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Interlocking Boards in the Life Sciences Sector: A Revitalized Antitrust Risk to Prepare for Among Firms and Investors

By Scott Sher (Partner, Washington, D.C.), Todd Hahn (Senior Counsel, New York), and John Ceccio (Associate, Washington, D.C.)

A combination of recent events indicates that the life sciences sector and its investors should prepare for increased antitrust scrutiny under Section 8 of the Clayton Act and potentially Section 5 of the Federal Trade Commission (FTC) Act. Below is a summary of these events and key takeaways to help life sciences clients navigate the topic of interlocking directorates moving forward.

Section 8 of the Clayton Act: A Renewed Enforcement Priority

The prohibition on interlocking directorates has existed since 1914, but government scrutiny has been rare. However, this has changed with recent enforcement efforts by the antitrust agencies. Specifically, in October 2022, the Department of Justice (DOJ) announced that seven directors resigned from their board positions due to Section 8 concerns it raised.[1] Given the renewed enforcement priority against interlocks, it is important for clients

1 Wilson Sonsini Alert, "Seven Directors Resign from Five Public Company Boards" (Oct. 24, 2022), https://www.wsgr.com/en/insights/seven-directors-resign-from-five-public-company-boards.html.

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Exclusive Interview with Shahram Seyedin-Noor, Founder and General Partner of Civilization Ventures

Wilson Sonsini's chief business advisor for life sciences, Matthew Meyer, recently sat down with Shahram Seyedin-Noor, founder and general partner of Civilization Ventures (CV), a so-called "mentor capital firm" focused on supporting cutting-edge innovations in health tech and biology. Among other topics, they discussed Shahram's notable career and explored his perspective on investing and innovation in the life sciences industry.

Matt: You've had a remarkable career, starting as a Wilson Sonsini corporate attorney, then transitioning to an investment banker, and most recently as a venture investor. How did your tenure as a law firm associate prepare you for your current role at CV?

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to understand the contours of Section 8 described briefly below.

Section 8 of the Clayton Act generally prohibits a *"person"* from sitting on the boards of two *"corporations"* that are *"competitors."* The term "person" is broadly defined to include individuals, corporations, and unincorporated entities such as limited partnerships or limited liability companies. Further, the DOJ takes the position that a limited partnership, such as a private equity firm, can violate the statute if it appoints different representatives to serve on the boards of competitors.[2] The term "corporation" includes both public and private companies. The term "competitors" looks to the nature of the business and geographic location of operation of the two corporations. The statute states that two corporations are competitors if the "elimination of competition by agreement between them would constitute a violation of any of the antitrust laws."[3] Importantly, the DOJ has sought to use a far-reaching definition of competitors in recent Section 8 investigations, considering markets as broad as "cybersecurity" and "online advertising."

Parties are strictly liable for a violation of Section 8, meaning that the interlock does not have to lead to actual competitive harm. However, there are several safe harbors and exceptions to consider when assessing whether a violation exists:

- **Net Asset Threshold** – Section 8 applies only if both corporations have at least $41,034,000 in total capital, surplus, and undivided profits (adjusted annually).
- ***De Minimis* Exceptions** – Section 8 does not apply if either corporation's (1) competitive sales are less than $4,103,400 (adjusted annually); (2) competitive sales are less than 2 percent of that corporation's total sales (meaning its gross revenues for all products and services in the most recent fiscal year); or (3) each corporation's competitive sales are less than 4 percent of its total sales.
- **One-Year Grace Period** – If changes in the "affairs" of a corporation cause a director to become ineligible—such as a move into a new business line creating an overlap—then the corporation has one year to remove the director.

Life Sciences and Private Equity in the Spotlight

Shortly after the DOJ's Section 8 enforcement announcement in October 2022, several well-known Stanford professors published a paper claiming that their "[a]nalysis of over 2,200 life science companies reveals a network of potentially illegal interlocked boards."[4] The authors assert that the paper's "findings provide a data-driven roadmap for policymakers, regulators, and companies to further investigate the contribution of anticompetitive behavior to increased healthcare costs and to enforce the law against illegal interlocks between firms."[5] The paper also made its way through several legal publications, signaling that the DOJ will likely gain access to the complete dataset and analysis identifying the numerous life sciences companies with alleged interlocks.[6]

The same day the paper was published, top enforcers from the U.S. antitrust agencies gathered at a symposium in Salt Lake City where FTC Chairwoman Lina Khan highlighted private equity health deals as an area of focus, stating that "quality degradation…from PE rollups in the healthcare space" is "something [they are] looking at closely."[7] Chairwoman Khan's recent statements regarding healthcare deals align with her more specific focus on pharmaceutical mergers. Earlier this year, she spearheaded a two-day workshop focused solely on pharmaceutical mergers where those involved discussed a blanket presumption against large companies purchasing smaller start-ups.[8]

In conjunction, these events make it vital for the life sciences sector to understand the various ways Section 8 of the Clayton Act can manifest throughout the industry, including through board appointments of venture capital and private equity investors.

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[2] Take, for example, a private equity group that invests in multiple portfolio companies in the life sciences industry. If the private equity group designates Employee A to serve on the board of Portfolio Company A and Employee B to serve on the board of Portfolio Company B, its competitor, then the DOJ could view this arrangement as an illegal interlock unless an exception applies.

[3] 15 U.S.C. § 19(a)(1).

[4] Mark Lemley et al., "Analysis of Over 2200 Life Science Companies Reveals a Network of Potentially Illegal Interlocked Boards" (2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4253144.

[5] *Id.* at 2.

[6] Adam Lidgett, "Study Warns Life Sciences Cos. May Be In Antitrust Trouble," *Law360* (Oct. 25, 2022), https://www.law360.com/articles/1542474.

[7] Leah Nylen, "Private Equity Health Deals Prompt Scrutiny by Antitrust Agency," *Bloomberg* (Oct. 21, 2022), https://news.bloomberglaw.com/health-law-and-business/private-equity-health-deals-prompt-scrutiny-by-antitrust-agency.

[8] *See* FTC/DOJ Pharmaceutical Task Force Workshop, Federal Trade Commission (June 14-15, 2022), https://www.ftc.gov/news-events/events/2022/06/future-pharmaceuticals-examining-analysis-pharmaceutical-mergers.

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Section 5 of the FTC Act: A New Tool for Interlocking Board Members?

In early November, the FTC issued its long-awaited "Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act" ("Policy Statement").[9] The statement outlined the FTC's view that it has sweeping authority under Section 5 to take action against "unfair methods of competition" that are not in-and-of-themselves prohibited by the Sherman Act or Clayton Act. In particular, the FTC called out "interlocking directors and officers of competing firms not covered by the literal language of the Clayton Act" as an example of a potential violation under Section 5.[10] Thus, given the FTC's newfound aggressive approach to antitrust enforcement, there is reason to believe that firms and their directors could face scrutiny for alleged interlocking directorates even if they fall within a safe harbor or exception under Section 8.

Recommendation for Life Sciences Corporations

To avoid the distraction and upheaval resulting from an interlocking directorate investigation, firms in the life sciences industry would be well advised to implement an antitrust compliance program that includes a process to screen directors, officers, and potential directors and officers for affiliations with competitors. Even in situations where a safe harbor applies under Section 8, a director serving on the boards of two competitors creates a risk that competitively sensitive information will be shared, which can create business disadvantages or possibly lead to antitrust scrutiny under Section 1 of the Sherman Act, and now, potentially Section 5 of the FTC Act.

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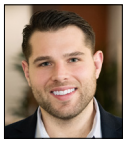

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[9] Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act, Federal Trade Commission (Nov. 10, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-regarding-scope-unfair-methods-competition-under-section-5-federal-trade-commission.
[10] *Id.* at 15.

Wilson Sonsini Hosts Women in Biotech Fall Mixer

On October 25, 2022, the firm hosted a Women in Biotech Fall Mixer for clients in the San Francisco Bay Area life sciences and biotech community. Held at the Foundry and Lux at The Cove At Oyster Point in South San Francisco, the networking event provided an opportunity for senior-level women, board members, and VC investors to reconnect and expand their networks across biotech, pharma, medtech, digital health, diagnostics, and medical devices. Overall, nearly 30 guests attended the mixer, in addition to several Wilson Sonsini women attorneys.

