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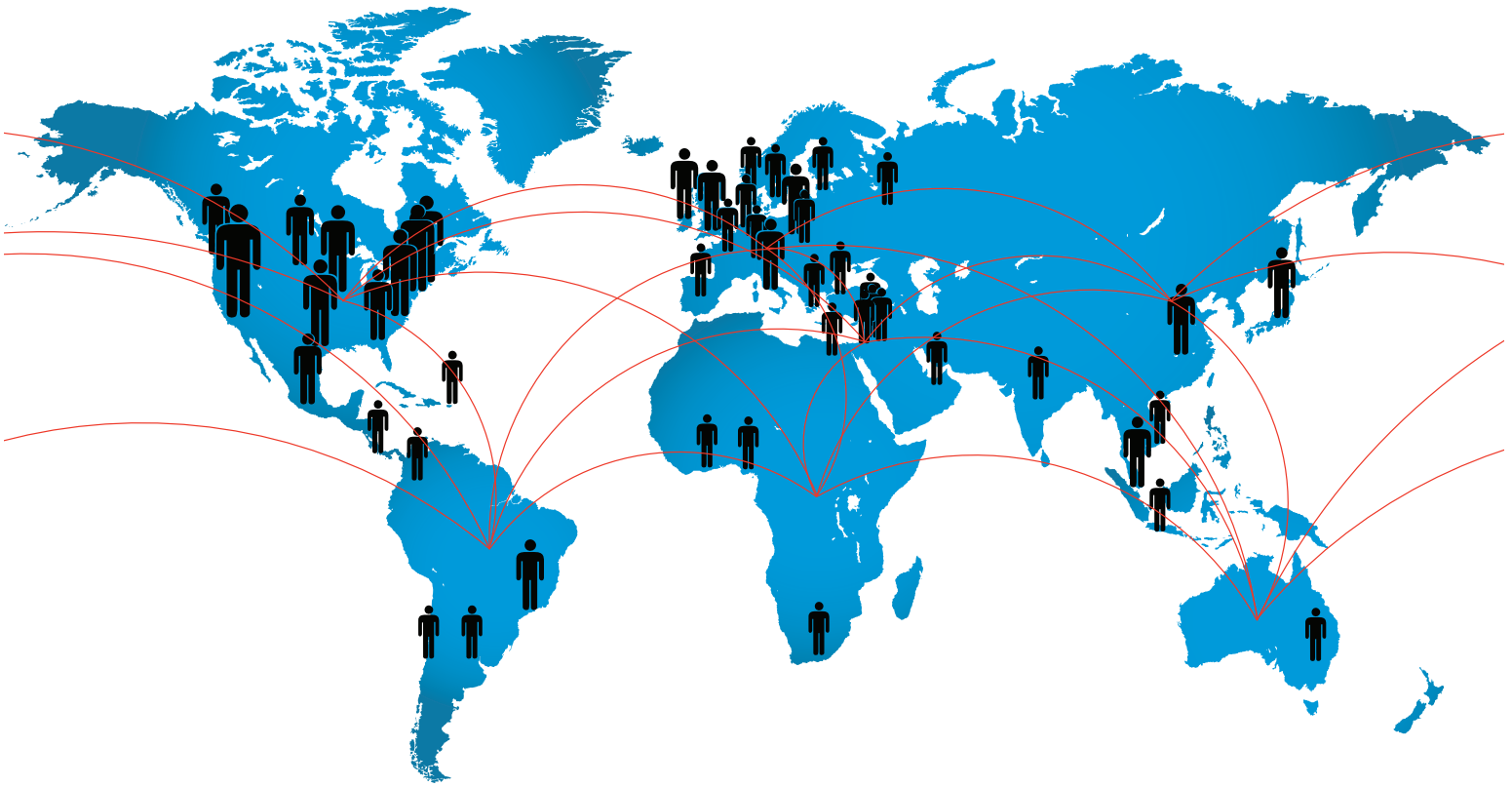

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The Evolving Landscape of the Life Sciences Sector: New Approaches in Therapeutic R&D

Daniel Janiak

Class 17

Since the early 2000s, the rise of on-demand cloud computing platforms such as Amazon Web Services[1] has drastically reduced the costs associated with forming new technology ventures across a variety of industry verticals.[2] In particular, new IT tools, platforms, means of distribution, payment methods, and peer learning environments are driving down cost. The number of accelerators and incubators has increased as well, providing a much-needed support infrastructure for young companies.

