



Digital Health Business Forum

July 26, 2017

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Vice President, Head of Legal Affairs and Compliance, Proteus Digital Health

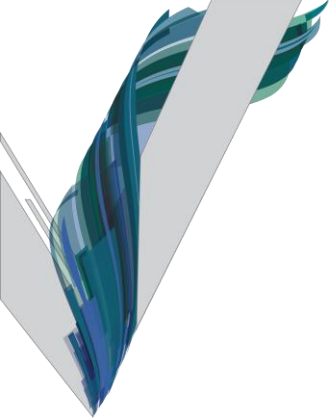
James E. Nelson
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Digital Health Business Forum

Agenda

- Welcome
- Legislative & Regulatory Update
 - Repeal and Replace
 - Developments in Telemedicine
 - HIPAA Breach Enforcement Update
- Company in the Spotlight
 - Proteus Digital Health
- Corporate Update



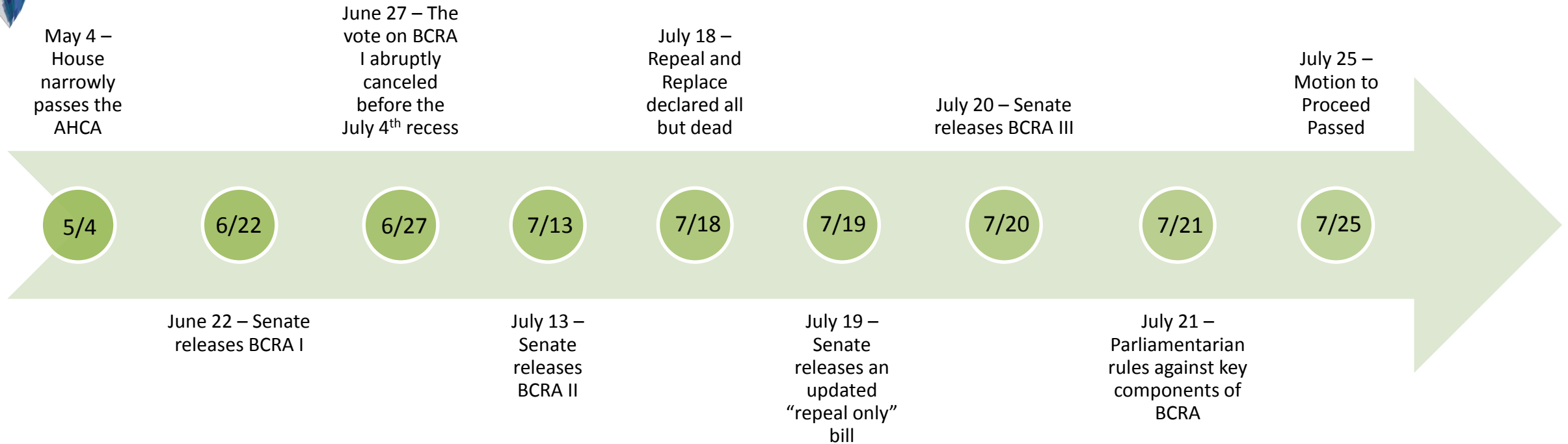


Legislative & Regulatory Update

Thora Johnson

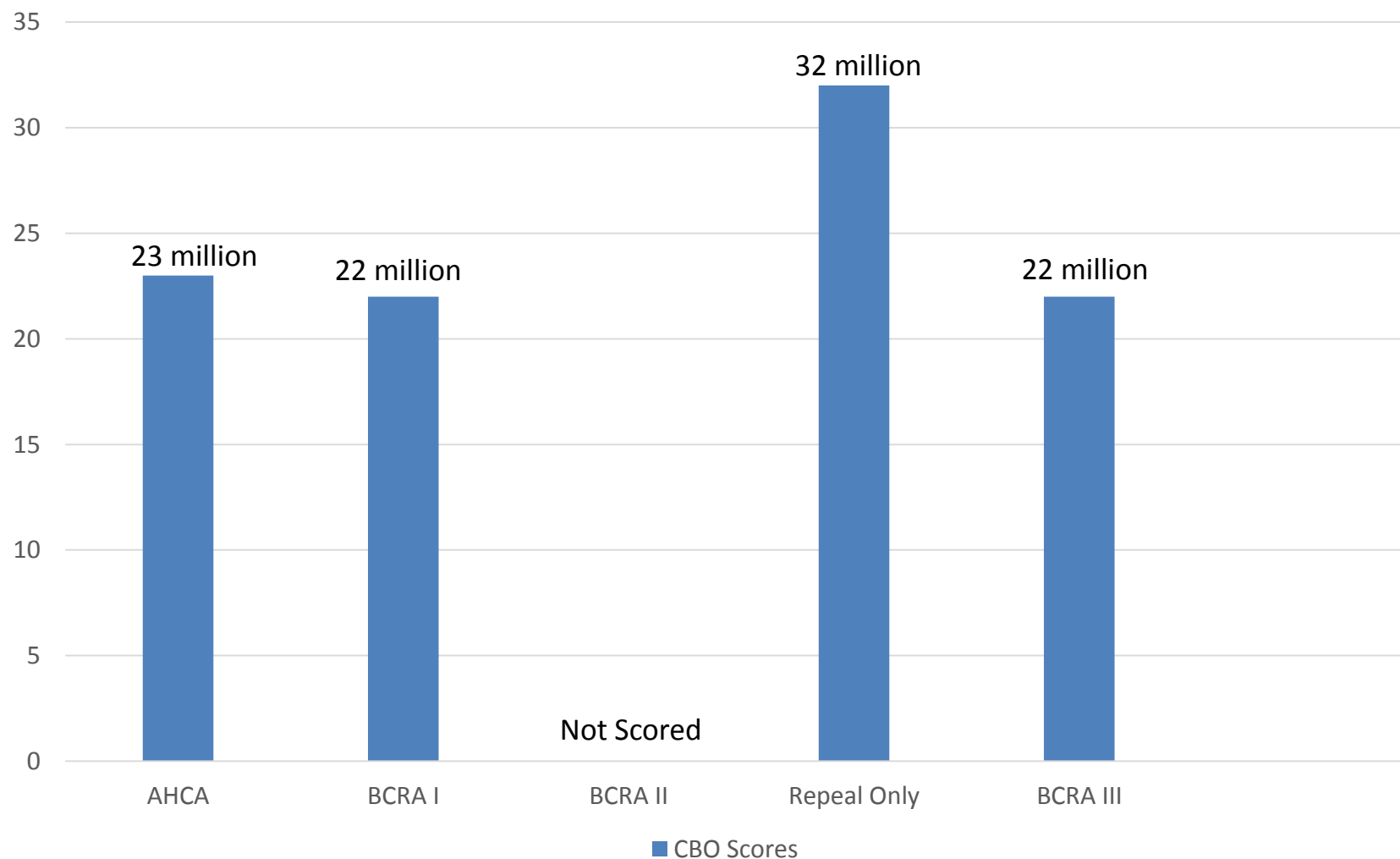
Drew Gantt

ACA Repeal and Replace *Timeline*



ACA Repeal and Replace

CBO Scores: Fewer Americans Covered in 2026





ACA Repeal and Replace

Impact on Digital Health

- Very little direct impact
 - Significantly, however, all of these bills permanently repeal the 2.3% medical device tax
 - If nothing passes, the moratorium ends December 31, 2017
- Rollback in coverage may put pressure on payors and providers to invest in digital technologies that drive efficiencies
- Pressure on big data and population management
- Consumers may look for alternative delivery models and transparency tools
- Increased role for telehealth



Telemedicine Update

- Research shows a growing trend in the use of telemedicine
- From 2008 to 2014, the number of telehealth visits for Medicare beneficiaries grew by over 500%
- Over 30 states plus the District of Columbia now have telehealth parity laws mandating that private insurers cover telehealth services as they would face-to-face services
 - The number of states passing these laws has doubled in the past 4 years



Teladoc Litigation

- Teladoc, the largest telehealth service provider in the country, sued the Texas Medical Board (TMB), challenging a TMB rule that required face-to-face physical examinations in order to establish a physician-patient relationship
- Within its complaint, Teladoc argued that the TMB's requirement violated antitrust laws because it was predicated on physicians' concerns about competition
- Teladoc cited the 2015 Supreme Court case *North Carolina State Board of Dental Examiners*, which held that state licensing boards controlled by active market participants are not immune from antitrust claims unless they're actively supervised by the state