The event was organized by a group of the firm's women partners and others active in the life sciences and biotech space, including Maya Skubatch, Julia Minitti, Jennifer Knapp, Melissa Rick, Susan Reinstra, Amy Candido, Karen Wong, and Katharine (Kathy) Ku.

Exclusive Interview with Shahram Seyedin-Noor . . . *(Continued from page 1)*

Shahram: The art of investing and company-building involves many tools. Obviously, deep domain expertise and understanding the basics—like product-market fit (easier said than done), technical de-risking, people management, and sales—are a starting point. But what you find is that some other "structural basics" are too often ignored—things like proper board governance, effective business negotiations (often with tricky legal variables), and financial planning, for example. I think a deep training in law and finance early in my career allowed me to understand these structural elements, and that has paid dividends as an investor. In addition, it allowed me to bring hard skills to the table in starting companies as I teamed up with scientific founders to build great ventures.

Venture investing is a challenging business. What attracted you to it and what do you think makes a highly successful VC?

One key variable for me in starting a venture firm was the incredible growth we're now seeing in CV's sectors of expertise and interest within biotech, and realizing that I had a non-trivial head start as a successful operator and angel investor in the space. I wanted to capitalize on that hard-earned "unfair advantage" to pursue my passion for positive societal change through transformative life science investments. I am privileged to have the opportunity now to "invest in the change I want to see in the world." What I like a lot about venture investing is the opportunity it gives me to diversify across sectors. No less important is the opportunity it gives me to humbly mentor future leaders. After a few decades of working within companies, including ones I had founded, I really wanted to pass on my learnings to other young entrepreneurs. This "mentor capital" model that we are spearheading at Civilization Ventures is something that I am very passionate about and it sets us apart.

Tell me a little about CV's investment approach. Can you highlight one of your notable investments?

What sets us apart, I believe, is that we are not afraid to take a risk on green founders with high potential. In biotech, that's actually an innovation. In tech investing, it's standard. But the old guard of biotech is accustomed to replacing inexperienced management quickly—without really giving a new founder/CEO a chance to grow into the position, or providing the necessary mentorship to help get them there. We are dedicated to the concept that founders/CEOs are "athletes" who need coaching and training to achieve their full potential. One example is our investment in Rewrite Therapeutics, a genomic medicine (DNA editing) company acquired earlier this year by Intellia. We led the seed financing and rolled up our sleeves to help assemble a small but elite team of business veterans around the scientific founder and first-time CEO, Shakked Halperin. Within 18 months of our investment, Rewrite was acquired for $200 million by Intellia. Traditional biotech VCs would have "run" the company and replaced execs. We instead supported the brilliant founders and worked collaboratively to achieve a transformative outcome for them. I should mention we also helped secure a $30 million financing term sheet, which the founders ultimately decided to turn down for the acquisition.

The other major innovation is that we've gone after sectors within biotech that were long ignored by the traditional, dominant old guard of the VC industry: diagnostics, cutting-edge genomic medicine, and digital health. When I started Civilization Ventures in 2017, all these areas were novel. Now, less so—but fortunately, we've built a strong track record and head start with seven exits and four unicorns, with $100 million under management. We've been lucky, to be sure, but as I like to say, "It wasn't an accident."

As an alumnus of Wilson Sonsini, do you use the firm to support investments, and if so, how?

We use Wilson Sonsini as our fund's law firm, and we also use the firm heavily as corporate and IP counsel for our portfolio companies. We have close working relationships and a high level of trust with key partners at the firm, and for me personally, it's very gratifying to come full circle in my career. I started at Wilson Sonsini in 1999 as a first-year associate fresh out of Harvard Law School. The fact that I can now work with the firm in building the future of biotech is a privilege. Wilson Sonsini sets the bar very high. I should mention that my identical twin brother started with me at the firm right out of law school, and later became a partner in the litigation department before founding his own boutique litigation shop. So, my roots at Wilson Sonsini run deep! I have enormous respect for the lawyers there.

> "The fact that I can now work with the firm in building the future of biotech is a privilege. Wilson Sonsini sets the bar very high.... We highly recommend Wilson Sonsini's business advisory team to our founders."

Has the firm's business advisory practice worked with any of your companies? Do you see this as a valuable complement to Wilson Sonsini's legal offerings?

You and the rest of the firm's business advisory team are absolutely stellar (unpaid plug). Just to give one anecdote among many, Matt engaged early with Jake Chabon, the founder and CEO

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of Foresight Diagnostics—one of our largest investments—as Jake spun the company out of Stanford. I think Matt's early guidance and introductions made a real difference and were pivotal in getting the company to that first financing milestone. Starting a company is incredibly challenging and can be daunting, but having Matt and his team in your corner is an advantage. We highly recommend Wilson Sonsini's business advisory team to our founders.

Speaking of Foresight Diagnostics, the young company moved from the Bay Area to Denver in late 2020. Do you see this as a trend among Bay Area life science companies?

At the time, the move was seen by some as somewhat controversial, as Silicon Valley is viewed as the epicenter of talent and biotech innovation. However, we supported the founders from day one in following their own North Star and setting up headquarters where they thought best, for reasons having to do with both professional excellence and family connections in Colorado. In hindsight, the move was genius, as it set us up for future success. Foresight is "the" diagnostics company to work for in Colorado. As it turned out, the talent in Colorado is spectacular for life sciences and our team now is second to none.

Given the recent headwinds in the public and private markets, how are you seeing this impact your portfolio companies? Do you have any suggestions for VC-backed companies to best manage through this challenging environment?

I'm happy that gravity has finally taken hold and that the frothy markets are behind us. I've been on the record since 2019 calling out the obvious biotech bubble that was building. I think, if anything, the markets have overreacted now—as they often do—and there's perhaps a good buying opportunity in the public markets. For us, the lower valuations are a welcomed return to sanity that allows us to reduce our cost basis in new investments and hopefully will lead to better long-term exit multiples. The real test will be which funds can show their mettle in the new normal—which really is the old normal—in biotech. Back to the future. Having said all that, the innovation we're seeing now is transformational and no short-term market correction will change that trajectory. It's an exciting time to invest in biotech.

Given your tenure at the firm, can you share a good Wilson Sonsini story with us?

I started out at Wilson Sonsini in the Alan Austin group in 1999. Alan was the managing partner of the firm at that time, and a revered name in Silicon Valley. I felt truly privileged to be in his group. Less than a year after my joining, he left to join Accel as a partner, and many of the senior associates in the group also left. It was a heady time. I remember working on IPOs during the winter holidays at the end of 1999 late into the night, watching the Nasdaq index climb ever higher. As an econ undergrad (Pomona College - go Sagehens!), I had studied market bubbles and it was obvious to me then that we were in a major bubble as soon as I started working at Wilson Sonsini the week after taking the California bar earlier that year. When I told this to one of the partners in my group, a junior partner at the time whom I worked with and liked, his cheeky response was, "Ha! Go back to your cave, you bear!" That memory makes me smile and reminds me both of the craziness of that era and the fun (and intense) culture at the firm. I had fun and learned a ton.

Prior to founding Civilization Ventures in 2017, Shahram Seyedin-Noor was a life sciences entrepreneur and angel investor for more than a decade. He was the founding CEO and later Executive Chairman of Rgenix, a biotech company with multiple first-in-class therapeutics for cancer now in Phase 2 clinical trials. Prior to Rgenix, Shahram was founding CFO and VP of Corporate Development at NextBio, a genomics pioneer acquired by Illumina. He sits on the boards of Rewrite and Foresight, and has been one of the first checks into frontier tech companies such as Omada Health, CatalogDNA, Evonetix, BilliontoOne, Lemonaid Health, Outpace Bio, Ample, Avantome (acquired by Illumina), Bina (acquired by Roche), Rocket Pharma (IPO), and Counsyl (acquired by Myriad). Shahram began his career in Silicon Valley over 20 years ago at Wilson Sonsini and went on to advise some of the world's preeminent technology leaders while at Goldman Sachs. He earned his J.D. from Harvard Law School and obtained a B.A. in economics from Pomona College. To learn more about Civilization Ventures, visit https://civilizationventures.com/.

San Francisco-based Matthew Meyer leads Wilson Sonsini's life sciences business advisory practice—an innovative practice aimed at providing start-up and emerging growth life sciences companies with business insights, capabilities, transactional support, and strategies to help them thrive and address some of their most challenging issues. Matt is an experienced business executive and corporate attorney who has held diverse roles of increasing responsibility across a wide range of private and public biopharma, medtech, and precision medicine companies, including Pfizer, Novartis, and CareDx. Click here to learn more about the firm's life sciences business advisory practice.