Similarly, but less noticeably, a number of factors are driving down costs in the life sciences sector. My work at Mercury Fund focuses on early-stage life sciences investing and company creation, and involves extensive communication with stakeholders across the therapeutics-development pipeline. In this article, I draw on my experience to describe the impact of five specific catalysts: research and development externalization, patient advocacy emergence, increasing talent availability, policy innovation, and contract infrastructure maturation. These factors are remodeling the life sciences sector, resulting in significant decreases in the costs and timeframes associated with the discovery and development of new therapeutics. Here, *therapeutics* refers to new drugs that are of chemical origin (i.e., pharmaceuticals) or biological origin (i.e., biopharmaceuticals).

Technology versus Life Sciences[3]: An Overview

The rapid decrease in the cost of new company creation in the technology sector has resulted in a bifurcation in total capital flows (figure 1) and deal volumes (figure 2) when compared to the life sciences sector. In response to the decreasing costs associated with new tech company formation, the traditional capital providers—including early-stage venture funds—have shifted their investment models to accommodate companies with lower capital requirements at

[1] http://aws.amazon.com/economics/.

[2] Joe McHendrick, "How Cloud Computing is Fueling the Next Startup Boom," *Forbes*, 1 November 2011, http://www.forbes.com/sites/joemckendrick/2011/11/01/cloud-computing-is-fuel-for-the-next-entrepreneurial-boom/; Quentin Hardy, "The Era of Cloud Computing," *New York Times Bits Blog*, 11 June 2014, http://bits.blogs.nytimes.com/2014/06/11/the-era-of-cloud-computing/; Maija Palmer, "Cloud Computing Cuts Startup Costs," *Financial Times*, 29 February 2012, http://www.ft.com/intl/cms/s/0/fc871bca-58e1-11e1-b9c6-00144feabdc0.html#axzz3GoqImKA1.

[3] The funding data presented here for the healthcare and biotechnology industries serve as a proxy for the life sciences.

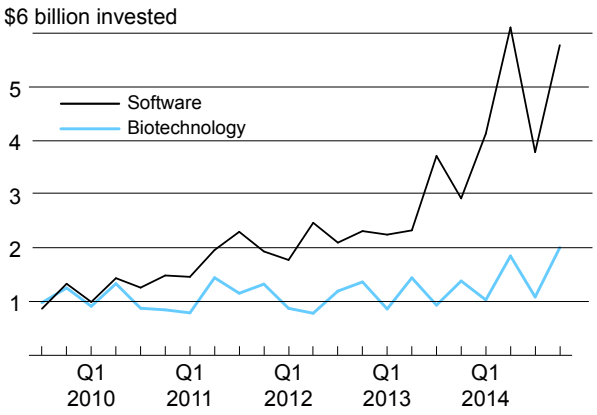

Figure 1. Invested Capital in Biotechnology and Software, 2009–2014. Author's figure, numbers from PWC Moneytree Historical Trend Data, https://www.pwcmoneytree.com/HistoricTrends/CustomQueryHistoricTrend.

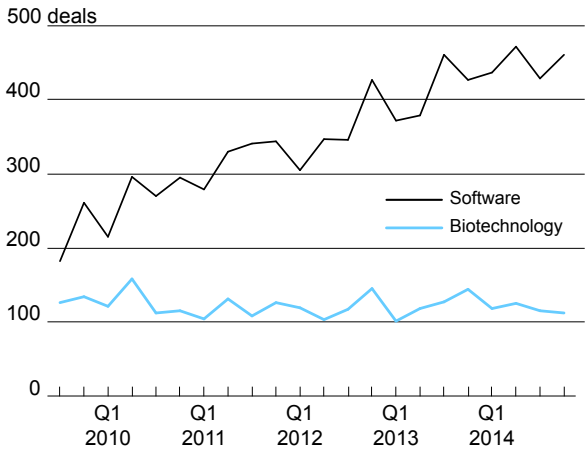

Figure 2. Number of Deals in Biotechnology and Software, 2009–2014. Author's figure, numbers from PWC Moneytree Historical Trend Data, https://www.pwcmoneytree.com/HistoricTrends/CustomQueryHistoricTrend.

the formation stage. New institutional capital providers have emerged, and these micro VC funds and "super angel" groups (such as SV Angel[4]) have established a strong track record of accessing coveted early-stage deal flow.