- Texas subsequently enacted law allowing doctors to diagnose and treat patients remotely without initial face-to-face meeting



Telemedicine Update (continued)

- 21st Century Cures Act of 2016
 - Overwhelmingly passed both houses of Congress with bipartisan support
 - The Act:
 - Creates a mechanism by which the Centers for Medicare and Medicaid Services (CMS) and the Medicare Payment Advisory Commission (MedPAC) conduct studies and evaluate how Medicare/Medicaid populations can benefit from the expansion of telehealth services
 - Bars the FDA from regulating mobile health apps designed to maintain or encourage a healthy lifestyle if unrelated to the diagnosis, prevention, or treatment of disease
 - Envisions a strong federal role for ONC in the regulation and development of HIT standards
 - The bill aims to drive greater interoperability by having ONC help public-private partnerships create a “trusted exchange framework, including a common agreement among health information networks nationally”



Telemedicine Legislation Currently in Congress

- There have been nearly 20 telehealth bills introduced in Congress this year
- Proposed by both Democrats and Republicans, these bills seek to expand the use of telehealth services, particularly to treat kidney disease and stroke
- Several of the most comprehensive bills are:
 - Medicare Telehealth Parity Act of 2017
 - Expands where telehealth services can be used and expands reimbursements for them
 - CONNECT for Health Act of 2017
 - Expands access to telemedicine, lifts restrictions on use of telehealth, and sets up testing models
 - VETS Act of 2017
 - Improves the ability of healthcare professionals to treat veterans using telemedicine



Status of HIPAA Breach Enforcement

- One-third of Americans' (113 million) health data was breached in 2015 (Anthem, Premera, Excellus), because of hacking/IT incidents (compared to theft/loss of mobile media in past)
 - There were 253 healthcare breaches, each of which affected >500 people
 - Worst year ever
- 2016 breaches affected 16.5 million
 - Second-worst year ever
- Health information 50X more valuable than credit ID information



Status of HIPAA Breach Enforcement (continued)

