JANUARY 2024

WILSON SONSINI

THE LIFE SCIENCES REPORT

In This Issue

Wilson Sonsini's Business Advisory Practice Supports French Gene Therapy Start-Up's Expansion into the U.S.

In early 2023, the firm's Business Advisory Practice (BAP) engaged Nervosave Therapeutics, based in Montpellier, France, to support its expansion into the United States. Nervosave is a preclinical-stage biotech focused on developing preventative and curative gene therapies for the treatment of myelin-related disorders, with an initial focus on central nervous system diseases. The company's core technology is licensed from the French National Institute of Health and Medical Research (INSERM). Their lead program, NVO-101, is a best-in-class gene therapy (AAV9 with RNAi transgene) for Charcot-Marie-Tooth disease type 1a (CMT1a), a debilitating orphan neurological disorder. CMT1a is a progressive, degenerative disease involving the peripheral nerves that branch out from the brain and spinal cord to other parts of the body, including the arms, hands, legs, and feet. Currently, there is no effective therapy for the disease.

Continued on page 2...

USPTO to Issue Guidance on AI Innovation Protection, Inventorship, and Patent Eligibility

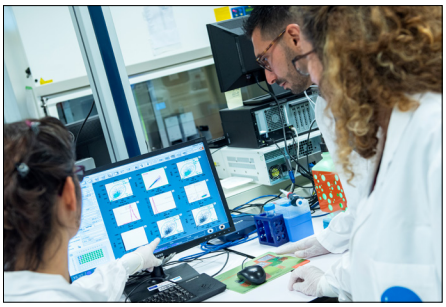
By Hin Au (Associate, Palo Alto) and Ali Alemozafar (Partner, San Francisco)

On October 30, 2023, President Biden issued an Executive Order (EO) on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. The EO noted that promoting responsible innovation through investments in artificial intelligence (AI)-related research and development (among others) will allow the United States to lead in AI and unlock the technology's potential to solve some of society's most difficult challenges. At the same time, the EO recognizes the need to simultaneously tackle novel intellectual property (IP) questions and other problems to protect inventors and creators.

The EO contains numerous references that relate to the use of AI in the life sciences and in healthcare. For example, the EO mentions the intersection of AI and synthetic biology, including generative AI models trained on biological data, and the generation of synthetic nucleic acid sequences. In addition, the EO encourages private sector and Health and Human Services (HHS) collaborations to support AI-enabled tools that develop personalized immune-response profiles for patients.

Continued on page 3...

Wilson Sonsini's Business Advisory Practice Supports French Gene Therapy . . . *(Continued from page 1)*



Nervosave has generated strong preclinical data in multiple validated animal models (humanized mouse, rat, monkey, and sheep), and is preparing for an Investigational New Drug (IND) submission of NVO-101 in Q2 2025. The company expects to leverage the U.S. Food and Drug Administration's Accelerated Approval pathway to seek approval by the first half of 2028.

The BAP has advised Nervosave on its strategy to move to the United States, helped establish the company at a well-respected life science incubator in the New York metro area, and identified a highly accomplished big pharma executive to serve as interim CEO, whom the company hired. In addition, the BAP has successfully expanded Nervosave's corporate presence and strategic network in the U.S. and has connected the company with potential investors and strategic partners in support of its Series A financing. Further, the Wilson Sonsini corporate team is advising Nervosave on establishing a U.S. corporate subsidiary.

"We've really benefited from working with Wilson Sonsini's business advisory group," said Nicolas Tricaud, Nervosave co-founder, CEO, and CSO. "Their network of strategic partners and investor contacts has allowed us to accelerate our efforts in the U.S. market in a cost-effective manner. It's nice to have this service integrated into the firm's broad legal offerings, which we plan to use as we raise additional funding and further expand operations in the Northeast."

About Wilson Sonsini's Business Advisory Practice

The firm's unique and innovative Business Advisory Practice (BAP) provides emerging and more established life sciences companies with support covering company financings, building and scaling management teams, executing a partnering or similar transaction, and product commercialization. The BAP complements the firm's outstanding legal counsel with industry-experienced business and licensing advisors to support and accelerate growth through strategic business advice. For more information, please visit https://www.wsgr.com/en/life-sciences-business-advisory-practice.html.

Matthew J. Meyer
(415) 947-2097
mjmeyer@wsgr.com

LaunchBio and Wilson Sonsini Introduce NextGen VC Podcast Focused on Life Sciences Investing

In November 2023, LaunchBio and Wilson Sonsini introduced the NextGen VC Podcast – Empowering Venture Capital Associates to provide insight into the dynamic world of life sciences investing. Hosted by Wilson Sonsini partners Michael Hostetler and Jennifer Fang, the podcast unpacks the opportunities, challenges, and breakthroughs shaping such investment. Each episode features interviews with seasoned venture capitalists, successful entrepreneurs, and industry leaders. Listeners will gain an understanding of how the pros have navigated challenges, made strategic decisions, and achieved remarkable success.

Episode 1: Neena Kadaba, Entrepreneur in Residence at Apple Tree Partners
Neena discusses her journey from studying chemistry at MIT to becoming a venture capitalist in the biotech industry. She discusses her initial attraction to science, her experience as a Kauffman Fellow, and her role at Apple Tree Partners, a life science venture fund that creates biotech companies to translate emerging science into new therapies. Neena also emphasizes the importance of curiosity, communication, and building a network in the world of venture capital.

Episode 2: Hyung Chun, Director at Foresite Capital Management
Dr. Chun brings a unique perspective to the investment landscape, evaluating opportunities and understanding how to drive early discoveries to the clinic. He discusses how to learn what you don't know, the similarities between being a physician-scientist and a venture capitalist, and his vision for the future of biotech.

To subscribe to the NextGen VC Podcast, visit https://launchbio.org/nextgen-vc-podcast/.

USPTO to Issue Guidance on AI Innovation Protection, Inventorship . . . *(Continued from page 1)*

The EO also supports the funding of initiatives that explore ways to improve healthcare-data quality, to support the responsible development of AI tools for clinical care, real-world-evidence programs, population health, public health, and related research.

To promote innovation and clarify issues related to AI and inventorship of patentable subject matter, the United States Patent and Trademark Office (USPTO) has been tasked by the EO to provide guidance to patent examiners and applicants over the course of the coming months.

The first guidance, to be published within 120 days of the EO (by February 27, 2024), will address inventorship and the use of AI, including generative AI, in the inventive process. Specifically, the guidance will include illustrative examples in which AI systems play different roles in inventive processes and how, in each example, inventorship issues ought to be analyzed.

The second guidance, to be published within 270 days of the EO (by July 26, 2024), will include additional guidance to address other considerations at the intersection of AI and IP. Those considerations may include, as the USPTO Director deems necessary, updated guidance on patent eligibility to address innovation in AI and critical and emerging technologies.

The aforementioned USPTO guidance will be relevant for companies and institutions that are developing innovations in AI (e.g., creating new foundation models) or using AI for specific applications. For instance, AI is increasingly being used for drug discovery and the development of therapeutics, including target identification, hit screening, lead identification, lead optimization, preclinical evaluations, clinical trial optimization, drug manufacturing, and analysis of post-market real world evidence (RWE). AI is also used in digital health, for example in telemedicine, digital therapeutics, and Software as a Medical Device (SaMD). On the medical device/equipment front (including MedTech), there has been an increase in the number of AI/machine learning (ML)-enabled devices for use in various medical disciplines, such as radiology, cardiovascular, ophthalmology, hematology, neurology, gastroenterology-urology, and pathology.

In seeking patent protection on AI-related inventions, it is important for innovators and entrepreneurs to be familiar with current jurisprudence relating to inventorship. Under U.S. patent laws, an inventor needs to be a person, which the U.S. Court of Appeals for the Federal Circuit (CAFC) affirmed in *Thaler v. Vidal*, 43 F.4th 1207 (Fed. Cir. 2022). A key takeaway of the *Thaler* decision is that an AI system is not eligible to be an inventor on a patent application. However, in the *Thaler* decision, the CAFC was "not confronted … with the question of whether inventions made by human beings with the *assistance* of AI are eligible for patent protection." *Thaler v. Vidal*, 43 F.4th at 1213.

The first set of USPTO guidance on AI and inventorship is likely to at least address the above issue of inventorship. Under U.S. patent law, a key part in determining inventorship is identifying who contributed to the conception of a given invention. As the standard for inventorship evolves, innovators and entrepreneurs that are using AI (including generative AI) in healthcare and the life sciences may consider keeping a detailed log of how the AI is being used, and the degree of independent novel contributions by the AI (if any) during the inventive process. Examples of factors to consider include: (1) whether the AI has or will contribute significantly to an invention such that human input or involvement is minimal, and (2) whether a human used the AI as a tool during the inventive process, in a manner such that the role of the AI is ancillary to the role of the human inventor who mainly contributed to conception.