While the technology sector has flourished, driven by substantial decreases in the amount of capital required to form new companies, the life sciences sector has languished. For example, healthcare Seed and Series A financing rounds have remained relatively stagnant over the past year, accounting for approximately 20% of dollar share.[5]

Numerous structural differences between technology and the life sciences drive this immense divergence between the sectors' availability of seed capital—including but not limited to the timeframe from company formation to product launch, capital availability, total capital requirements, product development cycles, exit options and timeframe, and many more. As a result, it is unlikely that a Cambrian explosion[6] in the life sciences is imminent.

However, a number of structural shifts (some originating as far back as the early 1990s) are beginning to exert their effects, driving the transition from a traditionally closed system to an open, highly-networked life sciences sector characterized by an emphasis on collaboration and the principles of shared-risk. Pharmaceutical companies are externalizing research and development, resulting in increased access to an experienced and skilled labor pool for startups and the establishment of an integrated contract research infrastructure. Patient-advocacy groups are emerging as a significant source of support for biomedical innovation, and key regulatory agencies are engaging in aggressive policy innovation.

As a result of these shifts, the remodeled life sciences sector will have more in common with the technology sector, supported by a drastically reduced cost structure and a sophisticated infrastructure of research service providers that serves as a platform for new company formation and growth. In this article, I focus on the individual and collective potential of these shifts to drastically

[4] Quora, "What is the business model of SV Angel?", n.d., http://www.quora.com/What-is-the-business-model-of-SV-Angel.

[5] CB Insights, "Healthcare IPOs Remain Strong but VC Funding Weakens," 1 November 2014, Share of Healthcare VC by Series - Dollars of Funding, Last Five Quarters, https://www.cbinsights.com/blog/healthcare-venture-capital-q3-2014/.

[6] An evolutionary burst during which the plans of most major animal species appeared; "A Cambrian Moment," *The Economist* (18 January 2014), Special Report, http://www.economist.com/news/special-report/21593580-cheap-and-ubiquitous-building-blocks-digital-products-and-services-have-caused.

decrease the cost and timeframe associated with the discovery of new therapeutics.

R&D Externalization

Historically, companies engaging in the development of new medicines performed the bulk of their discovery and research efforts in-house. As the industry matured, competitive pressures increased and the resultant search for product differentiation propelled research into high-risk, high-cost projects characterized by lower probabilities of technical success. As figure 3 highlights, the research and development cost of approved drugs has been rising steadily for over 60 years. Facing decreasing research productivity, dwindling clinical pipelines, and impending patent cliffs that threatened to severely deplete revenue streams, companies gradually began the process of externalizing select portions of their research and development efforts in the early 1990s.

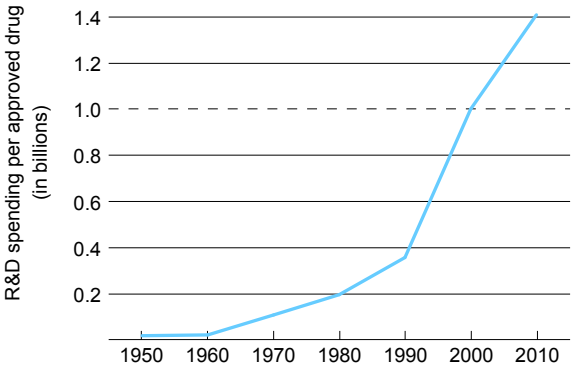

Figure 3. R&D Spending (in Billions) per Approved Drug, 1950–2010. Author's figure, data from http://www.nature.com/nrd/journal/v11/n3/fig_tab/nrd3681_F1.html.

As the search for viable externalization platforms began, Eli Lilly achieved early success with Chorus, an outsourcing effort that began as a pilot program in 2002. Chorus is structured as an autonomous, external organization focused on decreasing the costs and timeframes associated with advancing promising Lilly drug candidates from discovery through clinical proof-of-concept. As of 2009, Chorus had assumed development responsibilities for a portfolio of 24 molecules at various stages ranging from candidate identification through the end of Phase I clinical studies. In the 5-year period from 2004 through 2008, Chorus advanced molecules through clinical proof-of-concept within 29 months at a mean total cost per molecule of $6.0 million, representing extraordinary cost and time savings versus historical industry averages.[7]

In addition to Eli Lilly, many other established companies began to design and refine their externalization strategies using various partnerships, internal and external initiatives, and multi-stakeholder collaborations. While an exhaustive review of the details and differences between these strategies is beyond the scope of this article, a limited selection of externalization initiatives is worth highlighting.

