How The HealthTech Industry Is Entering A (Probable) Recession, And Ways Management Teams Can Navigate Newly Unchartered Waters

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Introduction

Already into the last quarter of 2022, we find ourselves once again in unprecedented times. Our collective digital health industry (and community) hasn't felt a similar such 'sea change' previously, as we were largely not-yet-extant during the Great Recession of 2007-08, let alone the dot-com bubble and subsequent crash era of 2000-01, per the following key milestones or inflection points:

- Epic and Cerner founded, 1979
- First iPhone released June 2007
- MobiHealthNews launched on January 31, 2009, into an environment that looked like this: "iPhone was a year and a half old. The iPad was just a rumor. The Apple Watch wasn't even that. There was no such thing as a Fitbit. CMS didn't have an innovation center and the FDA didn't have any guidelines about apps. Telemedicine had been around for a while, but it was something that involved bulky carts. No one thought that Apple, Google, or Amazon would ever be thought of as a healthcare company."[1]
- Enactment of the American Reinvestment and Recovery Act (ARRA) and the accompanying Health Information Technology for Economic and Clinical Health (HITECH) Act, 2009. The HITECH Act authorized more than $35 billion worth of "incentives for the use of Health Information Technology."[2]
- On a more personal note, I first heard of "WellDoc Communications" (later just "Welldoc"), my first "mHealth" (i.e., "mobile health") company and started consulting for them, in 2007; results of the company's first 30-person RCT were published in May of 2008; I joined the company in 2010 and we received our first FDA clearance shortly thereafter, in July of 2010, making Welldoc's "DiabetesManager" (later re-branded as, "BlueStar") the world's first, regulatory-agency approved, prescription-only (at the time) "digital therapeutic" (i.e., prescription digital therapeutic, or "PDT").

Current Situation

How We Got Here

From 2011 to the end of 2021, we witnessed an increase in annual U.S. digital health venture funding from $1.2B to $29.1B (a CAGR of 37.55%), and average deal size over the same period go from $12.3MM to $39.9MM (Rock Health, 2022; Or, $1.9B to $44B, a CAGR of 36.92%, from the global Startup Health dataset). In that decade-long run-up, it felt like we were making more tangible progress and that almost anything was possible, as:

- More individuals (whether consumers, employees, patients, members and their associated 'sponsor' or provider organizations) became aware of and were utilizing digital health solutions (more awareness, access and utilization),
- FDA reduced its regulatory burden for digital health solutions overall, with the categories of software as a medical device (SaMD) and digital therapeutics (DTx) evolving subsequently
- Levels of interoperability were (gradually) increasing (more data),
- More health conditions or health statuses were addressed by those digital health solutions (more coverage, more potential to positively impact more people), and
- CMS and private (commercial) payers began to cover the costs of at least some of the distinctly digital offerings, particularly for telehealth, RPM and several specific conditions (more reimbursement coverage)

Subsequently, as a nascent industry subsegment sprang up, the number of digital health companies also grew (dramatically) from dozens of companies in the aughts to thousands of companies today. In fact, there are more than 1,900 digital health startup companies in the United States alone that have individually raised more than $2 million USD in venture funding, and which in total have raised more than US $77 billion in venture capital funding since 2011.[3]

And then the global coronavirus pandemic happened. While the entire world adjusted to our collective "new normal", providers – particularly the large, integrated delivery networks (IDNs) – struggled to manage the incredible burden on their EDs and ICUs (and their staff). Accordingly, the pandemic required a rapid shift in how care was provided, from the traditional, primary reliance on "brick and mortar" settings, to remote or "virtual" technologies and offerings for the provision of (many aspects of) primary and even some types of specialty care (i.e., "click & mortar"), creating a very powerful – if largely temporary – "virtual" forcing function and adoption accelerator for many digital health solutions, particularly for "remote" and home-based technologies and offerings.

This sudden and exponential rise in adoption and utilization grabbed the attention of a considerable amount of inexperienced, indifferent, and/or 'tourist' investors in healthcare, and an unprecedented amount of capital was subsequently infused into the space in the 2020-21 timeframe.