- In April, a wireless health services provider reached a \$2.5 million settlement with HHS after a laptop was stolen from an employee's car
- Though this is a first for wireless health service providers, there have been more than 50 resolution agreements in the past decade
- The Trump administration is aggressively enforcing HIPAA
- Settlements range from \$25,000 to \$5.55 million, with the majority of the costliest settlements coming in the past two years; class action lawsuits cost much more (Anthem \$115M – largest data breach settlement ever)



Company in the Spotlight – Neela Paykel

Digital Medicines Overview

Proteus Digital Medicines

Existing drug therapy is not always fully effective

- Chronic non-communicable diseases (e.g. diabetes, cardiovascular disease) consume over 80% of health expenditures and are treatable with proven, readily available medicines
- Patient adherence to medication is a significant problem (less than 50% taken as prescribed) and reduces the effectiveness of treatment
- Reduced effectiveness of treatment leads to acute problems (e.g. stroke, heart attack) and increased associated costs of acute / social care

Digital Medicines: a new category of drug therapy...

- Proteus created a new category of therapy: Digital Medicines
 - widely used drugs, formulated to communicate when they have been taken
 - ingestible sensors and wearable patches that capture and measure physiologic response to drug ingestion
 - mobile applications record and transmit information and data analytics (e.g. smart phone recording / transmission to the cloud)
- Data is able to be reviewed and analysed easily, supporting efficient and effective patient self-care and physician decision making at an individual level, and serve the needs of health system managers when aggregated



...with wide-reaching benefits

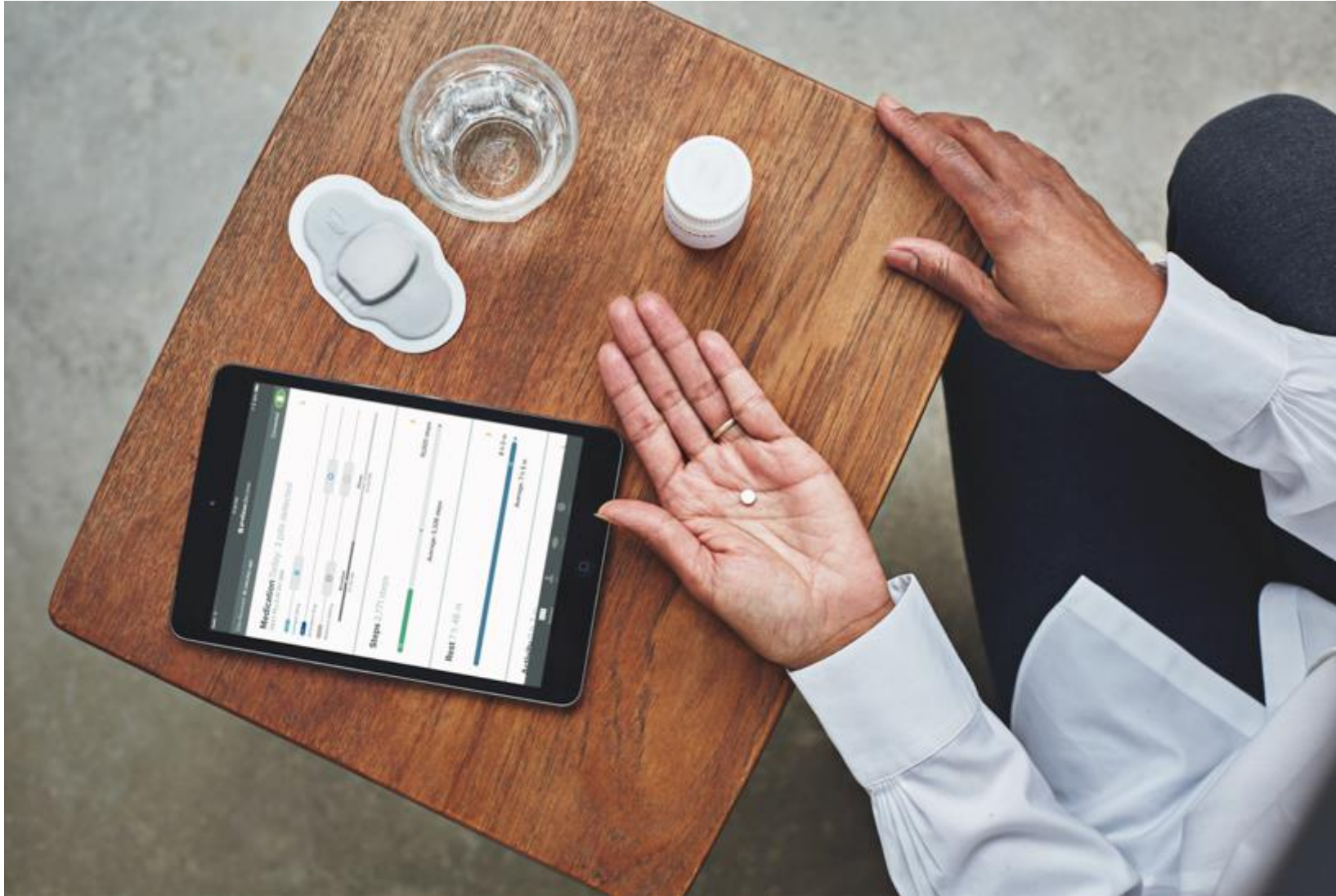
- High levels of adherence, significant increases in appropriate use of medicines and stronger patient engagement and satisfaction
- Better risk management through improved allocation of physician resource based on patient need, as opposed to time between visits
- Expansion of the care infrastructure by leveraging consumer's own smartphone devices and existing cloud-based architecture to deliver health services

