Digital Therapeutics and the Future of Pharma

February 2020
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Preface and Executive Summary
Torreya provides strategic advice to companies in the life sciences industry. Global biopharmaceutical companies are a key competence area and we have a 40+ person team dedicated to the sector. As part of our industry coverage, we track and analyze the impact of new technologies on biopharma companies.

This report covers:

• an overview of the digital health landscape,
• a deeper dive into the category of Digital Therapeutics ("DTx") or Prescription Digital Therapeutics ("PDT"), including an overview of new products in development, impact to key healthcare stakeholders and recent Digital-Biopharma deals, and
• a summary of key trends and observations for digital therapeutics, including input from leading senior executives and investors

Please contact the below members of the Torreya Biopharma team if you have any questions or comments.

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Executive Summary

1. Digital transformation in biopharma is inevitable
   • As a sector biopharma firms have been slow to leverage the transformative effects of digital technology
   • In 2019, US digital health startups raised a total of $7.4B\textsuperscript{1}—the second largest funding year ever
   • Biopharma companies that don’t incorporate digital into their platforms risk being left behind

2. The impact of digital therapies on biopharmaceutical development and treatment of patients will be both revolutionary and evolutionary—driving efficiencies for some and changing paradigms for others
   • Potential for lower cost, reduced development timelines and overall lower risk for new product development
   • Products offer a compelling pharmacoeconomic benefit to the healthcare system
   • Digital therapies can offer patients on-demand access to care, including the ability to treat and diagnose patients earlier
   • Data generated from digital therapeutics may generate multiple benefits, including real-time changes to products, personalized medicine and improvements to patient treatment paradigms
   • Potential for first mover advantage for biopharma companies entering the modality in its infancy
   • FDA is highly supportive of digital therapies and has issued guidance to facilitate the development of new products
   • Payers have signaled acceptance of digital therapies with two of the “Big Three” PBMs establishing digital formularies in the last year

1) RockHealth
3. Deal momentum between digital therapeutics and biopharma companies continues to gather pace
   • Over 10 Digital-Biopharma deals representing >$450M in deal value\(^1\) in the last twelve months
   • Key stakeholders (FDA, HCPs, payers, and patients) embrace the use of digital therapeutics as a form of therapy
   • Digital therapies offer increased ability for biopharma companies to directly engage with patients
   • Recognition of need for new products with near-term commercial launches
   • A majority of digital therapies are complementary to pharmacological interventions and intended to be used in combination, particularly within CNS and behavioral health and for disease management of chronic indications

4. Key industry players recognize the digital opportunity
   • Our interviews with senior industry executives and investors revealed a bullish outlook on the sector
   • While there are some near-term tactical challenges around commercialization, pricing, and reimbursement, the end game is clear: digital will be a meaningful part of the biopharma treatment landscape

5. Digital therapeutics: Undeniably the future for biopharma
   • **Long-term**: Digital will be incorporated into every facet of the patient journey
   • **Near term**: Digital therapeutics need to demonstrate to biopharma that there are viable pathway(s) to successful commercialization

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\(^1\) Company Press Releases
Overview of Digital Health Landscape
How do we define the Digital Health universe? Digital Health is broadly defined as healthcare companies utilizing information technology (“IT”) or software as a primary means of differentiation. The companies span across the healthcare sector, addressing all three key stakeholders: *payers, providers and patients*. Companies working in digital health range from start-ups to established unicorns (Proteus and 23andMe) to large cap tech conglomerates (Google and Apple). In an effort to stratify the universe we group companies into the following 6 sub-verticals in the table below with illustrative companies for each category.

<table>
<thead>
<tr>
<th>Pharma</th>
<th>Providers</th>
<th>Insurance &amp; Benefits</th>
<th>Consumer Health &amp; Wellness</th>
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<tbody>
<tr>
<td>Digital Therapeutics</td>
<td>Telemedicine &amp; virtual visits</td>
<td>Consumer-focused care &amp; coverage</td>
<td>Wearable &amp; wireless devices</td>
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<tr>
<td>Supply chain</td>
<td>(primary and specialty care)</td>
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<td>Wellness, fitness trackers</td>
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<td>R&amp;D (real world evidence &amp; clinical trial support)</td>
<td>Electronic medical record systems</td>
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<td>and nutrition apps</td>
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<td>Clinical decision support</td>
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<th>Genomics</th>
<th>Diagnostics</th>
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<td>DNA genetic testing</td>
<td>Imaging</td>
</tr>
<tr>
<td>Early cancer detection</td>
<td>Pathology</td>
</tr>
</tbody>
</table>

Sources: CB Insights
Digital Health By the Numbers

Significant investment into the sector by both strategic and financial investors

- In 2019, US digital health startups raised a total of $7.4B—the second largest funding year ever
- Nearly 60% of active digital health investors in 2019 had previously made an investment in the sector
  - **Venture capital (“VC”)** has invested across all stages (Seed to D+ and growth rounds); 62% of VCs were repeat investors in 2019, more than 50% of VCs have been repeat investors since 2014
  - **Corporate venture capital (“CVC”)** has invested mainly in mid-stages (B+) and later; 64% of CVCs were repeat investors in 2019, more than 50% of CVCs have been repeat investors since 2018
  - **Private equity (“PE”)** growth, hedge funds and asset managers have invested mainly in later stages (D+ and growth rounds); 56% of later stage investors were repeat investors in 2019, about 50% have been repeat investors since 2015
- Six digital health companies entered the public market in 2019: Livongo, Health Catalyst, Phreesia, Change Healthcare, Peloton and Progyny. As of January 1, 2020, the combined market cap of the six IPOs is $17B
More In-Depth Look into Digital Therapeutics ("DTx")
The Digital Revolution
Digital technology has revolutionized how many of our everyday tasks are undertaken; it is poised to do the same in biopharma

New Functionality

- Accuracy
- Alarm

- Mobile calls
- Instant short message service via text

- On-demand service
- Real time price and time estimates

- On-demand access to care
- Personalized therapy, and more to come...
The Future of Digital & Biopharma

While today digital appears to only offer minor incremental improvements, it has the potential to truly create a paradigm shift in the biopharma sector.