One common example of research externalization involves the participation of established companies as limited partners in life science-focused venture funds.[8] As LPs, these companies can serve as a stable source of both capital and expertise for venture funds and their portfolio investments. In return, they gain valuable insight into early-stage pipeline opportunities as well as early access to external research trends.

More recently, this type of relationship has evolved into a more sophisticated structure characterized by an enhanced degree of collaboration between the parties involved. One such example is COI Pharma, a collaboration between GlaxoSmithKline (GSK) and Avalon Ventures. Formed in 2013, this partnership allows GSK to access the company-building expertise of Avalon and provides them with a capital-efficient strategy for accessing an external portfolio of development candidates.

[7] Chorus, *The Chorus Story* (June 2009), 1, http://www.choruspharma.com/Chorus.Brochure.02June2009.pdf.

[8] Ron Leuty, "Bayer Pumps $25 Million into New Versant Ventures Biotech, Device Fund," *San Francisco Business Times*, 4 November 2014, http://www.bizjournals.com/sanfrancisco/blog/biotech/2014/11/bayer-versant-ventures-inception-5-new-fund.html; Ryan McBride, "Amgen, Novartis Aim to Fuel Biotech Startups in Alliances with Atlas Venture," *Fierce Biotech*, 15 May 2013, http://www.fiercebiotech.com/story/amgen-novartis-aim-fuel-biotech-startups-alliance-atlas-venture/2013-05-16.

The collaboration is structured such that Avalon supplies approximately $3 million in equity capital for each project while GSK commits an additional $7 million in non-dilutive support. In return for this support, GSK receives an exclusive option to purchase each project for approximately three to four times Avalon's initial investment, at a pre-defined timepoint, with the potential to achieve returns in excess of 14x if a drug from these projects eventually reaches market.[9]

Structured collaborations between industry and academia have also proven to be a popular form of research externalization, and broad, multi-year industry-academia partnerships are on the rise.[10] In an effort to further enhance the level of collaboration associated with such partnerships, Pfizer recently launched its Centers for Therapeutic Innovation. Within these Centers, university scientists and researchers are co-located with experienced Pfizer scientists in an effort to expedite the sharing of knowledge, networks, tools, and techniques, to accelerate the discovery of new therapeutics.[11]

Johnson and Johnson (J&J) has a differentiated approach to accessing external research through its JLABS[12] initiative: a network of incubators providing emerging companies with access to shared equipment and facilities that far exceed the budgets of most early-stage companies. In addition to infrastructure, JLABS offers flexible leasing models that provide tenant companies with the option to expand or contract as needed. Co-localization with other early-stage companies and J&J employees yields the additional benefit of providing all parties with knowledge sharing and the potential to develop strong relationship networks. Through JLABS, J&J benefits from having early insight and awareness into emerging technologies and external drug development programs that could serve as a source of new candidates for clinical development at some point in the future.

The continuing trend of research and development externalization has the potential to decrease the barriers associated with the discovery and development of new therapeutics across multiple axes. Industry-academic partnerships and strategic allocations to venture investment funds result in an increase in the availability of risk capital. In addition, these partnerships may serve to produce a higher quality of pipeline candidates through tighter collaboration and synergies derived from the transfer of expertise across the participating organizations. Strategic leasing initiatives such as JLABS and other incubators, accelerators, and facilities that provide shared workspace and infrastructure will have a significant impact on the fixed capital costs associated with the launch of new research efforts. Finally, innovation in the structural and financial components of contracts will emerge to support new partnerships between public and private enterprises, improve the risk-reward balance, and drive inflows of fresh capital to support the advancement of high-risk, early-stage life science efforts.

Patient Advocacy

The rise of patient-advocacy groups as a source of financing for early-stage life sciences companies has been rapid, welcomed, and impactful. The research and development financing provided by philanthropic organizations such as the Michael J. Fox Foundation, the Juvenile Diabetes Research Foundation, and the Leukemia and Lymphoma Society increased from $737 million in 2011 to over $1.3 billion in 2012—a year-over-year rise of nearly 80%.[13] Recently, the Cystic

[9] Stacy Lawrence, "2013 Financing of the Year Nominee: GSK/Avalon Team Up," *IN VIVO*, 17 December 2013, http://invivoblog.blogspot.com/2013/12/2013-financing-of-year-nominee_17.html.

[10] FasterCures, *Consortia Pedia: An In-Depth Look at the Research-by-Consortium Trend in Medical Research and Development* (Milken Institute, 2013), http://www.fastercures.org/assets/Uploads/Consortia-pedia.pdf.

