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THE LIFE SCIENCES REPORT

Wilson Sonsini to Open Boulder Office

In February 2022, the firm announced plans to open a new office in Boulder, Colorado, from which it will support the region's thriving life sciences businesses

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In This Issue

Can Medtech Start-Ups Show Us Where the Industry Is Headed? Insights from MedTech Innovator and Industry Leaders

By Glenn Snyder (Medical Technology Sector Leader, Deloitte LLP), Simon Gisby (Principal, Co-Lead Healthcare Strategy and Growth, Deloitte Corporate Finance LLC), and Leena Gupta (Manager, Deloitte Center for Health Solutions)

Executive Summary

Medical technologies are often the result of years of research and development. In the U.S., they are a foundation of a rich ecosystem of innovation. Start-ups offer advanced technologies that hold the promise of producing data, delivering better care, and driving insights that can improve patient outcomes. These products, services, and capabilities show that we are rapidly moving toward our vision of the Future of Health™ where real-time, interoperable data enable prevention and early detection, and shift the focus away from acute intervention.

In spring 2021, Deloitte's Center for Health Solutions collaborated with MedTech Innovator (MTI)—the world's largest health care accelerator for medical devices, digital health, and diagnostic companies—to evaluate trends across the medical technology start-up landscape. We analyzed MTI's database of 1,000 start-ups that applied in 2021 to participate in the organization's global competition for support from MTI's accelerator program. To deepen our understanding and learn about where stakeholders think the industry is going, we also interviewed leaders from start-ups and medtech companies that could be strategic acquirers ("strategics").

Through our data analysis and interviews, we quantified the following trends:

- **Start-ups and strategics are expanding beyond episodic care and procedures:** Companies that have historically targeted specific therapeutic areas defined by a procedure (e.g., implanted devices) are adding products and solutions to their portfolios to help address the full patient journey—from diagnosis to rehabilitation. Nearly half of start-ups (46 percent) have a focus on prevention and/or wellness or detection/diagnosis, and only 19 percent include a focus on treatment.
- **Care is shifting away from the traditional inpatient setting:** Ambulatory clinics, at-home care, self-administered diagnostics, and always-on remote monitoring are growing areas of interest. Seventy percent of start-up companies in the diagnostics sector have a product applicable to the point-of-care. These trends have implications for reimbursement and clinical support.
- **Medical technology is getting smarter:** Seventy percent of start-up technologies include digital capabilities such as artificial intelligence (AI) and machine learning (28 percent). Strategics

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seeking acquisition targets might be looking for these capabilities.

- **Start-ups are choosing less burdensome regulatory paths:** A majority of innovators are planning to enter the market with 510(k) (47 percent) or unregulated (29 percent) products.
- **Pre-seed rounds have been commonplace, with significant step-ups in average round sizes and limited runway:** In their most recently closed funding, the average round size for pre-seed (39 percent) was $0.25 million, seed (42 percent) was $1.31 million, and Series A (13 percent) was $4.85 million. The average seed stage company has six months of funding before it will need to find additional capital.
- **Series A investors are looking beyond proof of concept:** Investors have become more astute over the last few years in assessing value, clinical efficacy, and reimbursement potential. Innovators have gotten the message that investors may be less willing to make significant investments without clinical evidence or near-term regulatory approval. Most companies seeking Series A are clinical or later in their development stage (66 percent).

COVID-19 has been both a positive and a negative from the business perspective. Interviewees told us they are largely recovering financially from having fewer non-emergency surgeries in 2020. They have learned how to engage with physicians—and support their products—remotely. Funding for medtech and health-tech innovation has remained strong, reaching record levels in 2020. Moreover, the commitment to developing innovative products that support the whole patient journey appears to be even stronger than it was before the pandemic.

In addition, we found that both start-ups and strategics are addressing diversity and health equity. Nearly all of the company executives we interviewed—and 83 percent of the companies in the MTI database—have diversity and inclusion strategies for talent, though representation still has room for improvement. While 49 percent of start-ups have female employees in leadership positions, only 16 percent have BIPOC leadership, and 35 percent have other POC leadership. Medtech companies are also working to:

- Make their products broadly accessible
- Keep diversity in leadership in mind as a part of M&A
- Use real-world data to look at outcomes by race and gender

Introduction

Deloitte's Center for Health Solutions continually evaluates trends in all aspects of health care, with a focus on the Future of Health™. Over the next 20 years, we expect the health care industry will shift from a reactive focus on care to a proactive focus on wellness and prevention, which will all be centered around the consumer. While we might never completely eliminate disease, we expect that breakthroughs in science, data, and technology will make it possible to identify disease in its earliest stages, intervene proactively, and understand disease progression. These anticipated trends could help consumers more effectively and actively manage their own care and sustain their well-being. Specifically, we expect:

- An explosion of data access and analytics will shift us to real-time, pervasive computing that enables earlier detection and intervention.
- Consumers will no longer be led by doctors but will instead be empowered to bring ideas to the table.
- The health care system will transition from a provider-centric model to a consumer-centric model.
- Well-being and care enablement will eclipse sick care.

To play a larger role in the health system of the future, medtech companies will likely need to expand both their scope and their capabilities. One route may be through partnerships with consumer health organizations.[1] Another could be through new business models that could include managing the entire patient journey around a disease or becoming an ecosystem data and analytics provider.[2] Start-up partnerships and acquisitions might offer another important pathway for strategics to explore new models and remain relevant.

Given that start-up companies reflect the leading edge of innovation, we analyzed MedTech Innovator's database of early-stage innovators to determine if start-ups could serve as the backbone for the strategic shift in the medtech industry. The database includes a wide variety of medical technologies that address a wide range of therapeutic areas and needs. The database also indicates whether the start-up community's effort align with our vision for the Future of Health.

To view the full report, including detailed research findings, please visit https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-insights-from-medtech-innovator-and-industry-leaders.pdf.

For this report, Deloitte analyzed 1,000 companies applying to participate in MTI's 2021 program. This database reflects applicants who have developed at

[1] https://www2.deloitte.com/us/en/insights/industry/health-care/future-of-medtech.html.
[2] https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/medical-technology-trends-six-winning-roles.html.

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Background and Methodology

MedTech Innovator (MTI), the world's largest health care accelerator, has a particular emphasis on medical devices, digital health, diagnostics, and life science tools. MTI is a 501(c)(3) non-profit, purpose built to ensure that viable innovations successfully reach patients and with maximum value. Companies apply with no fees or strings attached and are selected solely based on merit.

Incentives to apply are corporate membership and access to MTI partners, industry recognition, visibility and exclusive ability to pitch at leading conferences, education via the MTI LIVE webinar series, investor introductions and showcases, access to a peer network, and cash awards in competitions on the "main stages" of The MedTech Strategist Summit, Wilson Sonsini's Medical Device Conference, and AdvaMed's The MedTech Conference. Across all cohorts, $1 million in non-dilutive funding [was] awarded in 2021 by MTI. To learn about MTI, visit https://medtechinnovator.org.

