

## THE LIFE SCIENCES REPORT

### Life Sciences Venture Financings for Wilson Sonsini Clients

By Scott Murano, Partner (Palo Alto)

The table on page 4 includes data from life sciences transactions in which Wilson Sonsini Goodrich & Rosati clients participated across the second half of 2019 and the first half of 2020. 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.

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### Wilson Sonsini Clients on the Front Lines of the COVID-19 Pandemic

We at the firm are extremely proud of our work with innovative life sciences companies, many of which are currently working to address challenges associated with COVID-19. There are examples from numerous sectors—including biotech, digital health, medical devices, and pharmaceuticals—ranging from companies developing and testing treatments and prospective vaccines to those involved in manufacturing personal protective equipment, medical supplies, or other key components needed to care for those who are experiencing illness.

Below is a sampling of COVID-19-related client activity in which our firm has recently been involved:

- **Amerimmune**, a research center and immunology laboratory with a strong focus on identifying underlying mechanisms of immune disorders, and Histogen, a clinical-stage therapeutics company focused on developing therapeutics that ignite the body's natural process to repair and maintain healthy biological function, entered into a collaborative development and commercialization agreement to jointly develop emricasan, an orally active caspase inhibitor, for the treatment of COVID-19. Additionally, Histogen has received Investigational New Drug (IND) approval from the FDA to initiate a Phase 1 study of emricasan in mild COVID-19 patients to assess safety and tolerability. Amerimmune,

which will lead the development efforts of emricasan, selected clinical sites at two major medical centers in the New York City metropolitan area to conduct the study. Wilson Sonsini represented Amerimmune in the transaction.

- **AuraVax Therapeutics**, a Houston-based biotech company developing novel vaccines and therapies to help patients defeat debilitating respiratory diseases such as COVID-19, entered into an exclusive license option agreement with the University of Houston with respect to the intellectual property covering a novel intranasal vaccine technology. Under the terms of the agreement, AuraVax has the option to exclusively license patents covering this technology. In addition, AuraVax entered into an exclusive license agreement with Massachusetts General Hospital (MGH) covering certain IP and technology rights regarding compositions and discoveries of liposomal STING agonists led by Mei X. Wu, Ph.D., of the Wellman Center for Photomedicine at MGH. The transaction bolsters the development of AuraVax's lead COVID-19 intranasal vaccine and strengthens its platform for therapeutic development targeting a range of viral infections. Wilson Sonsini is advising AuraVax Therapeutics on business advisory and corporate legal matters, and represented the company

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## Wilson Sonsini Clients on the Front Lines of the COVID-19 Pandemic *(Continued from page 1)*

in connection with the above agreements.

- **The Canadian COVID Coalition**, a group of companies that have joined forces in the war on COVID-19, has volunteered its time and resources to identify the nanobodies that are activated in the immune response against COVID-19. The Coalition is offering free, non-exclusive, and limited exclusive licenses to foster rapid development of diagnostic and therapeutic tools to help neutralize COVID-19's impact. The group has published 51 antibodies that show promising ability to bind to the COVID-19 virus by attaching to its crown-like spikes, which could result in neutralizing the virus by preventing it from invading human cells. Other Coalition members include Novobind, Cedarlane, SignalChem, and Natural Products Canada. Wilson Sonsini is advising the Coalition on IP strategy to ensure that the resulting products are accessible to all countries around the world.
- **CorVent Medical**, a Coridea portfolio company focused on developing versatile, reusable, lifesaving ventilators, announced that the FDA has issued an Emergency Use Authorization (EUA) for primary critical care use of the company's RESPOND-19 Ventilator, which is designed for rapid expansion of critical care ventilation capacity to allow hospitals to treat more patients suffering from acute respiratory distress syndrome (ARDS) during times of greatest need. The surge support system is optimized for long-term storage and ensures cost-efficient healthcare preparedness. With EUA granted, the RESPOND-19 Ventilator is now available for commercial use

in the United States. In addition, CorVent announced an agreement with Siemens Healthineers for U.S. distribution of the RESPOND-19 Ventilator to their network of hospital, healthcare system, and government customers. Wilson Sonsini handles all of CorVent's corporate work and advised on the company's seed financing in May 2020.