Concept proven and cleared, commercial contracts active

- Proteus commenced research in 2003; to date, the development of Digital Medicines has involved over 70 clinical studies, issuance of 430 patents and investment of over US\$500 million; real-world use has confirmed the durability of outcomes (e.g. high adherence to medication in patients, reduced CV risk factors in comorbid patients and downward trend in emergency department visits)
- Proteus has obtained regulatory clearances in the USA, Europe and China and are in process in Japan
- Launched in 2016, Digital Medicines are now in commercial use in nine major US health systems
- The first fully integrated Digital Medicine, Abilify, is advancing towards the US market (PDUFA date October 2017) and three additional Digital Medicines are in development

Source: Company information

Digital Medicines: They Communicate with Your Mobile When Swallowed



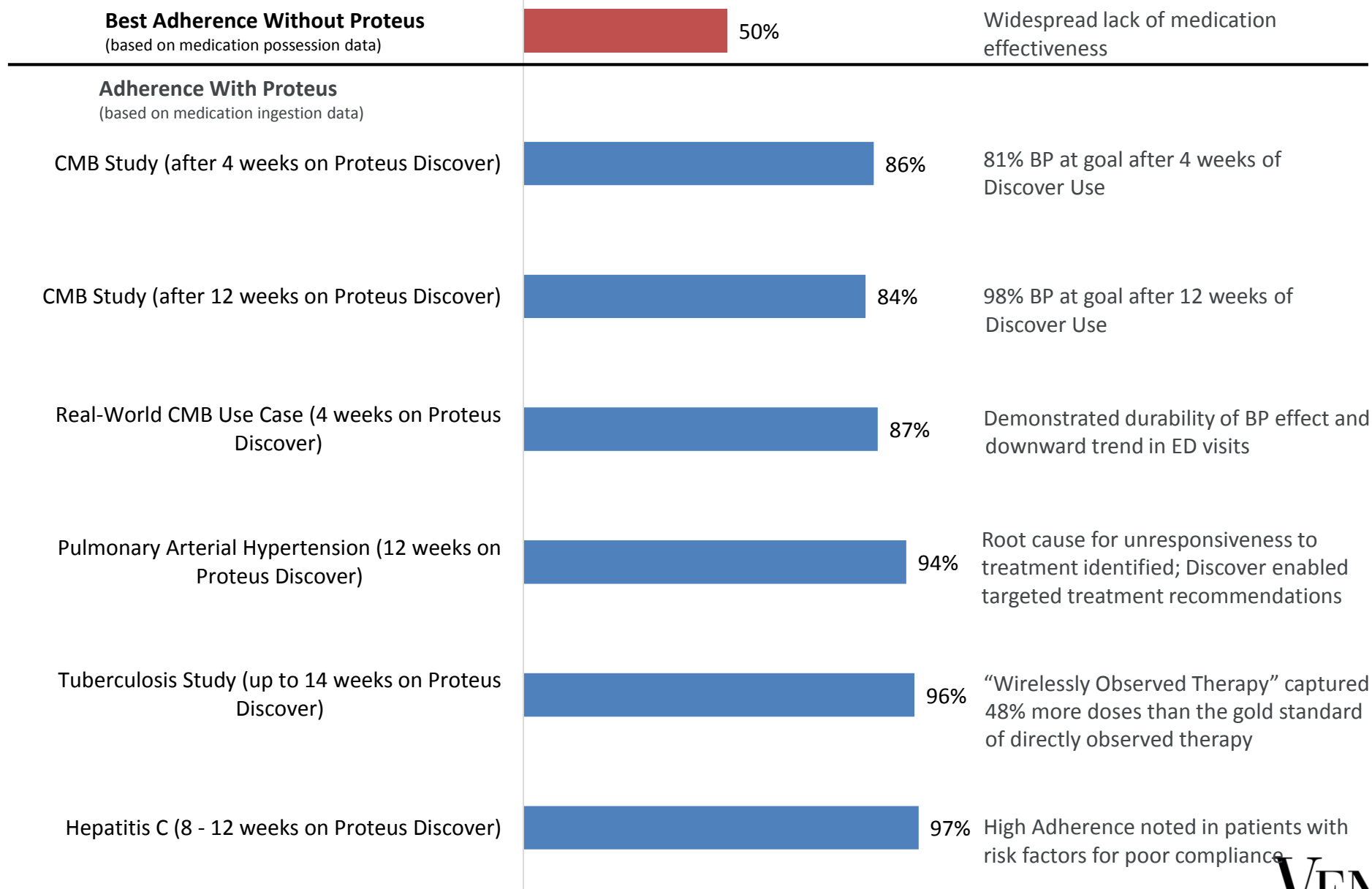


Clinical Validation: Extensive Testing Across Diverse Populations

	RESEARCH & DEVELOPMENT	PHASE 4	INVESTIGATOR-INITIATED
Number	112	5	6
Total Subjects	1,611*	357	468
Therapeutic Areas	Cardiovascular Endocrine Mental Health	Cardiovascular Endocrine Infectious Disease Pulmonary	Cardiovascular Infectious Disease
Diseases	Bipolar disorder Diabetes Hypercholesterolemia Hypertension Schizophrenia Schizoaffective disorder	Diabetes Hepatitis C Hypercholesterolemia Hypertension Pulmonary Arterial Hypertension	Heart Failure Human Immunodeficiency (HIV) Tuberculosis
Key Statistics	20,993 sensor ingestions 6,407 days of patch wear 97.3% of sensors detected 100% correct identification 0% false identification No serious adverse events 12.4% limited localized rash	35,067 sensor ingestions	Included in Phase 4 number