Regarding the overall investment thesis: "Healthcare is a $4 trillion sector of the US economy, accounting for roughly 20% of the nation's GDP. It's also a sector that is rife with inefficiency, with as much as $935 billion of that spend associated with waste, fraud or abuse (Note: With $58.5 billion to $83.9 billion of that being categorized as "fraud and abuse."[4]). One might assume that 20% of venture capital investment dollars would accordingly flow to healthcare. Yet of the $329.9 billion invested by venture capital firms in the United States in 2021, the $29.1 billion that Rock Health reported as going to healthcare constituted just 8.8% of the total amount invested. Through this lens, it seems as though we are very likely in the early stages of the digital health boom."[5]

That said, and while I do believe we are at the early to mid-stages of the "digitization of healthcare", I've also lost count of how many times that I, myself, have said this: "healthcare is different", and consequently, investors must have a unique knowledge and understanding of how

healthcare works (or does not), including the roles of the many industry stakeholders, the consumer (as 'patient') and provider perspectives, the state-of-the-art in technology, the nature of regulation in the healthcare space, and the overall interconnectedness and complexities of the industry and its many sub-verticals. To wit, "Healthcare venture capital is not for the faint of heart. Reviewing the data over the last thirty years, over half of all venture-backed companies return less than 1.0x, and 90% of the value created comes from only 31% of invested capital. And unlike tech venture capital, multibillion-dollar outcomes are few and far between."[6]

With more capital flowing into the space, competition for deals also reached an unprecedented level, and emotion prevailed (see: FOMO). As a direct result, deals got done with little to no due diligence and one can easily imagine the numerous negative, downstream impacts in which this kind of (irrational) behavior can result.

Public markets were similarly 'irrationally exuberant' about the prospects of digital health, and we witnessed 13 digital health companies go public via traditional IPO, and 14 via SPAC, in 2021. Seemingly, the 'good times' were never going to end.

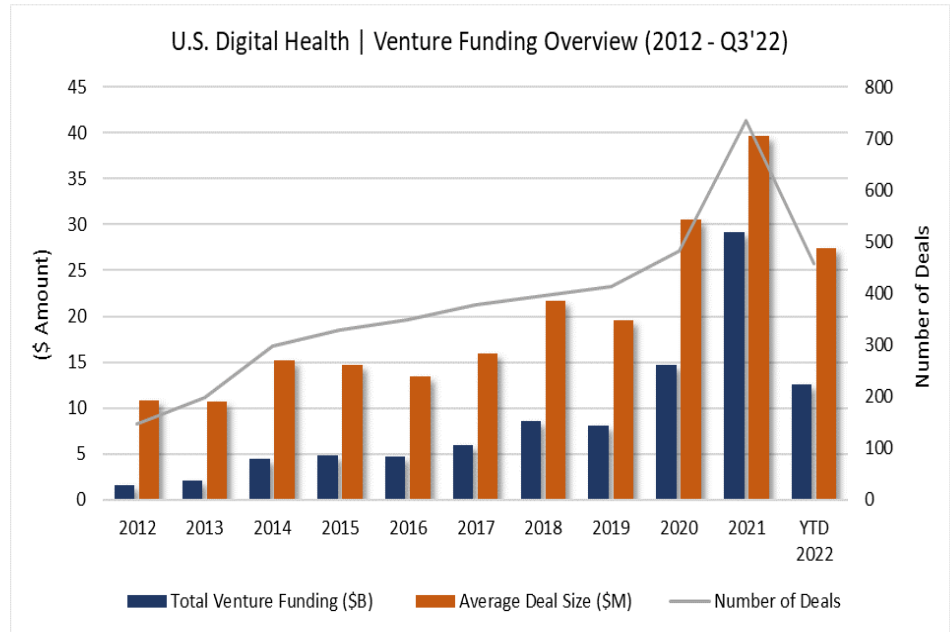
Until they did. Come January 2022, we are faced with a much different world politically and economically, with lingering, multi-dimensional and truly global effects of the pandemic, particularly impacting the global supply 'chain-wreck', "geopolitical instability" (i.e., war breaking out in Ukraine in February 2022), rising interest rates, rampant and persistent inflation, and omnipresent threat of the "r" word, continuing to the present day.