**2020**
Early days; incremental benefits to existing pharmacological treatments, such as:
- Improvements in behavior-mediated indications,
- Improved adherence,
- Real-time access to therapy

**2025**
Real world data and analytics will drive R&D and patient treatment decisions
- Biomarkers used for clinical trials
- Data generated recommendations for treatments

**2030**
Continuous biomarker monitoring will be ubiquitous, e.g.
- Remote monitoring and diagnosis,
- Digitally monitored drug delivery,
- Prediction of exacerbation risk

The future and beyond
Digital is expected be incorporated into every aspect of healthcare, driving both value-based care and precision medicine in:
- Diagnosis,
- Treatment,
- Ongoing patient monitoring
Digital Therapeutics Represent the Intersection of Three Business Models: Technology, Biopharma and Direct-to-Consumer Access

The resulting data and analytics offer invaluable insights to improve clinical, commercial and patient outcomes.

**Technology**
- Reduced product development timelines and increased PTRS
- Products are easy to scale
- Facilitates data collection and analytics
- Product can be dynamic or personalized to patient

**Direct-to-Consumer**
- On-demand access to therapy
- "Patient-activated" therapeutic areas such as insomnia or anxiety
- Therapeutic areas with behavioral treatment attributes such as diabetes and hypertension

**Biopharma**
- Statistically significant clinical data
- Rx required for therapy
- Potentially reimbursed
- Potential to increase sales of existing product portfolio

**Data and Analytics**
**What is a Digital Therapeutic?**

- Digital therapeutics utilize software or applications to treat a disease, and may also include ancillary components such as connected hardware device(s), adjunctive pharmacotherapy, or live clinical support, but the software component could still drive meaningful outcomes as an independent contributor to treatment.
- In contrast to traditional pharmacological therapeutics, digital therapeutics typically have shorter development and commercialization timelines, smaller investments and may not require FDA approval.

**How is a DTx used with pharmacological interventions?**

- **Monotherapy or Standalone**: Software or application only.
- **Combination Products**:
  - **Companion**: Usually not FDA-approved; can be used to treat a condition alongside pharmacological product and/or HCP treatment.
  - **Combination**: Application or sensor that is designed to be used in conjunction with a specific pharmacological product (e.g. type of insulin).
  - **Adjunct**: Application or sensor that is designed to be used with a pharmacological intervention (e.g. all types of insulin) or HCP treatment.

**What therapeutic areas are most relevant for digital therapeutics?**

- **CNS**: Digital therapeutics have demonstrated the potential to favorably impact areas within CNS in two main areas:
  - **Behavioral-mediated indications**, such as Depression, Anxiety, Insomnia, Panic Attacks.
  - **Indications where neural stimulation** can be utilized to impact changes to the brain: ADHD, Parkinson’s and Stroke Recovery.
- **Disease management for chronic indications** with significant behavioral, lifestyle and drug compliance requirements within the treatment paradigm; such as: diabetes, asthma and COPD, and other cardiometabolic conditions.
There is a Wide Continuum of Digital Therapeutics

We stratify the market by two key factors: level of clinical evidence and approach to commercialization. Biopharma is most likely to focus on the products that may augment or work in concert with current pharmaceutical therapies.

<table>
<thead>
<tr>
<th>Level of clinical evidence</th>
<th>Primary Commercialization Approach</th>
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<tbody>
<tr>
<td>FDA approved</td>
<td>While an Rx is not required (not FDA approved), these products may have clinical data, help manage a disease or optimize medication; often provided by health plans &amp; systems, employers or directly to patients</td>
</tr>
<tr>
<td>OTC</td>
<td>Largely address general health and wellness as opposed to specific indications</td>
</tr>
<tr>
<td>Rx</td>
<td>Initially the strongest alignment with biopharma; pursing FDA approval to treat specific indications</td>
</tr>
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</table>

(1) Companies with products approved by the FDA or conducting clinical trials with the intention of seeking FDA approval. Sources: Company Websites and CB Insights
Examples of Digital Therapeutics

A significant number of therapies in development for CNS indications due to the ability to impact neuroplasticity and behavior-mediated indications

**Monotherapy Products** (software only)

<table>
<thead>
<tr>
<th>AKILI</th>
<th>Big Health</th>
<th>MEDRhythms</th>
<th>welldoc</th>
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<tbody>
<tr>
<td>Adaptive sensory stimulus software delivered via a video-game for ADHD, autism, major depressive disorder, multiple sclerosis and inflammatory diseases</td>
<td>Automated and personalized cognitive behavioral programs for mental health, including insomnia and anxiety</td>
<td>Uses neurologic music therapy via a combination of a sensors, music, and AI to measure and improve walking</td>
<td>Proprietary cognitive and neurobehavioral platform that optimizes user engagement for a variety of indications, including MDD, migraine, insomnia and acute coronary syndrome</td>
</tr>
</tbody>
</table>

*BlueStar® helps guide individuals with chronic diseases (e.g. Type 2 Diabetes) by helping them self-manage their conditions, while connecting them to their own healthcare team.*