The second set of USPTO guidance is likely to expand the scope of inquiries beyond inventorship by including guidelines on patent eligibility. Under current U.S. patent law, a claimed invention is patentable if, among other criteria, the invention is subject matter eligible. It is possible that certain AI inventions or AI-assisted inventions may be deemed to lack subject matter eligibility under the current eligibility test (as set forth by the U.S. Supreme Court, and further articulated in guidance published by the USPTO in 2016 and 2019). The second set of USPTO guidance may provide additional insight on the above, for instance by publishing guidelines for analyzing subject matter eligibility of AI inventions or AI-assisted inventions.

For additional information, please contact the authors or any other member of Wilson Sonsini's patents and innovations group.

Hin Au
(650) 849-3064
hau@wsgr.com

Ali Alemozafar
(415) 947-2054
aalemozafar@wsgr.com

Wilson Sonsini Client Spotlight & Founder Interview: Kenneth Greenberg, Ph.D., CEO of SonoThera, Inc.

Ultrasound Makes Waves in Genetic Medicine

Wilson Sonsini attorney Dustin Luettgen recently interviewed Kenneth Greenberg, the co-founder, president, and CEO of SonoThera, Inc., a biotechnology company dedicated to treating the root cause of human disease through genetic therapy. They discussed several topics, including the origins of SonoThera and its novel technology, the challenges of current gene therapies, the potential impact of the SonoThera platform on the future of genetic medicines and patient access, and the company's history with Wilson Sonsini.

What makes SonoThera special, and how do you envision it impacting the future of genetic medicines?

Gene therapy has incredible potential to treat and even cure a variety of different conditions, ranging from rare, inherited conditions to more common diseases such as cancers, heart disease, and neurological conditions that affect a significantly larger portion of the population. But to date, there have been only a few innovations brought to market because of significant delivery vehicle challenges, including limited organ biodistribution, immunogenicity, small payload capacity, uncertain durability, and complex and costly manufacturing processes.

SonoThera was founded to overcome these problems. Our unique approach is unlike any other gene therapy on the market or in development today. We are developing a non-viral platform that employs sonoporation, a targeted, ultrasound-guided, microbubble-mediated biophysical process, to non-invasively deliver genetic payloads.

Our platform applies non-invasive ultrasound to a targeted area of the body to control the location of delivery of the genetic payload. This is in contrast to traditional gene delivery vehicles such as Adeno-Associated Viral (AAV) vectors or lipid nanoparticles (LNPs), which suffer from poor biodistribution, low efficiency, and off-target effects when administered systemically. In addition, these delivery vehicles cannot target certain organs, do not allow for patients to be redosed due to immunogenicity resulting from the gene therapy treatments, and may fail to provide a lifelong treatment due to lack of durability in gene expression. In contrast, the process of sonoporation provides for highly targeted delivery to most organs in the body, may allow for patients to receive multiple treatments as needed, is not constrained by viral vector carrying capacity, and significantly increases the number of potential diseases and patients that can benefit from gene therapies.

In addition to the treatment benefits, sonoporation may expand access to gene therapy, something that can be financially improbable for many patients today. Microbubbles and ultrasound are FDA-approved technologies with well-established safety profiles. Microbubbles and genetic materials are also relatively straightforward to manufacture.

How was SonoThera founded?

SonoThera was founded shortly after I met my co-founders, Steve Feinstein, M.D., and Michael Davidson, M.D. I had been working in the gene therapy field since 2001 and had become all too familiar with the delivery challenges that are commonplace when using existing viral and non-viral delivery modalities. We were introduced by a mutual friend and venture capital investor who recognized the potential impact of Steve and Michael's proof-of-concept data, and also their need for a gene therapy expert to help transform this idea into a company capable of building a robust technology platform and pipeline of gene therapy products. Steve and Michael provided a compelling and novel gene delivery approach in using ultrasound, one that I instantly recognized could potentially be used to address the majority of the delivery problems that have plagued the field of genetic medicine.

Was there an "aha" moment when you realized the potential of sonoporation?

For me, the "aha" moment was when I saw their proof-of-concept data showing the targeted delivery of large genetic payloads to multiple organs, in a redosable manner, without immunogenicity and without the use of any viral or non-viral vectors. At that time, no one had been able to accomplish this in gene therapy, and I realized that the platform had the potential to revolutionize the field, solving problems such as immunogenicity, poor biodistribution, off-target delivery, low efficiency, transient durability of gene expression, limited genetic payload capacity, and manufacturing complexity.

Since closing its Series A financing, what advancements has SonoThera made?

We have made incredible progress over the past year in both building

Continued on page 5...

Wilson Sonsini Client Spotlight & Founder Interview . . . *(Continued from page 4)*

the company and in developing the sonoporation platform technology.

One area where we have made significant progress is with platform optimization and validation. We have built out a fully integrated, end-to-end capability that includes advanced acoustic engineering, novel genetic payload design, in-house manufacturing, and in vitro and in vivo testing, along with sophisticated downstream analytical methods, generating a wealth of qualitative and quantitative data. The success in platform optimization has already allowed us to begin advancing several therapeutic programs in multiple organ systems, which are leveraging the platform's robust organ targeting, durability, redosing, and large payload capacity profile.

In addition, we have had outstanding success with recruiting a highly skilled, interdisciplinary team of biotech and pharma professionals, with each member having extensive experience in their own domains. Much of our team has prior experience in gene therapy and gene editing, and is familiar with the challenges in the space. For example, our team includes Dr. Steve Feinstein as our Chief Scientific Officer, the inventor of the first two FDA-approved ultrasound microbubble contrast agents, bringing nearly 30 years of experience in the development and clinical utilization of ultrasound and microbubbles; Dr. Zoya Gluzman-Poltorak, Ph.D., as our Chief Development Officer, bringing 20 years of executive-level leadership experience in early development biotechnology companies, having advanced multiple cell-, gene-, and protein-based products from idea through pre-clinical and clinical development in various therapeutic areas; and Carolyne Zimmermann, M.B.A., as our Chief Business Officer, bringing over 20 years of experience in bio-pharma corporate strategy, business development, venture investing, and leadership in the development and successful execution of partnering strategies, having served as VP of Transactions & Innovation Partnering at the J&J Innovation Center in San Francisco, and as a member of the Global Business Development Leadership Team at Novartis Pharmaceuticals.

Was it challenging to recruit such an experienced and sophisticated team?

Recruiting was far easier than expected, even though a number of our candidates held excellent positions with industry leaders in the space. The ease with which we were able to build our team is a testament to the strength of the platform technology we are developing, and the opportunity it presents to revolutionize the genetic medicine options for patients. The excitement for the sonoporation platform we are developing and the potential it has to positively impact the lives of patients extends from the company's executive leadership to our research associates, investors, partners, and collaborators.

How do you envision SonoThera's platform impacting patient access?

One of the most significant barriers to widespread adoption of gene therapies is high product costs and the inability to obtain insurance reimbursement for all but rare diseases. Recently, the FDA approved two gene therapies for Hemopathies, one for Hemophilia B costing $3.5 million and another for Hemophilia A costing $2.9 million. While the high cost of genetic medicines is expected, considering their complexity—for example, as it relates to viral vectors and LNPs—it is likely to limit the availability of genetic medicines to patients. If gene therapies are consistently priced at this level, it will be challenging to obtain reimbursement from health insurers for therapies intended to treat more common conditions.

"One of the most exciting things about SonoThera's platform is the anticipated expanded patient access resulting from its improved safety and reduced manufacturing costs"

One of the most exciting things about SonoThera's platform is the anticipated expanded patient access resulting from its improved safety and reduced manufacturing costs. Both microbubbles and ultrasound are already FDA approved, widely used for a variety of diagnostic purposes, and have well-established safety. The manufacturing of SonoThera's genetic payload is significantly less complex, as it does not require encapsulation of the payload within vectors that require a complex and expensive manufacturing process. Thus, the resulting SonoThera genetic medicine is expected to provide significant healthcare value and enable broader access even in indications with large patient populations.

Further, SonoThera's sonoporation platform opens the door for gene therapies to be administered multiple times to a patient, which has the potential to further reduce development costs by providing patients with a treatment platform that can be repeated as needed, as opposed to viral, vector-

Continued on page 6...

