

Morgan Lewis

FAST BREAK: **HEALTHTECH** **STARTUPS**

Jeff Bodle, Andy Ray & Jake Harper
April 25, 2019



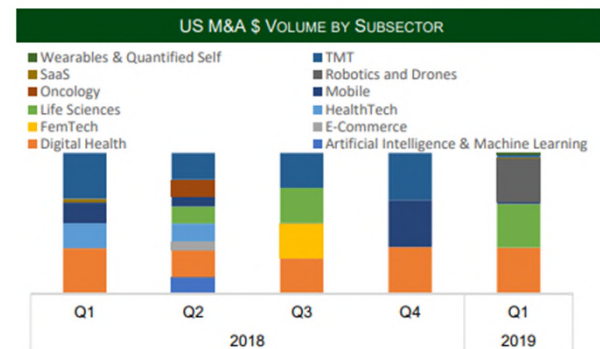
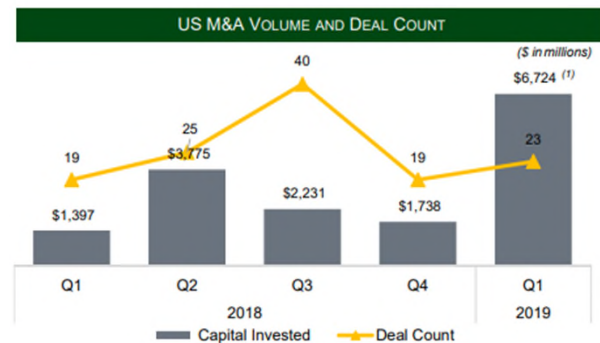
Agenda

- HealthTech Trends and Startup Financing
- Corporate Venture Capital (CVC)
- Common Healthcare Regulatory Issues for HealthTech Startups
- Investment Diligence Process

Healthcare Evolution

- The four pillars of healthcare evolution
 - Increase access
 - Increase quality
 - Decrease cost
 - Increase provider/patient satisfaction

- HealthTech and Digital Health focus is on realizing these aims



Evergreen Advisors Capital – Q1 2019 Digital Health Market Update

Key HealthTech Observations

NOTABLE TRENDS

- Artificial Intelligence applications continue to resonate with investors as healthcare payers and providers begin to deploy next-gen technologies
 - AI and machine learning applications will enable payers and providers to leverage the growing and complex datasets that are being built
 - AI promises increasing speed and accuracy of key functions including image diagnostics, pharmaceutical compositions and therapy recommendations
- Tech giants are taking steps to expand into the healthcare universe
 - Google, Apple and Amazon all made healthcare investments in 2018, intensifying its presence in the digital realm
 - Partnership announcements between retail players and large healthcare systems and payers are increasing in an effort to create new access channels
- Consolidation within the digital health industry continues
 - Startups represented much of the M&A activity in Q1 2019, with behavioral health companies garnering significant interest
- Health data privacy and security remain a top priority
 - With more connected devices accessing healthcare networks, healthcare providers and hospitals are seeking new ways to manage risk
 - Hospitals will look to hire more IT experts, including cloud-driven managed service providers, to mitigate cyber threats
- The transition to cloud technology in healthcare
 - Easy-to-use software and infrastructure-on-demand services, including AWS, are creating a new class of tech-enabled, third party administrators (TPAs) and service bureaus

KEY TAKEAWAYS

89%



89% of patients seek to take control of their own healthcare by adopting digital health tools, largely through wearable products

75%



75% of consumers use at least one digital device to access remote healthcare services

54%



54% of consumers and patients view reduced medical costs as the top advantage in virtual healthcare versus traditional in-person healthcare

50%



50% of healthcare providers and hospitals will integrate some form of data analytics workflow by the end of 2019

30%



The IoT healthcare market is expected to **grow 30% through 2022**, driven by the rise of AI and the increasing penetration of connected devices