**Combination Products** (software + pharmacological intervention)

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<thead>
<tr>
<th>CHRONO THERAPEUTICS</th>
<th>gloooko</th>
<th>Propeller</th>
<th>proteus</th>
<th>VOLUNTIS</th>
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<tr>
<td>Transdermal drug delivery wearable that integrates biologically-timed drug delivery with personalized digital support</td>
<td>Diabetes software products provide insights to improve outcomes for people with diabetes and their care teams</td>
<td>Digital companion connected to inhaled medication devices for asthma and COPD that transmits data to patients, physicians and healthcare organizations</td>
<td>Formulate drugs to communicate when ingested via a wearable patch that captures physiologic response; apps to support patient and physician decision-making in Cardiovascular and Infectious Disease</td>
<td>Mobile and web apps to deliver personalized recommendations to the patient and the care team so that they can, for example, adjust treatment dosage, manage side effects or monitor symptoms in Diabetes and Oncology</td>
</tr>
</tbody>
</table>

Source: Company Websites
A Closer Look at Two Digital Therapy Companies

PEAR THERAPEUTICS

• Discovers, develops, and delivers clinically-validated software-based therapeutics to provide better outcomes for patients, smarter engagement and tracking tools for clinicians, and cost-effective solutions for payers

• Two marketed products:
  • reSET is an FDA-cleared 12-week interval prescription therapeutic for Substance Use Disorder intended to provide cognitive behavioral therapy, as an adjunct to standard, outpatient treatment
  • reSET-O is an 84-day Prescription Digital Therapeutic (PDT) for Opioid Use Disorder intended to increase retention of patients in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management
  • An associated dashboard for clinicians and other health care providers can be used as part of treatment for both products. The dashboard displays information about patients’ use of the product, including lessons completed, patient-reported substance use, patient-reported cravings and triggers, patient-reported medication use, compliance rewards, and in-clinic data inputs such as urine drug screen results

• Over 10 products in development across therapeutic areas, including insomnia, depression, schizophrenia, IBS, pain, PTSD, migraine, bipolar disorder, multiple sclerosis, epilepsy and various oncology indications

Propeller

• Digital therapeutics company providing connected health solutions for people with COPD and asthma

• Uses sensors with inhalers to track medication usage and provide personal feedback and insights that enables integration of care through the progression of the disease

• Platform is used by patients, providers and healthcare organizations in the US, Europe and Asia

• Over 75 commercial programs with healthcare systems

• Pharma partnerships with GSK, BI, Novartis, Orion, 3 unannounced

• Acquired by ResMed in 2018 for $225 million

Source: Company Websites
Impact of Digital Therapeutics to Key Stakeholders

Significant benefits to the entire healthcare continuum

**Patient benefits:**
- On-demand or easy access to treatment and care
- Personalized treatment programs that use machine learning and AI to continuously update and tailor software to meet the needs of the patient based on real-time data analytics
- Increased access to evidence-based interventions

**Pharma benefits:**
- More favorable risk/reward product development with higher PTRS and shorter timeframe for product development
- Potential for increased patient compliance to pharmacological interventions
- Increased direct and earlier patient engagement

**Payer benefits:**
- Improved clinical and health economic outcomes and reduction in overall medical costs, including decreased HCP visits and reduction in pharmacological intervention
- Improvement in overall health and wellness and disease prevention
- Compelling safety profile; could be a step-edit before pharmacological intervention

**Provider and health system benefits:**
- Digital therapeutics can be used as a monotherapy or in concert with other therapies to optimize patient care and health outcomes
- Increased access to novel treatment options
Significant Deal Momentum with >10 Substantial Digital-Biopharma deals announced in 2019

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<th>Date</th>
<th>Digital Therapeutic</th>
<th>Biopharma</th>
<th>Description</th>
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| 11/21/19   | welldoc             | astellas         | • Jointly develop and commercialize BlueStar® in Japan and certain other Asian markets for patients with diabetes, collaborate to broaden the adoption of BlueStar® in the U.S., and jointly develop and commercialize digital therapeutics in other therapeutic areas globally.  
• Astellas will make an upfront payment of $15 million to Welldoc, as well as development and commercialization milestones and royalties on any future sales. |
| 10/30/19   | PEAR Therapeutics   | Ironwood         | • Evaluate Prescription DTx for selected indications within the gastrointestinal space                                                                                                                                                                             |
| 10/14/19   | omada               | Abbott           | • Partnering to integrate Abbott’s FreeStyle Libre system, a continuous glucose monitoring technology, with Omada Health’s pioneering digital care program                                                                                                    |
| 10/01/19   | noom                | Novo Nordisk     | • Collaboration on digital health solutions focusing on weight management.  
• Follows a successful 8-month pilot that combined Noom’s behavior change programs with Novo Nordisk’s experience with chronic diseases                                                                 |
| 9/17/19    | ONE DROP            | Bayer            | • $40 million Series B financing led by Bayer  
• Commercial licensing deal for Bayer to use One Drop’s platform in Bayer’s global bio-digital efforts in oncology, cardiovascular disease and women’s health                                                                 |
| 9/17/19    | happify             | Sanofi           | • Collaboration deal focusing on developing app based solutions for management and improvement of physical outcomes in people with multiple sclerosis                                                                                           |
| 8/20/19    | gaia                | orexo            | • Orexo has partnered with GAIA to create a new digital therapy (DTx) for people with opioid use disorder (OUD) which is expected to be launched in the US in 2022  
• Orexo to carry out clinical development, regulatory approval and commercialization, while GAIA is eligible for royalties, milestone payments and compensation during development                                                                 |
| 3/07/19    | Akili               | Shionogi         | • Shionogi to Oversee Clinical Development, Sales and Marketing for ADHD and Autism Spectrum Disorder Digital Therapeutics in Japan and Taiwan  
• Upfront and potential milestones for commercialization valued up to $125 million                                                                                                               |
| 1/03/19    | Click Therapeutics  | Otsuka           | • Collaboration to develop and commercialize a prescription digital therapeutic for MDD  
• Upfront, development and potential milestones for commercialization up to $302 million  
• Click will receive tiered, double-digit royalties on global sales                                                                                                                                 |