[11] Pfizer, "Areas of Interest," n.d., http://www.pfizer.com/partnering/areas_of_interest/; Pfizer, "Centers for Therapeutic Innovation: Translating Leading Science into Clinical Candidates Through Networked Collaboration," http://www.pfizer.com/research/rd_partnering/centers_for_therapeutic_innovation.

[12] Johnson & Johnson, "About JLABS," 2015, http://www.janssenlabs.com/about/overview.

[13] Research!America, *U.S. Investment in Health Research, 2012* (n.d.), 1, http://www.researchamerica.org/uploads/healthdollar12.pdf.

Fibrosis Foundation received a lump-sum cash payment of $3.6 billion for the royalty rights to Kalydeco, a treatment used for a subgroup of cystic fibrosis patients who have a specific genetic mutation. The Foundation had invested more than $150 million in the development of the treatment.[14]

The data suggest that patient advocacy groups and philanthropic foundations are likely to become an increasingly significant source of research funding, as the collaborative, networked approached to new therapeutics discovery and development continues to gain traction. Furthermore, the strategic grants and investments these groups can provide will offset the capital traditionally acquired from fully-dilutive sources, effectively lowering the amount of risk capital needed at formation.

In addition to risk capital, patient foundations and advocacy groups can provide tremendous in-kind support through connections to clinical and scientific experts, clinical trial networks, patient registries, access to clinical samples, disease natural history data, and more. When Mercury Fund formed Apsara Therapeutics, we had a series of conversations and interactions with the Guthy-Jackson Charitable Foundation, the patient advocacy group for a rare inflammatory disorder of the central nervous system called Neuromyelitis Optica (NMO). As a result of these discussions, Apsara rapidly forged connections with leading researchers, clinical experts, and key opinion leaders in the field of NMO and related neuroinflammatory disorders. As Apsara matures into a clinical-stage company, the Guthy-Jackson Charitable Foundation will facilitate access to patient databases, clinical samples, and their network of clinicians in an effort to expedite enrollment in clinical studies.[15]

This form of non-financial support, combined with an increasing propensity from foundations to provide financial support to new therapeutic development efforts has the potential to dramatically shift cost and time curves within the industry.

Firm	2005 year-end	2013 year-end	Change
Pfizer[a]	151,700	77,000	-49%
Merck[b]	96,500	76,000	-21%
Eli Lilly	44,500	38,000	-15%
Bristol-Myers Squibb	43,000	24,000	-44%
AstraZenica	64,000	51,500	-20%
GSK	100,000	99,500	0%

Figure 4. Workforce Reductions in Pharmaceutical Research Staff, 2005–2013.
Author's figure. [a] Includes Wyeth. [b] Includes Schering-Plough and Organon; Merck's goal is to further reduce employment to 65,000, a 43% decrease overall.[16]

Talent Availability

A direct consequence of the trend toward research externalization, the third factor reshaping the life sciences sector is the increased availability of experienced talent to provide guidance to emerging companies and drive high-risk research projects. As established companies continue to dismantle their research infrastructures in efforts to cut costs and improve efficiencies, their collective research workforce has declined significantly in the past decade (figure 4).[16] As a direct result, many highly skilled workers with significant experience in the pre-clinical and clinical development of new medicines are available to participate in new research efforts as founders, full- or part-time employees, advisors, consultants, and other roles.

[14] Ben Fidler, "CF Foundation Cashes Out on Kalydeco in $3.3B Sale to Royalty Pharma," *Xconomy*, 19 November 2014, para. 2, http://www.xconomy.com/boston/2014/11/19/cf-foundation-cashes-out-on-kalydeco-in-3-3b-sale-to-royalty-pharma/.

[15] Portfolio company files.

[16] Mizuho, "Restructuring the Pharmaceutical Industry," *Mizuho Industry Focus* 155, no. 11 (2014): 7, http://www.mizuhobank.com/fin_info/industry/pdf/mif_155.pdf.