- **Density**, a start-up building AI-powered, people-counting infrared sensors, closed a \$51 million Series C financing round. Kleiner Perkins led the round, with contributions from o1 Advisors, Upfront Ventures, Founders Fund, Ludlow Ventures, Launch, LPC Ventures, and individual investors Alex Rodriguez, Alex Davis, Kevin and Julia Hartz, and Cyan and Scott Banister. The infusion brings the start-up's total raised to over \$74 million, following \$23 million in previous funding. In many ways, Density's products were tailor-made for a global health crisis, as cities around the world have imposed limits on businesses regarding the number of customers they allow in. Density co-founder and CEO Andrew Farah says the \$51 million will be put toward addressing "unprecedented demand" from offices, manufacturers, grocery stores, industrial plants, and governments trying to abide by capacity limits during the pandemic. Wilson Sonsini represented Density in the transaction.
- **Ellume**, a digital diagnostics company, announced that its rapid, at-home COVID-19 antigen test has been granted Emergency Use Authorization (EUA) from the FDA. The Ellume COVID-19 Home Test will be available without a prescription for the detection of active COVID-19 in individuals with or without symptoms, and in adults and children two years of age or older. The test—the first of its kind to be granted an EUA—will help reduce the spread of COVID-19 through rapid self-detection, providing users with real-time results in the safety of their own homes, enabling self-isolation and patient education on escalation of medical care. As such, it provides an essential new tool to help combat the COVID-19 pandemic. Wilson Sonsini assisted Ellume in their discussion with the FDA and is working with Ellume to help commercialize and distribute their COVID-19 Home Test.
- **Everlywell**, a leading digital health company that received the first FDA Emergency Use Authorization of its kind for its COVID-19 Test Home Collection Kit in May 2020, announced an oversubscribed Series D financing of \$175 million. New investors participating in the round include funds and accounts managed by BlackRock, The Chernin Group (TCG), Foresite Capital, Greenspring Associates, Lux Capital, Morningside Ventures, and Portfolia, as well as existing investors Goodwater Capital, Highland Capital Partners, and Next Coast Ventures. This investment brings the total capital raised by the company to over \$250 million. Everlywell plans to use the funds to expand its virtual care offerings, scale its testing and infrastructure, drive clinical research and disease management through testing, and grow its national leadership position in the at-home testing market. Wilson Sonsini represented Everlywell in the transaction.
- **Gauss Surgical**, the leading developer of computer vision

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## Wilson Sonsini Clients on the Front Lines of the COVID-19 Pandemic *(Continued from page 2)*

applications for healthcare, and Cellex, a leading biotechnology company specializing in point-of-care diagnostic testing, announced an exclusive partnership to launch a rapid, at-home and point-of-care COVID-19 antigen test. Cellex, which was the first company to receive an FDA Emergency Use Authorization for rapid COVID-19 antibody testing in April 2020, is in advanced clinical trials with a rapid antigen test that demonstrated nearly 90 percent sensitivity and 100 percent specificity in early trials. When paired with a newly developed, AI-powered application from Gauss that enables users to perform and interpret the test with a smartphone, its use can be expanded to aid in the rapid diagnosis of SARS-CoV-2 infections. Users follow video instructions to collect a nasal swab sample and perform the rapid antigen test. Within 15 minutes, the app prompts the user to scan their rapid test with their smartphone and then processes the image with network architecture optimized for the Cellex assay. The app informs the user if the test result is negative or positive for SARS-CoV-2 antigens within seconds. Cellex and Gauss aim to have the antigen test and companion app authorized by the FDA in early 2021. Wilson Sonsini advised Gauss with respect to the arrangement.