Wilson Sonsini Client Spotlight & Founder Interview . . . *(Continued from page 5)*

based therapies that can only be administered once and present safety concerns associated with genetic integration events.

In combination, we expect that the platform's well-established safety aspects, the potential for retreatment, and the relatively simple manufacturing processes will provide for competitive drug pricing and treatments that are widely available to patients following approval.

How do you envision SonoThera progressing over the next few years?

We are building a pioneering biotechnology company that advances the gene therapy space at large through the development of our sonoporation platform, as well as specific genetic medicine products. We are pursuing strategic partnerships with certain biotech and pharma partners to assist in commercialization and are nearing the initiation of IND-enabling studies. We plan to move our first gene therapy program into the clinic in 2025; we have not yet publicly disclosed the indication.

We believe there is vast unmet need in the neurological, cardiovascular, hematologic, metabolic, and renal disease spaces that will be revolutionized by the introduction of sonoporation-based gene therapies, as many of these patient populations are underserved by viral vectors or LNPs for a variety of reasons. Following establishment of the sonoporation platform in treating monogenic inherited conditions, we plan to pursue some of the more complicated conditions that affect larger patient populations, allowing the sonoporation platform to positively impact the lives of many more patients.

Had you worked with Wilson Sonsini prior to founding SonoThera?

Yes, I previously worked with the patent and innovations practice at Wilson Sonsini in preparing IP strategies for a number of prior companies I co-founded or worked with, collaborating with Maya Skubatch and Vern Norviel. I have found the patent practice at Wilson Sonsini to be second to none, offering the most sophisticated advice and placing their clients in the best possible IP position.

As it relates to SonoThera, Wilson Sonsini advised the company on its Series A financing round, leading to a $60.75 million raise that closed in late 2022. The fundraise included an investor syndicate led by ARCH Venture Partners and joined by Illumina Ventures, Johnson & Johnson Innovation – JJDC, Inc., Vertex Ventures HC, and Medical Excellence Capital. Also participating in this financing round were Eli Lilly & Company, Alexandria Venture Investments, Lifespan Investments, Formic Ventures, and Foothill Ventures.

I have greatly enjoyed working with Wilson Sonsini and look forward to many more years of partnership with the firm.

Dr. Kenneth Greenberg has more than 20 years of experience in biotechnology company creation, strategy, team leadership, applied research, and drug discovery of genetic medicines spanning diverse disease mechanisms and technology platforms, including viral and non-viral gene therapy, antisense oligonucleotide, recombinant protein, immunotherapy, and small molecule-based modalities. Prior to co-founding and joining SonoThera, Dr. Greenberg led Janssen's Western North America, Australia, and New Zealand External Innovation in all biologic modalities (Cell & Gene Therapy, Antibody & Protein Therapy, Gene Editing, and CMC) across all therapeutic areas at Johnson & Johnson. Prior to J&J, he established and led the neuroscience discovery program at UNITY Biotechnology. Previously, Dr. Greenberg co-founded CODA Biotherapeutics and Oncorus. He completed his Ph.D. in Visual Neuroscience and a Kirschstein-NRSA postdoctoral fellowship in MCB Neurobiology, both at the University of California, Berkeley. Dr. Greenberg is an inventor on over two dozen patents and patents-pending and has co-authored over 50 journal articles and conference presentations.

Dustin Luettgen
(858) 350-2221
dluettgen@wsgr.com

Maya Skubatch
(650) 849-3330
mskubatch@wsgr.com

*This article and interview reflect the views of SonoThera and the authors, but they do not represent the views of Wilson Sonsini.

Option Pool Sizes for Life Sciences Companies

By Brian Appel (Partner-Elect, Palo Alto)

When entering into an equity financing transaction, our life sciences clients often are asked to refresh their existing option pool to provide sufficient available shares to incentivize their service providers. The appropriate size of an available option pool is generally based on a company's hiring needs over the runway period that the equity financing is projected to provide, and we advise clients to compile an option budget delineating projected issuances to negotiate pool size. On occasion, clients ask us about typical "market" sizes for option pools at a given financing stage.

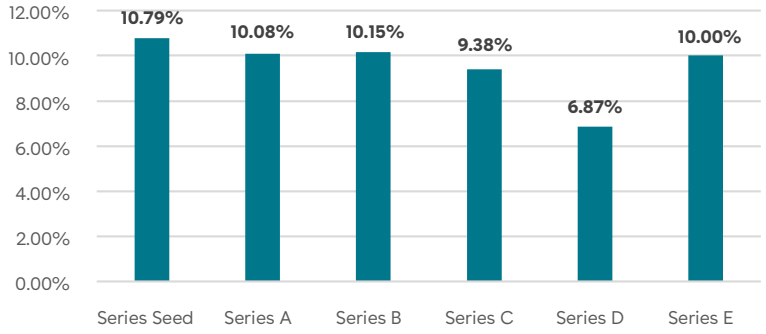
The below data was derived from 329 life sciences equity financing transactions in which Wilson Sonsini clients participated from 2020 through the first quarter of 2023, comparing average available option pool sizes immediately following closing across industry segments and financing stages. The data demonstrates that in financings from Series Seed through Series C, average pool sizes are within a percentage point of 10 percent, with a somewhat smaller average available pool size for Series D companies. Similarly, average available pool sizes are consistently near 10 percent across industry segments, with smaller average available pools for medical information services companies.

Brian Appel
(650) 849-3277
bappel@wsgr.com

Series Financing Analysis (2020 – Q1 2023)

Financing Round	Total Number of Financings
Series Seed	71
Series A	127
Series B	74
Series C	32
Series D	18
Series E	5

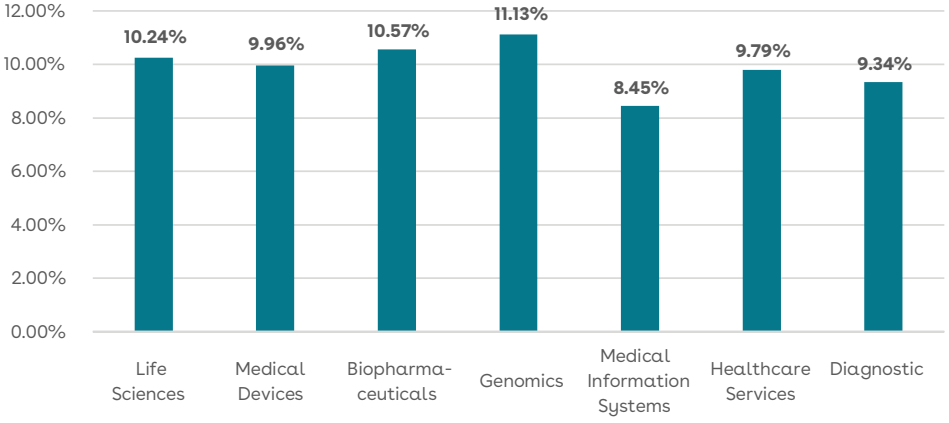
Average Available Pool Size by Series Financing



Industry Analysis (2020 – Q1 2023)

Financing Round	Total Number of Financings
Life Sciences	70
Medical Devices	119
Biopharmaceuticals	85
Genomics	11
Medical Information Systems	22
Healthcare Services	29
Diagnostics	18

Average Available Pool Size by Industry



Source: Wilson Sonsini venture financing data, 2020 - Q1 2023.

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 2022 and the first half of 2023. 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 2022	2H 2022	2H 2022	1H 2023	1H 2023	1H 2023
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	51	$1,219.25	$23.91	70	$882.74	$12.61
Genomics	4	$25.77	$6.44	9	$128.05	$14.23
Diagnostics	9	$99.68	$11.08	14	$156.77	$11.20
Medical Devices & Equipment	28	$360.23	$12.87	69	$483.33	$7.00
Digital Health	23	$664.38	$28.89	35	$372.46	$10.64
Healthcare Services	19	$345.79	$18.20	28	$153.25	$5.47
Total	**134**	**$2,715.10**		**225**	**$2,176.60**	

The data demonstrates that venture financing activity decreased from the second half of 2022 to the first half of 2023 with respect to the total amount raised, but increased with respect to the total number of closings. Specifically, the total amount raised across all industry segments decreased 19.8 percent, from $2,715.10 million to $2,176.60 million, while the total number of closings across all industry segments increased 67.9 percent, from 134 to 225.