Source: Press Releases
Two Recent Digital – Biopharma Deals

**SHIONOGI & AKILI**
- Akili Interactive is a digital medicine company creating prescription treatments for people living with cognitive dysfunction and brain-related conditions.
- Shionogi & Co., Ltd. is a major research-driven pharmaceutical company focused in two therapeutic areas: infectious diseases, and pain/CNS disorders.
- Strategic partnership to develop and commercialize AKL-T01 and AKL-T02 in Japan and Taiwan.
- AKL-T01 is currently under review with the FDA as a potential digital treatment for children with ADHD; AKL-T02 is in late stage development as a potential treatment for cognitive dysfunction and related symptoms in children with Autism Spectrum Disorder.
- Shionogi to oversee clinical development, sales and marketing for both products in Japan and Taiwan.
- Shionogi made an upfront payment to Akili of $20 million and Akili will be eligible to receive development and commercial milestones of up to $105 million and royalties on sales of products in Japan and Taiwan.

**OTSUKA & CLICK**
- Click Therapeutics, Inc. develops and commercializes software as prescription medical treatments through cognitive and neurobehavioral mechanisms.
- Otsuka is a global healthcare company with a significant presence in the area of mental health.
- Otsuka has agreed to commit capital to fully fund development of Click’s novel mobile application CT-152 for Major Depressive Disorder, and to commercialize this application world-wide upon achievement of regulatory approvals.
- CT-152 is a software application (app) that will leverage evidence-based cognitive therapy principles and Click’s patient engagement platform to treat patients either independently or in conjunction with prescribed pharmacotherapies; the app will be classified as Software as a Medical Device (SaMD).
- Otsuka will pay Click up to $10 million in upfront and regulatory milestone payments, along with an estimated $20 million in development funding. An additional $272 million in commercial milestone payments are contingent upon regulatory approvals and Click will receive tiered, double-digit royalties on global sales of the software and the digital therapeutic applications that result.

Source: Press Releases

*Torreya did not advise on these transactions*
The optimal business model(s) to scale and commercialize a digital therapeutic successfully is still being determined. There are multiple methodologies currently being deployed, each with its own advantages and challenges. Given how nascent the use of a digital therapeutic is, it will likely be several years before it will be clear which business model(s) will bear fruit.

Pharma companies are still evaluating how to best operationalize a digital therapy, whether it is in combination with a pharmacological treatment or building out a separate digital commercialization unit.

### Business Model For Digital Therapeutics Commercialization

**The optimal path to commercialization is still being determined**

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<thead>
<tr>
<th>Business Model</th>
<th>Advantages</th>
<th>Considerations</th>
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</table>
| Direct-To-Consumer                          | • Early revenue opportunities  
• Demonstrate product traction                   | • High costs to commercialize  
• Consumers expect healthcare costs to be covered by insurance |
| Self-insured employer benefits (sell services to a self-insured employer to offer as a benefit) | • Faster sales cycle                           | • May require an additional sales step to employee to capture a usage fee |
| **Health Systems & Payers**                 |                                                 |                                                     |
| Fee-for-service                             | • Digital formularies have been recently launched by CVS and Express Scripts  
• DTx may contract directly with a payer to set a rate for app usage | • Potentially a long contracting process  
• May require a pilot or testing period |
| Value-based reimbursement                    | • Cost savings for health systems and payers    | • Difficult to allocate costs savings to a product |
| Device-like reimbursement                    | • Dedicated CPT or HCPCS codes will facilitate reimbursement | • Requires FDA approval  
• Path from FDA approval to reimbursement is still undefined |
Outlook for Reimbursement

Given the nascency of commercialized digital therapeutic products, there is not a well-established framework to establish pricing and reimbursement for new products

• Since there is a broad range of digital therapeutic products, it is unlikely there will be a singular or formulaic approach to securing reimbursement akin to traditional pharmacological interventions

• Despite the lack of history with digital therapies, payers are highly receptive to digital therapies because the may offer the following key benefits:
  • Favorable safety profile,
  • Potential to drive health economic benefits, such as decreased HCP visits,
  • Increased patient access to care, and
  • Help manage chronic conditions that carry significant cost burdens.

Livongo REIMBURSEMENT CASE STUDY

• Successfully contracted with the full continuum of the payer universe:
  • National PBMs: CVS and Express Scripts
  • Health Plans: BCBS Michigan, HCSC
  • CMS: Approved as an enrolled provider
  • Channel Partners: Mercer, Willis Towers Watson

• $1,908 per participant per year gross medical savings in diabetes

Source: Livongo website
Outlook for Reimbursement (continued)

In the last year, two of the largest Pharmacy Benefit Managers ("PBMs"), Express Scripts and CVS, have created digital formularies. These two payers alone comprise over 50% of the PBM market.