- **Mammoth Biosciences**, which is harnessing the diversity of nature to power the next-generation of CRISPR products, received a contract from the National Institutes of Health (NIH) as part of its \$1.5 billion Rapid Acceleration of Diagnostics (RADx) program, making it the first CRISPR-based initiative to be funded by the

program. The award will help scale Mammoth Biosciences' CRISPR-based DETECTR BOOST™ test onto high-throughput automated platforms in commercial labs for COVID-19 diagnostics at an accelerated rate, increasing access to accurate tests with faster turnaround across the country. With a \$1.5 billion investment from federal stimulus funding, the RADx initiative infuses funding into early innovative technologies to speed development of rapid and widely accessible COVID-19 testing. The Rapid Acceleration of Diagnostics Tech (RADx Tech) program specifically aims to support the development and commercialization of innovative technologies to significantly increase the U.S. testing capacity for SARS-CoV-2.

Subsequently, Mammoth signed agreements with MilliporeSigma and Hamilton Company targeting commercialization of the DETECTR BOOST™ high-throughput CRISPR-based SARS-CoV-2 test after Emergency Use Authorization from the FDA. The test will leverage Mammoth's DETECTR BOOST™ platform and will provide a turnkey solution for commercial laboratories to enable a multi-fold increase in testing capacity. According to the company, the high-throughput systems will be compatible with both nasal swab and saliva samples and are targeting 1,500 tests per eight-hour shift with minimal user interaction.

In addition, Mammoth recently announced that it has secured a subcontract with MRIGlobal, the prime contractor with the Defense Advanced Research Projects Agency, to develop CRISPR-based

diagnostics and biosurveillance technologies for the Department of Defense. Under the program, Mammoth will leverage its DETECTR platform to detect emerging biological threats.

Wilson Sonsini Goodrich & Rosati represented Mammoth Biosciences in the above transactions.

- **Pattern Bioscience**, a privately held in vitro diagnostics company founded in 2016 to help combat the problem of antibiotic resistance, announced a \$9 million Series B-1 financing. The round of funding will accelerate the development and clinical validation of its rapid bacterial identification and susceptibility testing (ID/AST) technology. The company's phenotypic testing platform is well suited to address all common bacterial infections, including complex infections (like pneumonia) that elude other rapid antibiotic susceptibility testing technologies—a characteristic that is important during COVID-19, when more patients are hospitalized and in need of mechanical ventilation. Ventilated patients carry higher risk of developing bacterial pneumonia and are commonly treated with antibiotics before current antibiotic susceptibility tests can be completed. Pattern's faster bacterial tests can reduce the risk of antibiotic misuse and enable focused treatment, improving patient outcomes and reducing selective pressures that lead to drug resistance. Wilson Sonsini represented Pattern in the financing transaction.

Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 1)*

	2H 2019	2H 2019	2H 2019	1H 2020	1H 2020	1H 2020
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	42	\$770.62	\$18.35	56	\$1,627.89	\$29.07
Genomics	9	\$81.96	\$9.11	7	\$103.32	\$14.76
Diagnostics	13	\$183.98	\$14.15	16	\$243.01	\$15.19
Medical Devices & Equipment	39	\$308.92	\$7.92	53	\$715.67	\$13.50
Health IT	18	\$180.02	\$10.00	18	\$280.77	\$15.60
Healthcare Services	15	\$465.01	\$31.00	17	\$359.54	\$21.15
<b>Total</b>	<b>136</b>	<b>\$1,990.50</b>		<b>167</b>	<b>\$3,330.20</b>	

The data demonstrates that venture financing activity increased from the second half of 2019 to the first half of 2020 with respect to total number of closings and total amount raised. Specifically, the total number of closings across all industry segments increased 22.8 percent, from 136 to 167, while the total amount raised across all industry segments increased 67.3 percent, from \$1,990.5 million to \$3,330.2 million.

Notably, the industry segment with the second-largest number of closings during the first half of 2020—medical devices and equipment—experienced the largest increase in both number of closings and total amount raised from the second half of 2019 to the first half of 2020. Specifically, the number of closings in the medical devices and equipment segment increased 35.9 percent, from 39 to 53, while the total amount raised increased 131.7 percent, from \$308.92 million to \$715.67 million. Similarly, the industry segment with the largest number of closings during the first half of 2020—biopharmaceuticals—experienced the second-largest increase in both number of closings and total amount raised over the same period. Specifically, the number of closings in biopharmaceuticals increased 33.3 percent, from 42 to 56, while the total

amount raised increased 111.2 percent, from \$770.62 million to \$1,627.89 million.