Notably, the industry segment with *nearly* the largest number of closings during the first half of 2023—medical devices and equipment—increased in both number of closings and in total amount raised from the second half of 2022 to the first half of 2023. Specifically, the number of closings in medical devices and equipment increased 146.4 percent, from 28 to 69, while the total amount raised increased 34.2 percent, from $360.23 million to $483.33 million. Similarly, the industry segments with the fifth- and sixth-largest number of closings during the first half of 2023, diagnostics and genomics, respectively, saw an increase in both number of closings and total amount raised. Specifically, the number of closings in the diagnostics segment increased 56.6 percent, from nine to 14, while the total amount raised increased 57.3 percent, from $99.68 million to $156.77 million. The total number of closings in the genomics segment increased 125.0 percent, from four to nine, while the total amount raised increased 396.9 percent, from $25.77 million to $128.05 million.

> From 2H 2022 to 1H 2023, the total amount raised across all industry segments decreased 19.8 percent, while the total number of closings across all industry segments increased 67.9 percent

In contrast, the industry segment with the largest number of closings during the first half of 2023—biopharmaceutics—experienced a substantial increase in number of closings, but a decrease in total amount raised from the second half of 2022 to the first half of 2023. Specifically, the number of closings in the biopharmaceuticals segment increased 37.3 percent, from 51 to 70, while the total amount raised decreased 27.6 percent, from $1219.25 million to $882.74 million. Similarly, digital health and healthcare services, the industry

Continued on page 9...

Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 8)*

segments with the third- and fourth-largest number of closings during the first half of 2023, respectively, increased in number of closings, but decreased in total amount raised from the second half of 2022 to the first half of 2023. Specifically, the number of closings in the digital health segment increased 52.2 percent, from 23 to 35, while the total amount raised decreased 43.9 percent, from $664.38 million to $372.46 million. The total number of closings in the healthcare services segment increased 47.4 percent, from 19 to 28, while the total amount raised decreased 55.7 percent, from $345.79 million to $153.25 million.

In addition, our data generally suggests that Series A, Series B, and Series C and later stage financing activity, as a percentage of all financing activity and measured by number of closings,

Our data generally suggests that Series A, Series B, and Series C and later stage financing activity, as a percentage of all financing activity and measured by number of closings, decreased from 2H 2022 to 1H 2023, while Series Seed and bridge financing activity increased

decreased from the second half of 2022 to the first half of 2023, while Series Seed and bridge financing activity increased. Specifically, the number of Series A closings as a percentage of all closings decreased from 26.2 percent to 16.6 percent, the number of Series B closings decreased from 10.6 percent to 7.0 percent, and the number of Series C and later stage financing activity decreased from 11.3 percent to 7.0 percent. On the other hand, the number of Series Seed closings as a percentage of all closings increased from 4.3 percent to 7.0 percent, while the number of bridge financing closings increased substantially, from 13.5 percent to 22.3 percent.

Average pre-money valuations for life sciences companies decreased for Series Seed and Series C and later stage financings and increased for Series A and Series B financings from the second half of 2022 to the first half of 2023. Specifically, the average pre-money valuation for Series Seed financings decreased 36.2 percent, from $20.65 million to $13.18 million; for Series C and later-stage financings, it decreased 55.3 percent, from $332.79 million to $148.7 million; for Series A financings, it increased 47.2 percent, from $22.95 million to $33.78 million; and for Series B financings, it increased 5.1 percent, from $180.3 million to $189.51 million.

Overall, the data indicates that financing activity among our life sciences clients, as measured by total amount raised, declined from the second half of 2022 to the first half of 2023, but increased in terms of number of closings. Moreover, that trend was consistent

Average pre-money valuations for life sciences companies decreased for Series Seed and Series C and later stage financings and increased for Series A and Series B financings from 2H 2022 to 1H 2023

among the top four performing industry segments as measured by number of closings, except for medical devices and equipment, which saw an increase in both number of closings and total amount raised. Series A, B, and C and later stage financing activity was down and bridge financing activity was up—suggesting that investors are hunkered down and focused on bridge financing their portfolio companies through the challenging fundraising environment, at the expense of new equity investments. While we do not expect the level of financing activity to change substantially in the foreseeable future, given the continued instability of the financial markets, we are encouraged by the recent surge in financing closings, and hope to see the overall amount of investment dollars follow that trend as the economy improves.

Scott Murano
(650) 849-3316
smurano@wsgr.com

Congress Attempts to Improve the Patent Eligibility of Medical Diagnostics

By Richard Torczon (Senior Counsel, Washington, D.C.)

For the past 40 years, the Supreme Court has consistently taken a narrow view of the eligibility of patents directed to natural phenomenon and natural products, a position that it re-affirmed more than a decade ago. Lower courts have followed suit. Nonetheless, life science innovators continue to press for a predictable—and more inclusive—eligibility framework when patenting their inventions.

To address the challenges medical-diagnostic patents face, legislation to codify an expanded view of patentability has been introduced in the Senate. The chair and ranking member of the Senate Intellectual Property subcommittee introduced the bipartisan Patent Eligibility Restoration Act of 2023 (S. 2140) in June 2023, and the subcommittee has held hearings. The bill would eliminate the Supreme Court's exceptions to patent eligibility in favor of much narrower statutory exceptions that would mainly exclude purely mathematical or mental processes, business methods, and unmodified natural materials.

> The Patent Eligibility Restoration Act of 2023 (S. 2140) would eliminate the Supreme Court's exceptions to patent eligibility in favor of much narrower statutory exceptions that would mainly exclude purely mathematical or mental processes, business methods, and unmodified natural materials

While this development hints at progress toward a resolution, a healthy dose of caution is warranted. Variations on this bill have been introduced in previous congressional sessions without success. Expansion of eligibility continues to be contentious for stakeholders. High-tech stakeholders, in particular, worry about patents directed to ideas rather than implementations, while medical stakeholders worry about patents that appear to restrict rather than promote access to important new diagnostic services and therapies. Balancing these interests has not become any easier in the last decade, and the current effort has not generated a groundswell of political support.

Moreover, recent research has blunted one of the main criticisms of the Supreme Court rule: that it is unpredictably applied and leads to arbitrary results. A recent empirical study (by law professors Jason Rantenan and Nikola Datzov) indicates that the lower courts are quite good at consistently reaching decisions that the Federal Circuit will affirm. Federal Circuit decisions have also rejected United States Patent and Trademark Office efforts to read the case law expansively. This suggests that outcomes are quite predictable, if not nearly as favorable as many patentees would wish.

So where does this leave a congressional reform addressing the current narrow scope of patent eligibility? Further progress is unlikely in the near term. Moreover, given the ongoing contention over whether reform is even necessary, this bill is a poor candidate to be part of a pre-election rush to complete legislation. Even if the bill is enacted, the Supreme Court will undoubtedly be asked to weigh in on whether Congress even has the power to sweep away the Court's judicial exceptions to patent eligibility and, if so, whether it has properly exercised its power. In the meantime, meeting the eligibility challenges for diagnostic patents will continue to require attention and skill.

Richard Torczon
(202) 973-8811
rtorczon@wsgr.com

DOJ Offers New Incentives for Life Sciences Companies to Self-Disclose Misconduct

By Tarek Helou (Partner, Washington, D.C.) and Jessica Lonergan (Of Counsel, New York)

When business leaders learn about criminal misconduct in their company, they face a difficult decision: handle the misconduct internally and hope that everything gets resolved quietly, or disclose the misconduct to the government?

The Department of Justice (DOJ) encourages business leaders to disclose their company's criminal misconduct by offering to reduce or even eliminate penalties in return. While these incentives have been around for several years, 2023 brought a wave of updates that will impact life sciences companies' calculus for whether and how to engage with the DOJ.

The DOJ's Self-Disclosure Policy

The DOJ will presumptively decline to prosecute a company that (1) voluntarily self-discloses its misconduct, (2) fully cooperates with the DOJ's investigation, and (3) timely and appropriately remediates. One important caveat, however, is that this policy does not apply if "aggravating factors" are present. The DOJ has not explicitly laid out all of the aggravating factors, but they include senior executive involvement, significant profits from the misconduct, and pervasive misconduct throughout the company.

In 2023, the DOJ created an avenue for companies to receive declinations *even when* there are aggravating factors. To qualify, a company must meet a higher standard: its self-disclosure must be "immediate," its cooperation and remediation must be "extraordinary," and it must have an effective compliance program *that identified the misconduct*. The DOJ did not define those terms, but a DOJ prosecutor recently said during a conference that "immediate" generally means "a matter of weeks" after determining that employees violated the law. The meaning of these terms will further take shape as the DOJ begins applying this new standard. Regardless, this new policy indicates that the DOJ continues to encourage business leaders to self-disclose misconduct even in the presence of aggravating factors. To learn more about this new standard and how it could apply to your company, please read our government investigation group's client alert on the topic.