This talent base can capitalize on an increase in flexibility and efficiency gained through participation in multiple projects, generating cost savings through enhanced time utilization. In 2011, for example, Boehringer Ingelheim, Merck, and AstraZeneca all closed research sites in Montreal (laying off approximately 1,500 people). The AstraZeneca site was donated to the provincial government of Quebec, and the facility was populated with contract research organizations (CROs), life sciences companies, startups, investors, and others to promote the formation of a drug discovery hub.[17]

As a result of the site closures and the establishment of the hub, Jeff Albert was able to found IntelliSyn (a CRO), recruit and retain top-tier talent, and build his new venture in a state-of-the-art facility. Jeff compares IntelliSyn to a "perfectly controlled experiment" in demonstrating the advantages of R&D externalization. He estimates that external to AstraZeneca, IntelliSyn has achieved productivity gains of approximately 1.5x as measured in both cost and time, doing similar work with the same people, same building, and same infrastructure.[18]

Policy Innovation

In stark contrast to the majority of companies that receive venture financing, companies developing new therapeutics operate within a highly regulated framework. The regulatory barriers associated with bringing new medicines to market add multiple layers of risk and complexity, resulting in lengthened development timeframes, larger capital requirements, and greater uncertainty. In an effort to decrease the regulatory burden and construct a more transparent and efficient regulatory review process, the FDA has recently launched a number of innovative new policy initiatives designed to foster greater collaboration between regulators and industry. (See also Anh Nguyen, p. 43.)

The Fast Track program provides eligible companies with a number of incentives, including more frequent interactions with the FDA to decrease ambiguity and ensure that the appropriate pre-clinical and clinical development plan required for approval is being properly managed and executed. In addition, Fast Track designees can seek accelerated approval and priority review if certain criteria are met.[19]

Accelerated Approval allows a company to seek approval for their investigational drugs based on surrogate endpoints, which are intended to serve as a substitute for clinical (functional) endpoints. For example, if a decrease in the blood levels of a specific protein is known to correlate with increased survival in a specific disease, the company can seek approval for its therapy once a sustainable decrease in that protein has been demonstrated in the relevant patient population. The result of Accelerated Approval is shorter clinical studies, lower costs, decreased regulatory burdens, and faster access to new therapies for patients.[20]

Priority Review decreases the FDA review timeline from 10 months to 6 months. Fast Track designees are also eligible for a rolling review, in which separate portions of the regulatory documents and data packages required for approval can be submitted individually. In the standard review process, a complete package has to be submitted before the review process is initiated.[21]

The Breakthrough Therapy designation provides a higher level of engagement with senior regulators and experienced reviewers to ensure that the drug granted breakthrough designation is expedited in both its development and review. In addition, each drug

17 Jeff Albert, personal communication, January 2015.

18 Ibid; while some companies have experienced an increase in total workforce (related to M&A, restructuring, etc.), the trend in R&D has been generally to the downside.

19 U.S. Food and Drug Administration, "Frequently Asked Questions: Breakthrough Therapies," 16 January 2015, http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm341027.htm.

20 Ibid.

21 Ibid.

designated as a Breakthrough Therapy is assigned a cross-disciplinary project lead to enable more effective engagement and collaboration between the various stakeholders. The overarching goal is to ensure a streamlined regulatory and development process for evaluating the safety and efficacy of promising drugs in development for severe diseases.[22]

While the Breakthrough Therapy designation has a very limited history, the results of the program to date are very encouraging. According to the FDA, 70 requests for Breakthrough Therapy designation were received between October 1, 2013 and June 13, 2014. More than 98% of the requests received a response within 60 days, a testament to the FDA's increased commitment to improving their regulatory processes and procedures, and 16 requests were granted.[23] Three drugs granted Breakthrough Therapy designation were approved in 2013, and nine in 2014.[24]

As these numbers reflect, regulatory policy innovation can have a significant impact on drug development timeframe and budgets. Over time, such changes will result in a transparent, efficient regulatory environment where the cost and time burden associated with the regulatory process is diminished and de-risked, increasing the flow of risk-capital toward emerging entities and early-stage research.

Contract Infrastructure

A direct effect of research externalization, the emergence, growth, and maturation of a highly capable, highly specialized contract research infrastructure is a key factor driving the remodeling of early-stage life sciences research. The U.S. contract research market is expected to grow by approximately 5-6% per year, from approximately $23-25 billion in 2014 to over $30 billion in 2018.[25] In addition, Bank of America Merrill Lynch estimates the total market size for outsourced life science research tasks is $90-95 billion, representing approximately two-thirds of the R&D expenditures of the top 500 biopharma companies.[26]

The services provided by these contract research organizations vary immensely and span all aspects of the drug discovery and development value chain. Additionally, organizations such as Charles River, PPD, Aptuit, and a number of others have assembled the resources and expertise to shepherd projects from early-stage discovery through the start of clinical trials (and in some cases further).[27] As an example, Aptuit has demonstrated the ability to reduce nonclinical development timelines by approximately 50% at a cost savings of approximately 40-60%.[28]

A number of these contract research organizations have expressed an interest in pursuing creative risk-sharing collaborations in which they waive a significant portion of the upfront expense to access their services, in exchange for equity, downstream royalties, milestone payments, or various combinations thereof. The ability to tailor compensation schemes and cash outflows will allow emerging companies to create significant value for their products on a decreased capital base.