*Some subjects have participated in more than one R&D study

Patients Using Digital Medicines Have High Levels of Adherence



Digital Medicines Leverage Established Cloud-Based Architecture



Three interlinked software applications

- Patient
- Provider
- Health system

Scalable, secure, modular, configurable

Agile development with quarterly releases

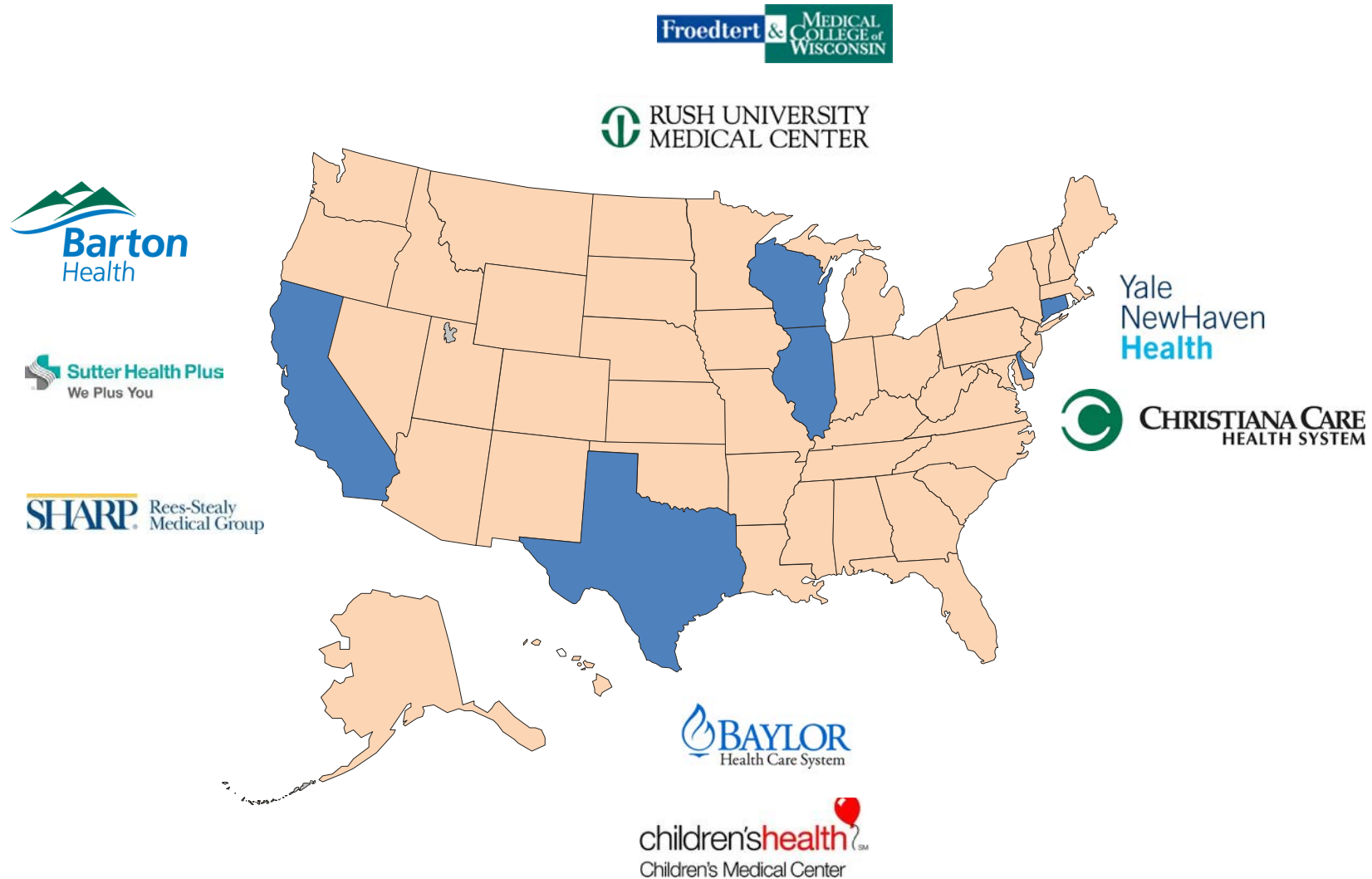
Three initial use-case targets

- Co-Morbid HTN (Chronic management)
- HF (Readmission management)
- HCV (Specialty drug management)

