Digital Health Business Forum

July 26, 2017

Moderator and Presenter: W. Andrew (Drew) H. Gantt III
Co-chair of the Venable Healthcare Group

Presenters:
Thora A. Johnson
Co-chair of the Venable Healthcare Group

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

James E. Nelson
Corporate Partner, Partner in Charge of Venable’s San Francisco Office
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

May 4 – House narrowly passes the AHCA

June 27 – The vote on BCRA I abruptly canceled before the July 4th recess

July 18 – Repeal and Replace declared all but dead

July 20 – Senate releases BCRA III

July 25 – Motion to Proceed Passed

June 22 – Senate releases BCRA I

July 13 – Senate releases BCRA II

July 19 – Senate releases an updated “repeal only” bill

July 21 – Parliamentarian rules against key components of BCRA
ACA Repeal and Replace

CBO Scores: Fewer Americans Covered in 2026

- AHCA: 23 million
- BCRA I: 22 million
- BCRA II: 32 million (Not Scored)
- Repeal Only: 32 million
- BCRA III: 22 million

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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.
• 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

<table>
<thead>
<tr>
<th></th>
<th>RESEARCH &amp; DEVELOPMENT</th>
<th>PHASE 4</th>
<th>INVESTIGATOR-INITIATED</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>112</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total Subjects</strong></td>
<td>1,611*</td>
<td>357</td>
<td>468</td>
</tr>
<tr>
<td><strong>Therapeutic Areas</strong></td>
<td>Cardiovascular</td>
<td></td>
<td>Cardiovascular</td>
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<tr>
<td></td>
<td>Endocrine</td>
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</tr>
<tr>
<td></td>
<td>Mental Health</td>
<td></td>
<td>Mental Health</td>
</tr>
<tr>
<td><strong>Diseases</strong></td>
<td>Bipolar disorder</td>
<td></td>
<td>Bipolar disorder</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td></td>
<td>Diabetes</td>
</tr>
<tr>
<td></td>
<td>Hypercholesterolemia</td>
<td></td>
<td>Hypercholesterolemia</td>
</tr>
<tr>
<td></td>
<td>Hypertension</td>
<td></td>
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<tr>
<td></td>
<td>Schizophrenia</td>
<td></td>
<td>Schizophrenia</td>
</tr>
<tr>
<td></td>
<td>Schizoaffective disorder</td>
<td></td>
<td>Schizoaffective disorder</td>
</tr>
<tr>
<td><strong>Key Statistics</strong></td>
<td>20,993 sensor ingestions</td>
<td>35,067 sensor ingestions</td>
<td>Included in Phase 4 number</td>
</tr>
<tr>
<td></td>
<td>6,407 days of patch wear</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>97.3% of sensors detected</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100% correct identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0% false identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No serious adverse events</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>12.4% limited localized rash</td>
<td></td>
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</tbody>
</table>

*Some subjects have participated in more than one R&D study
<table>
<thead>
<tr>
<th>Study Description</th>
<th>Average Adherence (%)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMB Study (after 4 weeks on Proteus Discover)</td>
<td>86%</td>
<td>81% BP at goal after 4 weeks of Discover Use</td>
</tr>
<tr>
<td>CMB Study (after 12 weeks on Proteus Discover)</td>
<td>84%</td>
<td>98% BP at goal after 12 weeks of Discover Use</td>
</tr>
<tr>
<td>Real-World CMB Use Case (4 weeks on Proteus Discover)</td>
<td>87%</td>
<td>Demonstrated durability of BP effect and downward trend in ED visits</td>
</tr>
<tr>
<td>Pulmonary Arterial Hypertension (12 weeks on Proteus Discover)</td>
<td>94%</td>
<td>Root cause for unresponsiveness to treatment identified; Discover enabled targeted treatment recommendations</td>
</tr>
<tr>
<td>Tuberculosis Study (up to 14 weeks on Proteus Discover)</td>
<td>96%</td>
<td>“Wirelessly Observed Therapy” captured 48% more doses than the gold standard of directly observed therapy</td>
</tr>
<tr>
<td>Hepatitis C (8 - 12 weeks on Proteus Discover)</td>
<td>97%</td>
<td>High Adherence noted in patients with risk factors for poor compliance</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Digital NDA</td>
<td>- Digital Abilify program progressing</td>
</tr>
<tr>
<td></td>
<td>- FDA feedback addressed</td>
</tr>
<tr>
<td></td>
<td>- Anticipated PDUFA Date October 2017</td>
</tr>
<tr>
<td>Portfolio Expansion</td>
<td>- 3 Additional Digital Medicines in mental health portfolio in development</td>
</tr>
<tr>
<td>Formulation Collaboration</td>
<td>- Exchange of detailed technical updates on digital medicine development</td>
</tr>
<tr>
<td>Ongoing Development Budget</td>
<td>- Extends through 2019</td>
</tr>
<tr>
<td>Order and Supply Agreement</td>
<td>- Supply Agreement established for development and commercial products</td>
</tr>
</tbody>
</table>
Proteus Evolving Along a Familiar Path for Technology Platforms