Express Scripts® (MAY 2019): FIRST TO ESTABLISH A DIGITAL FORMULARY

- Digital health devices or software to undergo review by physicians, pharmacists and other experts to prove their outcomes, value, usability and security
- Includes 15 clinically validated programs available as of January 2020
- Aid in the management of eight of the country’s most common chronic conditions: diabetes, prediabetes, hypertension, asthma, pulmonary disease, depression, anxiety and insomnia

CVS Health. (JUNE 2019): CREATING A VENDOR BENEFIT MANAGEMENT

- Open-platform service designed to help CVS Caremark PBM clients manage relationships with digital and non-digital health and wellness benefit solution vendors with which they choose to contract
- Big Health, a digital therapeutics company, is the first participating vendor, and Sleepio, its automated, personalized digital sleep improvement program, will be available to CVS Caremark clients via Vendor Benefit Management
- May include solutions such as smoking cessation and substance abuse support, care management solutions, medication optimization and adherence, and tools that help members navigate their benefits

Sources: Express Scripts, CVS
FDA Approval Pathway

The FDA actively supports the approval of prescription digital therapies

• Digital Health is regulated by the Center for Devices and Radiological Health ("CDRH")

• Many products follow a traditional medical device regulator pathway:
  • 510(K) for devices that have a predicate device. Examples: WellDoc, Voluntis and Palo Alto Health Sciences
  • De Novo for novel devices

• CDRH has established the Digital Health Innovation Action Plan ("DHIAP") which outlines the pathway for approval for new digital health products

• In 2017 the CDRH launched the a pilot program known as the Digital Health Software Precertification ("Pre-Cert") program in an effort do establish a new regulatory framework for digital health
  • Program is for products that develop software-as-as-medical device ("SaMD")
  • Focused on the technology developer, and then the specific product
  • July 2019: Pear Therapeutics submitted the first application for FDA marketing authorization through the pre-cert program for Somryst, a digital cognitive behavioral therapy for the treatment of adults with chronic insomnia and depression

Source: FDA website, Canaccord equity research
Key Trends and Observations
Top 10 Observations and Trends in Digital Therapeutics

We went straight to the “horse’s mouth” and sought the opinion of key industry leaders

• We identified 10 key trends and observations as a result of our research and interviews with over a dozen senior executives in the digital therapeutics sector, ranging from:

  • Senior executives of digital therapeutics companies
  • Investors supporting these companies
  • Senior executives at leading pharmaceutical companies

• We stratified the observations and trends into four categories:
  1. Overall
  2. Impact to biopharma
  3. Impact to patients
  4. Impact to payers, providers and health systems
Top 10 Observations and Trends in Digital Therapeutics

**Overall**

1. **New modality of therapy with the potential to drive true therapeutic outcomes, deliver insight, optimize therapies and lower costs to the healthcare system**

2. **Two thirds of the top 25 biopharma companies are developing digital programs in-house and over half have invested in outside digital programs**

3. **Recent deals between digital therapeutics and biopharma demonstrate potential value of digital medicines**

4. **Data and insights can drive value and efficiencies across all of biopharma, from R&D through commercialization**

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1) BioCentury
Recent Observations and Trends in Digital Therapeutics (continued)

Overall

- “Hundreds of millions are being invested into the space, but we are just scratching the surface. Pharma and others will invest billions once we see significant commercial traction. Digital therapeutics are already creating real impact now and will continue to become mainstream. Companies that embrace digital will succeed and first movers will be well positioned to control markets. For example, a properly launched program to treat migraine can meaningfully impact the pharma landscape.”
  **David Benshoof Klein, CEO, Click Therapeutics**

- “All of pharma is curious. There is definitely a sense of FOMO (Fear of Missing Out) and hence you are seeing different strategic initiatives across the companies. Some are actively embracing across the organizations. Others are more limited initiatives confined to corporate VC investments. For investors, the headline exits are not there yet as business models are still being evaluated. There is a lot of trial and error and it may take 5 – 10 years for the field to work out issues on the clinical, commercial and reimbursement side of things. We are cautiously optimistic that they will get there.”
  **Aidan King, Managing Partner and Co-Founder, Fountain Health Partners**

- “Large pharma should be investing in DTx; while I believe it will generate outsized returns, even if you disagree, it will be important to get a look at the tech, data and changing business models, it is another tool to improve patient outcomes and the data from DTx could drive marketing, patient journey maps, and when/how to treat patients in the disease progression”
  **Owen McCarthy, President and Founder, MedRhythms**

- “AI and machine learning are very exciting; as the patient uses the product, it will customize the treatment, collecting data that can be used for the patient and for future product development”
  **Debra Reisenthel, Founding President and CEO, Palo Alto Health Sciences**

- “In 5 years, there will be at least half a dozen patient-facing DTx companies worth $1B+, we’ll see a shift toward telemedicine, and CVS/Walmart will provide primary care physician services. In 10 years, virtually all clinical trials will include a digital tracking and data collection component, and many, if not most, will measure a digital biomarker.”
  **Antoun Nabhan, VP Corporate Development, Pear Therapeutics**

- “Data collection from using digital therapy and community apps: [will] help identify new patients for therapies, help treat patients and manage their conditions, provide disease specific communities to get support, advice and care, and educate patients about therapeutic options.”
  **Chris Wasden, Head of DTx, Happify**
Recent Observations and Trends in Digital Therapeutics (continued)

Biopharma

**5**

More efficient product development, including higher PTRS, lower costs and shorter development timelines for new therapies

**6**

Digital therapeutics function as both a monotherapy as well as in concert (as a companion, adjunct or combination) with traditional pharmacological inventions

- “We are at a point where all of the major stakeholders are excited about novel technologies and Digital Therapeutics. There are a variety of models for how Digital Therapeutics work within the healthcare system, but, just like with pharmacologic interventions and medical devices, it’s best to adopt an existing model than to try to disrupt a very rigid set of processes. We are at a very exciting point in time though where this wave has started, and it will continue to build. I believe that in 4-5 years, it will be common to be prescribed a DTx”.