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Life Sciences Venture Financings for Wilson Sonsini Clients

By Scott Murano (Partner, Palo Alto)

The table below includes data from life sciences transactions in which Wilson Sonsini clients participated across the second half of 2021 and the first half of 2022. Specifically, the table compares—by industry segment—the number of closings, the total amount raised, and the average amount raised per closing across the two six-month periods.

	2H 2021	2H 2021	2H 2021	1H 2022	1H 2022	1H 2022
Life Sciences Industry Segment	**Number of Closings**	**Total Amount Raised ($M)**	**Average Amount Raised ($M)**	**Number of Closings**	**Total Amount Raised ($M)**	**Average Amount Raised ($M)**
Biopharmaceuticals	52	$1,797.89	$34.57	47	$1,147.57	$24.42
Genomics	10	$332.08	$33.21	12	$268.64	$22.39
Diagnostics	12	$137.49	$11.46	19	$600.34	$31.60
Medical Devices & Equipment	41	$877.40	$21.40	59	$2,311.78	$39.18
Health IT	12	$146.82	$12.24	13	$341.42	$26.26
Healthcare Services	18	$553.77	$30.76	30	$586.74	$19.56
Total	**145**	**$3,845.45**		**180**	**$5,256.49**	

The data demonstrates that venture financing activity increased from the second half of 2021 to the first half of 2022 with respect to both the total number of closings and the total amount raised. Specifically, the total number of closings across all industry segments increased 24.1 percent, from 145 to 180, while the total amount raised across all industry segments increased 36.7 percent, from $3,845.45 million to $5,256.49 million.

Notably, the industry segment with the largest number of closings during the first half of 2022—medical devices and equipment—experienced a substantial increase in number of closings and total amount raised from the second half of 2021 to the first half of 2022. Specifically, the number of medical devices and equipment closings increased 43.9 percent, from 41 to 59, while the total amount raised increased 163.5 percent, from $877.40 million to $2,311.78 million.

> Venture financing activity increased from 2H 2021 to 1H 2022 with respect to both the total number of closings and the total amount raised. The total number of closings across all industry segments increased 24.1 percent, from 145 to 180, while the total amount raised increased 36.7 percent, from $3,845.45 million to $5,256.49 million.

In contrast, the industry segment with the second-largest number of closings during the first half of 2022—biopharmaceuticals—decreased in both number of closings and total amount raised from the second half of 2021 to the first half of 2022. Specifically, the number of biopharmaceuticals closings decreased 9.6 percent, from 52 to 47, while the total amount raised decreased 36.2 percent, from $1,797.89 million to $1,147.57 million.

Meanwhile, following the upward trend in medical devices and equipment, the industry segment with the third-largest number of closings during the first half of 2022—healthcare services—experienced an increase in both number of closings and total amount raised from the second half of 2021 to the first half of 2022. Specifically, the total number of healthcare services closings increased 66.7 percent, from 18 to 30, while the total amount raised increased 6.0 percent, from $553.77 million to $586.74 million. Similarly, the industry segments with the fourth- and fifth-largest number

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Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 6)*

of closings during the first half of 2022, diagnostics and health IT, respectively, experienced an increase in both number of closings and total amount raised from the second half of 2021 to the first half of 2022. Specifically, the total number of diagnostics closings increased 58.3 percent, from 12 to 19, while the total amount raised increased 336.6 percent, from $137.49 million to $600.34 million. The total number of health IT closings increased 8.3 percent, from 12 to 13, while the total amount raised increased 132.5 percent, from $146.82 million to $341.42 million.

Finally, genomics—the sixth-largest industry segment during the first half of 2022—experienced an increase in total number of closings and a decrease in total amount raised from the second half of 2021 to the first half of 2022. Specifically, the total number of genomics closings increased 20 percent, from 10 to 12, and the total amount raised decreased 19.1 percent, from $332.08 million to $268.64 million.

In addition, our data generally suggests that earlier-stage financing activity, as a percentage of all financing activity and measured by number of closings, decreased from the second half of 2021 to the first half of 2022, while later-stage activity improved. In particular, Series A and Series B financing activity decreased from the second half of 2021 to the first half of 2022, and Series C and later activity increased. Specifically, the number of Series A closings as a percentage of all closings decreased from 22.1 percent to 17.8 percent, and the number of Series B closings as a percentage of all closings decreased from 17.5 percent to 14.1 percent. The number of Series C and later closings as a percentage of all closings increased from 7.8 percent to 11 percent.

> From 2H 2021 to 1H 2022, average pre-money valuations for life sciences companies increased across the board for earlier-stage equity financings, including Series Seed, Series A, and Series B financings, and decreased for Series C and later-stage financings

From the second half of 2021 to the first half of 2022, average pre-money valuations for life sciences companies increased across the board for earlier-stage equity financings, including Series Seed, Series A, and Series B financings, and decreased for Series C and later-stage financings. The average pre-money valuation for Series Seed financings increased 35.8 percent, from $8.27 million to $11.23 million; for Series A financings, it increased 22.2 percent, from $33.58 million to $41.04 million; and for Series B financings, it increased 60.2 percent, from $181.49 million to $290.82 million. On the other hand, the average pre-money valuation for Series C and later-stage financings decreased 64.9 percent, from $810.13 million to $284.71 million.

Overall, the data generally indicates that there was more financing activity during the first half of 2022 compared to the second half of 2021 in terms of number of closings and total amount raised—a welcome shift from our prior report. That said, the data demonstrated a shift away from earlier-stage financing activity in favor of Series C and later-stage financing activity. Companies fortunate enough to secure earlier-stage financing were rewarded, however, with significantly improved pre-money valuations over the prior six-month period, while companies raising Series C and later-stage financing were not able to raise money at similar valuations as the prior six-month period, notwithstanding the relative increase in activity. We would expect this trend to continue as the economy continues to emerge from a prolonged period of inflation and ongoing concerns about a recession.

*For further analysis regarding recent venture financing transactions handled by Wilson Sonsini, please refer to the firm's Q3 2022 edition of *The Entrepreneurs Report*.

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FDA Clarifies Its Digital Health Policy for Clinical Decision Software Functions Exempt from FDA Regulation

By James R. Ravitz (Partner, Washington, D.C.), Georgia C. Ravitz (Partner, Washington, D.C.), and Paul S. Gadiock (Of Counsel, San Francisco)

In the past decade, the digital health industry has witnessed the proliferation of clinical decision support (CDS) software. At a very high level and subject to the limitations discussed below, CDS is software that is intended to display or analyze a patient's medical information for the purpose of supporting or providing recommendations to a health care professional about the patient's disease or condition. To qualify as CDS, it is essential that the software enable the health care professional to independently review the basis for the recommendations so that the health care professional does not rely primarily on the CDS recommendations to make a clinical diagnosis or treatment decision. CDS can take many forms, such as computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information. The software's utility is not the sole driver of its expansion—CDS manufacturers and developers enjoy a statutory carve-out from U.S. Food and Drug Administration (FDA) regulation.

The 21st Century Cures Act was enacted in December 2016 and specified that digital health software functionalities satisfying the four criteria below would be excluded from the Federal Food, Drug, and Cosmetic Act's definition of medical device and therefore not regulated by the FDA:

1. The software is not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
2. The software is intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information;
3. The software is intended for the purpose of supporting or providing recommendations to a health care provider (HCP) about prevention, diagnosis, or treatment of a disease or condition; and
4. The software is intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

In September 2022, the FDA issued its digital health final guidance, "Clinical Decision Support Software," a critical policy tool in determining whether a software functionality will be considered CDS software, particularly in light of the complex criteria above. The final guidance is actually the FDA's third attempt at explaining how it will apply the criteria. The first two attempts came in the form of a 2017 draft guidance and a 2019 *revised* draft guidance, and the policy has shifted, at times substantially, between the three iterations.

A few of the final guidance's most significant changes since the 2019 revised draft guidance relate to Criteria 2 and 3 above. With respect to Criterion 2, the FDA clarified its position that to be considered "medical information about a patient," the information must be the type of information that normally is, and generally can be, communicated between HCPs in a clinical conversation or between HCPs and patients in the context of a clinical decision, meaning that the relevance of the information to the clinical decision being made is well understood and accepted. Prior to the final guidance, many industry participants interpreted "medical information about a patient" to be much broader than what is normally communicated between HCPs in a clinical conversation, so the final guidance's policy represents an apparent narrowing of the criterion.