Meanwhile, the industry segment with the third-largest number of closings during the first half of 2020—health IT—experienced no change in number of closings, but a significant increase in total amount raised: the number of

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closings remained at 18, while the total amount raised increased 56 percent, from \$180.02 million to \$280.77 million. The industry segment with the fourth-largest number of closings during the first

half of 2020—healthcare services—was unique in that it experienced an increase in number of closings, but a decrease in total amount raised. Specifically, the number of closings in the healthcare services segment increased 13.3 percent, from 15 to 17, while the total amount raised decreased 22.7 percent, from \$465.01 million to \$359.54 million. The genomics segment experienced the opposite, a decrease in the number of closings and an increase in total amount raised: the number of closings decreased 22.2 percent, from 9 to 7, while the total amount raised increased 26.1 percent, from \$81.96 million to \$103.32 million. The final remaining industry segment—diagnostics—experienced an increase in both number of closings and total amount raised. Specifically, the number of closings increased 23.1 percent, from 13 to 16, and the total amount raised increased 32.1 percent, from \$183.98 million to \$243.01 million.

In addition, our data suggests that Series B financing activity and bridge financing activity, in each case as a percentage of all other financing activity, increased from the second half of 2019 to the first half of 2020, while Series A (including Series Seed) financing activity and Series C and later financing activity as a percentage of all other

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## Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 4)*

financing activity decreased across the same period. Specifically, the number of Series A (including Series Seed) closings decreased from 30.8 percent to 27.5 percent, the number of Series B closings increased from 15.4 percent to 17 percent, and the number of Series C and later closings decreased marginally from 15.4

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Other data taken from transactions in which all firm clients participated in the first half of 2020 suggests that life sciences remains the most active industry for investment among our clients. In that period, the life sciences industry represented 33 percent of total funds raised by clients.

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percent to 15.2 percent. Bridge financing activity as a percentage of all other financing activity experienced the most significant change, increasing from 21.7 percent during the second half of 2019 to 28.1 percent during the first half of 2020.

Average pre-money valuations for life sciences companies increased across the

board for all stages of equity financings from the second half of 2019 to the first half of 2020. The average pre-money valuation for Series A (including Series Seed) financings increased 51.8 percent, from \$14.32 million to \$21.74 million; the average pre-money valuation for Series B financings increased 12.5 percent, from \$71.81 million to \$80.81 million; and the average pre-money valuation for Series C and later financings increased 53.1 percent, from \$214.31 million to \$328.1 million.

Other data taken from transactions in which all firm clients participated in the first half of 2020 suggests that life sciences remains the most active industry for investment among our clients. During that period, the life sciences industry represented 33 percent of total funds raised by our clients, while the software industry came in second, at 30 percent of total funds raised.

Overall, the data indicates that access to venture capital for the life sciences industry increased in the first half of 2020 compared to the second half of 2019, with the most active segments—medical devices and equipment and biopharmaceuticals—driving the increased activity. Moreover, those dollars were raised at higher valuations across the board—for Series A (including Series Seed), Series B, and Series C and later financings. It is noteworthy that more of those investments were made in the form of Series B and bridge financings than in the prior period,

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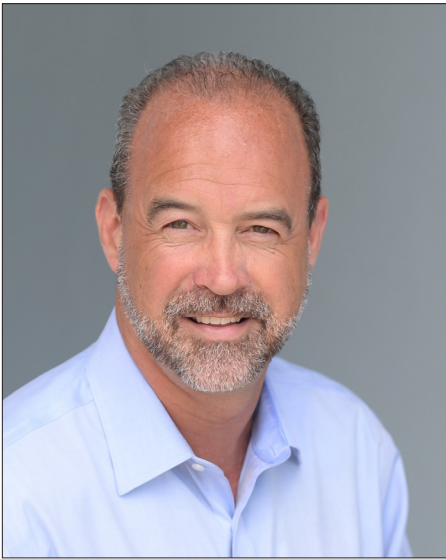
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which is consistent with the notion that investors have been more focused on reserving and deploying capital for existing portfolio companies in this COVID financing world, rather than making new investments in the form of Series Seed or Series A investments.