Nineteen co-encapsulated digimeds today

- Expansion based on customer requests
- Expansion based on partner requests

Digital Medicines in Commercial Use at Nine Major U.S. Health Systems



First Fully Integrated Digital Medicine Advancing Towards U.S. Market



First Digital NDA

- Digital Abilify program progressing
- FDA feedback addressed
- Anticipated PDUFA Date October 2017

Portfolio Expansion

- 3 Additional Digital Medicines in mental health portfolio in development

Formulation Collaboration

- Exchange of detailed technical updates on digital medicine development

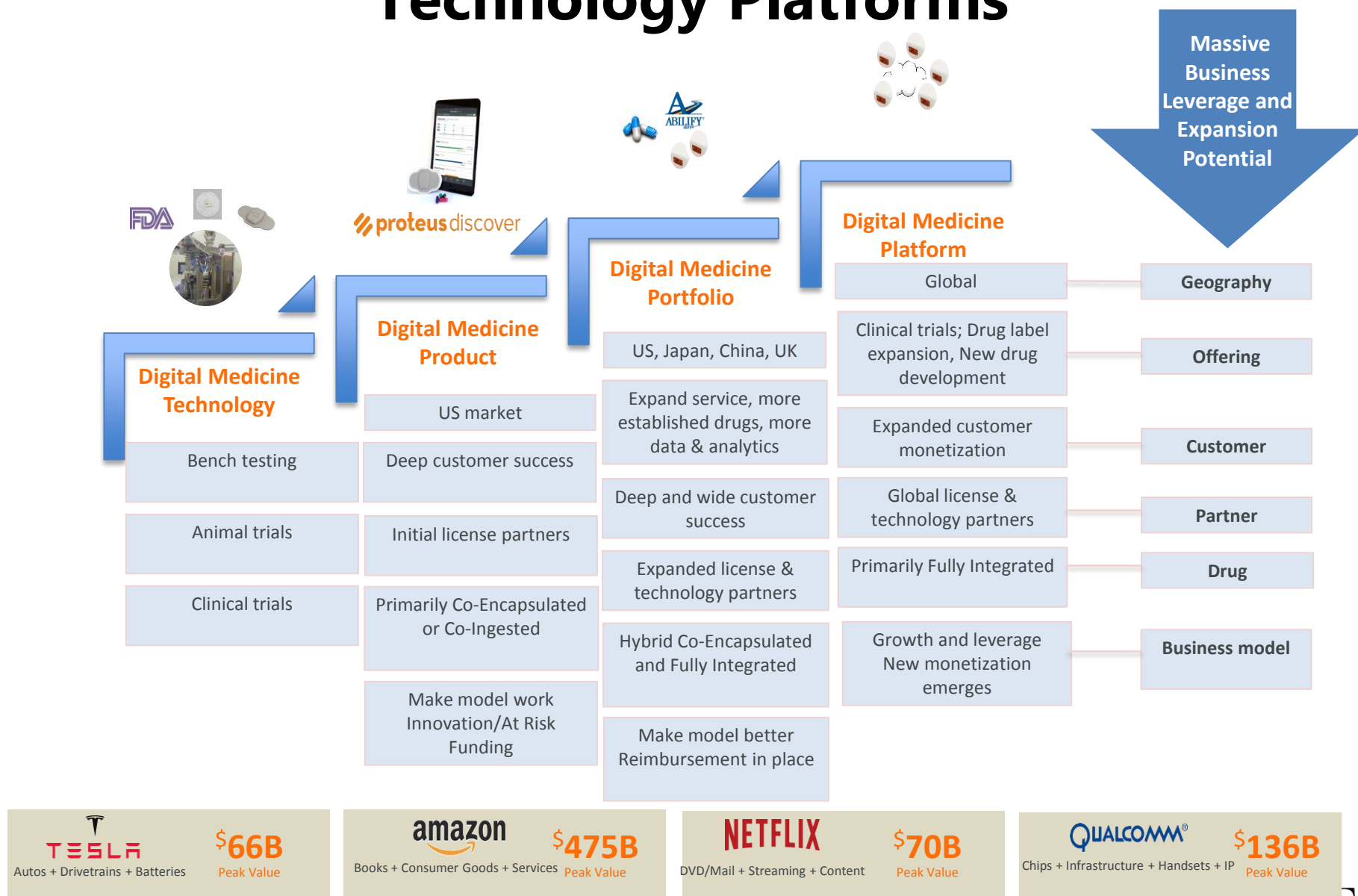
Ongoing Development Budget

- Extends through 2019

Order and Supply Agreement

- Supply Agreement established for development and commercial products

Proteus Evolving Along a Familiar Path for Technology Platforms





Legal Issues for Digital Health

- Privacy, privacy, privacy
- Security, security, security
- Corporate practice of medicine
- FDA-regulated device (versus not)
- Anti-kickback risk
- Pharmacy services risk



References

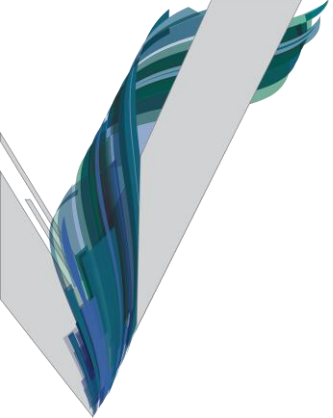
Frias J, Virdi NS, Raja P, Kim Y, Savage G, Unger J, Raikhel M, Osterberg L. Evaluation of a Digital Health Offering to Optimize Blood Pressure and Lipid Control in Patients With Uncontrolled Hypertension and Type 2 Diabetes: A Pilot, Cluster Randomized Study. *Circulation*. 2016;134:A17375.