New Opportunities to Reduce Fines

Not all companies will receive a presumption of a declination, for example, if their misconduct involved aggravating factors or was brought to the DOJ's attention before self-disclosure. To encourage those companies to cooperate in investigations, this year the DOJ announced new incentives in the form of reduced financial penalties:

- If there are aggravating factors but the company still voluntarily self-disclosed, cooperated, and remediated, the DOJ will recommend that the company's fine be reduced by 50 to 75 percent off the low end of the Sentencing Guidelines fine range.
- If the company did not voluntarily self-disclose but still cooperated and remediated, the DOJ will recommend a reduction of up to 50 percent.

Another new way for companies to reduce their penalties is by shifting the financial consequences onto the responsible individuals. Under a new pilot program, the DOJ will have discretion to reduce financial penalties owed by a company by the amount of money that the company can claw back from bonuses paid to its culpable employees and their supervisors. Even if a company's good-faith efforts fail to recover compensation, the DOJ will still recommend that the company's fine be reduced by up to 25 percent of the money the company sought to claw back.

New Criteria for Evaluating Compliance Programs

The DOJ's charging decision and the conditions on which it will settle are based in part on the effectiveness of a company's compliance program. The DOJ publishes criteria for how it evaluates compliance programs, and it released a 2023 update with two main additions.

First, a compliance program needs to manage employees' communications on their personal devices or on "off-channel" messaging apps, such as iMessage, WhatsApp, Signal, and WeChat. Each company's policy should be tailored to its risk profile and its need for such communications, but it should at least implement a policy to ensure that business-related communications are preserved and accessible, train employees on the policy, and impose discipline on employees who violate it.

Second, a company should use compensation structures to promote compliance, by imposing financial penalties for misconduct and granting

Continued on page 12...

DOJ Offers New Incentives for Life Sciences Companies . . . *(Continued from page 11)*

bonuses or promotions to employees who improve compliance. Relatedly, as part of the pilot program discussed above, the DOJ announced that all corporate resolutions will now require companies to include compliance-related criteria in their compensation and bonus structures. If you are interested in learning more about remediating your company's use of off-channel communications or changing its compensation structure, please read our client alert on these new policies.

Other Self-Disclosure Policies

All of the policies detailed above were issued by the DOJ's Criminal Division, which brings many corporate cases and leads all Foreign Corrupt Practices Act (FCPA) prosecutions. But many life sciences companies also face enforcement from the Consumer Protection Branch (CPB), a component within the DOJ's Civil Division that handles criminal matters under the Food, Drug, and Cosmetic Act (FDCA).

In 2023, the CPB adopted its first formal policy for rewarding self-disclosure. The CPB's policy generally follows the Criminal Division's policy, but there are some key differences that make CPB's policy more stringent. For example, the Criminal Division's policy offers the presumption of a declination, whereas the CPB's policy offers only a presumption that it will not seek a *guilty plea*. This distinction leaves the door open to deferred or non-prosecution agreements, which typically carry weightier penalties and conditions. Additionally, the CPB's policy does not offer any benefits for companies that self-disclose with aggravating factors. And the CPB's list of aggravating factors goes beyond the Criminal Division's and includes conduct that targets vulnerable victims or puts consumers at significant risk of death or serious bodily injury.

Over the past decade, other components of the DOJ have aggressively pursued life sciences companies for violations of the False Claims Act and anti-kickback statutes, and those components also have their own voluntary self-disclosure policies. The policy of the U.S. Attorney's Offices, for instance, offers qualifying companies only a presumption that they will not seek a guilty plea, rather than a full declination. The policy of the Civil Division's Commercial Litigation Branch is less well-defined, merely stating that companies may receive "credit" for self-disclosing, cooperating, and remediating violations of the FCA; it does not offer presumptions of specific benefits or identify aggravating factors that would disqualify companies from those benefits. But because DOJ leadership has directed every component to at least award qualifying companies a presumption that it will not seek a guilty plea, the policy of the Civil Division's Commercial Litigation Branch may be revised soon.

Example of a Life Sciences Declination

To see the DOJ's policies in practice, consider the recent FCPA case of Lifecore Biomedical, a manufacturer of biomaterials and medical devices. In November 2023, the DOJ declined to prosecute Lifecore even though Lifecore's subsidiaries bribed Mexican officials to avoid having to properly discharge wastewater. The DOJ declined to prosecute Lifecore in part because Lifecore self-disclosed the misconduct just three months after opening an investigation and just hours after its investigation confirmed the violations. The DOJ also applauded Lifecore's remediation efforts, including terminating the responsible employee and withholding the employee's bonus and other compensation.

A declination is, in many situations, one of the best outcomes for a company in Lifecore's position. Its decision to self-disclose, remediate, and withhold bonuses and other compensation should be viewed as validation of the DOJ's new policies.

New M&A Safe Harbor Policy

Shifting gears into the transactional space, in October 2023 the DOJ announced its Mergers & Acquisitions Safe Harbor Policy. Under that policy, it will presumptively decline to prosecute an acquiring company for misconduct at an acquired company, as long as the acquirer (1) discloses the misconduct to the DOJ within six months of closing, (2) cooperates with the DOJ's investigation, and (3) remediates the misconduct within 12 months of closing. Those timelines may be adjusted to address the unique circumstances of a deal, such as if the transaction is complex or if the misconduct causes ongoing harm. Notably, the acquirer may receive a declination even in the presence of aggravating factors. This policy applies to misconduct falling under the purview of any DOJ component, not just the Criminal Division. To learn more about this new policy and its implications for corporate transactions moving into 2024, please read our recent client alert on the topic.

Conclusion

The DOJ continues to try to incentivize companies to self-disclose misconduct. Nevertheless, business leaders and their advisors should carefully weigh the pros and cons of doing so. The DOJ's policies

Continued on page 13...

DOJ Offers New Incentives for Life Sciences Companies . . . *(Continued from page 12)*

do not guarantee favorable outcomes; the DOJ has wide latitude to determine whether all the criteria are met and whether aggravating factors are present. Even if the DOJ awards a declination, it will likely still require the company to disgorge profits, and the declination will be public.

Furthermore, resolving a criminal case with the DOJ may be just a fraction of a company's legal troubles. This concern is especially present in the life sciences industry, where companies will often face further challenges from qui tam whistleblowers under the FCA, the Department of Health and Human Services, and foreign regulators, and upset shareholders and consumers.

Despite these risks, the DOJ's latest incentives should be top of mind for business leaders trying to decide whether to self-disclose criminal misconduct.

Tarek Helou
(202) 973-8863
thelou@wsgr.com

Jessica Lonergan
(212) 453-2849
jlonergan@wsgr.com

Wilson Sonsini and LaunchBio Co-host NextGen VC Forums Focused on Life Sciences

In 2023, Wilson Sonsini and LaunchBio co-hosted a series of invitation-only, half-day NextGen VC Forums focused on life sciences—premier events for venture capital associates to expand their skills and expertise while growing their network. Held in San Francisco, New York, and Boston, the Forums featured three curated educational panel sessions focused on the life sciences industry, as well as a networking breakfast and lunch. Topics included negotiating term sheets, leveraging IP diligence, and understanding board governance.

The sessions were curated by Wilson Sonsini patents and innovations partner Michael Hostetler, Ph.D., and corporate partner Dan Koeppen.

For more information, please visit https://launchbio.org/programs/nextgen-vc-forum/.

NextGen VC FORUM

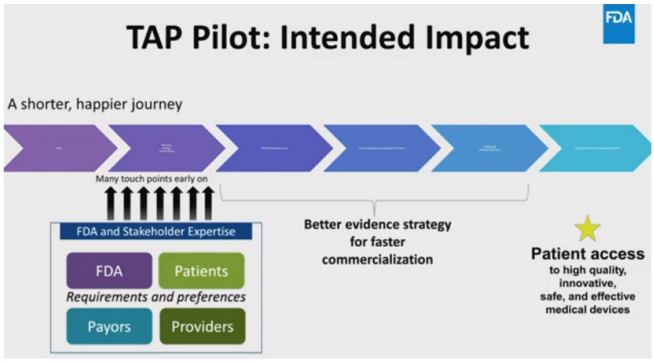
Q&A with Ed Shenkan: Decreasing Risk from Medical Device Concept to Commercialization

Getting innovative medical devices to the market is a complex process, and many devices, even after obtaining marketing authorization from the U.S. Food and Drug Administration (FDA), are lost to the "valley of death" and never make it into the hands of patients or doctors. When Pear Therapeutics, a digital therapeutics company that had successfully obtained multiple FDA clearances, filed for bankruptcy in 2023, it surprised many in the industry and served as a reminder that commercial success requires more than just FDA clearance/approval and that getting to the market does not always translate to market acceptance or widespread adoption.