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## A Discussion with Cyrano Therapeutics CEO Rick Geoffrion About the Early Feasibility Studies Program



Wilson Sonsini attorney Charles Andres recently sat down with Rick Geoffrion, a medical device and life sciences entrepreneur who is currently the founder, president, and CEO of Cyrano Therapeutics, to discuss the importance of the Early Feasibility Studies Program for medical device manufacturers.

**Charles: Rick, thanks for being here. Can you tell our readers a little bit about your background?**

Rick: I have been in the medical device and life sciences industry for the last 35 years, founded or co-founded eight private venture-backed companies, mostly in the cardiovascular sector, and experienced a number of transactions. My current company, Cyrano Therapeutics, is developing a treatment for chronic smell and flavor loss. I also serve as the vice chairman of The Mullings Group Companies and sit on the executive committee and board of directors of the Medical Device Innovation Consortium, where I co-chair the Cardiovascular Early Feasibility Study (EFS) initiative. I consider the EFS

Program, established by the U.S. Food and Drug Administration (FDA) in 2013, to be one of the hallmark advancements in U.S. regulatory policy over the last 20 years. For that reason, I am excited to be here today to discuss its merits.

**What is the Early Feasibility Studies (EFS) Program?**

The FDA issued guidance in 2013 for an Early Feasibility Study Investigational Device Exemption (IDE) pathway, effectively devising an early-stage clinical trial process that could go through an FDA review with more appropriate pre-clinical and engineering data suitable for an early-stage device. Before that, all IDE approvals were based on the clinical requirements of a full-blown Premarket Approval (PMA), disincentivizing most companies from considering clinical research in the U.S. until well proven in outside-the-U.S. clinical studies.

**How did EFS come about?**

To understand the background for the creation of EFS, you have to go back to a watershed moment in the history of medical device innovation in the United States—the approval of the first percutaneous aortic valve in the U.S., the Edwards Sapien valve. This transformative, life-saving valve was approved in November 2011, more than four years after CE Mark (Europe) and nearly 10 years after the first-in-human clinical experience. At that time, many clinicians, industry, the FDA, and even Congress realized there was a disconnect in getting novel, life-saving devices to U.S. patients. And the four-year gap in approval between U.S. and Europe became a rallying cry for process improvement to improve access for highly innovative medical devices.

**So, before EFS, device clinical trials and approvals would often occur in Europe years before the devices were studied or cleared in the U.S.?**

Yes. When the EFS Program was established by the FDA in 2013, virtually all early-stage clinical research in medtech was being conducted outside the U.S., primarily in Europe. U.S. patients were getting access to new medical innovations approximately four years after patients in Europe would access them. That was despite the fact that the majority of the world's medtech companies were housed in the U.S. The majority of medtech innovation was happening here in the U.S. and the majority of funding available for medtech innovation was here in the U.S. It was being created here, but only being tested there. It made no sense.

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## A Discussion with Cyrano Therapeutics CEO Rick Geoffrion . . . (Continued from page 6)

For example, if you were an early-stage medtech company before 2013, not only did you perform your first-in-man study outside of the U.S., but if you were a Class III significant risk device, you would perform your entire CE Mark study for approval in Europe, outside the U.S., then use that data to finally start a study here in the U.S. Sometimes that was only a feasibility study, not even a pivotal study. As a consequence, patients in the U.S. would wait four years longer to gain access to a medtech innovation that was invented right here in the U.S.

Once U.S. patients did get access, they were often stuck with a first-generation device that was inherently inferior to second- and third-generation devices being used at the same time in Europe and elsewhere in the world. So, from a patient standpoint, the most important standpoint, it was suboptimal, to say the least. There were real human costs. In addition, devices were starting to be developed specifically for non-U.S. markets. The U.S. was falling behind, the quality of healthcare delivery was impacted, and the FDA started to take notice.