For example, Calvert Research employs a hybrid service-equity model to offset costs for emerging companies developing therapies at the late pre-clinical stage. In this model, a portion of the normal retail cost of certain study services is committed by Calvert in exchange for equity. As a result, the company is able to access

22 Ibid.

23 Ibid.

24 Riley McDermid, "The FDA's Breakthrough Therapy Program by the Numbers," *BioSpace*, 31 December 2014, para. 6, http://www.biospace.com/news_story.aspx?StoryID=359491&full=1.

25 Hemavli Bali, Brigitte de Lima, and Carrie Yang, *CROs and Other Outsourced Pharmaceutical Support Services: M&A Drivers and Trends* (Results Healthcare, 2013), 3, http://www.resultshealthcare.com/media/114306/20131128_cros_and_other_outsourced_pharmaceutical_support_services_m_a_drivers_and_trends.pdf.

26 Ibid., 10.

27 Based on Mercury Fund's many conversations with these and other contract research organizations, January 2015.

28 Aptuit representatives, private communication, January 2015.

semi-dilutive capital and conserve cash while simultaneously advancing the development of their product, without any of the discontinuities associated with an extensive fundraising process. In exchange, Calvert receives an equity stake in the company with the potential to realize significant upside in a future liquidity event.[29]

As the company progresses into clinical development, firms specializing in the design and execution of clinical trials (e.g., Integrium Clinical Research) offer similar service-equity models. In addition to their traditional fee-for-service model, Integrium has partnered with a firm (PoC Capital) that invests $250,000 to $1.5 million in microcap, small cap, and privately held pre-IPO biotech companies within the early clinical proof-of-concept stages of the development cycle.[30] These investments allow Integrium to exchange its clinical services and expertise in exchange for participation in future share price appreciation. The company is able to conserve capital while generating critical, value-increasing clinical data.

As an increasing fraction of total R&D spending is allocated to external partners, the contract research infrastructure will continue to flourish and expand, with new entrants augmenting the efforts of traditional research service providers. For example, a number of academic centers have been successful in aggregating the skills and expertise to advance drug-discovery efforts in a capital-efficient manner. The Academic Drug Discovery Consortium, a nonprofit founded in 2012 to connect drug discovery scientists across academic institutes, currently consists of 121 centers across the 50 U.S. states and 9 countries worldwide.[31] Many of these centers offer their services to industry through various partnership structures and fee-for-services agreements, providing a viable alternative to more traditional providers of outsourced research and development.

The contract research industry is rapidly evolving, and a new breed of technology-enabled organizations is giving rise to a sharing economy characterized by disownership of core laboratory instruments and facilities and distributed research organizations. Powered by advances in robotics and automation technology, these firms have the potential to transform the contract research industry and empower the formation of a new class of ultra-lean life science companies.

One example is Emerald Therapeutics, founded in 2010 and pioneering the Emerald Cloud Lab: a web-based system in which researchers design their experiments over the web to be conducted at the Emerald facilities using their proprietary experiment-management software and automation technology. Upon completion of the experiment, the data is available for collection, analysis, and sharing using Emerald Cloud Lab's open source workstation.[32] Fees range from $1 to $100 per sample, with an averge cost of $5-$25 per sample.[33] Emerald currently offers 42 experiments using its platform, with plans to add another 64 by 2016.[34]

In addition to cost and time savings, it is likely that an automated experiment design and execution platform such as Emerald's will result in less error and more robust data generation, as the human component required for the execution of complex experimental protocols is minimized. Transcriptic[35] is another provider of on-demand laboratory services that allows users to draft custom experiment protocols

[29] Calvert Research, private communication, January 2014; http://calvert-research.com/.

[30] Integrium representatives, private communication, January 2015; http://www.integrium.com/.

[31] Academic Drug Discovery Consortium, "ADDC Statistics, Drug Discovery Centers," accessed 19 January 2015, http://addconsortium.org/about-statistics.php.