Understanding the market conditions and what payors and users are willing to pay are important factors that medical device developers should consider early in their product development process, when devices, indications, and clinical trials can be tweaked or optimized to decrease the "valley of death" risk, increase valuation, and obtain more clinical and cost-effectiveness evidence to support the device's reimbursement pathway. To learn more about the challenges faced by medical device start-ups and strategies for decreasing risk and increasing the likelihood of commercial success, Wilson Sonsini partner Eva Yin recently chatted with Ed Shenkan, an independent consultant and medical device industry veteran.

What are some of the common pitfalls you have seen with start-ups? What are your recommendations for early-stage companies for surviving tough fundraising times?

Ed: Start-ups often forget to talk to a large audience of potential physician users and hospital purchasers when designing products. Without developing a comprehensive understanding of how healthcare providers will adopt the product, companies may develop flawed business models. Successful products fit into the workflow of the healthcare providers and are supported by a business model that includes reimbursement. After understanding the market, the company can have informed discussions with medical societies that can support the creation of new reimbursement codes. Many start-ups do not have the expertise or resources to focus on reimbursement before they begin their clinical study.



Source: FDA, Total Product Life Cycle Advisory Program (TAP), available at https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap.

At Shenkan Advisors, we help companies to develop go-to-market strategies for products that can gain widespread adoption. We create the product strategy after interviewing and surveying healthcare providers, chiefs of medical departments, and payors about the product and competitor products. Data from the interviews and surveys allow us to build a comprehensive financial model, which enables investors to appreciate the full valuation of the company. If the company shares the analysis with investors and potential acquirers, it can help companies raise capital and also educate potential acquirers of the product's value.

When capital is hard to raise, companies are forced to scrutinize which programs to continue to fund. I encourage companies to eliminate spending that will not add value to the potential acquirer. By understanding potential acquirers' needs, companies can focus on developing products that acquirers value most.

In difficult economic times, hospitals and physicians tend to continue to purchase "must-have" products, but might forgo purchasing "nice-to-have" products. Acquirers also pay more for physician preference products that enable their sales team to be present in procedures. Physician preference products can be the backbone of a large company's portfolio, which drives a higher takeout valuation for these novel products. Physician preference and "must-have" products are extremely valuable because they enable the company to bundle the rest of their portfolio for customers. If a product is the most important in the bundle, its valuation can be magnified above the revenues it might generate alone. Therefore, products that enable a large company to bundle a portfolio of products tend to drive higher valuation and interest from investors.

Could you share a bit about your recent experience at the FDA Center for Devices and Radiological Health (CDRH) and the Total Product Life Cycle Advisory Program (TAP) Pilot, which you helped to launch in 2023?

Ed: Although I no longer work at FDA, I am pleased to share a bit about the

Continued on page 15...

Q&A with Ed Shenkan . . . *(Continued from page 14)*

TAP Pilot that FDA launched in 2023. CDRH Director Dr. Jeff Shuren and his Deputy Director for Science, Dr. Doug Kelly, wanted to build a customer-focused consultancy within FDA and recruited me to launch TAP because of my experience as a strategy consultant and sell-side equity financial analyst at JPMorgan and other investment banks. TAP is helping to make CDRH interactions with companies less formal. This is a culture change for CDRH and will take time.

TAP is the innovation arm of CDRH and will help to pilot innovative programs. The first program TAP launched is designed to help breakthrough devices obtain reimbursement. FDA has recruited talented leaders from within the agency, as well as experts from the industry and payors, to build a team of FDA TAP advisors to work with participating companies.

With FDA's TAP assistance, the company receives advice on commercialization, including reimbursement. TAP advisors can join the company in the medical society meetings and help to prepare the company for such meetings.

The clinical evidence the company develops is the golden asset that ensures the clinical and commercial success of the company and is the core of the strategic plan. FDA is working with companies to develop more robust clinical evidence to reduce the risks of reimbursement and commercialization. As FDA discusses the pivotal clinical study design, TAP advisors connect the companies with payors, patients, physicians, and medical societies. These discussions can inform the design of a more robust clinical trial, which will help to ensure commercial success by including coding, coverage, reimbursement, and eventually inclusion in the guidelines. Including more patients in the studies will likely result in a longer time to complete the trial and additional expense, but this may ensure reimbursement and commercial success. It is expected that some of these companies may decide not to pursue a product due to the high expense. An informed decision to not bring a product into clinical studies will avoid wasted capital and resources.

For start-ups with limited resources that are debating whether it is worth applying for a Breakthrough Device Designation (BDD), how would you advise them to think about the pros and cons? Some companies have expressed that receiving the BDD did not help to expedite their regulatory review process with FDA. Do you think TAP aims to change that?

Ed: Yes. BDD enables companies to apply for TAP. Each TAP product receives a personal TAP advisor to help the product sponsor with the regulatory review, reimbursement, and commercialization. TAP brings together the ecosystem of payors, providers, medical societies, and patients to inform the company's clinical trial design. TAP advisors are FDA employees who help the company to better understand the pathway toward coding, coverage, reimbursement, and inclusion in medical guidelines. TAP advisors also connect the company with payors to hear feedback regarding what data will be needed for future coverage. FDA is an advisor, but the company drives these processes. TAP advisors help the company to prepare for these stakeholder meetings, and FDA participates when requested as an observer in the meetings and as an advisor to help companies prepare for and debrief the meetings.

TAP advisors can also connect the companies to patient groups, which may lead to focus groups, patient interviews, and patient advisory panels. Information learned from patients' perspectives on the products can greatly help FDA medical directors to better understand what will be needed in the clinical trials. FDA medical directors appreciate hearing patient feedback as they consider new products. Sometimes this can be even more impactful for FDA than speaking with key opinion leaders.

Criteria for enrolling in TAP are as follows:

- Devices will be those with a granted BDD; in FY2026-27, devices with a granted request for inclusion in the Safer Technologies Program (STeP) may also be eligible
- Have not submitted a Pre-Submission about the device after being granted a BDD
- Early in the device development process (e.g., have not yet initiated a pivotal study for the device) at the time of enrollment
- Each potential participant will have a maximum of one device enrolled in the TAP Pilot per fiscal year

Source: FDA, Total Product Life Cycle Advisory Program (TAP), available at https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap.

Currently, TAP is only considering OHT2 (Office of Cardiovascular Devices) and OHT5 (Office of Neurological and Physical Medicine Devices) devices, but will expand to include other Offices of Health Technology (OHTs). To be considered for TAP, a product must have received BDD.

How is a TAP advisor different from a lead reviewer?

TAP advisors are additional resources who can help ensure that breakthrough innovative products are not delayed as they navigate the FDA review process. For TAP devices, the review process for the sponsors with the review staff is

Continued on page 16...

Q&A with Ed Shenkan . . . *(Continued from page 15)*

unchanged. It is in the public health's interest that novel products come to market in a timely manner to improve healthcare for everyone.

The TAP advisors are included in the review process and join the sponsors for meetings with the lead reviewer. TAP advisor continuity can be beneficial when the lead reviewer of a product changes. When challenging topics are discussed with FDA, the TAP advisor can help with communication between the company and FDA.

TAP advisors are connectors, liaisons, or network enablers for participating companies, and they can connect companies to experts to help with quality initiatives, manufacturing, and financing, as well as make introductions to physicians or hospitals that might be included in the trials.

Lead reviewers of TAP products can join the sponsors for interactions with payors. Over time, the lead reviewers of TAP products will gain a better understanding of the payor reimbursement process, which can benefit future products. In time, TAP could even become part of the Office of Product Evaluation and Quality (OPEQ).

Based on your interactions with VCs, private equity firms, and more established medical device companies, what are their views on TAP? Is this something they are looking for when investing in start-ups?

Ed: Investors are very supportive of TAP. They see TAP as a program to reduce risk for the products by decreasing the timeline for reimbursement. As risk decreases, the product valuation increases.

Since TAP is a pilot, FDA is encouraging companies to help TAP to trial new offerings that may be beneficial to the companies. Although not a formal TAP offering, TAP advisors can make introductions to investors. Another trialed service is having TAP advisors provide input on the company's investor slide deck.

What is your advice for CEOs and boards?