The FDA also introduced the concept of "sampling frequency," and its impact on qualifying as CDS is significant. If information is considered "medical information about a patient," it is permitted under Criterion 2; however, if the information is a pattern, it would not qualify under Criterion 1 and consequently exclude the software from the CDS paradigm. To help illustrate the distinction, a single, discrete test or measurement result that is clinically meaningful (e.g., a blood glucose lab test result) is medical information, while a more continuous sampling of the same information (e.g., continuous glucose monitor readings) is a pattern/signal. As discussed above, a software function that is intended to acquire, process, or analyze a pattern/signal from a signal acquisition system fails Criterion 1 and remains a device.

The final guidance also describes a couple ways in which a software provides "specific preventive, diagnostic, or treatment output or directive," which would exclude it under Criterion 3 (even though the basis for the recommendations is provided to satisfy Criterion 4). The first relates to the concept of "automation bias," the

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FDA Clarifies Its Digital Health Policy . . . *(Continued from page 8)*

propensity of humans to over-rely on a suggestion from an automated system. The FDA believes that automation bias would fail to meet Criterion 3 and states that providing a *list* (which can be a prioritized list) of preventive, diagnostic, or treatment options rather than a single recommendation can help avoid it. The final guidance also states that software that provides information that a specific patient may exhibit signs of a disease or condition, or one that identifies a risk probability/score for a specific disease or condition, would similarly be providing a specific preventive, diagnostic, or treatment output and therefore not satisfy Criterion 3.

It is important that readers keep in mind that the CDS final guidance does not exist in a vacuum and should be considered alongside other critical FDA digital health guidance, such as the General Wellness: Policy for Low Risk Devices; Policy for Device Software Functions and Mobile Medical Applications; and Multiple Function Device Products: Policy and Considerations. Indeed, if a software functionality does not fit within the CDS paradigm, it may still be eligible for decreased FDA regulation or even enforcement discretion. For additional information on this topic and the FDA's Digital Health Initiative, please read the Wilson Sonsini Insight, "FDA Finalizes Clinical Decision Support (CDS) Software Guidance."

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FDA Completes First Pre-Market Consultation for Lab-Grown Meat Using Animal Cell Culture Technology

By Georgia C. Ravitz (Partner, Washington, D.C.) and Eva F. Yin (Partner-Elect, Seattle)

In November 2022, the U.S. Food and Drug Administration (FDA) evaluated safety assessment information submitted by UPSIDE Foods, Inc. (UPSIDE) on its animal cell culture technology for human food consumption. This technology takes living cells from chickens and grows cells in a controlled environment to make cultured animal cell food products for human consumption. Following its pre-market consultation, the FDA concluded that foods comprised of or containing the cultured cellular material resulting from the production process defined in UPSIDE's submission are "as safe as comparable foods produced by other methods and would not contain substances that adulterate the food."[1] This decision marks a watershed moment in the food industry, as animal cell culture technology continues to revolutionize the global meat and poultry industry. For U.S. consumers, this decision marks a major step toward having more food options in supermarkets, restaurants, and consumers' homes.

The FDA pre-market consultation process is not an approval process, as companies that operate in this space are subject to regulation by both the FDA and the United States Department of Agriculture (USDA). The FDA's pre-market consultation covers an evaluation of a firm's production process and the cultured cell material made by the production process, including cell lines, cell banks, manufacturing controls, and any other components of the food. In addition to FDA regulatory requirements with respect to facility registration for the cell culturing part of the process, manufacturers are subject to inspection by the USDA's Food Safety and Inspection Service (USDA-FSIS) for the food manufacturing portion of the establishment. The labeling of the food products is subject to regulation by both the FDA and USDA. Before the food enters the U.S. market, it must include a mark of inspection from USDA-FSIS. The FDA has stated that it is ready to work with other companies developing cultured animal cell food and production processes, and encourages companies to engage with the FDA early in their product and process development phase, well in advance of making any submissions.

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[1] FDA response letter to UPSIDE, available at https://www.fda.gov/media/163260/download.

Wilson Sonsini and Other Key Life Sciences Stakeholders Launch Representative Term Sheet

Since the spring of 2020, Wilson Sonsini and a group of academic institutions, investors, and other law firms—listed below—have been working together to create a "representative" term sheet that an investor and an academic institution might use to begin discussions around launching a life science start-up. The objective was to create a reasonable approach, with terms and clauses that most parties could use in most situations. The philosophical underpinnings can be found here: "Term Sheet Recommendations for Launching University Life Science Startups" and "Recommended Process Improvements for Launching University Life Science Startups," initially released in December 2020.

The hope is to significantly reduce the amount of time spent negotiating these deals across the early-stage life sciences industry, which could result in therapeutics, diagnostics, and medical devices reaching the market months or years earlier, with corresponding benefits to patients worldwide

Since then, the creators have incorporated those principles into a term sheet template (available in both PDF and Word versions) with full clauses, which can be downloaded and used freely by any parties that wish to do so. The hope is to significantly reduce the amount of time spent negotiating these deals across the early-stage life sciences industry, which could result in therapeutics, diagnostics, and medical devices reaching the market months or years earlier, with corresponding benefits to patients worldwide.

One important note: The creators use "representative" to describe the term sheet because the great majority of the terms would be considered reasonable by parties on both sides. As a result, in many situations, the term sheet could be used without significant further edits. However, it should be noted that any given institution or investor may have certain preferred approaches or policies about which they may feel strongly. For instance, some institutions have particularly strong feelings around sublicensing income, reservation of rights, or access to future improvements—and some investors have equally strong feelings about equity, success fees, or board observer seats. Realistically, it would have been impossible to create a single document that incorporated all possible variations. Accordingly, some of the contributing entities and other parties may need to use alternative approaches to those in the term sheet template, even if they have approved the general approach promoted here, so nothing in these documents should be seen as binding any of the creator organizations. Rather, the term sheet should be viewed as a reasonable approach overall for most situations.

Over the next few months, the creators hope to release a full license agreement template based on this term sheet. For any questions, comments, or concerns, or if you would like to have your institution added to the list of endorsers below, please email techtransferVCstartups@gmail.com.

The creators of the term sheet include the following (individual contacts noted in parentheses):

Academic institutions: Columbia (Orin Herskowitz, Ofra Weinberger, and Melissa Cohen), Duke (Robin Rasor), Harvard (Isaac Kohlberg), Johns Hopkins (Steve Kousouris), MIT (Lauren Foster), Stanford (Karin Immergluck), Indiana University (Teri Willey), University of Michigan (Rick Brandon), University of Kentucky (Ian McClure), University of Pennsylvania (John Swartley), and Yale (Jon Soderstrom)

Venture capital firms: 5AM Ventures (Galya Blachman, Jessica Alfano, and Deb Palestrant), Atlas (Kevin Bitterman), Omega Funds (Deirdre Cunnane), OUP (Kirsten Leute and Bill Harrington), Polaris (Amy Schulman and Alexandra Cantley), RA Capital (Sarah Reed, Nadim Shohdy, and Josh Resnick), and Venrock (Cami Samuels)

Law firms: Cooley (Geoff Spolyar), Goodwin (Sarah Solomon), and Wilson Sonsini (Kathy Ku)

The term sheet has been reviewed and is endorsed by the technology licensing offices of California Institute of Technology (Caltech), Columbia, Cornell University, Duke, Harvard, Indiana University, Johns Hopkins, MIT, New York University, Stanford, University of Michigan, University of Kentucky, University of Pennsylvania, and Yale, as well as venture capital firms 5AM Ventures, A16z, Atlas, F-Prime, Omega Funds, OUP, Polaris, RA Capital, Sofinnova Investments, and Third Rock Ventures.

Jon Soderstrom Joins Wilson Sonsini as Chief Licensing Advisor

On November 28, 2022, Wilson Sonsini announced that Jon Soderstrom has joined the firm as its chief licensing officer (East) in the New York office. Jon is well known throughout the East Coast's venture capital and academic communities as an expert in technology transfer. He was the managing director of Yale University's Office of Cooperative Research (now Yale Ventures) until June 2021, when he stepped down to take a role as strategic advisor for technology transfer and commercialization. During Jon's more than 25 years at the university, his department was responsible for managing Yale's intellectual assets in a way that generates the most benefit for the public and offers a financial return to back additional research efforts through corporate partnerships. It also oversaw the development of business concepts for new companies based on the university's intellectual property.