Markets are contracting, and within the space of a few months, everything is (very) different. We went from an overall environment of strong tailwinds to stiff headwinds rather quickly, and entrepreneurs, investors and limited partners are all still trying to sort things out – along with Chairman Powell at the Federal Reserve.

The subsequent healthcare fallout has been substantial, particularly in public markets, but private markets have been demonstrably affected as well. Inexperienced management teams (many of which attracted cheap equity in a bullish market over the last couple of years) are completely blindsided, and their "growth at all costs" and "hope as a strategy" mindsets are dashed on the rocks of the harsh reality of prevailing economic conditions. Those heady market conditions of 2021 would indeed not continue indefinitely. And since the 'sea change', valuations and the overall fundraising environment have shifted decidedly from "founder friendly" back to "investor friendly", down rounds are much more prevalent (some think this is a big deal, others, not so much), and overall 2022 investment is shaping up like this (U.S. only): 2021 ($29.2B) > 2022 (~$15B(E)) > 2020 ($14.7B). Global healthcare innovation funding in 1H22 ($16B) was down 29% from 1H21 ($22.5B), with investments downshifting from Q1 to Q2, across most (if not all) metrics. U.S. digital health investment during 3Q22 came in at a meager $2.2B, down 48% from Q2's $4.2B (in fact, "it's the lowest quarter by dollars raised in digital health since Q4 2019 ($2.1B)")[7].

Figure 1

[Source for graphic: https://rockhealth.com/insights/q3-2022-digital-health-funding-the-market-isnt-the-same-as-it-was/]



Those looking for bright spots in the data must be content with the following: According to data from Digital Health Business and Technology, there were 286 Seed and Series A venture capital deals through 3Q22—which is the highest total ever recorded. For comparison, there were 256 Seed and Series A venture capital deals through 3Q21. In addition, seed deals averaged more than $5MM, which is $2 million more than last year's record. Finally, there were nearly 100 Seed and Series A venture deals in the third quarter compared to 102 in the third quarter of 2021. With the focus on early-stage deals, the average size of Series B through Series H deals through the first three quarters of 2022 is nearly 50% lower than it was a year ago[8]. And, in light of the "investor friendly" market conditions, venture capital firms are increasingly utilizing cumulative dividends as part of their early-stage deal structures in an effort to further increase their downside protections, with the use of such roughly doubling from the end of 2021 through 3Q22.[9]

On the global M&A front, we began the summer on a very, very high and concordant note, with eight back-to-back quarters of over $1 trillion in deals. But the melody has turned sour, since – with only $640 billion in deals agreed to since the beginning of July, we're on track for M&A's worst quarter since the pandemic brought dealmaking to a halt in 2020.[10] Digital health M&A is down also, with 109 deals through 1H22, versus 136 in 1H21. Perhaps more concerningly, the 30 digital health M&A deals during 2Q22 are below the 10-year averages for each of those months. It feels like many potential or would-be acquirers are sitting on the sidelines, waiting for one or more market conditions indicators to flip "positive". Some private equity firms and/or those going the LBO route, may have trouble securing financing from now-cautious banks in the current environment to complete transactions. Ken Moelis, a prominent investment banker and founder of Moelis & Company, went so far as to say recently that, "It's almost impossible, now, to get a deal financed."[11] Taken all together, many finance and economics professionals see the near-term climate as one that will (only) celebrate strong management teams with proven product-market fit, and punish those who have histories of missed deadlines and lackluster growth projections.

On the private-to-public front, we've seen no traditional IPOs in the space this year, with multiple potential go-public offerings postponed or completely shelved. On the SPAC front, there are currently 674 total

active SPACs, with 552 (or almost 82%) of those in "pre-deal" status, meaning that they've secured the funds, but not the "target".[12] And with the market conditions as they are, it is likely that the vast majority of those "pre-deal" SPACs will be forced to liquidate, unable to find a dance partner, with some of those certainly in the healthcare milieu. And those SPACs that have merged this year with a target business saw shareholders redeem 80% or more of their cash – and that means a public listing, with little to no 'cash runway'. There has been one completed SPAC this year, as of the most recent quarter, with the newly formed Akili, Inc. listing on the Nasdaq in August, and currently trading at just shy of 95% off of its intraday and all-time high of $37.58 on August 21, 2022.