Ed: In these challenging times for raising capital, companies must decrease risk for investors. I encourage companies to reevaluate the potential impact of their products on the healthcare system. By dedicating time, energy, and resources to reevaluate the product's go-to-market strategy to include reimbursement and outcomes, companies can decrease risk for investors. By including input from patients, payers, and healthcare providers in the product strategy, investor returns will increase. With decreased risk, investments and innovation in healthcare will increase, which will be beneficial to patients and the healthcare system. With investor support, a clear strategy, and a focus on products that improve patient outcomes, creative CEOs can lead their companies through these challenging times.

For more information about Shenkan Advisors, please visit https://www.shenkanadvisors.com/.

Eva Yin, Ph.D., M.P.H.
(206) 883-2572
eyin@wsgr.com

Wilson Sonsini Partners with B7% on Panel Session Addressing Boardroom Best Practices

On September 26, 2023, the firm partnered with Breaking7% (B7%) to host an insightful panel discussion on best practices in the boardroom tailored for venture capital investor-appointed directors and observers. Held in Wilson Sonsini's San Francisco office, the event attracted 25 attendees, most of whom were women in the life sciences VC sector.

The panel, which was moderated by corporate partner Melissa Rick and featured fellow corporate partners Christina Poulsen, Lianna Whittleton, and Andrew Hoffman as speakers, discussed effective governance generally and fiduciary duty considerations in the context of down rounds and similar transactions. Attendees received practical advice and learned strategies to enhance board effectiveness in venture-backed companies, while also having the opportunity to connect with investors, share experiences, and learn from industry experts.

B7% is a women's networking group that aims to build impactful connections and relationships among women in VC/investment and business development deal-making capacities. Wilson Sonsini partner Maya Skubatch coordinated with B7% to organize the event.

Firm Hosts 28th Annual Phoenix Conference

On October 11-13, 2023, Wilson Sonsini hosted its 28th Annual Phoenix Conference, which brought together nearly 150 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. Held at The Ritz-Carlton in Half Moon Bay, California, the exclusive 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 11 with a women's reception featuring a panel of women leaders—Mary Hailey of Relievant Medsystems, Inc., Jinny Lee of Edwards Lifesciences, and Stacey Pugh of Endogenex, moderated by Lisa Wipperman Heine of Nyra Medical—who are creating value through effective strategies for clinical evidence generation, reimbursement, and market access, and building the next generation of great medtech companies. The evening continued with a cocktail reception and welcome dinner.

The formal program began the next morning with a series of panel discussions addressing topics that included managing medtech company building in a constrained environment; leveraging real-world data to optimize product portfolios, clinical trials, reimbursement, and commercial execution; using generative AI to take advantage of new opportunities in the medtech ecosystem; and the goals, opportunities, and challenges of the FDA's newly established Total Product Lifecycle Advisory Program (TAP). The first day's programming also included a fireside chat with Ashley McEvoy (EVP and Worldwide Chairman, MedTech at Johnson & Johnson) and Lisa Earnhardt (EVP, Medical Devices at Abbott).

On the evening of October 12, the event featured the 2023 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: GammaTile Therapy by GT Medical Technologies

Emerging Growth Company Award: PROCEPT BioRobotics

Innovator Award: Inceptus Medical's Bob Rosenbluth & Brian Cox

Lifetime Achievement Award: Retired Wilson Sonsini partner Casey McGlynn, a longtime leading medtech attorney who advised hundreds of companies over a decades-long career

On Friday, October 13, the Phoenix Conference concluded with sessions addressing the current state of medtech investment and strategic considerations, opportunities, and challenges that characterize cardiovascular M&A, as well as a Medical Device Innovation Consortium (MDIC) panel on early-stage clinical development and a fireside chat with David Sabow, the Head of Technology and Healthcare at HSBC who previously spent more than a decade at Silicon Valley Bank, most recently leading their North America Technology and Healthcare practice.

In addition, Lifetime Achievement Award winner Casey McGlynn was interviewed by David Cassak of the MedTech Strategist to discuss his accomplished career. Click here to view a video tribute to Casey that was shown at the event.

For more information regarding the 2023 Phoenix Conference, please visit https://phoenix.wsgrevents.com/.

Wilson Sonsini Hosts 2023 Life Sciences Investment Forum

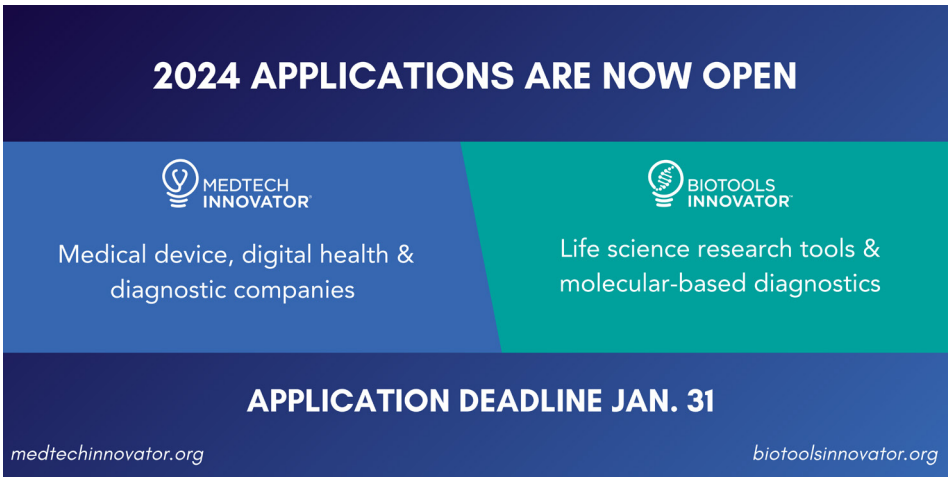
On October 18-19, 2023, Wilson Sonsini hosted its annual Life Sciences Investment Forum, where 28 venture capitalists from 24 firms met with over 50 life sciences companies seeking funding. Held in person at the firm's Boston office, the Forum offered a unique opportunity for investors to connect with promising life sciences start-up clients to discuss potential funding and/or collaborations.

Overall, 140 interested entrepreneurs and growth-stage life sciences companies in the firm's client network applied to privately pitch their companies/ideas for investment, with 78 selected and 52 ultimately participating in meetings at the Forum. Participating VCs included Accelerator Life Science Partners, Aisling Capital, Alexandria Venture Investments, aMoon, ARTIS Ventures, AXA IM, Bison, Dolby Family Ventures, F-Prime Capital, Iaso Ventures, Newpath Partners, OMX Ventures, OrbiMed, Pacific 8 Ventures, PagsGroup, RA Capital, RiverVest Venture Partners, Solasta Ventures, Taiho Ventures, LLC, Two Bear Capital, Vida Ventures, and Xontogeny.

In preparation for the event, the firm presented a webinar, "Crafting a Winning Investor Pitch and Post-VC Meeting Tactics," that addressed how to prepare for a pitch, key components and goals of an effective presentation, and best practices for VC follow-up, among other topics. Held on September 27, the session featured Wilson Sonsini patents and innovations partner Matt Bresnahan and Chief Life Sciences Business Advisor Matt Meyer.

MedTech Innovator and BioTools Innovator Applications for 2024 Now Open

As a longtime partner of MedTech Innovator, the world's largest accelerator for medical device, digital health, and diagnostic companies, Wilson Sonsini is pleased to share that the 2024 application cycle for MedTech Innovator and BioTools Innovator is now open. Applications are due January 31, 2024; please see below for more information.



MedTech Innovator is the largest and highest-performing accelerator of medical technology in the world and the medtech industry's premiere showcase and competition 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. Over the last decade, its nonprofit program has empowered 600+ companies to obtain nearly 300 FDA clearances and $7 billion in additional funding.

Each year, 50+ companies will be selected to participate in the MedTech Innovator Accelerator and receive access to leading investors, strategic partners, suppliers, and peer networks for ongoing coaching and mentoring. Early-stage accelerator companies (pre-Series B) will compete for up to $500,000 in non-dilutive cash prizes. To apply, visit https://medtechinnovator.org/apply/.

BioTools Innovator (powered by MedTech Innovator) is the world's first and only accelerator dedicated to advancing a broad spectrum of tools and diagnostic platforms that enable the life sciences. It supports entrepreneurs developing a broad spectrum of biotechnology products, platforms, and services that are enabling the future of healthcare, matching industry leaders with innovative early-stage and emerging growth biotechnology-focused companies for mentorship and support. In its first three years, BioTools Innovator has empowered over 40 companies to raise nearly $100 million in additional funding.

BioTools Innovator selects the best-in-class start-ups across the life science tools industry to receive a slot in the BioTools Innovator virtual accelerator. Accelerator companies will compete for up to $300,000 in non-dilutive cash prizes. To apply, visit http://biotoolsinnovator.org/apply.