"Jon was crucial in Yale's development of research projects that brought cutting-edge technology and ideas into everyday life," said Ian Edvalson, Wilson Sonsini partner and co-leader of the firm's technology transactions practice. "His standing within the entrepreneurial community on the East Coast will help Wilson Sonsini develop important relationships with clients. His grasp of technology and pharmaceuticals—as well as his understanding of how companies are built—will be a huge benefit to our clients. We are excited that Jon has joined the firm and look forward to the future."

Jon recently represented Yale in a collaboration that created a "VC and Tech Transfer Template for an Early-Stage Life-Science Startup License" to help entrepreneurs launch start-ups based on their discoveries and innovations. Please see the article on page 10 for more information.

Jon was also instrumental in the development of more than 45 new ventures at Yale that raised over $1 billion in venture capital backing. The companies include Achillion Pharmaceuticals (NASQ: ACHN), Arvinas (NASQ: ARVN), NextCure (NASQ: NXTC), Biohaven Pharmaceuticals (NYSE: BHVN), and Inozyme Pharma (NASQ: INZY).

Before joining Yale in 1996, Jon served as the Director of Program Development at Oak Ridge National Laboratory and as the Director of Technology Licensing for Martin Marietta Energy Systems, where he negotiated the first patent license and Cooperative Research and Development Agreements from a National Laboratory to a commercial partner. Jon earned a Ph.D. from Northwestern University in 1980 and a B.A. from Hope College in 1976.

"[Jon's] standing within the entrepreneurial community on the East Coast will help Wilson Sonsini develop important relationships with clients. His grasp of technology and pharmaceuticals—as well as his understanding of how companies are built—will be a huge benefit to our clients."

- Wilson Sonsini partner and technology transactions co-leader Ian Edvalson

To learn more about Jon's background, please see his wsgr.com bio.

Firm Holds Annual Life Sciences Investment Forum

From December 6-8, 2022, Wilson Sonsini held its annual Life Sciences Investment Forum, which provided a unique opportunity for investors to connect with promising life sciences start-ups to discuss potential funding and/or collaborations. More than 150 life sciences companies applied to privately pitch their company or idea for investment, with over 90 investors registered to review submissions in advance and select the applicants they wanted to meet with. Overall, more than 250 one-on-one meetings were scheduled over the course of the three days. We look forward to future editions of the forum continuing to foster funding innovation.

Wilson Sonsini Hosts 27th Annual Phoenix Conference

On October 19-21, 2022, the firm hosted its 27th annual Phoenix Conference, which was attended by more than 180 top-level executives from large healthcare companies and CEOs of small, venture-backed firms who discussed critical issues of interest to the medical device industry today. Held at The Ritz-Carlton in Half Moon Bay, California, the event also provided an opportunity for attendees to network and gain valuable insights from both industry leaders and peers.

The conference kicked off on Wednesday, October 19 with a panel discussion on the importance of diversity and inclusion initiatives in the medtech industry to optimize business, followed by a cocktail reception and welcome dinner. The next morning, the program began with a series of panel sessions addressing topics that included successful medtech companies facing and overcoming seemingly dire challenges; the evolving reimbursement landscape; lessons learned with respect to operating in the new "beyond COVID" environment; and the current climate for medtech investment in private companies and exits through M&A and public offerings.

During the evening of October 20, the conference featured the 2022 Phoenix Hall of Fame Reception, Dinner, and Awards Ceremony, which honored the accomplishments of companies and individuals in the following categories:

Most Promising New Product Award: The Intracept® System by Relievant

Emerging Growth Company Award: ShockWave Medical Inc.

Innovator Award: Mir Imran, Founder, InCube Labs, InCube Ventures, and more than 20 other medical device companies; holds over 400 issued patents

Lifetime Achievement Award: Dr. Paul Yock, Martha Meier Weiland Professor in the Stanford School of Medicine; Stanford Professor of Bioengineering, Emeritus; and Co-founder, Stanford Biodesign

Finally, on Friday, October 21, the conference concluded with sessions addressing novel financing models and considerations for sourcing capital in the current landscape; insights as to how medtech may fare in a recessionary environment; and what the 2022 midterm elections will mean for investors, innovators, and America. In addition, Lifetime Achievement Award winner Dr. Paul Yock sat down for an interview with David Cassak of the Medtech Strategist to discuss his career path.

For more information on the 2022 Phoenix Conference, visit https://phoenix.wsgrevents.com/.

USJMF, Japan Society of Northern California, and Wilson Sonsini Host Successful Japan Trade Mission and Roadshow for Healthcare Companies

During the week of October 31, 2022, U.S.-Japan Medtech Frontiers (USJMF), in conjunction with its new partner, The Japan Society of Northern California,

and Wilson Sonsini, led a group of representatives from U.S. start-up and growth-stage life sciences companies to Japan for the Ninth Annual Japan Healthcare Week. The week's activities—which took place primarily in Tokyo and Awaji Island—included various conferences, symposiums, site visits, and social events designed to facilitate access to potential Japanese partners, investors, distributors, customers, and others; help the companies gain visibility; and provide a hands-on introduction to the Japanese medical device and life sciences ecosystem.

The Ninth Annual Tokyo Executive Symposium on "The Future of Precision and Predictive Healthcare" took place in conjunction with the U.S. Embassy in Tokyo. At the exclusive, invite-only event, the U.S. delegate companies had the opportunity to pitch themselves to approximately 150 senior executives of large Japanese healthcare and diversified businesses who were in attendance. The symposium also featured speeches by USJMF Chairman Jack Moorman; Wilson Sonsini partner Elton Satusky; and Akihiko Soyama, president and CEO of the Life Science Innovation Network Japan, a co-organizer of the symposium, as well as a keynote address from renowned Fogarty Institute CEO Andrew Cleland.

"Participating in the symposium was a unique and rewarding opportunity that has resulted in fruitful discussions with several Japanese strategics," said Kirk Zeller, CEO and co-founder of Progressive Neuro, Inc.

In addition, the U.S. delegates attended the Healthcare Forum on Awaji Island (Hyogo Prefecture) in conjunction with Pasona Corporation. The forum drew a broad audience from Japanese medical device and life sciences companies, academic translational medicine, parties interested in biodesign, and others in the healthcare ecosystem. Representatives from the U.S. companies also participated on panels at the event.

"For me, the highlight of the trip following a long absence due to COVID was deepening relationships with old friends and networking with new attendees whom I had not previously met," said Elton Satusky.

"Just being there, you make so many connections, as there are only a couple degrees of separation in healthcare—and it's amazing how many mutual connections you already have. I was absolutely delighted to observe so many Japanese and U.S. companies networking and to hear about the productive discussions that resulted from those new relationships," added Chairman Moorman.

Founded in 2013, USJMF is a Silicon Valley-based nonprofit whose mission is to share best practices for medical device innovation and promote networking and collaboration between U.S. and Japanese medical device organizations. Wilson Sonsini is a co-founder and sponsor of USJMF, and partners Casey McGlynn and Elton Satusky serve on the organization's board of directors, along with Chairman Moorman, Dr. Fumiaki Ikeno of the Stanford University Biodesign Program, Kirk Zeller of Silicon Prairie Center and Nichibei MedTech Advisors, LLC, and Masa Ishii of Azca

Continued on page 14...

USJMF, Japan Society of Northern California, and Wilson Sonsini Host . . . *(Continued from page 13)*

Venture Partners. In 2021, USJMF merged with The Japan Society of Northern California and created US-Japan Healthcare Connection, under which the events will be marketed moving forward.

"When we decided to form USJMF, Casey McGlynn had one condition—that we do a trip every year!" said Chairman Moorman. "As a result of that commitment, we have grown our flagship events and added even more to the program, so that now it's an entire week of value-add networking and other events. In 2013, it was difficult to find Japanese start-ups while large Japanese companies were slow to act and reluctant to take risks. We have seen incredible progress over the past several years, and we are proud to have played a small role in that development."