More than 7,000 companies have applied to MTI since 2013. MTI is highly selective, with less than a 5 percent acceptance rate. Within its portfolio of 420 alumni companies, 95 percent are still operating or have been acquired. Graduates have raised $4.5 billion in follow-on equity funding, achieved 25 acquisitions, and brought 135 products to market.

least a prototype and have not progressed beyond a Series D round of funding. Some highlights about this pool of companies:

- 76 percent of applicants have raised equity funding, collectively raising $3.9 billion
- Applicants hail from 43 countries and 48 U.S. states
- 33 percent are pre-clinical; 28 percent are clinical/pre-approval; 9 percent are approved; and 22 percent have customers

For each company in the MTI database, data was analyzed in the following areas:

- Development stage
- Product categorization (clinical and technical)
- Completed milestones
- Completed funding amounts, rounds, and investor sources
- Upcoming fundraising and milestones
- Customer types and healthcare economics
- Market access plans
- Competitive advantage
- Intellectual property
- Regulatory path and status
- Validations, traction, and sales
- Revenue model
- Team
- Diversity, equity, and inclusion

In addition to analyzing the MTI dataset, Deloitte also interviewed 14 leaders from start-ups and executives from established medtech companies that could be strategic buyers. They offered their perspectives on the start-up landscape, trends in the industry, and barriers to successful innovation.

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groups, and ancillary service healthcare companies.

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Her research focuses on emerging trends and issues in the life sciences industry, with an emphasis on medical devices and technologies as well as emerging therapies in pharma. Leena holds a bachelor of science degree in biological sciences from the University of Missouri-Columbia and a master's degree in public health in Epidemiology from the Tulane University School of Public Health and Tropical Medicine.

Wilson Sonsini to Open Boulder Office *(Continued from page 1)*

and other growth enterprises. The launch of the Colorado office—which is located in downtown Boulder—follows the firm's recent opening of a Salt Lake City office, and means that Wilson Sonsini now has a total of 18 offices worldwide (13 in the U.S., three in Greater China, one in Brussels, and one in London).

The team in the Boulder office includes Wilson Sonsini partners Vern Norviel and Tony Jeffries—who will split their time between Colorado and California—as well as several associates and staff professionals.

"Our firm's attorneys have established a strong base of relationships with the many innovative entrepreneurs, companies, institutions, and investors in Boulder and other parts of Colorado and the Mountain West region," said Doug Clark, managing partner of Wilson Sonsini. "Opening in Boulder reinforces our interest in expanding our life sciences and technology practice in that important market."

According to a report by the Colorado BioScience Association in late 2021, more than 700 life sciences companies are located in Colorado, and in 2021 they raised a record $2.4 billion in financing—twice the amount raised in 2020 and the fifth consecutive year that the total raised exceeded $1 billion. Overall, Colorado companies raised $6.5 billion in venture financing in 2021, according to PitchBook's Venture Monitor report.

Firm Connects Investors with the Burgeoning Colorado Life Sciences Industry

In April, a team of Wilson Sonsini life sciences attorneys and business professionals hosted a visit for representatives from leading venture capital firms as part of the firm's expansion into the growing Colorado market.

The program provided exclusive access for the investors to presentations by early-stage life sciences companies associated with the University of Colorado (CU) and the SPARK program at the Anschutz Medical Campus in Aurora, including firm client Foresight Diagnostics. The participating VCs also had the opportunity to meet with leaders of the life sciences innovation programs located at CU and informally interact with Wilson Sonsini attorneys. Finally, the group was given a presentation on motion and time by Dr. Jun Ye, a fellow at CU Boulder's Joint Institute for Laboratory Astrophysics (JILA), a physical science research institute.

"Connecting investors and early-stage companies is a valuable service that builds ecosystems, especially when those connections span different geographic regions. The Gateway to Colorado VC Roadshow was incredibly well received and catalyzed new and fruitful relationships between VC firms and our local, high-potential start-ups. We are delighted that Wilson Sonsini is opening an office here in Boulder and look forward to collaborating to grow great companies together," said Bryn Rees, Associate Vice Chancellor, Research & Innovation, and Managing Director, Venture Partners, at the University of Colorado Boulder.

Wilson Sonsini already represents clients in Colorado that fall into a range of life sciences sectors, including: drug discovery; biotech, genomics, and proteomics; screening and diagnostics; medical devices and supplies; pharmaceuticals; health services; and agtech and foodtech. In fact, the firm advised on a number of recent life sciences venture capital financings, M&A transactions, and IPOs in the region, including the 2021 IPO of Edgewise Therapeutics, a leader in the search for lifesaving medicines for rare muscular disorders, and the Series A financing for Foresight Diagnostics, which has developed promising technology for the early detection of cancers.

For more information, please see the firm's press release on the new Boulder office.

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 first and second halves of 2021. 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.

	1H 2021	1H 2021	1H 2021	2H 2021	2H 2021	2H 2021
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	48	$2,326.07	$48.46	52	$1,797.89	$34.57
Genomics	4	$11.15	$2.79	10	$332.08	$33.21
Diagnostics	10	$156.17	$15.62	12	$137.49	$11.46
Medical Devices & Equipment	33	$788.16	$23.88	41	$877.40	$21.40
Health IT	14	$225.95	$16.14	12	$146.82	$12.24
Healthcare Services	25	$890.23	$35.61	18	$553.77	$30.76
Total	**134**	**$4,397.74**		**145**	**$3,845.45**	

The data demonstrates that venture financing activity increased from the first half of 2021 to the second half of 2021 with respect to the total number of closings, but decreased with respect to the total amount raised. Specifically, the total number of closings across all industry segments increased 8.2 percent, from 134 to 145, while the total amount raised across all industry segments decreased 12.6 percent, from $4,397.74 million to $3,845.45 million.

Notably, the industry segment with the largest number of closings during the second half of 2021—biopharmaceuticals—experienced a slight increase in number of closings, but a meaningful decrease in total amount raised from the first half of 2021 to the second half of 2021. Specifically, the number of closings in the biopharmaceuticals segment increased 8.3 percent, from 48 to 52, while the total amount raised decreased 22.7 percent, from $2,326.07 million to $1,797.89 million. The industry segment with the second-largest number of closings during the second half of 2021—medical devices and equipment—increased in both number of closings and total amount raised from the first half of 2021 to the second half of 2021. Specifically, the number of closings in medical devices and equipment increased 24.2 percent, from 33 to 41, while the total amount raised increased 11.3 percent, from $788.16 million to $877.40 million.