  **Andy Molnar, VP Commercialization, Cognoa**

- “Once we have a large enough data set, digital therapies can then change by adapting their algorithms and be able to become a personalized medicine. Lots of potential for DTx to be used early on in a disease as a monotherapy; perhaps later stage it would be used either as a monotherapy or in combo with a Rx; the sum of the parts could be greater than individual therapies and throughout be used as a diagnostic “

  **Owen McCarthy, President and Founder, MedRhythms**

- “Positive on combination products, [DTx] delivery model can increase efficiencies, boost patient engagement and improve gross margins... [will become] part of the treatment ecosystem. I think the hard part is finding the right economics for adjunct digital therapeutics; in the near-term it may be better to bundle or attach to another reimbursement schema for more or less free, but get upside from continuing maintenance of therapy”

  **Zach Gonzales, Vice President, Norwest Venture Partners**
Recent Observations and Trends in Digital Therapeutics (continued)

Patients

“Healthcare at your fingertips”: DTx allows patients to access care on-demand

Digital therapeutics combines technology and evidence-based medicine to deliver personalized patient care

- “So much of our overall health is driven by behavioral or mental health, and yet we’ve had this artificial dichotomy between mental and physical health. This is going away as there is increasing appreciation that they are in fact linked, and our mental health is a critical factor for our overall health. Digital therapeutics have greater ability to impact our mental health.”
  
  Aaron Gani, Founder and CEO, BehaVR

- “In many therapeutic categories, such as autism and stroke, patients are lost in a complex system from diagnosis through treatment, which is often times, both frustrating and frightening. Digital Therapeutics offer the potential to fill that gap by streamlining the entire patient journey. By creating a new standard of care, we will ensure that patients understand their options and receive the care they need when they need it most.”

  Andy Molnar, VP Commercialization, Cognoa

- “Allows patients to access their data and manage their own care...becoming an increasingly consumer-driven healthcare marketplace”

  Debra Reisenthel, Founding President and CEO, Palo Alto Health Sciences
Recent Observations and Trends in Digital Therapeutics (continued)

Payers, Providers & Health Systems

9  Digital medicines service delivery model promotes the evolution of value-based care

10  Digital therapeutics offer compelling safety profile and may become the new first-line treatment for selected indications

- “We’re particularly excited about the power of VR in DTx in particular for behavioral health, because of the incredibly powerful neurological effects VR offers. Behavioral health is a significant problem with huge unmet needs, there is an acute provider shortage, and still stigma around getting help; [DTx enables] more scalable, more cost effective and better access to care for patients”
  
  Aaron Gani, Founder and CEO, BehaVR

- “Ideally using preventive measures and catching people earlier in their symptoms. Catch people before they develop major systems will truly impact value-based care..., be preventive rather than prescriptive...goal is the keep people healthy instead of solving health problems.”
  
  Shubh Anand, Analyst, City Light Capital

- “Payers could eventually require this as a step-edit over a schedule 4 IV drug for insomnia...the challenge is overcoming the stigma that these programs will not be reimbursed at good prices. We are designing trials along with payers, who see the value in facilitating more effective care to patients at a lower cost.”
  
  David Benshoof Klein, CEO, Click Therapeutics

- “The mindset to treat disease has changed tremendously in the last 20 years. From patients to payers, we have seen a philosophical shift from treating issues after they occur to preventative medicines. Digital Therapeutics can help identify and treat diseases, but they can also be a first line to prevent chronic conditions from occurring or worsening. Additionally, as we see patients owning their own healthcare, Digital Therapeutics empower them to care for themselves and their loved ones, and enhance traditional therapies for better outcomes”
  
  Andy Molnar, VP Commercialization, Cognoa

- “DTx challenges in the near term: prove reimbursement, convince payers of the HEOR improvements, and find pricing structures that align payment incentives across stakeholder’s: The HCP, payer, and therapeutic developer / pharma co.”
  
  Antoun Nabhan, VP Corporate Development, Pear Therapeutics
Conclusion
• While we do not believe that digital therapies will replace traditional pharmaceutical products, i.e. a digital app will not replacing PCSK9 inhibitors, insulin, statins or PD1-inhibitors, but they will be incorporated into every facet of the patient journey

• We do believe that digital will be incorporated into the treatment paradigm as follows:
  • As a diagnostic tool
  • Potential first-line therapy of treatment for selected indications
  • Companion, adjunct or in combination with pharmacological product
  • Possibilities that we have not even identified, yet

• As the use of digital within the biopharma sphere is still in its infancy, we have yet to even scratch the surface on the potential for how data and analytics can impact the sector, from drug development, to patient identification and stratification, to using real-world evidence to inform physician recommendations

• Biopharma companies investing now may reap the words of a first mover advantage into this modality

• Lastly, as the US healthcare system evolves to a value-based care model, digital is a natural partner to enable efficiencies and cost savings
The Near Term Outlook

While there are still several major challenges for the adoption of digital therapies, there is significant momentum at the moment and we expect it to accelerate.

**Headwinds**
- Optimal pathway(s) to scale and commercialize still unchartered
- Can be challenging to secure reimbursement by payers and healthcare systems
- IP and product protection yet to be fully vetted and tested
- Limited digital therapeutic company exits via M&A
- Recent dissolution of multiple digital-biopharma partnerships and lack of commercial uptake for recent digital therapy product launches

**Tailwinds**
- Digital therapeutic products have demonstrated clinically meaningful outcomes
- Potential for patients to access therapy on-demand
- Potential for shorter development timelines with higher PTRS and lower costs than traditional pharmacological interventions
- FDA is supportive of digital therapeutics
- Digital therapies present favorable pharmacoeconomics, which align with healthcare’s overall shift towards value-based care
- Digital therapies combine technology and evidence-based medicine to deliver personalized patient care
- Early Biopharma adopters may have a first mover advantage
Torreya Team and Capabilities
Torreya’s Experience in Digital Health

With extensive Life Sciences experience, Torreya is uniquely positioned to advise the growing digital health sector.