Meanwhile, digital health unicorns are losing their horns and shedding employees[13] and the "well run" companies - even those consistently beating the Street – are now being unfairly evaluated, punished and/or hamstrung by over(ly)-corrective markets and fearful, uncertain and doubting investors. And with the less "well run" companies, e.g., the ones with inexperienced management teams and those numerous, as-yet unprofitable companies which might also have unappealing incremental margins, i.e., with higher revenues potentially widening losses instead of shrinking them.

Unfortunately, there are few or no network effects or economies of scale in the direct provision of healthcare. Provider organizations still only scale effectively via the addition of people or inorganically, via M&A. Technology has not (yet) lifted us beyond the necessity of actual humans, and we can't realistically "self-serve" our own healthcare, hence the very real need for clinicians – which are in high demand and short supply, these days.

Consequently, we've already seen a few private equity firms executing "take private" transactions and even boomerang buybacks, particularly for those companies with more robust growth prospects and those that are overachieving with regard to growth and profitability metrics, with the likelihood of at least a few more to come.

Who, if anyone, is in the best position to benefit from the current chaos? Most likely, it will be the 'traditional' healthcare venture capital and private equity investors, i.e., those who can (more accurately and reproducibly) spot value and who have the requisite 'patient' capital to go the distance. Secondarily, there will also be a handful of winners in the entrepreneurial and startup crowds, as economic downturns truly do represent unique opportunities for both significant experimentation and change. And some within the current crop of digital health "NewCos" will get it more "right" than others, developing a solution – or better yet, a platform, with multiple, modularized solutions – which is able to cut through all of the competitive noise, nail the product-market fit equation on an ongoing basis, plug into value-based care initiatives, and deliver sustainable growth and profitability over time, as well as (Oh, yeah!) positive clinical and financial outcomes.

Future Outlook

What A Potential Future Might Look Like

Without the 'benefit' of market exuberance, it's clear that key stakeholders (i.e., entrepreneurs, investors, employers, providers, payers, manufacturers, governments, etc.) have been directionally correct (recognizing, supporting and accelerating the powerful and obvious shifts from traditional to virtual and value-based care and the continuing digitization of healthcare) but specifically wrong, as most of the consensus business models and playbooks for the direct provision of care are lacking or are not fundamentally strong across one or more aspects of the overall business model.

As an example, there are very few solutions that I would consider to be "ideal" across the board, in terms of the business model, technology platform, degree of interoperability,

use of data and analytics, the level of care integration and integration within existing, clinical workflows, engagement and utilization, the multiple perspectives of user experience, scalability, and clinical and financial outcomes, let alone across the metrics of chronic disease prevalence trends, efficiency (vs. wastage) and the more recent, historically neglected "hot buttons" of diversity, equity and inclusion – which are all very much 'works in progress' (i.e., how many companies can you point to that are crushing the objectives of the "Quintuple Aim"?). And while the progress may feel quite slow at times, there are a few bright spots on the horizon, particularly from an investment perspective, i.e., there is a wholly unprecedented amount of "dry powder" on the sidelines, at present:

- Global venture capital firms have raised $573 billion since 2016 (and a record setting $261 billion in the last 6 quarters alone)[14]
- Venture capital fundraising activity for 2021 eclipsed $100 billion for the first time, notching a yearly total of $142.1 billion across 858 funds and representing an almost 67% year-over-year increase compared to 2020's record of $85.3 billion
- The median and average fundraising value in 2021 also saw a notable jump to $50 million and $188.1 million, respectively, a significant increase over 2020's median and average fundraising value of $42.1 million and $156.9 million[15]
- In 1Q22, 199 funds raised $73.8 billion (which was already 86.5% of what had been raised during the entirety of 2020[16]
- U.S. venture funds have closed on $150.9 billion through Q3 of this year, already surpassing 2021's full-year (and prior record) total of $142.1 billion[17]
- Global venture capital 'dry powder' reached almost $539 billion in July[18]
- Healthcare venture capital funds raised nearly $16 billion in the first half of 2022 alone, 50% more than the entirety of 2019[19]

Since it seems unlikely that these venture capital firms will give the raised funds back to limited partners, the important question then becomes, "How do entrepreneurs and startups better position themselves to survive the current downturn until such time that investment and M&A dollars freely flow into the space again?" Read on, for at least one set of potential solutions.