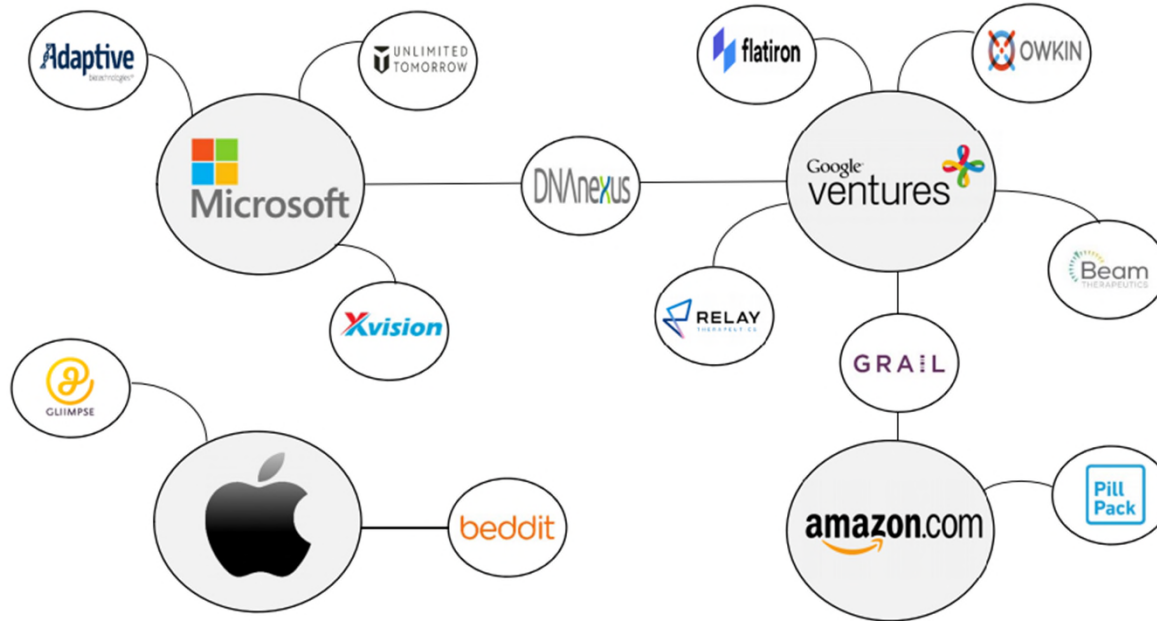
20%



Healthcare spending will hit nearly **20% of US GDP** over the next decade, representing 5.5% annual growth over this period

Tech Now Loves Healthcare

- Increased focused on R&D, acquisitions, and investments



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A Company is Born

- What is the general trajectory of a HealthTech company?
- Common profile of HealthTech entrepreneurs
- Initial goals
 - Vision
 - Execution
 - Contacts
- Understanding and projecting the future of the healthcare marketplace



The Big Question – Where's the Money?

- Turning an idea into a business requires capital
- Funding rounds may include:

Round	Players	Timeframe
Initial Startup	Friends & Family, Incubators/Accelerators, Grants, university or parent company resources (if spinout), bootstrapping (i.e. customer revenue)	Year 1
Pre-seed / Seed	Same plus Angels and Seed Venture Capital Funds	Years 1-3
Series A / Series B / Series C	Same for Series A plus Venture Capital Funds and CVC	Years 1-4
Later Stage and Growth Equity	VC, Growth Equity Funds, Private Equity and CVC	Year 4+

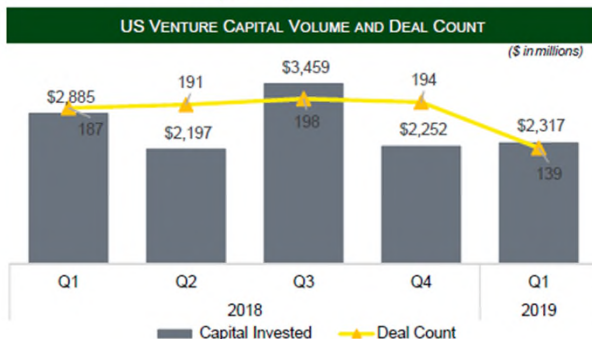
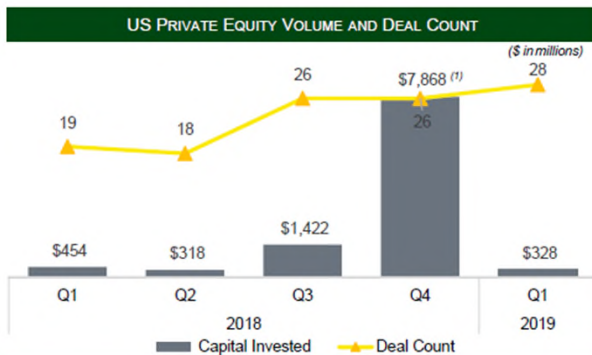
Financing Considerations