> From the first half to the second half of 2021, the total number of closings across all industry segments increased 8.2 percent, from 134 to 145, while the total amount raised across all industry segments decreased 12.6 percent, from $4,397.74 million to $3,845.45 million

Meanwhile, the industry segment with the third-largest number of closings during the second half of 2021—healthcare services—experienced a decrease in both number of closings and total amount raised from the first half of 2021 to the second half of 2021. Specifically, the total number of closings for healthcare services decreased 28 percent, from 25 to 18, while the total amount raised decreased 37.8 percent, from $890.23 million to $553.77 million. Similarly, the industry segment tied with diagnostics for the fourth-largest

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Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 5)*

number of closings during the second half of 2021—health IT—also experienced a decrease in both number of closings and total amount raised from the first half of 2021 to the second half of 2021. Specifically, the total number of closings for health IT decreased 14.3 percent, from 14 to 12, while the total amount raised decreased 35.0 percent, from $225.95 million to $146.82 million.

Rounding out the field, diagnostics—tied with health IT for the fourth-largest number of closings during the second half of 2021—experienced an increase in number of closings and a decrease in total amount raised from the first half of 2021 to the second half of 2021. Specifically, the total number of closings for diagnostics increased 20 percent, from 10 to 12, while the total amount raised decreased 12 percent, from $156.17 million to $137.49 million. Finally, genomics—the fifth-largest industry segment based on number of closings during the second half of 2021—experienced the most substantial increase on a percentage basis in total number of closings and total amount raised from the first half of 2021 to the second half of 2021. Specifically, the total number of closings in genomics increased 150 percent, from four to 10, and the total amount raised increased 2,877.5 percent, from $11.15 million to $332.08 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—increased from the first half of 2021 to the second half of 2021, while later-stage financing activity declined. Specifically, Series Seed and Series B financing activity increased from the first half of 2021 to the second half of 2021; Series A and bridge financing activity decreased only slightly across that same period; and Series C and later activity experienced a significant decrease. The number of Series Seed closings as a percentage of all closings increased from 9.8 percent to 11 percent and the number of Series B closings as a percentage of all closings increased from 10.5 percent to 17.5 percent. The number of Series A closings as a percentage of all closings decreased from 24.5 percent to 22.1 percent, and the number of bridge financing closings as a percentage of all closings decreased from 16.1 percent to 14.9 percent. Finally, the number of Series C and later closings as a percentage of all closings decreased significantly, from 14.0 percent to 7.8 percent.

> Overall, there seems to be robust financing activity and interest, but investors are deploying less capital overall, particularly to companies seeking later-stage financing

Average pre-money valuations for life sciences companies decreased across the board for earlier-stage equity financings, including Series Seed, Series A, and Series B financings, but increased for Series C and later-stage financings, from the first half of 2021 to the second half of 2021. The average pre-money valuation for Series Seed financings decreased 35.1 percent, from $12.73 million to $8.27 million; for Series A financings, it decreased 7.2 percent, from $36.17 million to $33.58 million; and for Series B financings, it decreased 19.6 percent, from $225.67 million to $181.49 million. On the other hand, the average pre-money valuation for Series C and later-stage financings increased 71.6 percent, from $472.14 million to $810.13 million.

Overall, the data indicates that there was more financing activity during the second half of 2021 compared to the first half of 2021 in terms of number of closings, but the total aggregate amount raised by our life sciences company clients decreased significantly over the same period. Moreover, the data suggests earlier-stage financing activity was favored over Series C and later-stage financing activity, but at lower valuations during the second half of 2021 compared to the first half of 2021, while those companies that were able to secure the more elusive Series C and later-stage financing during the second half of 2021 were rewarded with higher valuations than the prior period. Overall, there seems to be robust financing activity and interest, but investors are deploying less capital overall, particularly to companies seeking later-stage financing. We would expect this trend to persist as the economy continues to seesaw through ongoing surges of the pandemic, war, and rising inflation.

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CRISPR Gene Editing Patents: Priority Fight Between University of California and the Broad Institute Continues

By Rona Lamiquiz (Associate, Palo Alto) and Sarah Cohen (Patent Agent, New York)

The latest battle between the Regents of the University of California, University of Vienna, and Emmanuelle Charpentier (collectively "UC" or "CVC") and the Broad Institute, Massachusetts Institute of Technology, and Presidents and Fellows of Harvard College (collectively "Broad") was heard by the Patent Trial and Appeal Board (PTAB) in February. In Interference No. 106,115, *University of California v. Broad Institute*,[1] the PTAB determined that Broad had priority over UC on CRISPR-Cas9 gene editing application in eukaryotic cells. However, this PTAB decision does not negate the provenance of the CRISPR-Cas9 system without restriction to the environment, which remains with UC.

The CRISPR/Cas System

The CRISPR/Cas system of genetic editing is hailed as a revolutionary technology that has given scientists the tools to modify the basic building blocks of life. Genetic editing is an umbrella term for a multitude of scientific technologies, including Zinc Finger Nucleases (ZFNs), Transcription Activator-Like Effector Nucleases (TALENs), and, most famously, Clustered Regulatory Interspaced Short Palindromic Repeats (CRISPR). The CRISPR/Cas system, which was originally discovered as a part of bacterial immune systems, is a group of DNA sequences that bind to bacteriophages (viruses that infect bacteria). Cas (CRISPR-associated system) enzymes then identify and cleave the viral DNA, resulting in protection of the bacterial host.

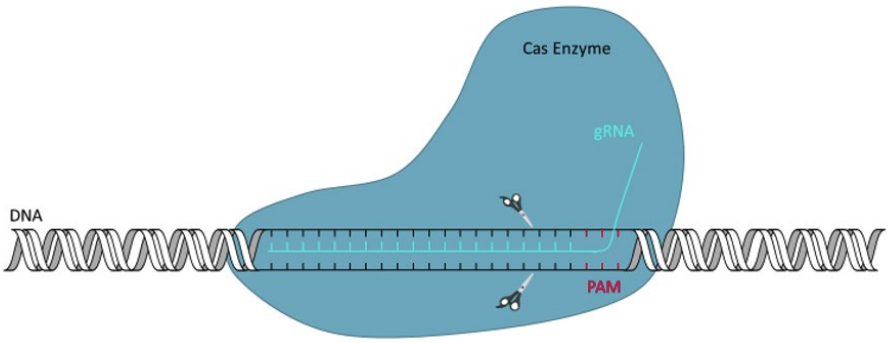
In realizing the potential of this system for genetic engineering, scientists have harnessed this bacterial immunological system into an easily workable tool for genetic engineering that can selectively cut a nucleotide sequence and modify it. Guide RNAs (gRNAs) direct the Cas enzyme to a specific section of the DNA. gRNAs are designed to be located near a protospacer adjacent motif (PAM), a type of short sequence found throughout the genome that informs the Cas enzyme on exactly where to cut the DNA. After the Cas enzyme cuts the DNA, scientists can delete segments, add in new segments, or switch out portions of the DNA. Over the years, this system has expanded from the classic Cas9-based system to include additional enzymes, such as deactivated Cas enzymes (dCas), which can affect epigenetic modifications rather than the DNA itself, and miniCas enzymes, which are smaller and allow for easier delivery to the target genome.