- In March 2019, Saama Technologies, a CA-based advanced clinical data and analytics company, closed a $40 million structured debt financing with Perceptive Advisors, a leading healthcare investor.
- Saama will use the proceeds from the financing to expand their Life Sciences Analytics Cloud (LSAC) technology, an AI-powered platform which transforms clinical trial pathways via AI, enabling its customers to make timely decisions at all stages of the process and disrupting the planning, designing, and conduct of clinical trials across various stages of clinical development.
  - The fundamental value proposition of Saama’s technology is its ability to compress the clinical development timeline by optimizing trial planning and operations, thereby improving a drug’s probability of success during the drug development process.
- The award-winning platform gives unprecedented real-time visibility into clinical data, enabling sponsors to file New Drug Applications (NDAs) more efficiently to bring drugs to market faster and at lower costs.
- Saama will mainly utilize the funds to bolster its platform through R&D investment and a revamped sales infrastructure.
- Torreya served as financial advisor to Saama Technologies on the financing transaction.

- Developer of implantable bioelectronic devices or “neural dust” platform which is comprised of millimeter-sized ultrasonic devices.
- Technology has the ability to interface with nerves and organs through devices in the body, the platform enables unprecedented monitoring, recording and modulation with high nerve and organ specificity, capabilities of enormous potential in the diagnosis and treatment of diseases.
- Torreya has helped to form and advise this company.

- Torreya has identified digital health as a key sector of growth.
- Senior attendance at key conferences that establish thought leadership for the sector.
- Significant investment into building intellectual capital and expertise in digital health.
Torrema is a Global Healthcare Investment Banking Firm

We are known for:

- **Deep Relationships**
  We have strong personal relationships across the pharmaceutical and healthcare sectors.

- **Operating Perspective**
  Many of our senior colleagues come from industry and bring decades of experience.

- **Deal Excellence**
  Torreya is known as a firm that gets tough deals done. Our team is skilled in highly structured transactions.

- **Healthcare Focus**
  Our healthcare focus spans pharma, biotech, bioproduction, pharma services, physician services and HCIT.

### Representative Transaction Work

<table>
<thead>
<tr>
<th>Mergers &amp; Acquisitions</th>
<th>Generic Pharma</th>
<th>Spec Pharma</th>
<th>Bioproduction</th>
<th>Spec Pharma</th>
<th>Biotech</th>
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</thead>
<tbody>
<tr>
<td><strong>sawal</strong></td>
<td>Acquisition of generics business of UPSH-SMITH</td>
<td>$1.05 billion</td>
<td>June 2017</td>
<td></td>
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<tr>
<td><strong>CHOLEA THERAPEUTICS</strong></td>
<td>Sale to</td>
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<tr>
<td><strong>cobra-bio</strong></td>
<td>Sale to</td>
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<tr>
<td><strong>AVENUE THERAPEUTICS</strong></td>
<td>Option to be acquired by CIPLA</td>
<td></td>
<td>$215 million</td>
<td>January 2019</td>
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<tr>
<td><strong>oncoseer</strong></td>
<td>Sale of Majority Stake to FarmaPharma</td>
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<td>SIRTeX</td>
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<thead>
<tr>
<th>Licensing, Asset Sales and JVs</th>
<th>Asset Sale / Biotech</th>
<th>Divestiture / Spec Pharm</th>
<th>License / Biotech</th>
<th>License / Biotech</th>
<th>JV / Spec Pharma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phenex Pharmaceuticals AG</strong></td>
<td>Sale of FXR program to GILEAD</td>
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<tr>
<td></td>
<td><strong>Up to $470 million</strong></td>
<td><strong>January 2015</strong></td>
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<tr>
<td><strong>Malinckrodt Pharmaceuticals</strong></td>
<td>Sale of Intrathecal business to Piramal</td>
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<td></td>
<td><strong>$203 million</strong></td>
<td><strong>March 2017</strong></td>
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<tr>
<td><strong>NOVALIG</strong></td>
<td>License of NOV03 in North America to Bausch+Health</td>
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<td></td>
<td><strong>Up to $2.6 billion</strong></td>
<td><strong>January 2017</strong></td>
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<tr>
<td><strong>assembly</strong></td>
<td>License of Microbiome Program to Allergan</td>
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<td></td>
<td><strong>December 2019</strong></td>
<td></td>
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<tr>
<td><strong>China JVs</strong></td>
<td>China JV with AUTOBINDO</td>
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<td></td>
<td><strong>$50 Million</strong></td>
<td><strong>December 2018</strong></td>
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<thead>
<tr>
<th>Debt, Royalty Sales and PE Recaps</th>
<th>PE Recap / Generics</th>
<th>Debt / Spec Pharma</th>
<th>Debt / Services</th>
<th>PE Recap / CRO</th>
<th>Royalty / Spec Pharm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rubicon Research</strong></td>
<td>Sale of Majority Stake to General Atlantic</td>
<td></td>
<td></td>
<td></td>
<td>Royalty-backed acquisition financing for undisclosed spec pharma</td>
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<tr>
<td></td>
<td><strong>$125 million</strong></td>
<td><strong>April 2019</strong></td>
<td></td>
<td></td>
<td>$100 million</td>
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<tr>
<td><strong>Tris Pharma</strong></td>
<td>Recapitalization and Buy of Nextwave from Pfizer</td>
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<tr>
<td></td>
<td><strong>$125 million</strong></td>
<td><strong>September 2018</strong></td>
<td></td>
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<tr>
<td><strong>Mid-Atlantic Dental Partners</strong></td>
<td>Credit Facility from CRG</td>
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<td></td>
<td><strong>$70 million</strong></td>
<td><strong>October 2019</strong></td>
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<tr>
<td><strong>SIMBEC ORION GROUP</strong></td>
<td>Sale of Majority Stake to CBPE</td>
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<td></td>
<td></td>
<td></td>
<td><strong>February 2019</strong></td>
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<tr>
<td><strong>HealthCare Partners</strong></td>
<td>Royalty / Spec Pharm</td>
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<td><strong>February 2016</strong></td>
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We are a Leader in the Areas We Serve