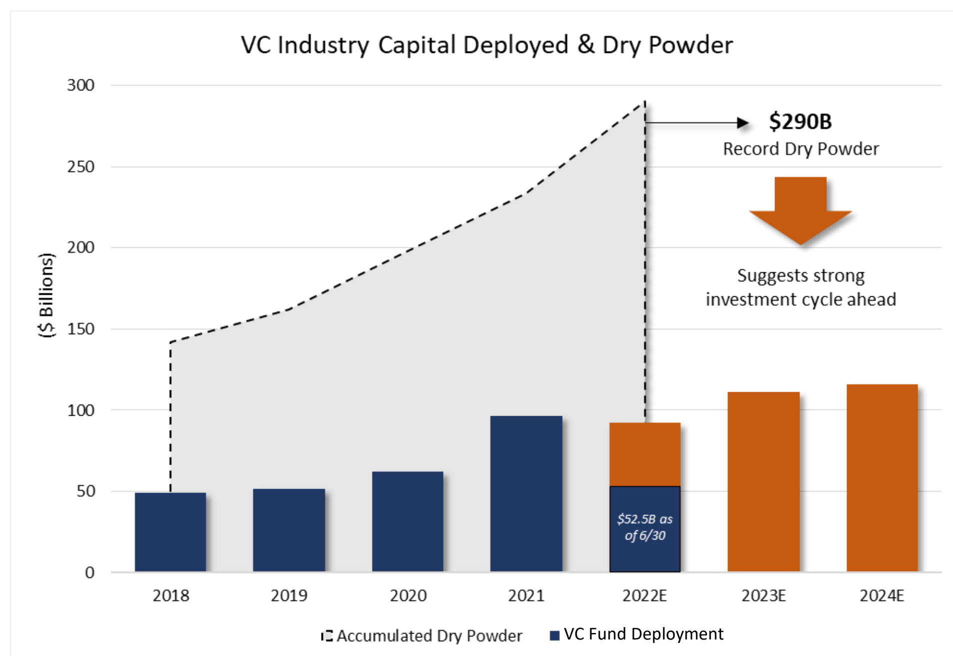


Figure 2

Source: [Source(s) for graphic: https://digitalhealth.modernhealthcare.com/finance/tracking-layoffs-across-health-tech-industry, PitchBook]

Surviving, Then Thriving

How many times over the last couple of months have you heard or read the phrases, “customer acquisition cost”, “unit economics”, “burn rate”, and/or “cash runway”?

How many articles have you seen citing or discussing layoffs, extension rounds, the difficult fundraising environment, and/or the dearth of exit opportunities during the same period?

Most likely, your answers to the above questions would be something akin to “innumerable”. But these are the current trends and portents with which we have to deal, in stark contrast from those of the heady days of 2021. And so, in order to make it to the “promised land”, wherein the deployment of all of that ‘dry powder’ capital begins in earnest (exactly ‘TBD’ months down the road, though some in the industry believe that it will be a year or more), startups must first a) survive, before they can b) really and truly thrive.

A Few Notes on Cost Cutting Measures

Being forced to cut costs by external parties or market forces is not a “fun” exercise, though it should be an entirely strategic one. Simply picking a percentage to cut – typically within a couple of points of 10%, seemingly, based on all of the headlines – is not at all strategic. If it is not, and in my experience, it rarely is, i.e., with functional or department heads handed a cost cutting goal which they need to achieve, then you are doing a disservice to your employees, your board of directors and your investors. So, before we get into ‘thriving’, let’s do a bit of a shallow dive in approaching your need to trim expenses and some of the options at hand.