"Based on all the feedback we received, it was an extremely informative and productive experience," noted Elton Satusky. "It's just another value-added service we provide to our clients—beyond being lawyers, we are business advisors with deep industry expertise, networks, and connections that can help our clients take their business to another level."

Wilson Sonsini to Hold Inaugural 1L Life Sciences Summit; Applications Due February 3

The firm is excited to announce that applications are now open for its inaugural 1L Life Sciences Summit on March 23-24, 2023. The summit, which will bring together law students from across the country with interest and/or experience in the life sciences, will be held over the course of two days in our Boston office.

The event will introduce 1L students to the firm's diversity of life sciences practice areas, to help them explore how they can leverage their life sciences background and interests in their future legal careers. They will have the opportunity to meet our attorneys, learn what it's like to practice law in each of our life sciences practice groups, hear from our clients and attorneys about their different career paths within the industry, and practice the art of networking. Attendees will also be matched with an attorney mentor and invited to virtual professional development trainings and a mock interview program following the summit.

Eligibility:
First-year law students enrolled at ABA-accredited law schools are eligible to apply. Pre-law students with life science backgrounds who have been admitted to ABA-accredited law schools will also be considered.

Applications:
To apply, please complete the 1L Life Sciences Summit Online Application. The following items will be required for each application: your resume; your undergraduate, graduate (if applicable), and first semester/quarter law school transcript; and the completion of an assessment using Suited. In addition, you may optionally submit a brief personal statement detailing any relevant background you have in the life sciences and/or your reasons for pursuing a life sciences practice.

The deadline for applications is Friday, February 3, at 5:00 p.m. Pacific. Applicants will be notified and travel arrangements made from February 20-24.

Travel and Costs:
Travel and reasonable related expenses, including transportation, lodging, and meal costs for the students selected to attend, will be covered by Wilson Sonsini in accordance with our travel policies. Currently, any individuals who visit a firm office or attend firm events must be fully vaccinated against COVID-19. You will be asked to attest to your vaccination status if you are selected to participate in the summit, and we encourage anyone who has not already done so to receive the COVID-19 vaccine as soon as possible.

For any questions about the 1L Student Life Sciences Summit, please contact lawstudents@wsgr.com.

MedTech Innovator and BioTools Innovator Applications for 2023 Now Open

As a longtime partner of MedTech Innovator—the world's largest accelerator for medical technology, digital health, and diagnostic companies—Wilson Sonsini is pleased to share that the 2023 application cycle for MedTech Innovator and BioTools Innovator is now open. Applications are due January 31, 2023. Please see below for additional details.

MedTech Innovator is the largest accelerator of medical devices in the world and the medical technology industry's global showcase and accelerator for innovative medical device, digital health, and diagnostic companies. Its mission is to improve the lives of patients by accelerating the growth of companies that are transforming the healthcare system. Accelerator companies compete for up to $500,000 in non-dilutive funding. To apply, visit http://medtechinnovator.org/apply.

BioTools Innovator (powered by MedTech Innovator) is the first-ever accelerator for life science tools and diagnostics. After nearly a decade in the MedTech industry, MedTech Innovator launched BioTools Innovator in 2021 with a mission of improving human health by supporting innovators developing a broad spectrum of biotechnology products, platforms, and services. Accelerator companies compete for up to $300,000 in non-dilutive funding. To apply, visit http://biotoolsinnovator.org/apply.

What They're Looking For:

MedTech Innovator is looking for outstanding early-to-mid-stage medical device, digital health, and diagnostics companies, while BioTools Innovator is seeking outstanding early-to-mid-stage life science research tools and molecular-based diagnostic companies.

Benefits:

Companies selected for MedTech Innovator and BioTools Innovator programs will receive:

- High-profile visibility
- Access to investors, stakeholders, and decision-makers
- A network of mentors and peers
- Participation in a customized educational curriculum

Companies selected for the 2023 cohort will also compete for $1 million in cash prizes. There is no application fee, and MedTech Innovator and BioTools Innovator do not charge or take equity for participation.

For More Information:

MedTech Innovator:
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BioTools Innovator:
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MedTech Innovator Asia Pacific:
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Select Recent Life Sciences Client Highlights

Arcellx and Kite Announce Strategic Collaboration to Co-Develop and Co-Commercialize Late-Stage Clinical CART-DdBCMA in Multiple Myeloma
On December 9, 2022, clinical-stage biotechnology company Arcellx and Gilead-owned biopharmaceutical company Kite announced a global strategic collaboration to develop and commercialize Arcellx's lead late-stage myeloma candidate. The deal includes up to $3.9 billion in total contingent consideration, with Kite providing Arcellx $225 million in an upfront payment, along with a $100 million equity investment. The companies will together share development, clinical trial, and commercialization costs for Arcellx's lead late-stage product candidate CART-ddBCMA. Wilson Sonsini advised Arcellx on the transaction.

Prometheus Biosciences, Inc. Announces Pricing of Public Upsized $500 Million Offering of Common Stock
On December 8, 2022, Prometheus Biosciences, Inc., a clinical-stage biotechnology company pioneering a precision medicine approach for the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment of immune-mediated diseases, announced the pricing of an underwritten offering of 4,545,455 shares of its common stock at a price to the public of $110 per share. The gross proceeds to Prometheus from the offering, before deducting underwriting discounts and commissions and other offering expenses, are expected to be $500 million. Wilson Sonsini advised Prometheus Biosciences on all aspects of IP and patent matters related to the transaction.

Cajal Neuroscience Launches with $96 Million
On November 29, 2022, Cajal Neuroscience, a biotechnology company integrating human genetics, functional genomics, and advanced microscopy to discover novel targets and therapeutics for neurodegeneration, announced its launch with the completion of a $96 million Series A financing. The financing was led by The Column Group and Lux Capital, with additional participation from Two Sigma Ventures, Bristol Myers Squibb, Evotec, Alexandria Venture Investments, Dolby Family Ventures, and other investors. Wilson Sonsini advised Cajal on the transaction.

Escient Pharmaceuticals Raises $120 Million Through Series C
On November 28, 2022, Escient Pharmaceuticals, a clinical-stage company focused on developing novel therapeutics for a broad range of neurosensory-inflammatory disorders, announced that it had raised $120 million through a Series C financing led by New Enterprise Associates (NEA), Abingworth, and Forge Life Science Partners. The fundraising included participation from other new investors including Avego, PFM Health Sciences, and The Eleven Fund, as well as existing investors The Column Group, 5AM Ventures, Redmile Group, Cowen Healthcare Investments, Sanofi Ventures, Osage University Partners (OUP), and Altitude Life Science Ventures. Wilson Sonsini advised NEA and Abingworth on the transaction.

Tenaya Announces $75 Million Public Offering
On November 21, 2022, clinical-stage biotechnology company Tenaya Therapeutics announced the closing of a public stock offering that raised approximately $75 million. The company sold 22,613,307 million shares at a price of $2.60 and pre-funded warrants allowing some investors to buy an additional 6,236,693 shares at a price of $2.599. Underwriters will have an option to purchase an additional 4,327,500 shares. Tenaya is focusing on developing therapies for rare genetic disorders and for heart conditions using gene therapy, cellular regeneration, and precise medicine. Wilson Sonsini advised Tenaya on the transaction.

CalciMedica Merges with Graybug
On November 21, 2022, Graybug Vision, Inc. and CalciMedica Inc. announced that they have entered into a definitive merger agreement to combine the companies in an all-stock transaction. The combined company will focus on further developing CalciMedica's lead product candidate Auxora,™ a proprietary, intravenous-formulated, small molecule calcium-release activated calcium (CRAC) channel inhibitor, to treat life-threatening inflammatory diseases for which there are no currently approved therapies. The combined company is expected to trade on the Nasdaq Global Market. Wilson Sonsini advised CalciMedica on patent matters related to the transaction.

SR One and Norwest Invest in Rezo's $78 Million Series A
On November 17, 2022, Rezo Therapeutics, a biotechnology company pioneering the integrated mapping of disease networks for precision therapeutics, launched with $78 million from a Series A financing. The financing was led by SR One, a16z Bio + Health, and Norwest Venture Partners, and also included SV Angel, Liquid 2 Ventures, and Hawktail. Rezo's Sequence to Systems to Drugs (SSD) platform integrates data from proteomics, genetics, structural biology,

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Select Recent Life Sciences Client Highlights *(Continued from page 16)*

and chemical biology approaches using sophisticated computational methods to create comprehensive maps of molecular disease networks. Wilson Sonsini represented lead investors SR One and Norwest in the transaction.