The figure below illustrates CRISPR gene editing in action. gRNAs direct a Cas enzyme to a segment of DNA that contains a PAM sequence. The PAM sequence informs the Cas enzyme where to cut the DNA. Once the Cas enzyme cuts the DNA, scientists can modify the genome by deleting, adding, or switching sections of DNA.

CRISPR gene editing has captured both scientific and wider imaginations by opening doors to new biological research and medical breakthroughs that were previously unimaginable. To recognize UC's Emmanuelle Charpentier and Jennifer Doudna's contribution to the discovery of CRISPR/Cas system, and to the entire field of genome editing, Drs. Charpentier and Doudna were awarded the 2020 Nobel Prize in Chemistry. Many scientists have expanded and developed the range of CRISPR/Cas systems through myriad discoveries and experiments. The related intellectual property field has also flourished, as a clutch of global research institutions and private companies hold patents on the CRISPR/Cas system.

CRISPR IP

UC and Broad stand out as the two main leaders in holding core CRISPR patents and have been continuing their efforts to develop CRISPR technology. Both parties have been involved in multiple interference and opposition proceedings in front of the U.S. Patent



[1] Document No. 2863 (https://acts.uspto.gov/ifiling/PublicView.jsp?identifier=106115&identifier2=null&tabSel=4&action=filecontent&replyTo=PublicView.jsp#).

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CRISPR Gene Editing Patents . . . *(Continued from page 7)*

and Trademark Office (USPTO) and the European Patent Office (EPO), and the early CRISPR patents from both parties still co-exist in the U.S.

Patent interference proceedings are governed by pre-AIA 35 U.S.C. § 102(g), and are used to determine which party is the first inventor of the same invention for applications and patents filed before March 16, 2013. In the first interference (Interference No. 106,048) between UC and Broad, the PTAB determined there was no interference-in-fact because Broad's patent claims, directed to CRISPR-Cas9 system in eukaryotic cells, and UC's patent claims, directed to CRISPR-Cas9 system without restriction to the environment, are separately patentable. *Regents of Univ. of California v. Broad Inst., Inc.*, 903 F.3d 1286 (Fed. Cir. 2018).

Without a declaration of interfering subject matter, PTAB cannot rule on priority of inventorship. Shortly after the conclusion of the first interference in 2018, UC triggered a second interference (Interference No. 106,115) by filing new patent applications directed to CRISPR-Cas9 editing in eukaryotic cells, claiming priority to U.S. provisional application 61/757,640 (filing date January 28, 2013). The second interference was declared by PTAB on June 24, 2019, noting the claim scope of the UC applications and the Broad patents directed to CRISPR-Cas9 system in eukaryotic cells are the same.

> Licensing considerations to both UC's and Broad's core CRISPR patent portfolios are likely still needed when developing CRISPR-Cas9 technologies with various commercial applications of the technology

After declaration of the second interference, in determining priority, the PTAB followed the legal standard established in *Cooper v. Goldfarb*, "[p]riority of invention goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive of the invention and that it exercised reasonable diligence in later reducing that invention to practice," 154 F.3d 1321, 1327 (Fed. Cir. 1998). For factual analysis, PTAB evaluated inventor testimonies with corroborative and independent evidence provided by both parties. UC argued that its inventors had complete conception of the claims by March 1, 2012; however, the PTAB was unconvinced and sided with Broad's argument that UC's reduction to practice of a CRISPR-Cas9 system in eukaryotic cells was not successful by August 9, 2012. Subsequently, the PTAB determined that Broad had priority when it ruled there was sufficient evidence to demonstrate Broad's actual reduction to practice by October 5, 2012.

In making its decision on priority, the PTAB carefully emphasized that "[t]here is no dispute in this proceeding over the patentability of those claims or that the CVC inventors were the first to invent a CRISPR-Cas9 system with a single guide RNA to cleave DNA in a generic environment."

Additionally, we note that UC's foundational CRISPR patents without restriction to the environment are unaffected by this second interference decision. UC may appeal this priority decision from the second interference, although UC probably will face an uphill battle, given the fact-dependent nature of this PTAB decision. However, the CRISPR patent dynamic between UC and Broad for dominance over CRISPR IP is unlikely to change in the near future. To that end, licensing considerations to both UC's and Broad's core CRISPR patent portfolios are likely still needed when developing CRISPR-Cas9 technologies with various commercial applications of the technology.

Conclusion

While this recent PTAB decision has minimal impact on basic research in the gene editing field, it may cause companies to approach their licensing strategies differently. We caution against such a shift because UC continues to hold foundational CRISPR-Cas9 patents without restriction to a eukaryotic environment, and because this decision is specific to the United States. Further, UC has numerous issued patents directed to various guide formats of the CRISPR-Cas9 system. Companies should continue to employ comprehensive and reasonable licensing strategies to avoid any potential freedom-to-operate issues.

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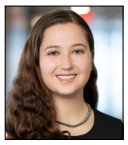

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Beyond Research Tools: When Is a Patented Product That Is Not Subject to FDA Premarket Approval a "Patented Invention" Under the Patent Safe Harbor of Section 271(E)(1)?

By Dennis D. Gregory (Senior Counsel, Austin) and G. Edward Powell III (Associate, Washington, D.C.)

The "safe harbor" against patent infringement[1] protects and incentivizes research and development of drugs, biologics, and medical devices in the United States by immunizing from patent infringement liability many pre-commercialization acts reasonably related to submissions to the U.S. Food and Drug Administration (FDA). But the actual application of this seemingly simple statute has been the source of controversy for decades.

A well-known and still unsettled example is the application of the safe harbor "research tools."[2] A closely related and sometimes overlapping issue involves a split among the district courts regarding what constitutes a "patented invention" subject to the safe harbor following the Federal Circuit's decision in *Proveris Sci. Corp. v. Innovasystems, Inc.* (2008).[3] A recent district court decision, *RegenxBio v. Sarepta* (2022),[4] exemplifies the ongoing controversy.

In *Proveris*, the defendant sold optical spray analysis (OSA) machines used in analyzing products subject to FDA approval.[5] The OSA device was "not subject to FDA approval" but was used "in connection with FDA regulatory submissions … to measure[] the physical parameters of aerosol sprays used in nasal spray drug delivery devices."[6] Innovasystems argued that the safe harbor applied because it "only offered to sell the OSA to pharmaceutical companies and the FDA [and] … it is undisputed that the OSA is and was used exclusively in applications for regulatory approval in accordance with the requirements of the FDCA."[7] The Federal Circuit held that the safe harbor did not apply:

> Because Proveris's patented product is not subject to a required [FDA] approval process, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f). At the same time, because Innova's OSA device also is not subject to a required [FDA] approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1).[8]

Proveris relied on the patent term extension (PTE) statute because PTE and the safe harbor were intended to be broadly complementary solutions to related problems when they were enacted together with the Hatch-Waxman Act. The Supreme Court had explained in *Eli Lilly & Co. v Medtronic, Inc.* (1990) that they were:

