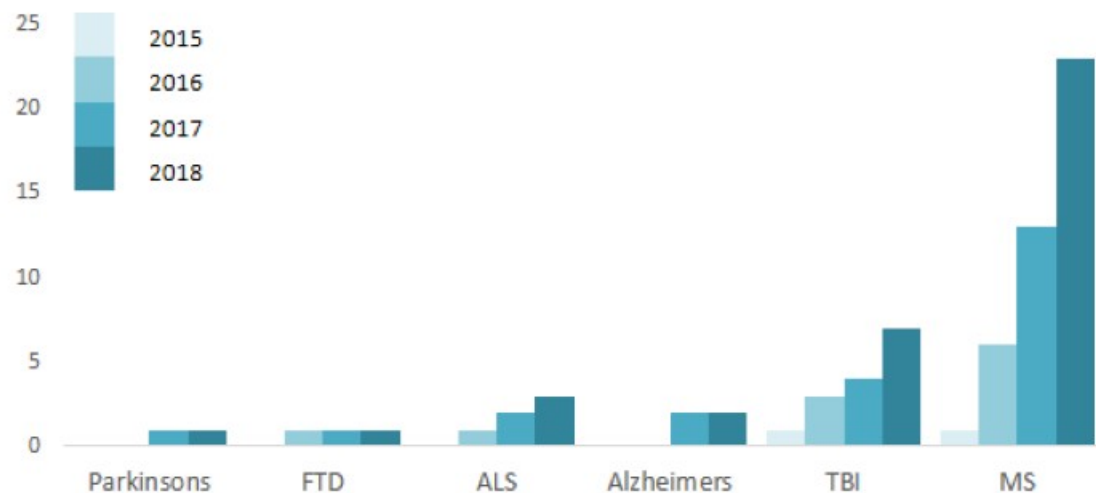
- Multiple sclerosis
- Alzheimer's Disease
- Guillain-Barre syndrome
- Frontotemporal Dementia
- Amyotrophic Lateral Sclerosis (ALS)
- Delirium
- Stroke
- Traumatic brain injury
- Concussion
- Chronic Traumatic Encephalopathy (CTE)
- Parkinson's disease
- Creutzfeldt-Jakob (prion) disease
- Huntington's disease
- Brain hypoxia
- Subarachnoid hemorrhage

## DIGITAL BIOMARKERS IMPACTING ALL AREAS OF BRAIN HEALTH:

- Tau
- P-Tau
- Amyloid b 40
- Amyloid b 42
- Nf-L
- BDNF
- GFAP
- UCH-L1
- NSE
- TNFa
- aSynuclein
- TDP43
- Inflammatory Cytokines
- Multiplex combinations



## NFL PUBLICATIONS

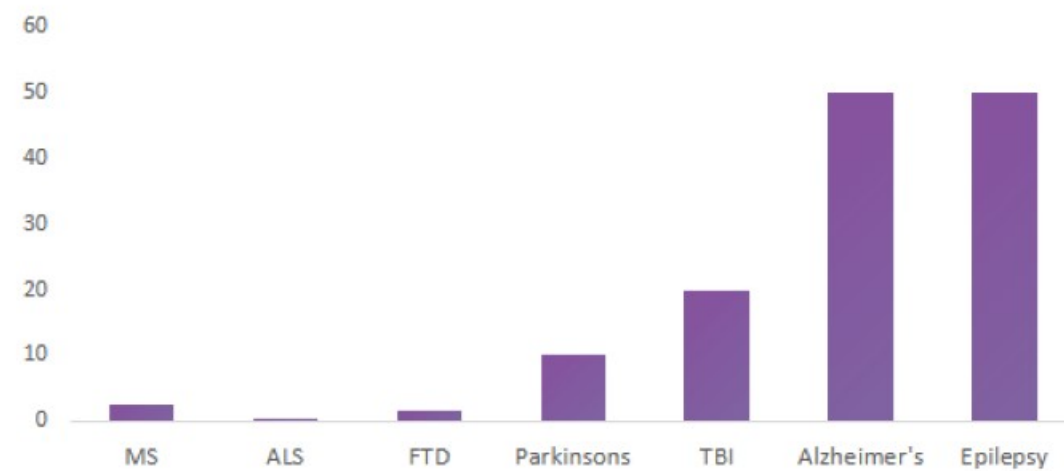


### STUDIES CONFIRM NFL CLINICAL UTILITY:

- Disease activity monitoring
- Drug efficacy monitoring
- Relapse/severity prognostic

Majority of published data obtained with Simoa NfL

## WW DISEASE INCIDENCE (MILLIONS)



### MULTIPLE SCLEROSIS:

- Avg. age of onset: 34 yrs; avg. life expectancy after onset: 30 yrs
- Standard of care: MRI 1-2X/yr
- NfL as MRI replacement: 3.5M tests/yr

Clinical Validation of NfL for MS is a Key Beachhead

# Five Key Catalysts are Driving Growth



## Five Key Catalysts are Driving Growth



- 2018 SR-X
- Potential SP-X Onco 1H'19, menu

## Five Key Catalysts are Driving Growth



- Share / TAM expansion
- FDA advance, sensitivity
- 800+ drug trials
- pharma services entry
- Investor selling model
- Captured leadership



## Five Key Catalysts are Driving Growth



- IVD Rights Regained  
TAM expansion
- Abbott blood screening
- LDT / CRO opportunity

## Five Key Catalysts are Driving Growth



- Aushon: CLIA, menu, pharma services, next gen planar technology

## Five Key Catalysts are Driving Growth



- Investors / media / publications, FDA
- PPH sponsorship

# Five Key Catalysts are Driving Growth



## NEW PRODUCTS

- 2018 SR-X
- Potential SP-X Onco 1H'19, menu

## COMMERCIAL

- Share / TAM expansion
- FDA advance, sensitivity
- 800+ drug trials
- pharma services entry
- Investor selling model
- Captured leadership

## STRATEGY

- IVD Rights Regained TAM expansion
- Abbott blood screening
- LDT / CRO opportunity

## M&A

- Aushon: CLIA, menu, pharma services, next gen planar technology

## AWARENESS MOMENTUM

- Investors / media / publications, FDA
- PPH sponsorship