MBX Biosciences Closes $115 Million Series B

On November 14, 2022, clinical-stage biopharmaceutical company MBX Biosciences announced that it has closed a $115 million Series B financing. Wellington Management led the fundraise, with participation from RA Capital Management and Norwest Venture Partners, as well as existing investors Frazier Life Sciences, New Enterprise Associates (NEA), and OrbiMed. Proceeds of the financing will support MBX into early 2025 as it develops transformative therapeutics PEPs,™ designed to overcome limitations of traditional peptide therapeutics. Wilson Sonsini advised Norwest on the financing. A separate Wilson Sonsini team advised MBX Biosciences on patent matters related to the transaction.

ScienTech Medical Raises $83.4 Million in IPO

On November 8, 2022, LEPU ScienTech Medical Technology (Shanghai) Co., Ltd. (ScienTech Medical) successfully listed on the Main Board of the Stock Exchange of Hong Kong, raising approximately HK$654.6 million (US$83.4 million) from a global offering of 22,455,000 H shares, or approximately HK$752.7 million (US$95.9 million) if the underwriters fully exercise their over-allotment option to purchase 3,368,000 additional H shares. ScienTech Medical is a leading interventional medical device provider in China for congenital heart diseases. Wilson Sonsini acted as U.S. and Hong Kong counsel to ScienTech Medical in the global offering and listing.

Inscopix Acquired by Bruker

On November 8, 2022, Bruker Corporation, a developer, manufacturer, and distributor of high-performance scientific instruments and analytical and diagnostic solutions, announced it had acquired Inscopix, Inc., a neuroscience pioneer and market leader of miniaturized microscopes known as miniscopes. The acquisition enhances Bruker's strong reputation as a technology leader for in-vivo brain functional imaging with Ultima multiphoton microscopes at the cellular level and preclinical MRI systems at the organismal level. Wilson Sonsini advised Inscopix on the transaction.

Insilico Medicine Announces Collaboration with Sanofi

On November 8, 2022, Insilico Medicine, a clinical-stage artificial intelligence-driven drug discovery company, announced a multi-year, multi-target strategic research collaboration with Sanofi. Under the terms of the agreement, the collaboration will leverage Insilico Medicine's AI platform, Pharma.AI, to advance drug development candidates for up to six new targets. Under the terms of the agreement, Sanofi will pay Insilico Medicine a total of up to $21.5 million covering the upfront and target nomination fees to benefit from Insilico's end-to-end Pharma.AI platform and gain access to a team of interdisciplinary drug discovery scientists to identify, synthesize, and advance high-quality lead therapeutic compounds up to development candidate stage. Additional payments will be made if key research, development, and sales milestones are met, and could total up to $1.2 billion. Wilson Sonsini advised Insilico Medicine on the transaction.

Zenas BioPharma Announces $118 Million Series B

On November 7, 2022, global pharmaceutical company Zenas BioPharma announced a $118 million Series B equity financing that will be used to develop and bring to market immune-based therapies. In addition to Enavate Sciences, which led the Series B equity financing, new Zenas shareholders include Longitude Capital, Vivo Capital, Rock Springs Capital, Perceptive Advisors, Agent Capital, Pivotal bioVenture Partners, and Superstring Capital. Existing investors Fairmount, Wellington Management, Tellus BioVentures, Quan Venture Fund, and Xencor, Inc. also participated in the financing. Wilson Sonsini advised Enavate Sciences and Longitude Capital in the financing.

Alto Neuroscience Closes $35 Million Series B

On October 25, 2022, Alto Neuroscience announced the closing of a $35 million Series B financing led by Lightswitch Capital and partners of Alkeon Capital, with participation from other new investors including Sobrato Capital, Novartis Pharma AG, Valor Equity Partners, Korify Capital, Vine Ventures, and Gaingels. The financing also included participation from existing investors Apeiron Group, WhatIf Ventures, Windham Venture Partners, and others. This round brings Alto's total funding to $75 million to date. Wilson Sonsini advised Alto Neuroscience on the transaction.

Denali Therapeutics Closes $316 Million Public Offering

On October 24, 2022, Denali Therapeutics, a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier (BBB) for neurodegenerative diseases, announced the close of its upsized underwritten public offering of 11,933,962 shares of its common stock at a price to the public of $26.50 per share, which includes

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Select Recent Life Sciences Client Highlights *(Continued from page 17)*

the exercise in full by the underwriters of their option to purchase additional shares. The total gross proceeds from the offering, before deducting underwriters' discounts and commissions and estimated offering expenses, are approximately $316 million. Wilson Sonsini advised Denali Therapeutics on the transaction.

Prime Medicine Announces $175 Million IPO

On October 19, 2022, Prime Medicine, Inc., a biotechnology company committed to delivering a new class of differentiated one-time curative genetic therapies, announced the pricing of its upsized initial public offering of 10,294,118 shares of its common stock at a price to the public of $17.00 per share. The shares began trading on the Nasdaq Global Market on October 20 under the ticker symbol "PRME." The gross proceeds of the offering, before deducting underwriting discounts and commissions and other offering expenses payable by Prime Medicine, are expected to be $175 million. Wilson Sonsini advised Prime Medicine on all patent matters related to the transaction.

Zymeworks Enters Exclusive Licensing Agreement with Jazz Pharmaceuticals

On October 19, 2022, Zymeworks BC Inc. and Jazz Pharmaceuticals Ireland Ltd. announced that they have entered into an exclusive license agreement to develop and commercialize zanidatamab. Under that arrangement, Jazz will receive an exclusive license from Zymeworks to develop and commercialize zanidatamab in the United States, Europe, Japan, and all other territories except for those Asia/Pacific territories that Zymeworks previously licensed to BeiGene, Ltd. Wilson Sonsini advised Zymeworks on the transaction.

NEA Leads Inversago Pharma's $70 Million Series C

On October 17, 2022, Inversago Pharma Inc., a clinical-stage biotech company with a unique portfolio of peripherally acting CB1 inverse agonists, announced the completion of a Series C funding of $95 million CAD (approximately $70 million USD) led by New Enterprise Associates (NEA). Additional new investors Forbion's Growth Opportunities Fund and Amgen Ventures joined current investors, including Forbion's Ventures Fund IV, Fonds de solidarité FTQ, Genesys Capital, AmorChem, JDRF T1D Fund, and adMare BioInnovations, in the financing round. Wilson Sonsini advised NEA on the financing.

DICE Therapeutics Closes $345 Million Public Offering

On October 17, 2022, DICE Therapeutics, Inc., a biopharmaceutical company leveraging its proprietary technology platform to build a pipeline of novel oral therapeutic candidates to treat chronic diseases in immunology and other therapeutic areas, announced the closing of its previously announced upsized underwritten public offering of 9,452,054 shares of its common stock, including the full exercise of the underwriters' option to purchase 1,232,876 additional shares, at a public offering price of $36.50 per share. The gross proceeds to the company from the offering, before deducting underwriting discounts and commissions and other offering expenses, were approximately $345.0 million. Wilson Sonsini advised DICE Therapeutics on all patent matters related to the public offering.

Enliven Therapeutics Merges with Imara

On October 13, 2022, Enliven Therapeutics, a clinical-stage precision oncology company focused on the discovery and development of next-generation small molecule kinase inhibitors, and Imara announced that they have entered into a definitive merger agreement to combine the companies in an all-stock transaction. The combined company will focus on advancing Enliven's pipeline of precision oncology product candidates. Wilson Sonsini is advising Enliven on the transaction.

ATP Launches Ascidian Therapeutics

On October 12, 2022, life sciences venture capital firm ATP announced the launch of new biotechnology company Ascidian Therapeutics. ATP developed the company and provided $50 million of Series A financing. Ascidian uses therapeutic targeting of large genes and genes with high mutational variance and focuses to treat human diseases through the replacement of mutated exons at the RNA level. With $2.65 billion of committed capital, ATP focuses on providing flexible capital and access to venture partners looking to provide therapeutics that improve human lives. Wilson Sonsini advises Ascidian on patent matters, corporate matters, and technology transactions matters.