> designed to remedy two unintended distortions of the standard … patent term produced by the requirement that certain products receive premarket regulatory approval: (1) the patentee would as a practical matter not be able to reap any financial rewards during the early years of the term while he was engaged in seeking approval; and (2) the end of the term would be effectively extended until approval was obtained for competing inventions, since competitors could not initiate the regulatory process until the term's expiration.[9]

The court, however, noted that the statutes are not perfectly symmetrical, and "disequilibrium" exists because "the § 271(e)(1) noninfringement provision applies 'whether the patent term is extended or not,' and even with respect to 'patents which cannot qualify for a term extension.'"[10]

The concepts of "symmetry" and "disequilibrium" between the safe harbor and PTE are a constant theme in the case law. For example, in *AbTox v. Exiron* (1997),[11] the Federal Circuit held that perfect symmetry between the safe harbor and PTE was not required. The claims related to an apparatus and method for sterilizing medical devices using plasma gas, a Class II medical

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[1] 35 U.S.C. § 271(e)(1).
[2] *See, e.g., Merck KGaA v. Integra Life Sciences I, Ltd.*, 545 U.S. 193, 205 n.7 (2005) ("We therefore need not—and do not—express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of 'research tools' in the development of information for the regulatory process.")
[3] *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008).
[4] *Regenxbio, Inc. v. Sarepta Therapeutics, Inc.*, No. 20-1266-RGA, 2022 U.S. Dist. LEXIS 1945 (D. Del. March 14, 2022).
[5] *Proveris Sci.*, 536 F.3d at 1256.
[6] *Id.* at 1259.
[7] *Id.* at 1264.
[8] *Id.* 1266.
[9] *Eli Lilly & Co. v Medtronic, Inc.*, 496 U.S. 661 (1990).
[10] *Id.* at 673 n.4.
[11] *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027 (Fed. Cir. 1997).

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device. The court held that development of Class II medical devices can be protected by the safe harbor even though only Class III medical device patents are potentially eligible for § 156 patent term extension. *Eli Lilly* "explicitly accepted a statutory interpretation 'in which a patentee will obtain the advantage of the [Section 156] extension but not suffer the disadvantage of the [Section 271(e)(1)]

> Most [district court cases] have held that the embodiment of the "patented invention" must be subject to regulatory approval and correspond to the classes of patents potentially extendable by patent term extension under Section 156

noninfringement provision, and others in which he will suffer the disadvantage without the benefit.'"[12] "[A]s long as [an] activity is reasonably related to obtaining FDA approval," § 271(e)(1) "does not look to the underlying purposes or attendant consequences of the activity."[13]

In *Momenta I* (2012),[14] the majority dismissed the dissent's view that the court "must reject any disequilibrium … that is, the safe harbor should not be available unless a patent term extension is also available." The court said that "*Eli Lilly* noted that equilibrium was not always achieved. We too have rejected this strict interpretation of the safe harbor, explaining that 'statutory symmetry is preferable but not required.'"[15] But in *Momenta II* (2015), the court cited *Proveris* for the proposition that "research tools or devices that are not themselves subject to FDA approval may not be covered."[16]

Following *Proveris*, some district court cases have held that any invention claimed in a patent is a "patented invention" and potentially subject to the safe harbor.[17] Most have held that the embodiment of the "patented invention" must be subject to regulatory approval and correspond to the classes of patents potentially extendable by patent term extension under Section 156.[18] But at least one court has held that the safe harbor applies to all inventions claimed in any patent.

Regenxbio v. Sarepta,[19] currently pending before Judge Andrews in the District of Delaware, exemplifies many post-*Proveris* issues. The defendant, Sarepta, is developing a clinical-stage gene therapy for Duchenne Muscular Dystrophy (DMD) using an adeno-associated virus (AAV) as a vector. Sarepta's AAV vector containing the DMD gene therapy is a biologic drug subject to FDA approval. AAVs are popular administration vectors for many different types of gene therapy, and various companies provide services related to making AAV gene therapies. The plaintiffs, Regenxbio and the University of Pennsylvania, sued Sarepta for patent infringement, asserting that by making the gene therapy product, Sarepta infringed their patent to a "cultured host cell" containing a recombinant nucleic acid molecule encoding the relevant AAV capsid protein.

Judge Andrews denied Sarepta's motion to dismiss the complaint under the safe harbor in view of *Proveris*[20] on January 2, 2022. The court explained that "*Proveris* holds that a patented product that is not subject to FDA premarket approval is not a 'patented invention' under § 271(e)(1)."[21] The court found that safe harbor did not apply, at least at the pleading stage, because:

> Sarepta is not using the patented cultured host cells to obtain FDA approval to introduce generic cultured host cells to compete in the marketplace when the '617 patent

[12] *Id.* at 1029 (quoting *Eli Lilly*).
[13] *Id.* at 1030.
[14] *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1358 (Fed. Cir. 2012) ("Momenta I").
[15] *Id.* at 1361.
[16] *Momenta Pharmaceuticals, Inc. v. Teva Pharmaceuticals U.S.A. Inc.*, 809 F.3d 610 (Fed. Cir. 2015) ("Momenta II").
[17] *See, e.g., Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc.*, 20-cv-01958-H-AGS, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. May 4, 2021); *PSN Illinois, LLC v. Abbot Labs*, 09-cv-5879, 2011 U.S. Dist. LEXIS 108055 (N.D. Ill. Sept. 20, 2011); *ISIS Pharm., Inc. v. Santaris Pharma A/S Corp.*, 3:11-cv-2214-GPC-KSC, 2014 U.S. Dist. LEXIS 26148 (S.D. Cal. Feb. 27, 2014).
[18] *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 09 Civ. 10112 (KBF), 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y. July 16, 2013).
[19] *Regenxbio, Inc. v. Sarepta Therapeutics, Inc.*, No. 20-1266-RGA, 2022 U.S. Dist. LEXIS 1945 (D. Del. March 14, 2022).
[20] *Regenxbio, Inc. v. Sarepta Therapeutics, Inc.*, No. 20-1266-RGA, 2022 U.S. Dist. LEXIS 1945 (D.Del. Jan. 4, 2022).
[21] *Id.* at *10. Sarepta's briefing argued that the host cells were subject to FDA approval as part ofthe eventual BLA for Sarepta's AAV drug, but the court apparently accepted a contrary statement in the complaint as true.

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Beyond Research Tools . . . *(Continued from page 10)*

> expires. Instead, Sarepta is using the patented cells to develop its own patentable product. Sarepta can begin using the patented host cells immediately upon expiration of the patent because the cells are not subject to any FDA regulatory approval process.[22]

In other words, the court reasoned that Sarepta was not entitled to safe harbor protection at the pleading stage because the claims were directed to the host cells used to make the therapeutic AAV—even though it would have been protected had the claims been directed to the AAV itself. The fact that separate markets exist for host cells seems to have been an important factor.