- No single pathway or timeframe is correct
- Significant variables including:
 - Perceived market and demand
 - IP protections
 - Regulatory approvals (i.e., FDA)
 - Business model scalability
 - Profitability and capital needs
- Strategic partnerships and customer revenue are often as valuable as capital (and likely even more valuable)



HealthTech Investment Activity

- HealthTech investment continues to be active throughout 2018 and 2019

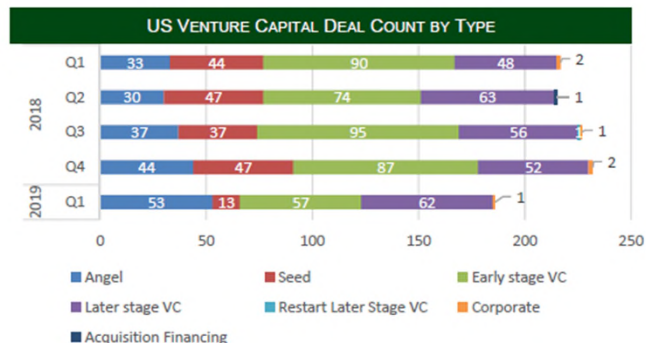


MOST ACTIVE INVESTORS

Investor	Recent Relevant Investments
F-PRIME	artemis HEALTH, FARAPULSE, KYRUUS
Sands Capital ventures	Health Catalyst (spite, auctoris, empirient), KARUNA PHARMACEUTICALS, KITCHECK
G/	OWKIN, the pill, DNAnexus
NEA New Enterprise Associates*	NAKED, strive HEALTH, PALADINA HEALTH
ROCK HEAL+H	ELEMENTAL MACHINES, Marigold HEALTH, Revive
khosla ventures	Clear Labs, VICARIOUS SURGICAL, CARROT

HealthTech Investment Activity, con't

- Maturation of investors, including tech and enterprise healthcare companies



Corporate Venture Capital (CVC)

- CVC now clearly entrenched as significant funding source
 - CVC historic highs in 2018 both in deals (32% increase over 2017) and dollars (47% over 2017)
 - 35% increase in new CVC investors from 2017 to 2018
 - 2,740 CVC global deals with \$53 billion in funding in 2018
- CVCs involved in 23% of all venture capital deals in 2018 (7% participation increase over last 5 years)
 - 773 active CVCs in 2018
 - CVCs increase participation in seed funding (31% increase in Series A participation and 25% increase in seed rounds)

CBInsights: "The 2018 Global CVC Report"

CVC in HealthTech

- 23% increase in CVC healthcare deal participation in 2018
- 51% increase in CVC healthcare deal funding to \$10.9 billion in 2018
- 39% increase in CVC Digital Health deals in 2018 but slight drop in total CVC Digital Health funding from \$3.4 billion to \$3.2 billion
- CVCs participated in around a third of all digital health deals over last 5 years
- Tech / Pharma / Healthcare Systems / Providers / Payers all among active HealthTech CVC investors

CBInsights: "The 2018 Global CVC Report"

Rock Health: "Q1 2019 Funding Report"

Why Do CVCs Invest?

- Financial return
- Ability to access disruptive technology
- Circumvention of corporate bureaucracy and enhancement of innovation culture
- Expansion of industry knowledge, including adjacent spaces to core CVC business
- Enhancement of corporate image
- Potential to satisfy strategic growth and marketing initiatives
- Fear of missing out (FOMO)

Why Do Startups Like CVCs?

- Credibility/validation
- Generates business momentum – strategic insights/industry expertise and relationships/customer relationships/distribution networks
- Funding source with potential deep pockets
- May lead to operational/commercial/strategic partnerships and revenue

What's the Catch with CVCs?