There is a significant body of work and research dedicated to the analysis of the multiple factors and actions (or inactions) that separate those companies which took “offensive” actions, versus those that took only “defensive” or reactive steps in the face or midst of an economic downturn. One of those key learnings is that, whatever you do, decide upon those actions and implement them quickly, as inaction by the executive team or board can (quickly) result in a startup’s death sentence [See “Perspectives on A Downturn” section]. To wit, I’ve seen several companies just this year shut down, go into bankruptcy, and/or completely shutter operations, without even the possibility of some kind of IP or asset sale, because either the CEO and executive team and/or the board had unrealistic expectations in mind (perhaps based on a completely different set of economic conditions), in terms of achievable goals (versus the timeframes required to actually achieve those goals), valuations, etc., and while they were having these conversations internally, they seemingly weren’t keeping tabs on the company’s balance sheet, and they simply ran out of money to fund continuing operations. Among these were some already-proven solutions (with substantive, positive clinical data) that could have made a real difference across healthcare and within a number of diverse conditions or therapeutic areas. So, rapid implementation. But what to implement?

One (strategic) way to determine your company’s offensive playbook for less-than-ideal economic conditions is to create and lead internally via a “market attack” or “crisis response” team, typically formed from departmental or functional leads and/or their direct reports. This team, fully empowered by management, can help to foster and maintain not only a sense of urgency in the organization, but also one of hope, as employees can see and point to the tangible efforts of such a team in the development of an offensive playbook and its subsequent execution. Some of the team’s efforts may focus on or coalesce around the following “survival of the fittest”-type actions:

- Understanding of the current environment, including analysis of your customers and competitors, and how the downturn is affecting them, a necessity for creation of the playbook
- Segmenting your customers by payment or credit risk,

profitability, their customer lifetime value (CLV), how strategic they are, or other applicable metrics that help you identify which accounts and actions to prioritize (because not all customers are created equally)

- Risk management (a.k.a, contingency planning), complete with alternative scenarios and easily identifiable 'triggers', or trackable metrics or events that serve to inform a company exactly when they should execute a particular alternative strategy
- Creative thinking on payroll expenses, which may utilize such strategies as hour reductions, furloughs, performance-based pay, and more efficient use of contractors
- Building or reconfiguring an IT infrastructure and organization (presumably at a lower opportunity cost during a downturn) with a modular foundation with the potential to reduce overall technical debt, as lower tech debt will ostensibly lead to a larger ROI on those IT investments
- Increasing business process automation (BPA) and digitization, with a particular focus on those projects or opportunities that have the potential to be "self-funding"
- Monitoring / maximizing your liquidity or cash position, e.g., calculating expected cash inflows and outflows, and using that data to produce a rolling weekly or monthly cash report, constantly staying on top of your growth-to-burn ratio

The above is not meant to be a definitive list, nor will the above guarantee your company's survival, even with flawless execution, but the types of strategic actions outlined above are fundamentally better than reducing current expenditures by certain predetermined percentages – or conducting four rounds of layoffs in 2022 alone. Not that anyone reading this would ever do that.

A Path to Maximizing Optionality

So, now that you've trimmed your OpEx in a strategic, intentional way, what if you are (still) in need of capital? Well, rest assured, there will soon be hundreds of digital health companies finding themselves in that same boat, so you'll have plenty of company. With most venture funds allocating 40 – 60% of their cash to current portfolio companies for follow-on rounds, that still leaves a sizeable chunk up for grabs in the "sometime" future, perhaps more than even recent, historical highs.

If you do indeed commit to a "survival of the fittest"-type strategy, then you should absolutely keep strategics and would-be investors up to date on your plans and progress, as it will already set you apart and positively differentiate you from all of your neighbors in the boat.

If You Need Capital

In addition to the traditional pitch and road show processes, you have, hopefully, at least some additional options:

- Crowdfunding, though you really must be careful if and when you choose this route, as it can definitely impact your cap table and future financeability, among other variables. If it goes really well, you can catch the attention of blue-chip investors and strategics. If it does not go well, that's pretty tough to come back from.
- Secure lines of credit, take out a bridge loan or take on convertible or venture debt, while always remembering that debt can limit some of your strategic options along the way.
- Co-create structured financings, e.g., utilizing a "build-to-buy" or milestone-based approach, particularly with "strategics", i.e., potential investors, partners, and/or acquirers
- Secure access to equity capital from non-traditional or non-market sources