Regenxbio'*s* holding is consistent with those of several other district decisions, such as a case holding that a drug company's use of S1P2 receptors to screen potential drug candidates was not protected "under *Proveris*, because the S1P2 receptors do not require regulatory approval, they are not a 'patented invention' within the meaning of § 271(e)."[23]

At least one district court reached the opposite conclusion. In *Teva v. Sandoz* (2013), the district court granted a motion to dismiss under the safe harbor. At issue were Teva's patented polypeptide markers used for calibrating chromatographic columns to measure the molecular weight characteristics of glatiramer acetate (Teva's Copaxone®).[24] The court stated that "the claimed markers are not themselves drug product, nor do they need approval from the FDA." Nevertheless, the court found that safe harbor applied, rejecting the plaintiff's argument that "*Proveris* has created some sort of opening through which their patented product squeezes: that it does not fall within the definition of 'patented invention.'... [T]hat takes the actual holding in *Proveris* too far. Supreme Court precedent makes that clear."[25] The *Teva* court relied on *Eli Lilly*'s statement that "[t]he phrase 'patented invention' in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone."[26]

> Until the Federal Circuit resolves the post-*Proveris* split, parties relying on the safe harbor should be cognizant of risks associated with using unlicensed patented technology that is not itself subject to FDA approval

Until the Federal Circuit resolves the post-*Proveris* split, parties relying on the safe harbor should be cognizant of risks associated with using unlicensed patented technology that is not itself subject to FDA approval, particularly if a separate market exists for that technology.

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[22] *Id.* at *12.
[23] *PSN Illinois, LLC v. Abbot Labs*, 09-cv-5879, 2011 U.S. Dist. LEXIS 108055 at *18 (N.D. Ill. Sept. 20, 2011). *See also ISIS Pharm., Inc. v. Santaris Pharma A/S Corp.*, 3:11-cv-2214-GPC-KSC, 2014 U.S. Dist. LEXIS 26148 (S.D. Cal. Feb. 27, 2014); *Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc.*, 20-cv-01958-H-AGS, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. May 4, 2021).
[24] *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 09 Civ. 10112 (KBF), 2013 U.S. Dist. LEXIS 91022 (S.D.N.Y. July 15, 2013). *See also* 35 U.S.C. § 100(a) ("When used in this title unless the context otherwise indicates . . . the term 'invention' means invention or discovery").
[25] *Id.* at *26.
[26] *Eli Lilly*, 496 U.S. at 665.

Select Recent Life Sciences Client Highlights

Mirvie Announces $60 Million Series B
On May 17, 2022, Mirvie, a pioneer in predicting unexpected pregnancy complications, announced it has raised $60 million in a Series B funding round. The financing was led by Decheng Capital, with additional funding from funds and accounts managed by BlackRock, Foresite Capital, General Catalyst, GV, Khosla Ventures, and Mayfield, as well as a debt facility with Comerica Bank. The Series B funding will support Mirvie's continued clinical and commercial development of the proprietary Mirvie RNA platform, which is the first to predict preeclampsia and preterm birth months before they happen by revealing the underlying biology of each pregnancy. Wilson Sonsini represented Mirvie in the Series B financing.

LaNova Medicines Enters Exclusive License Agreement with Turning Point Therapeutics
On May 5, 2022, Turning Point Therapeutics, Inc., a clinical-stage precision oncology company designing and developing novel targeted therapies for cancer treatment, announced that it has entered into an exclusive license agreement with LaNova Medicines Limited to develop and commercialize LM-302, a novel antibody drug conjugate (ADC) targeting Claudin18.2, in the U.S. and the rest of the world, excluding Greater China and South Korea. Under the terms of the agreement, LaNova will receive an upfront payment of $25 million and will be eligible to receive up to an additional $195 million in development and regulatory milestone payments. In addition, LaNova is eligible to receive commercial sales milestones and tiered royalties ranging from mid-single-digit to mid-teens percentages on net sales (subject to customary deductions). Wilson Sonsini advised LaNova on licensing and patent matters related to the transaction.

VitroLabs Closes $46 Million Series A
On May 4, 2022, VitroLabs Inc., a biotech company leading the development of a new scientific process to grow the world's first cellular cultivated animal leather, announced that it has closed a $46 million Series A financing to build and scale pilot production. The funding was led by Agronomics, and other investors included BESTSELLER's Invest FWD, global luxury group Kering, Khosla Ventures, actor and environmentalist Leonardo DiCaprio, New Agrarian, and Regeneration. VC. In addition, Kering continues its partnership with VitroLabs to bring support for product quality testing, tanning, and finishing. Wilson Sonsini advised VitroLabs on the transaction.

Belite Bio Announces Pricing of $36 Million IPO
On April 28, 2022, Belite Bio, Inc., a clinical-stage biopharmaceutical drug development company, announced the pricing of its initial public offering of six million American Depositary Shares (ADSs) at a public offering price per ADS of $6.00. The ADSs began trading on the Nasdaq Capital Market on April 29, 2022, under the ticker symbol "BLTE." The offering closed on May 3. Belite expects to use the net proceeds to fund the Phase 3 clinical trial of its lead candidate, LBS-008, for Stargardt disease and for further clinical development of LBS-008 for dry age-related macular degeneration, working capital, and other general corporate purposes. Wilson Sonsini has handled all IP matters for Belite since the company's inception and advised Belite on IP matters related to the transaction.

Wallaby Announces EUR 500 Million Acquisition of phenox
On April 21, 2022, Wallaby Medical, a global innovative medical technology company focused on developing and commercializing neurovascular interventional products for treating stroke, announced that it has acquired phenox GmbH, including phenox's femtos GmbH (femtos) (together, "phenox"), a German-based global innovation and technology leader in the neurovascular space, for a total consideration of approximately EUR 500 million, including milestone payments. The acquisition is one of the largest cross-border transactions in the medical device industry globally in recent years and is driven by strong growth opportunities in both product portfolio and geographic coverage. The transaction has received all necessary regulatory approvals and has been completed. Wilson Sonsini acted as international counsel to Wallaby in the transaction.

Octant Announces $80 Million Series B and Partnership with Bristol Myers Squibb
On April 21, 2022, Octant, a next-generation, data-driven therapeutics company developing programmable biology and chemistry to build precision medicines for complex diseases, announced an $80 million Series B financing round that was led by Catalio Capital Management and included participation from Bristol Myers Squibb and existing investors Andreessen Horowitz Bio Fund, Allen & Co., and Fifty Years. Octant also announced it has established a Deep Mutational Scanning (DMS) biopharma partnership with Bristol Myers Squibb. Proceeds from the Series B will be used to further expand Octant's platform capabilities and pipeline, advance its proprietary drug discovery technology, and generate extensive datasets that map the relationships between drug candidates, genetics, and the biochemical mechanisms of human cells. Wilson Sonsini represented Octant in the transactions.