- May expect more sophisticated (and implemented) regulatory/compliance strategy than a traditional VC
- Some only co-invest and do not lead rounds
- May expect commercial arrangement at time of investment
- May want a path to control
 - Right of first notice not uncommon, on occasion right of first refusal to match offers from a limited list of competitors is provided, anything more is unusual
- Traditional VC protections (veto rights, protective provisions, preemptive rights, info rights) can be tricky to navigate to achieve appropriate balance of CVC investor protection with company strategic flexibility given potential CVC strategic interest
- Some CVCs not as experienced as others

Bottom line

CVC investment can be a win-win for both the HealthTech startup and the CVC as long as both sides do their homework and investment and commercial expectations are aligned

Common HealthTech Regulatory Issues

- Reimbursement
 - Reimbursement
 - Reimbursement
- State Corporate Practice of Medicine Doctrines
- Stark Law / Kickback Considerations
- State Licensure
- Regulatory approvals
- HIPAA / Privacy

Common HealthTech Regulatory Issues, con't

- HCP involvement
 - Especially in diagnostic ordering arena
- Telehealth modalities and evolving legal framework
- Billing and revenue cycle management
- Insurer/TPA licensing
- TCPA and Direct to Consumer products/services
- The Great Debate – to target or avoid FHCPs?

Investment Diligence Process

- Every investor has different style and consideration of risk in transactions, but universally require some level of diligence prior to investing
- Where's the next meal coming from?
 - Focus of startups is launching, securing basic operating and growth capital, and focus on proving out business model and hyper-growth
 - May be more willing to take business and legal risks
 - Not focused on long-term compliance or strict adherence to corporate/regulatory processes
 - May not always align at the outset with VC or CVC risk tolerance, but the discipline that these investors bring can be value add to the startup

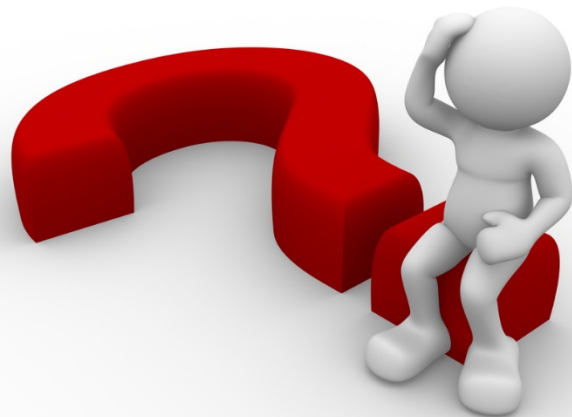
Investment Diligence Process

- Opportunities abound in HealthTech for savvy investors
 - Many incubators/accelerators are primarily focused on this area right now
- Competition among investors? What does that mean for a startup?
- Generally, diligence process is lighter than an established company acquisition given lack of corporate history and typically minimal operations
 - Unless product/service is unique, not squarely in a defined field, or otherwise suggests more apparent regulatory risk

Investment Diligence Process

- Diligence can be contentious at times as parties work to better understand the transaction and relevant risks
 - However, in startup financings, parties need to build a relationship and work together to grow the venture to achieve the desired outcome, so mutual respect and cooperation is critical to ensure the best chance of success for the venture, so diligence process is more collaborative
- Varying levels of sophistication typically exhibited, which can lead to confusion
 - Ensure that communication about risk is active and clear and focused on practical implications
- Transactions often involve co-investors (particularly for CVCs)
 - Ensure coordination between co-investors through diligence sharing where permissible and non-reliance letters

Questions?



Thanks!



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Jeffrey P. Bodle counsels emerging businesses and other innovative high-growth companies at every stage of their business lifecycle—including in mergers and acquisitions (M&A), angel and venture capital financings, IPOs, securities offerings and compliance, corporate partnering, joint ventures, formation advice, and other strategic and outside general counsel matters. Jeff also represents seed, venture capital, private equity, institutional, and strategic and corporate investors in financing, M&A, and portfolio company transactions. Jeff focuses primarily in the technology, healthcare, life sciences, venture capital, and private equity fields.

Thanks!



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Andrew Ray is the leader of the firm's interdisciplinary corporate practice in Washington, DC, where he represents public and private companies, financial sponsors, and management teams in a broad range of industries, including technology, financial services, life sciences, real estate, and the not-for-profit sector. Various industry publications recognize Andy as a leader in both M&A and in communications law, among other fields. He recently led the team representing Oculus VR in its \$2 billion sale to Facebook, which was named the *M&A Advisor* M&A Deal of the Year.

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

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Fast Break: Digital Health Regulatory Update

Featuring Michele Buenafe

➤ Thursday May 16, 2019 3:00 PM (EST)