- ○ [With all of the above] Seek help; though I would caution you to really think about the kinds or type of outside help that you take on, and do your own "due

diligence" on these external entities' track record, qualifications, reputation, and even their motivations for helping you – i.e., will they need to get paid for their efforts (not a negative, necessarily – it may even help to better align your collective objectives and goals), and if so, how will they get paid (e.g., in the form of a flat or hourly rate, or in the form of some kind of "success fee", wherein they get paid when a transactions closes and/or by how successful they are on your behalf)

- Keep an open mind, continually think creatively, and stay on top of funding / financing trends; additionally, keep in mind that leverage – while perhaps necessary in the short term – can effectively limit your downstream options and leave you little room to act opportunistically
- Maximizing Optionality: That is, don't limit your options with pre-conceived ideas, notions, or biases, or even because of the limited information that you have or are able to garner about the market. Because while you may sometimes be right, the market is *always* right.
- For example, you may be wed to the notion that if you need to raise capital, then traditional institutional capital is the way to go. However, that notion could limit or even negate the possibility of an acquisition – which may provide for better shareholder returns now than might ever be possible in the future (i.e., If you have actual market adoption and positive EBIT, think about best potential outcome for your shareholders overall, as entrepreneurs can no longer just expect a more favorable exit opportunity, some multiple years from now).
- Were you to come to Outcome Capital seeking help with either fundraising or inorganic growth, e.g., then we almost always commit to a "dual process", simultaneously working on and preparing both potential options in parallel. At the end of the day, you will be able to take the (overall) "best" option out of the range of different transaction types to your board and investors, not simply the better option from one category.

Given the above options, if you (still) think that seeking traditional institutional funding is the way to go in your situation, make sure that you give yourself enough time for the process (i.e., 1.5x – 2x longer than you think it should take), and further, if you currently plan to seek capital within 6 – 8 months, start the process now.

Finally, as we at Outcome Capital have written previously, "The amount of capital required to meet value-inflection milestones, investor appetite, likely path to liquidity / exit event, and return on capital are largely sector-dependent. Thus, savvy management should adopt an external, market-driven evaluation and analysis rather than inward-looking and uniformed biased judgment. Crafting a mature, market-aligned strategy will increase the probability of success."[20] That is, revisit the "Seek help" section, above.

If You Have Capital

(Let's say enough to fund your company's continued operations for the next 12 – 24 months or more)

Then, first of all, "Well done!", or, "It's better to be lucky than good."

If you find yourself on the "post-deal" side of a financing round, and/or are having considerable success on the sales front, then consider the following, particular in light of the current environment:

- Enabling Your Inorganic Growth / M&A Strategy: With the current economic conditions continuing to turn (more) negative, now (or soon) may be the time to contemplate leapfrogging your competition and redefining your industry via strategic consolidation, e.g., by developing, revitalizing, and executing on your inorganic growth strategy and subsequently acquiring:

- New capabilities, in the form of products, technology or even human capital
- Customers, ARR and/or market share
- Key partners or vendors of your most strategic customers, either for the cross-selling opportunity or to become even more "indispensable" to your largest client(s)
- Competitors, to take them off the field and leverage synergies (after all, there are simply too many companies in the market for them all to remain viable in
- Geographic expansion / diversity, real estate
- Economies of scale, as bigger can oftentimes be better
- Vertical integration, capturing a different link or links in the value chain

Summary

While 2022 is providing its fair share of added challenges to digital health entrepreneurs and startups, it also represents a once-in-a-decade inflection point in our industry. Fortunately (or unfortunately), 2022 will be the mile marker of our first industry-wide contraction and the beginning of the long-anticipated consolidation process that so many of us have been expecting. Though the coming months will be painful for some, we (as an industry) have been held back from broader adoption, success and positive impact in part due to the sheer number of point and niche solutions in the market, which has created a background 'noise' which many viable solutions and companies have just not been able to rise above. We are finally squarely faced with the looming consolidation wave. Every CEO, executive team and board of directors needs to be asking the $707K question ($64K, adjusted for inflation from 1955): Where do we want to be after the wave has crashed? The answer to that question, as well as the strategic plan and all of the tactical detail underneath it, will likely determine your company's ability to survive, let alone thrive. Why not give your company the best possible chance to accomplish both objectives? Because if you're only aiming for "survival", you may get just – and only – that.

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