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Select Recent Life Sciences Client Highlights *(Continued from page 12)*

Sierra Oncology Acquired by GSK
On April 13, 2022, GlaxoSmithKline plc (GSK) and Sierra Oncology, Inc. announced that they have entered into an agreement under which GSK will acquire Sierra Oncology, a late-stage biopharmaceutical company focused on targeted therapies for the treatment of rare forms of cancer, for $55 per share of common stock in cash, representing an approximate total equity value of $1.9 billion. Sierra Oncology's differentiated momelotinib has the potential to address the critical unmet medical needs of myelofibrosis patients with anemia. Wilson Sonsini advised Sierra Oncology on the transaction.

Real Announces $37 Million Series B Funding
On April 12, 2022, Real, a mental health care company building a new platform-based therapy model, announced a $37 million Series B funding round. The financing was led by Owl Ventures, with participation from former Cityblock CEO Iyah Romm and chief health officer Dr. Slyvia Room, as well as existing investors Lightspeed Venture Partners, Female Founders Fund, Forerunner Ventures, and BBG Ventures. Real is an affordable app-based therapy solution that offers programs and resources for creating a mental health care routine. Wilson Sonsini advised Real on the transaction.

Viz.ai Raises $100 Million in Series D Funding
On April 7, 2022, Viz.ai, a leading AI-powered disease detection and care coordination platform, announced it has raised a $100 million funding round at a $1.2 billion valuation. The Series D round was led by Tiger Global and Insight Partners. Early backers, including Scale Ventures, Kleiner Perkins, Threshold, GV (formerly Google Ventures), Sozo Ventures, CRV, and Suza, also participated in the round. The new funds will be used to support Viz.ai's growth, expand the "Viz Platform" to detect and triage additional diseases, and grow its customer base globally. Wilson Sonsini represented Viz.ai in the transaction.

IGM Biosciences Announces $230 Million Public Offering
On March 30, 2022, IGM Biosciences, Inc. announced the pricing of its underwritten public offering of 8,695,653 shares of its non-voting common stock at a price to the public of $23.00 per share. IGM also granted the underwriters a 30-day option to purchase up to an additional 1,304,347 shares of its voting common stock at a public offering price of $23.00, less underwriting discounts and commissions, which was fully exercised on March 30, 2022. IGM received total gross proceeds of approximately $230 million from this offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by IGM. The offering closed on April 1, 2022. Wilson Sonsini advised IGM on the transaction.

InSilico Enters Collaboration with EQRx
On March 24, 2022, InSilico Medicine, a clinical-stage end-to-end artificial intelligence (AI)-driven drug discovery company, announced it has entered into a strategic collaboration with EQRx, a company committed to developing and delivering innovative medicines to patients at radically lower prices. The collaboration will combine InSilico's AI-driven platform, Pharma.AI, to advance de novo small molecule design and generation with EQRx's clinical development and commercialization expertise. EQRx and InSilico will engage in a co-development partnership whereby each party will be eligible for a profit share proportional to its respective level of investment. Wilson Sonsini represented InSilico in the transaction.

Affini-T Therapeutics Completes $175 Million Financing
On March 22, 2022, Affini-T Therapeutics, Inc., a biotechnology company unlocking the power of T cells against oncogenic driver mutations, announced the completion of an oversubscribed $175 million financing co-led by Vida Ventures and Leaps by Bayer. Additional investors participating in the round included Humboldt Fund, The Parker Institute for Cancer Immunotherapy, Catalio Capital Management, Agent Capital, Alexandria Venture Investments, Erasca Ventures, Fred Hutchinson Cancer Research Center, and other leading blue chip life science investors. With proceeds from this financing, the company will operationalize its platform discovery engine and seek to drive multiple oncogene driver programs into the clinic while pursuing complementary technology licenses to bolster its cell therapy platform. Wilson Sonsini advised Affini-T Therapeutics on patent matters related to the transaction.

Apexigen Enters Business Combination with Brookline Capital Acquisition Corp.
On March 18, 2022, Apexigen, Inc., a clinical-stage biopharmaceutical company focused on discovering and developing a new generation of antibody therapeutics for oncology, and Brookline Capital Acquisition Corp., a special purpose acquisition company (SPAC), announced they have entered into a definitive business combination agreement, PIPE financing, and equity line facility. Upon closing of the transaction, Brookline Capital Acquisition Corp. will be renamed Apexigen, Inc. and the combined company expects to list its stock on Nasdaq under the ticker symbol "APGN." This transaction brings Apexigen public and strengthens the advancement of the Phase 2 development of the

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lead program, sotigalimab, as well as maximizes the therapeutic potential of Apexigen's APXiMAB™ antibody discovery platform and innovative pipeline of other antibody therapeutics. Wilson Sonsini is advising Apexigen on the transaction.

House Rx Secures $25 Million in Series A Financing

On March 14, 2022, House Rx, a health technology platform focused on improving affordability and patient access to specialty medications, announced it has secured $25 million in Series A financing led by Bessemer Venture Partners, bringing the company's total funding to $30 million. First Round Capital, Character.vc, and 1984.vc also participated in the Series A funding. The proceeds from this latest round will go toward continued investments in House Rx's technology platform and scaling pharmacy operations. Wilson Sonsini advised House Rx on the transaction.

NuVasive Victorious in Patent Dispute Against Key Competitor

On March 11, 2022, after a two-week jury trial, Wilson Sonsini secured a victory for its client, NuVasive, against spine surgery competitor Alphatec. In the early 2000s, NuVasive pioneered the eXtreme Lateral Interbody Fusion (XLIF) technique by developing groundbreaking spinal implants and access tools to allow surgeons to safely and effectively treat degenerative disc disease by removing a diseased disc from the spine and fusing the two vertebrae adjacent to that disc. In 2017, Alphatec began promoting a copycat of the patented system of tools used to perform NuVasive's XLIF technique. In 2018, NuVasive brought suit against Alphatec for infringement of patents that cover NuVasive's proprietary XLIF spinal fusion surgical tools and implants. In March 2020, the U.S. District Court for the Southern District of California granted NuVasive's motion for summary judgment of infringement of one of the patents. After the two-week trial before District Judge Cathy Ann Bencivengo of the U.S. District Court for the Southern District of California, the jury found that Alphatec infringed two NuVasive patents, that infringement of two of the three patents was willful, and awarded damages. Wilson Sonsini represented NuVasive in the matter.

ViFive Announces $5.8 Million Funding Round

On March 10, 2022, ViFive, an innovator in Vision AI technology, announced a pre-A funding of $5.8 million. The funding round saw investments from companies such as SV Investment, Smilegate Investment, Company K Partners, Lotte Ventures, and Dunamu & Partners. With this investment in their advanced Vision AI technology, ViFive plans to accelerate digital health transformation through a platform provided to healthcare providers so they can develop their own digital care solutions focused on personalized care, centered around patient-provider interaction and remote therapeutic monitoring (RTM). Wilson Sonsini advised ViFive on the financing.