What They're Looking For:

MedTech Innovator is looking for early-to-mid-stage start-ups in the medical device, diagnostic, or digital health/health IT spaces, while BioTools Innovator is looking for early-stage founders developing tools and services for biotechnology, biomedicine, cell biology, molecular biology, genetics, and biochemistry.

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 chosen for the 2024 cohort will also compete for up to $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
Diane Bouis, Ph.D.
diane@medtechinnovator.org

BioTools Innovator:
Jim West
jim@biotoolsinnovator.org

Select Recent Life Sciences Client Highlights

In the past six months, Wilson Sonsini has provided representation in connection with the below client matters:

- Represented **C4 Therapeutics**, Inc. in its license and research collaboration with Merck (December 2023)
- Advised **RayzeBio** on patent matters related to its acquisition by Bristol Myers Squibb (December 2023)
- Advised **Conexa Health** on its $5.1 million investment from Vivo Ventures (December 2023)
- Advised **Sudo Biosciences** on IP matters related to its $116 million Series B financing (December 2023)
- Represented **Visant Medical** in its acquisition by Amring Pharmaceuticals Inc., a subsidiary of Nordic Group B.V. (December 2023)
- Represented **BigHat Biosciences** in its research collaboration with AbbVie Inc. to discover and develop next-generation therapeutic antibodies in oncology and neuroscience (December 2023)
- Advised **Absci** on its collaboration with AstraZeneca to advance AI-driven oncology candidate (December 2023)
- Advised **Khosla Ventures** on patent strategy matters related to Vivodyne's $38 million Seed financing (November 2023)
- Acted as issuer's U.S. counsel in **WuXi XDC Cayman Inc.'s** (WuXi XDC's) US$470 million IPO and Hong Kong listing; also acted as U.S. and Hong Kong counsel for WuXi AppTec Co., Ltd., a controlling shareholder of WuXi XDC in connection with the transaction (November 2023)
- Advised **Nature's Toolbox (NTx)** on its $47.5 million Series B funding (November 2023)
- Represented **LENZ Therapeutics** in its merger agreement with Graphite Bio, Inc. (November 2023)
- Advised **Arcellx, Inc.** on its expansion of a strategic partnership with Kite, a Gilead company (November 2023)
- Represented **CARGO Therapeutics** in patent and technology transactions matters leading up to and with respect to its $281 million IPO (November 2023)
- Advised **Venatorx Pharmaceuticals, Inc.** on IP matters related to its licensing agreement with Melinta Therapeutics (November 2023)
- Advised **Forward Therapeutics** on IP matters related to its $50 million Series A financing (November 2023)
- Represented **Alpine Immune Sciences, Inc.** in its $150 million follow-on public offering (November 2023)
- Advised **Celest Therapeutics** on its strategic collaboration with Senti Biosciences (November 2023)
- Represented **IVIVA Medical, Inc.** in its acquisition by United Therapeutics (October 2023)
- Advised **Verve Therapeutics, Inc.** on IP matters related to the expansion of its relationship with Eli Lilly and Company (October 2023)
- Represented **Aqtual** in its $16 million Series A funding (October 2023)
- Advised **Novo Holdings** on MapLight Therapeutics' $225 million Series C financing
- Acted as IP and corporate counsel to **DermBiont** in connection with its $35.2 million Series B financing (October 2023)
- Advised **Quince Therapeutics** on patent matters related to its acquisition of EryDel S.p.A. (October 2023)
- Advised **Assembly Biosciences** on its partnership with Gilead Sciences (October 2023)
- Represented **BioMap** in its strategic collaboration with Sanofi (October 2023)
- Advised **ALX Oncology** on its $63 million public offering (October 2023)
- Advised **Iambic Therapeutics** on its $100 million Series B financing (October 2023)
- Represented **Soleno Therapeutics** in its $120 million public offering and concurrent private placement (September 2023)
- Advised **Azurity Pharmaceuticals, Inc.** on IP matters related to its acquisition of Slayback Pharma LLC (September 2023)
- Advised **Novo Holdings A/S** and **Vida Ventures** on Avalyn Pharma Inc.'s $175 million Series C financing (September 2023)

Continued on page 21...

Select Recent Life Sciences Client Highlights *(Continued from page 20)*

- Advised **Adela, Inc.** on patent matters related to its $48 million financing (September 2023)
- Represented **Applied Molecular Transport Inc. (AMT)** in its merger agreement with Cyclo Therapeutics (September 2023)
- Advised **JURA Bio** on its $16.1 million financing and research collaboration agreement with Syena, a subsidiary of Replay (September 2023)
- Advised **Related Sciences** on its drug discovery collaboration agreement with Charles River Laboratories International, Inc. (September 2023)
- Advised **RayzeBio** on IP matters leading up to and with respect to its $311 million IPO (September 2023)
- Advised **Insilico Medicine** on its $80 million global license agreement with Exelixis, Inc. (September 2023)
- Represented **Idorsia Ltd** in its agreement with Janssen Biotech Inc. for the reacquisition of global rights for aprocitentan (September 2023)
- Advised **Amber Therapeutics** on IP matters related to its acquisition of Bioinduction (September 2023)
- Represented **Kerecis** in its $1.3 billion acquisition by Coloplast (August 2023)
- Represented **Thorne HealthTech, Inc.** and the **Special Committee of the board of directors** in the company's agreement to be acquired by *L* Catterton (August 2023)
- Represented **Palette Life Sciences Inc.** in securing Federal Circuit affirmance of Patent Trial and Appeal Board (PTAB) victory (August 2023)
- Advised **Amber Bio** on its $26 million Seed financing (August 2023)
- Counseled **Pacific Biosciences of California** on patent matters related to its agreement to acquire Apton Biosystems, Inc. (August 2023)
- Advised **Foresite Capital** on IP matters related to CG Oncology, Inc.'s $105 million crossover financing (August 2023)
- Advised **Forte Biosciences** on its $25 million financing (August 2023)
- Represented **Boyu Capital** in its acquisition of Quasar Medical (July 2023)
- Advised **Versant Ventures** and **New Enterprise Associates (NEA)** on Nexo Therapeutics' $60 million Series A financing (July 2023)
- Represented **DTx Pharma** in its acquisition by Novartis (July 2023)
- Advised **SpyGlass Pharma** on its $90 million Series C financing (July 2023)
- Advised **IGM Biosciences, Inc.** on its upsized follow-on offering (July 2023)

Upcoming Life Sciences Events

rEVOLUTION 2024
May 1-3, 2024
Waldorf Astoria Washington DC
Washington, D.C.
https://revolution.wsgrevents.com/

Founded in 2002 and now in its 13th gathering, the rEVOLUTION symposium has become the place to discuss the most important strategic problems facing pharma and biotech CSOs. We will examine the organization and management of R&D to uncover new disruptive discovery and development models and assess the continued impact of pricing, reimbursement, regulation, and globalization on our industry.

Wilson Sonsini's Medical Device Digital Health Conference
June 13-14, 2024
The Palace Hotel
San Francisco, CA
https://mdc.wsgrevents.com/

Wilson Sonsini's 31st Annual Medical Device Digital Health Conference will address topics of critical importance to medical device and digital health companies today, including key healthcare regulatory considerations, the relationship between intellectual property and valuation, a look back at 2023's fundraising and deals, and how 2023 is shaping up, as well as partnering strategies in the current market. Join medical device and digital health entrepreneurs, CEOs of venture-backed companies, and business development executives from large Medtech companies, as well as angels, venture capitalists, and corporate investors, for two days of networking and programming that can help you craft a winning strategy.

Phoenix 2024: The Medical Device and Diagnostic Conference for CEOs
October 23-25, 2024
Ritz-Carlton, Half Moon Bay
Half Moon Bay, CA
https://phoenix.wsgrevents.com/

The 2024 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 event will provide an unrivaled experience that will help inform and shape company strategy for the years ahead.

Elton Satusky, Scott Murano, and Kimberly Stopak have editorial oversight of *The Life Sciences Report*. They would like to take this opportunity to thank all of the contributors to the report, which is published on a semi-annual basis.

Elton Satusky
(650) 565-3588
esatusky@wsgr.com

Scott Murano
(650) 849-3316
smurano@wsgr.com

Kimberly Stopak
(415) 947-2024
kstopak@wsgr.com

WILSON SONSINI

650 Page Mill Road, Palo Alto, California 94304-1050 | Phone 650-493-9300 | Fax 650-493-6811 | www.wsgr.com

Wilson Sonsini has 19 offices in technology and business hubs worldwide. For more information, visit wsgr.com/offices.