[32] Ashlee Vance, "Emerald Therapeutics: Biotech Lab for Hire," *BloombergBusinessweek*, 3 July 2014, http://www.businessweek.com/printer/articles/211287-emerald-therapeutics-biotech-lab-for-hire.

[33] Emerald Cloud Lab, "Frequently Asked Questions," 2014, para. 3, http://emeraldcloudlab.com/faq.

[34] Emerald Cloud Lab, "Lab Experiments," 2014, http://emeraldcloudlab.com/lab-experiments.

[35] https://www.transcriptic.com/.

for execution at their Foundry—an automated molecular biology facility and support infrastructure capable of performing a wide variety of studies. Transcriptic uses a slightly different billing approach, charging researchers based on the amount of time each piece of equipment is used to execute their protocol.[36]

Automated laboratories are not the only new elements of the contract research infrastructure, however. Assay Depot,[37] BIO BizLink,[38] and Science Exchange[39] are examples of online marketplaces that facilitate connections between scientists and researchers while dramatically expanding the equipment and knowledge base available to those researchers. Such services should ultimately result in decreased capital expenditures and staffing requirements.

Implications

With research externalization as a fundamental driver, the core components of a rental economy are infiltrating the historically closed drug discovery and development ecosystem. Increasingly, life sciences startups can take advantage of shared facilities, equipment, and administrative resources; marketplaces that enable access to top-tier researchers and service providers; an expanding and evolving fee-for-service infrastructure; and the creation of new alliances and knowledge-sharing networks. Alongside the reform of private capital markets and the emergence of crowdfunding platforms, these elements are creating an environment conducive to the formation of a new breed of companies that can achieve new efficiencies in operating leverage with decreased product development timelines and capital requirements.

As these structural changes continue to unfold and the life sciences sector becomes more tech-like, it will be interesting to watch how the process of developing new therapeutics is modified as a result. Will increased efficiencies truly decrease the costs associated with pre-clinical and clinical research, driving an increase in new company formation within the life science sector? Will pricing pressures exerted by payors drive the search for efficiencies even further? Will new company formation and capital flows into the life science sector remain the appropriate metric? Or, will a distributed ownership model take hold, where new therapeutics move more fluidly from discovery through development on a continuum of contracts between academia, contract research organizations, patient organizations, and established companies?

I believe the continued remodeling of the life science sector will fundamentally alter how new therapautics are discovered and developed, and by whom—shifting the industry away from a few fully integrated giants, and distributing efforts and expertise across an increasingly wide range of participants. These changes have implications for the formation of new therapeutics companies, but also for existing companies. Although progress may be gradual, a remodeled life science sector that results in innovative therapeutics, delivered to patients at a lower cost, will have a sustainable positive impact on human health.

Daniel Janiak

Dan is a Director with Mercury Fund, focusing on new company creation and early-stage investment opportunities in the life sciences. Previously, Dan was an Associate in Physical and Biological Technologies at In-Q-Tel. He holds a BS and a PhD from the University of Maryland, and was a Robert E. Fischell Fellow in Biomedical Engineering. Dan plays an active role in a number of Mercury Fund portfolio companies including Confluence Life Sciences, Apsara Therapeutics, DNAtrix, and Sinopsys Surgical. Kauffman Fellow Class 17. djaniak@mercuryfund.com

[36] Transcriptic, "Pricing," 2015, https://www.transcriptic.com/pricing/.

[37] https://www.assaydepot.com/.

[38] https://biobizlink.com/.

[39] https://www.scienceexchange.com/.

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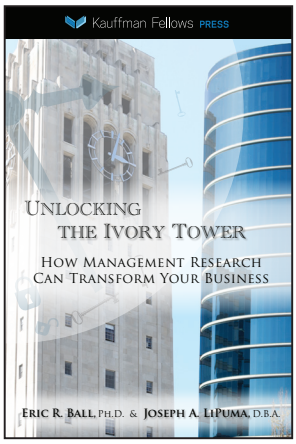

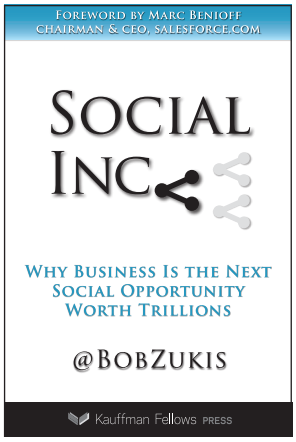

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