Beckman Coulter Acquires StoCastic

On October 11, 2022, Beckman Coulter Diagnostics, a global leader in clinical diagnostics, announced it acquired StoCastic, a leading artificial intelligence company that provides evidence-based decision support for hospital emergency departments. StoCastic's TriageGo will be a cornerstone of Beckman Coulter's artificial intelligence (AI)-enabled Clinical Decision Support (CDS) portfolio, a growing field that aims to further improve patient care by leveraging data-driven insights to clinicians and optimize clinical decision making. Wilson Sonsini advised Beckman Coulter on the transaction.

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Select Recent Life Sciences Client Highlights *(Continued from page 18)*

YS Biopharma Enters Merger Agreement with Summit Healthcare Acquisition Corp.
On September 29, 2022, YishengBio Co., Ltd (YS Biopharma), a commercialization-stage biopharmaceutical company focusing on innovative vaccines and therapeutic biologics, and Summit Healthcare Acquisition Corp. (Summit), a publicly traded special purpose acquisition company, announced that they have entered into a definitive agreement for a business combination of Summit and YS Biopharma. Upon the completion of the merger, the combined company will be renamed YS Biopharma Co., Ltd. and become a publicly traded company on the Nasdaq. Wilson Sonsini is representing YS Biopharma in the transaction.

Elucidata Raises $16 Million in Series A
On September 27, 2022, TechBio company Elucidata announced that it has raised $16 million in a Series A fundraising, which was led by Eight Roads Ventures. F-Prime Capital, IvyCap Ventures, and Hyperplane Venture Capital also participated. Elucidata focuses on life sciences research and development through its data-centric Machine Learning Operations platform Polly, which enables pharmaceutical and diagnostic companies to adopt a data-centric approach for artificial intelligence and machine learning. Wilson Sonsini advised Elucidata on the transaction.

RA Capital Management Leads Rivus Pharmaceuticals' $132 Million Series B
On September 22, 2022, Rivus Pharmaceuticals, a clinical-stage biopharmaceutical company dedicated to improving cardio-metabolic health, announced the completion of a $132 million Series B financing led by RA Capital Management with participation from Bain Capital Life Sciences, BB Biotech AG, and existing investors Longitude Capital, Medicxi, and RxCapital. Funds from the Series B will primarily be used to further support clinical advancement of lead candidate HU6, a first-in-class Controlled Metabolic Accelerator (CMA) designed to treat cardio-metabolic disease by addressing obesity. Wilson Sonsini advised RA Capital on the transaction.

Aadi Bioscience Announces $72.5 Million Private Placement Equity Financing
On September 22, 2022, Aadi Bioscience, Inc., a commercial-stage biopharmaceutical company focused on precision therapies for genetically defined cancers with alterations in mTOR pathway genes, announced it has entered into a securities purchase agreement with a new accredited investor and certain existing investors to issue and sell an aggregate of 3,373,526 shares of its common stock at a price of $12.50 per share, reflecting the closing price on September 21, 2022, on NASDAQ, and pre-funded warrants to purchase up to an aggregate of 2,426,493 shares of common stock at a purchase price of $12.4999 per pre-funded warrant share, through a private investment in public equity (PIPE) financing. Wilson Sonsini advised Aadi Bioscience on the transaction.

Ventyx Biosciences Announces $176.6 Million Private Placement of Common Stock
On September 19, 2022, Ventyx Biosciences, Inc., a clinical-stage biopharmaceutical company focused on advancing novel oral therapies that address a range of inflammatory diseases with significant unmet medical need, announced that it has entered into a stock purchase agreement for the sale of 5,350,000 shares of its common stock at an offering price of $33.00 per share in a private placement to certain qualified institutional buyers and institutional accredited investors. The gross proceeds of the private placement are expected to be approximately $176.6 million, before deducting placement agent fees and other expenses. Wilson Sonsini advised Ventyx on the transaction.

Redesign Health Closes $65 Million Series C Funding Round
On September 13, 2022, Redesign Health, a company that builds other healthcare start-ups, closed a $65 million Series C funding round. The funding was led by General Catalyst, with other investors including CVS Health Ventures, UPMC Enterprises, Eden Global Partners, Euclidean Capital, Samsung Next, TriplePoint Capital, and Declaration Partners also participating. The proceeds from the latest funding will benefit Redesign Health's own operations and platform. Wilson Sonsini advised Redesign Health on the transaction.

RayzeBio Raises $160 Million in Series D Financing
On September 13, 2022, RayzeBio, Inc., a targeted radiopharmaceutical company developing an innovative pipeline against validated solid tumor targets, announced a $160 million Series D financing co-led by Viking Global Investors, Sofinnova Investments, and Wellington Management. Additional new investors Ally Bridge Group, Sands Capital, Laurion Capital Management, Soleus Capital, and an undisclosed global investor also participated, as did RayzeBio's current investors. With this latest financing, RayzeBio has now raised $418 million since beginning operations in August 2020. Wilson Sonsini advised RayzeBio on patent matters related to the transaction.

Time BioVentures Leads Phatom Neuro's $6 Million Seed Funding Round
On September 12, 2022, Phantom Neuro, a first-of-its-kind neurotech start-up that delivers a low-power, high-accuracy system for lifelike control of robotic

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orthopedic technologies, announced a $6 million funding round led by new investor Time BioVentures. The round included participation from another new investor, Risk & Return (R^2), an innovative venture fund focused on "capitalism for good." Phantom Neuro aims to dramatically enhance the lives of amputees and other patients with function deficits. Wilson Sonsini advised Time BioVentures on the transaction.

Harmonic Discovery Launches with $8 Million Seed Round
On September 8, 2022, Harmonic Discovery, a therapeutics company building an integrated computational and experimental platform for kinase drug discovery and targeted polypharmacology, announced its launch with $8 million in seed funding. The round was led by Innovation Endeavors, with participation from Fifty Years, Y Combinator, Boom Capital, Caffeinated Capital, and select angel investors. Wilson Sonsini advised Harmonic Discovery on the transaction.

Good Therapeutics Acquired by Roche
On September 7, 2022, Good Therapeutics, a privately held company founded to create a new class of conditionally active therapeutics, announced it has entered into a definitive merger agreement to be acquired by Roche. With this acquisition, Roche will gain rights to Good Therapeutics' innovative, conditionally active, PD-1-regulated IL-2 program and an exclusive right to the platform technology for the development of PD-1-regulated IL-2 receptor agonist therapeutics. Wilson Sonsini advised Good Therapeutics on IP matters related to the transaction.

Metacrine Inc. Enters Merger Agreement with Equillium
On September 6, 2022, Equillium, Inc. and Metacrine Inc. announced that the two companies have entered into a definitive merger agreement pursuant to which Equillium will acquire Metacrine in an all-stock transaction. The transaction is anticipated to add $33 million in cash to Equillium's balance sheet at closing, which is expected to extend the company's cash runway into 2024. Wilson Sonsini is advising Metacrine on the transaction.

Upcoming Life Sciences Events

Wilson Sonsini's Medical Device Conference Dinner Interview
June 15, 2023
Sharon Heights Golf & Country Club
Menlo Park, CA

Wilson Sonsini's Medical Device Conference
June 16, 2023
Palace Hotel
San Francisco, CA
https://mdc.wsgrevents.com/

Wilson Sonsini's 2023 Medical Device Conference will address issues of critical importance to today's medical device companies. In a series of topical panels, attendees will hear from industry CEOs, venture capitalists, industry strategists, investment bankers, and market analysts. In addition, a Partnering Hall will offer personalized opportunities for investors and large medtech companies to meet with start-ups that are searching for and pursuing potential investment, partnering, and acquisition opportunities.

Phoenix 2023: The Medical Device and Diagnostic Conference for CEOs
October 11-13, 2023
Ritz-Carlton, Half Moon Bay
Half Moon Bay, CA
https://phoenix.wsgrevents.com/

The 2023 Phoenix Conference will bring together top-level executives from large healthcare companies and CEOs of small, venture-backed firms for an opportunity to discuss critical issues of interest to the medical device industry today, as well as to network and gain valuable insights from both industry leaders and peers. This year's exclusive, two-day event will provide an unrivaled experience that will help inform and shape company strategy for the years ahead.

Casey McGlynn, a leader of the firm's life sciences practice, has editorial oversight of *The Life Sciences Report* and was assisted by Elton Satusky, Scott Murano, Brian Appel, and Jesse Schumaker. They would like to take this opportunity to thank all of the contributors to the report, which is published on a semi-annual basis.

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