Corris PA, Day M, Gibiansky M, Kim YA, DiCarlo L. A pilot study of digital feedback to guide therapeutic decisions in pulmonary hypertension. *European Respiratory Journal*. Sep 2016;48(suppl 60):PA2407.

Browne S, Haubrich R, Moser KS, DiCarlo L, Peloquin CA, Benson CA. Wirelessly Observed Therapy (WOT): A New Paradigm in TB Therapy Monitoring. *CROI*. February 23-26, 2015, Seattle, WA.

Bonacini M, Kim YA, Reichert M, Travis E, Virdi N, Raja P, Savage G. A New Digital Health Feedback Offering to Keep Patients Adherent to Oral Hepatitis C Therapy. *Gastroenterology*. April 2016;150(4):S1159.

Real World CMB and Patient Satisfaction: Data on File



Corporate and Funding Update

Jim Nelson



Venture-Backed Market Overview

- VC Funds Continue Making Huge Raises
 - In 2016, VC Funds in the U.S. raised \$40.6 billion
 - Largest year since 2000, when the raise was \$101.4 billion
- Tech IPOs Greatly Outpacing Last Year
 - 9 went by June of 2017
 - 1 went by June of 2016
- Nonetheless, PEs and Strategics Continue to Outstrip IPOs
 - In 2016, 513 VC Tech Exits. Of that, 499 were M&A; not IPOs

Source: Pitchbook 2016 and 2017.

As Goes the Market, So Goes Digital Health

DIGITAL HEALTH FUNDING

2014-H1 2017

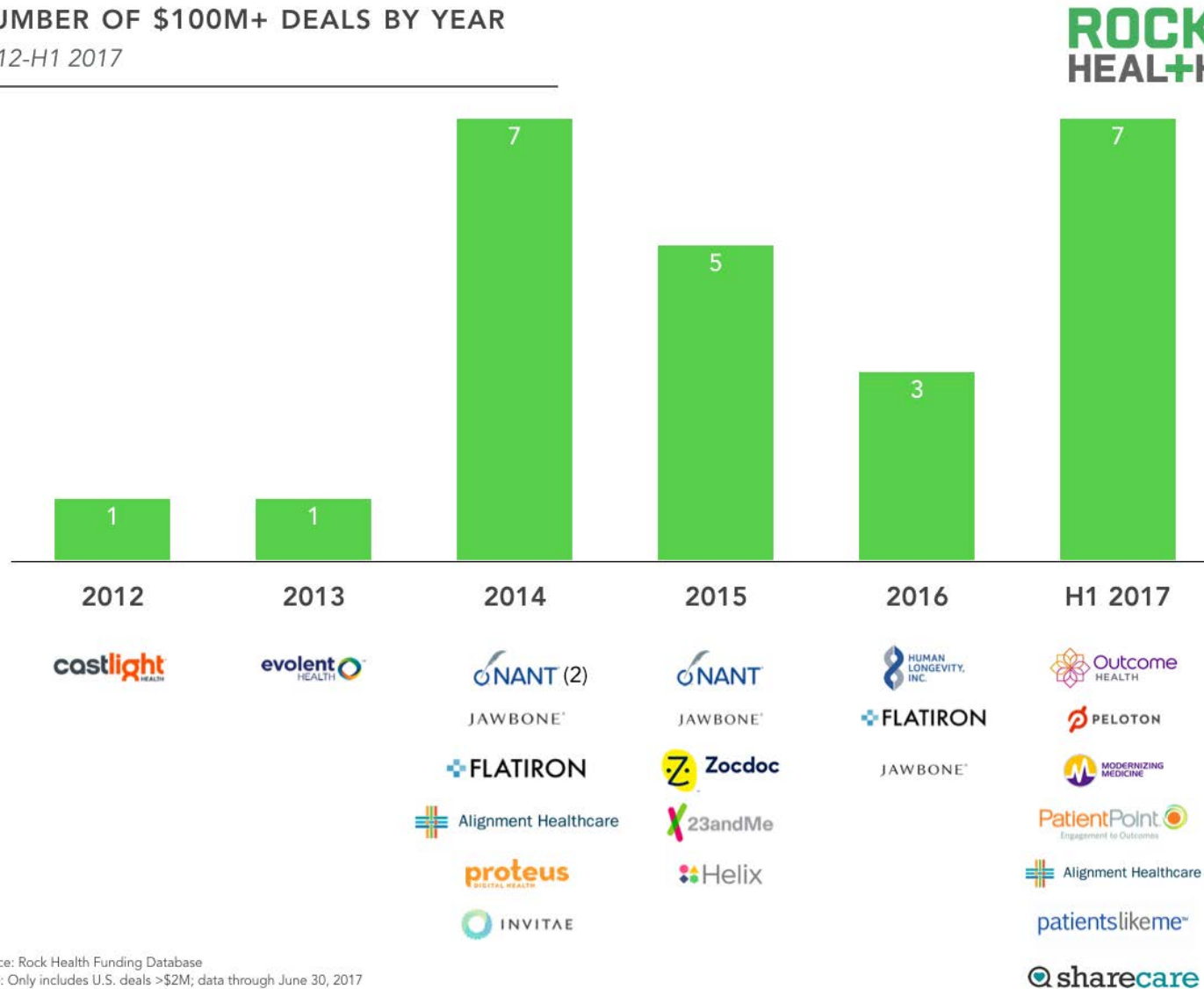
ROCK
HEAL+H



Source: Rock Health Funding Database
Note: Only includes U.S. deals >\$2M; data through June 30, 2017