<table>
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<th>Mergers &amp; Acquisitions</th>
<th>Pharma Divestitures and Joint Ventures</th>
<th>Capital Markets</th>
<th>Licensing</th>
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<tr>
<td><strong>Torreya Highlights</strong></td>
<td><strong>#1 global advisor in pharmaceutical asset-level transactions</strong>¹</td>
<td><strong>Over $1.5 billion raised for clients since 2007</strong></td>
<td><strong>#1 financial advisor worldwide in pharma licensing deals</strong>¹</td>
</tr>
<tr>
<td>• Top 3 in number of pharma M&amp;A deals</td>
<td>• Active in structuring joint ventures</td>
<td>• Top 3 advisor on royalty monetizations</td>
<td>• #1 financial advisor in regional pharma licensing deals¹</td>
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<tr>
<td>• 50% of volume is cross-border</td>
<td></td>
<td>• #2 agent worldwide in pharma for directly placed debt¹</td>
<td>• #1 financial advisor in licensing and M&amp;A in China¹</td>
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<td>• High share in therapeutics, generics, API and bioproduction</td>
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<td>• Highly active in private equity targeted deals</td>
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<td><strong>Specific Services</strong></td>
<td><strong>Commercial-stage asset sales</strong></td>
<td><strong>Private equity recaps</strong></td>
<td><strong>Pre-commercial</strong></td>
</tr>
<tr>
<td>• Corporate sales</td>
<td>• Asset-level acquisitions</td>
<td>• Debt financings</td>
<td>• Commercial-stage</td>
</tr>
<tr>
<td>• Acquisitions</td>
<td>• Joint Ventures</td>
<td>• Royalty monetizations</td>
<td>• Regional licensing</td>
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<tr>
<td>• Divestitures</td>
<td></td>
<td></td>
<td>• Proprietary economic valuation model</td>
</tr>
<tr>
<td>• Structured transactions</td>
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<tr>
<td>• Fairness opinions</td>
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¹ Capital IQ and Torreya calculations
Torreya is the Only Pharma Focused Investment Bank that is Competitive in All Major Regions

Top Five Investment Banking Firms in Pharmaceutical Industry M&A and Licensing Transactions by Region

Jan 1, 2017 to January 8, 2020 by Deal Count, Includes Announced and Closed Transactions.

<table>
<thead>
<tr>
<th>Region</th>
<th>RANK</th>
<th>FIRM</th>
<th>DEAL COUNT</th>
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<td>China</td>
<td>1</td>
<td>Torreya</td>
<td>8</td>
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<td></td>
<td>1</td>
<td>China Intl</td>
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<td></td>
<td>3</td>
<td>Centerview</td>
<td>3</td>
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<tr>
<td></td>
<td>3</td>
<td>Credit Suisse</td>
<td>2</td>
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<tr>
<td></td>
<td>3</td>
<td>Piper Jaffray</td>
<td>2</td>
</tr>
<tr>
<td>Europe</td>
<td>1</td>
<td>Rothschild</td>
<td>19</td>
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<td></td>
<td>1</td>
<td>Torreya</td>
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</tr>
<tr>
<td></td>
<td>3</td>
<td>JP Morgan</td>
<td>11</td>
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<tr>
<td></td>
<td>3</td>
<td>Bank of America</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Goldman Sachs</td>
<td>10</td>
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<tr>
<td>India</td>
<td>1</td>
<td>Torreya</td>
<td>10</td>
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<tr>
<td></td>
<td>2</td>
<td>Jefferies</td>
<td>4</td>
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<tr>
<td></td>
<td>3</td>
<td>SVB Leerink</td>
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<td></td>
<td>4</td>
<td>SPARK Advisors</td>
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<td>4</td>
<td>Centerview</td>
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<tr>
<td>Japan</td>
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<td>Evercore</td>
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<td></td>
<td>1</td>
<td>JP Morgan</td>
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<td>1</td>
<td>MTS Health</td>
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<td>4</td>
<td>Torreya</td>
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<td>4</td>
<td>Goldman Sachs</td>
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<tr>
<td>North America</td>
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<td>2</td>
<td>Centerview</td>
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<tr>
<td></td>
<td>3</td>
<td>MTS Health</td>
<td>23</td>
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<tr>
<td></td>
<td>4</td>
<td>JP Morgan</td>
<td>16</td>
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<tr>
<td></td>
<td>4</td>
<td>Bank of America</td>
<td>16</td>
</tr>
</tbody>
</table>

Source: CapIQ/Torreya calculations. Notes: Deal was counted in a region if a party on either side was in a region. Transactions are included in the pharmaceutical sector, the OTC sector and pharmaceutical manufacturing. Only transactions larger than $10mm included. When multiple advisors are present the deal credit is divided by the number of groups present to apportion deal value. Contingent payments are discounted by 75%.
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