ArrePath Raises $20 Million in Seed Financing

On March 3, 2022, ArrePath, an anti-infective drug discovery company addressing drug-resistant infections, announced it has raised $20 million in seed financing to advance its proprietary, machine learning (ML)-based platform for the discovery of new classes of anti-infectives to overcome antimicrobial resistance (AMR). The Boehringer Ingelheim Venture Fund, Insight Partners, and Innospark Ventures co-led the financing, which also included Viva BioInnovator, Arimed Capital, PTX Capital, and Nor'easter Ventures. According to ArrePath President and CEO Dr. Lloyd Payne, the funding will enable the advancement of initial leads and expansion of discovery efforts, as well as the enhancement of ArrePath's imaging platform and the application of machine learning in the discovery of new drugs to address critical global health challenges. Wilson Sonsini advised ArrePath on the transaction.

Scipher Medicine Completes $110 Million Financing

On February 24, 2022, Scipher Medicine, a precision immunology company matching each patient with their most effective therapy, announced the completion of a $110 million financing. The round was led by Cowen Healthcare Investments, with participation from new investors Neuberger Berman, Hitachi Ventures, Laurion Capital, and Monashee Investment Management. Existing investors Northpond Ventures, aMoon, Khosla Ventures, Optum Ventures, Echo Health Ventures, and Alumni Ventures also participated. Scipher is bringing precision medicine to patients with autoimmune diseases by commercializing blood tests that reveal a person's unique molecular disease signature and matching it to the most effective existing therapy, ensuring providers and payers can select optimal therapy from day one. Wilson Sonsini advised Scipher Medicine on patent matters related to the transaction.

Nalu Medical Announces $104 Million Equity Financing

On February 17, 2022, Nalu Medical, Inc., a private company focused on innovative and minimally invasive solutions for chronic neuropathic pain, announced a $104 million equity financing. The round was led by new investors MVM Partners and Gilde Healthcare. New investors Pura Vida Investments and Aperture Venture Partners, as well as existing investors Advent Life Sciences, Decheng Capital, Endeavour Vision, and Longitude Capital, also participated in the round. The proceeds are intended to be used for scaling commercial

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operations to accelerate growth, continued expansion of clinical evidence, and continuing product development, in addition to other general corporate purposes. Wilson Sonsini advised Nalu Medical on the transaction.

Terray Therapeutics Closes $60 Million Series A Financing

On February 15, 2022, Terray Therapeutics, an AI-powered drug discovery company, announced the closing of a $60 million Series A financing to advance its novel tNova platform and its discovery partnerships. The financing was led by Madrona Venture Group with participation from a broad syndicate of new and existing investors, including Two Sigma Ventures, Digitalis Ventures, KdT Ventures, Goldcrest Capital, XTX Ventures, Sahsen Ventures, Greentrail Capital, and Alexandria Venture Investments. This financing follows a previously unannounced $20 million seed round co-led by Digitalis Ventures and Two Sigma Ventures. Wilson Sonsini represented Terray Therapeutics in both financing transactions.

1859 Launches and Announces $40 Million Series A

On February 7, 2022, 1859, Inc., a platform company combining artificial intelligence and empirical pico-scale screening data at scale to discover new small molecule medicines for emerging disease targets, launched and announced the close of a $40 million Series A funding round led by Northpond Ventures and OMX Ventures. Existing investors FusionX Ventures and Vertical Venture Partners also joined the round. The proceeds from the financing will support the development of new capabilities and the scaling and advancement of preclinical discovery programs building upon a base of 16 pharmaceutical, biotech, and academic partners. Wilson Sonsini advised 1859 on corporate and IP matters related to the company's launch and financing.

Arcellx Announces Initial Public Offering

On February 4, 2022, Arcellx, Inc., a biotechnology company reimagining cell therapy through the development of innovative immunotherapies for patients with cancer and other incurable diseases, announced the pricing of its initial public offering of 8,250,000 shares of common stock at a public offering price of $15.00 per share. The gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses payable by Arcellx, are expected to be approximately $123.8 million. Arcellx's common stock began trading on the Nasdaq Global Select Market on February 4, 2022, under the ticker symbol "ACLX." Wilson Sonsini advised Acrellx on the transaction.

Firm Partners with Bakar Labs to Provide Legal Services to Incubator Tenants

In February 2022, Wilson Sonsini and Bakar Labs—the flagship life science-focused incubator at UC Berkeley's Bakar BioEnginuity Hub—announced a new partnership under which Bakar's tenant companies will benefit from corporate and intellectual property legal services provided by the firm's attorneys.

The firm, a Founding Affiliate of Bakar Labs, will offer entrepreneurs access to its leading attorneys, including Ph.D.-level professionals. In addition, the firm will contribute to start-up educational seminars, provide thought leadership in support of continuing education, and take an active role in advising incubator leadership on key strategic questions during the ramp-up phase of incubator operations, including participation in industry advisory meetings—all with the goal of improving the ecosystem for incubator tenants, achieving more equitable engagement, and expanding access to financial and other resources.

"We're delighted to be able to engage the support of Wilson Sonsini. Our community of start-ups will now be able to easily access expert advice that enables them to confidently grow their companies on a solid legal foundation and win the confidence of investors," said Gino Segre, Ph.D., managing director of Bakar Labs. "Bakar Labs' mission is to support the growth of as many as 50 life science start-ups developing innovations that can make meaningful difference in human health and sustainability. We offer well-equipped laboratory and office space, and a rich array of programming to empower our community of start-ups to succeed."

"Bay Area bio-entrepreneurs are incredibly innovative about seeing market needs and inventing and developing technologies to meet them. The level of technological expertise is extremely high. Wilson Sonsini is proud to have helped enable many founders to build their companies on solid corporate and intellectual property legal foundations, which is key to winning investors' confidence from the beginning. We look forward to engaging with tenants at Bakar Labs as they launch and grow their companies," said Wilson Sonsini partner Vern Norviel.

For more information, please see Bakar Labs' press release.

Upcoming Life Sciences Events

2022 BIO International Convention
June 13-16, 2022
San Diego, California

Join Wilson Sonsini at the 2022 BIO International Convention in San Diego California. We will foster networking opportunities and are proud to sponsor the Start-Up Stadium.

Wilson Sonsini's Medical Device Conference
June 17, 2022
San Francisco, California
https://mdc.wsgrevents.com/

Our 2022 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 searching for and pursuing potential investment, partnering, and acquisition opportunities.

Phoenix 2022: The Medical Device and Diagnostic Conference for CEOs
October 19-21, 2022
Half Moon Bay, California
https://phoenix.wsgrevents.com/

The 2022 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 help inform and shape company strategy for the years ahead, as well as celebrate the industry's incredible, life-saving work throughout the pandemic.

Wilson Sonsini's Life Sciences Investment Forum
December 6-8, 2022

Wilson Sonsini is planning our annual Life Sciences Investment Forum, a unique opportunity for investors to connect with promising life sciences start-ups to discuss potential funding and/or collaborations, for early December 2022. The Investment Forum is a private event for previously confirmed investors and is exclusive to our early-stage clients with a focus on therapeutics of all types (excluding digital and device-based therapeutics), diagnostics, genomics, tools, or synthetic biology.

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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