The Size of Rounds Is Growing Too

NUMBER OF \$100M+ DEALS BY YEAR
2012-H1 2017



Source: Rock Health Funding Database
Note: Only includes U.S. deals >\$2M; data through June 30, 2017

All Categories Across Digital Health Are Strong

TOP CATEGORIES OF FUNDING H1 2017

**ROCK
HEALTH**



\$757M

8 DEALS

Outcome Health (\$500M)

CONSUMER HEALTH INFORMATION

Dynamic (e.g., Q&A) and static health information content designated for consumers.



\$341M

3 DEALS

Peloton Interactive (\$325M)

DIGITAL GYM EQUIPMENT

Equipment designated for gyms (professional or at-home).



\$321M

17 DEALS

Blink Health (\$90M)

HEALTHCARE CONSUMER ENGAGEMENT

Consumer tools for the purchasing of healthcare services, health products, or health insurance.



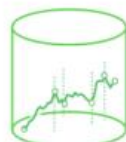
\$276M

11 DEALS

Modernizing Medicine (\$206M)

EHR / CLINICAL WORKFLOW

Electronic health records and surrounding applications, including clinical workflow support/augmentation.



\$240M

16 DEALS

Nuna Health (\$90M)

ANALYTICS / BIG DATA

Data aggregation and/or analysis to support a wide range of healthcare use cases.



\$235M

9 DEALS

Outset Medical (\$76M)

DIGITAL THERAPIES

Software/hardware designed to deliver specific clinical outcomes in a therapeutic area or multiple therapeutic areas.

Source: Rock Health Funding Database
Note: Only includes U.S. deals >\$2M; data through June 30, 2017

Digital Health Public Companies

DIGITAL HEALTH PUBLIC INDEX

H1 2017 public company performance



TICK	Company	IPO Year	Cap	Q12017 Open	Q22017 Close	YTD % Change
TDOC	Teladoc	2015	Small Cap	\$16.50	\$34.70	110.30%
CRCM	Care.com Inc	2014	Small Cap	\$8.37	\$15.10	80.41%
EVH	Evolent	2015	Small Cap	\$14.90	\$25.35	70.13%
MDSO	Medidata Solutions Inc	2000s	Mid Cap	\$50.87	\$78.20	53.73%
MODN	Model N	2013	Small Cap	\$8.75	\$13.30	52.00%
VEEV	Veeva Systems Inc	2013	Mid Cap	\$41.35	\$61.31	48.27%
VCRA	Vocera Communications Inc	2012	Small Cap	\$18.29	\$26.42	44.45%
IRTC	iRhythm	2016	Small Cap	\$29.99	\$42.49	41.68%
CPSI	Computer Programs and Systems	2000s	Small Cap	\$23.90	\$32.80	37.24%
SLP	Simulations Plus	1990s	Micro Cap	\$9.00	\$12.35	37.22%
CERN	Cerner Corporation	1980s	Big Cap	\$49.40	\$66.47	34.55%
ATHN	athenahealth, Inc	1990s	Mid Cap	\$108.55	\$140.55	29.48%
INOV	Inovalon	2015	Small Cap	\$10.35	\$13.15	27.05%
MB	Mindbody	2015	Small Cap	\$21.65	\$27.20	25.64%
OMCL	Omniceil, Inc.	2000s	Small Cap	\$34.40	\$43.10	25.29%
QSII	Quality Systems, Inc.	1980s	Small Cap	\$13.75	\$17.21	25.16%
BNFT	Benefit Focus	2013	Small Cap	\$30.00	\$36.35	21.17%
WBMD	WebMD Health Corp.	2000s	Mid Cap	\$49.93	\$58.65	17.46%
Q	Quintiles IMS Holdings, Inc	2014	Big Cap	\$76.93	\$89.50	16.34%
NVTA	Invitae	2015	Small Cap	\$8.75	\$9.56	9.26%
HSTM	HealthStream, Inc.	2000s	Small Cap	\$25.56	\$26.32	2.97%
TRHC	Tabula Rasa HealthCare Inc	2016	Micro Cap	\$14.91	\$15.05	0.94%
CSLT	Castlight Health Inc	2014	Small Cap	\$4.95	\$4.15	-16.16%
STRM	Streamline Health Solutions Inc.	1990s	Nano Cap	\$1.30	\$1.07	-17.69%
FIT	Fitbit	2015	Small Cap	\$7.94	\$5.31	-33.12%
NH	Nant Health	2016	Small Cap	\$9.83	\$4.23	-56.97%
CNXR	Connecture	2014	Nano Cap	\$1.71	\$0.62	-63.87%

Source: Rock Health's Digital Health Public Index

Questions



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