Digital Medicine Technology
- Bench testing
- Animal trials
- Clinical trials

Digital Medicine Product
- US market
- Deep customer success
- Initial license partners
- Primarily Co-Encapsulated or Co-Ingested
- Make model work Innovation/At Risk Funding

Digital Medicine Portfolio
- US, Japan, China, UK
- Expand service, more established drugs, more data & analytics
- Deep and wide customer success
- Expanded license & technology partners
- Hybrid Co-Encapsulated and Fully Integrated
- Make model better Reimbursement in place

Digital Medicine Platform
- Global
- Clinical trials; Drug label expansion, New drug development
- Expanded customer monetization
- Global license & technology partners
- Primarily Fully Integrated
- Growth and leverage New monetization emerges

Massive Business Leverage and Expansion Potential

Business model
- Customer
- Partner
- Drug

Geography
- Global

 Offering
- Clinical trials; Drug label expansion, New drug development
- Expanded customer monetization
- Global license & technology partners
- Primarily Fully Integrated
- Growth and leverage New monetization emerges

Potential Peak Values
- TESLA: $66B
- Amazon: $475B
- Netflix: $70B
- Qualcomm: $136B

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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


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

As Goes the Market, So Goes Digital Health

DIGITAL HEALTH FUNDING
2014-H1 2017

2015 $4.6B
2014 $4.4B
2016 $4.3B

Source: Rock Health Funding Database
Note: Only includes U.S. deals >$3M; data through June 30, 2017
The Size of Rounds Is Growing Too

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

2012: 1
2013: 1
2014: 7
2015: 5
2016: 3
H1 2017: 7

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

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### All Categories Across Digital Health Are Strong

#### Top Categories of Funding
**H1 2017**

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount</th>
<th>Deals</th>
<th>Example</th>
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</thead>
<tbody>
<tr>
<td><strong>Consumer Health Information</strong></td>
<td>$757M</td>
<td>8</td>
<td>Outcome Health ($500M)</td>
</tr>
<tr>
<td><strong>Digital Gym Equipment</strong></td>
<td>$341M</td>
<td>3</td>
<td>Peloton Interactive ($325M)</td>
</tr>
<tr>
<td><strong>Healthcare Consumer Engagement</strong></td>
<td>$321M</td>
<td>17</td>
<td>Blink Health ($90M)</td>
</tr>
<tr>
<td><strong>EHR / Clinical Workflow</strong></td>
<td>$276M</td>
<td>11</td>
<td>Modernizing Medicine ($206M)</td>
</tr>
<tr>
<td><strong>Analytics / Big Data</strong></td>
<td>$240M</td>
<td>16</td>
<td>Nuna Health ($90M)</td>
</tr>
<tr>
<td><strong>Digital Therapies</strong></td>
<td>$235M</td>
<td>9</td>
<td>Outset Medical ($76M)</td>
</tr>
</tbody>
</table>

**Source:** Rock Health Funding Database

*Note: Only includes U.S. deals H1 2017 data through June 30, 2017*
## Digital Health Public Companies

### Digital Health Public Index

**H1 2017 public company performance**

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

Source: Rock Health’s Digital Health Public Index

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Questions

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