### What kinds of medical devices are eligible for EFS?

Per the FDA, the EFS Program is open to devices subject to Premarket Approval, Premarket Notification [510(k)], De Novo classification, or Humanitarian Device Exemption (HDE). EFS may be applicable when clinical experience is necessary because non-clinical testing is unavailable or inadequate to provide the information needed to advance device development. Therefore, EFS may be conducted on new devices without prior clinical experience, and in some cases, EFS may also be conducted on devices with limited prior clinical experience.

“The most significant advantage [of an EFS] is that a company is likely to have a faster pathway to approval in the U.S. by initiating the pathway to approval or clearance in the U.S. at an earlier stage.”

### What are some key elements of an EFS?

- Small number of subjects; usually 10-15 to start.
- Can be a 510(k) (Class II) or a PMA (Class III) device.
- The study should be conducted early in the device’s development.
- Does not have to involve the first clinical use of the device.
- An EFS can be approved on less non-clinical data.
- The company is allowed to pause the study and change design midstream in an EFS.
- The majority of EFS applications can be approved within a 30-day period.
- It is always important to have a pre-submission meeting with the FDA. They can tell you if you are ready to submit for an EFS.

### How does an EFS translate into benefits for a medical device start-up company?

The most significant advantage is that a company is likely to have a faster

pathway to approval in the U.S. by initiating the pathway to approval or clearance in the U.S. at an earlier stage. Let’s assume the first 10-15 cases in an EFS are successful, safety looks good, and there appears to be an emerging signal on efficacy. The company can apply for an EFS extension to enroll more cases, until such time the company is ready to start a pivotal trial. So, the EFS can dovetail nicely into a definitive path to approval in the U.S. It is also data that can likely be leveraged toward a CE Mark application in Europe. And the EFS Program gives U.S. patients early access to the newest and most innovative therapy.

### Are a reasonable number of EFS typically run in the U.S. each year?

More than 50 EFS are approved each year.

### Can you provide more detail on how the Medical Device Innovation Consortium (MDIC) is working to make EFS better?

MDIC is working to make EFS better in several ways. First, we are creating attention and awareness around the EFS Program. Second, MDIC is working to engage the entire clinical research ecosystem to improve the time it takes to initiate and complete an EFS. We have a wonderful steering committee, chaired by Dr. David Holmes of Mayo Clinic, with participation from the FDA, senior clinicians, industry, and clinical sites. MDIC has dedicated staff for EFS, including a program director, and together we’ve worked on a number of projects and resources over the last few years to create meaningful improvements in the EFS ecosystem.

Next, after obtaining input from many stakeholders, we decided to start by

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## A Discussion with Cyrano Therapeutics CEO Rick Geoffrion . . . (Continued from page 7)

collecting the facts, the analytics on how well the ecosystem was working. We reached out to industry sponsors and asked them to provide to MDIC on a confidential basis the start-up statistics for their Early Feasibility Studies. MDIC was uniquely equipped to bring these groups together and get them to share this data. This was a first for industry to share this kind of data, but we had good cooperation from many companies and were able to gather a snapshot of the performance of the clinical ecosystem. We measured the FDA review cycles, the Institutional Review Board (IRB) review cycles, the contracting and budgeting timing, and the time to first patient enrollment. The results were eye-opening to all the stakeholders and really quantified what to many had previously been anecdotal information.

Here are the results of that first analysis conducted on 2015-17 EFS in the U.S.:

- We found that FDA approval of the IDE was taking on average 68 days, well within expectations for a timely approval cycle.
- IRB review times were slightly longer at 72 days—not that bad.
- Contract approval, however, was taking a surprisingly long 133 days—nearly four months on average for a sponsor and site to work through a contract and budget.
  - The time to first patient enrollment once all the administrative activities were complete was then a surprisingly long 187 days—nearly six months.

- Now some of these processes are done in parallel, like IRB and contracting, but it does objectively show that in the 2015-17 timeframe, it took nearly a year to get an EFS clinical site up and running in the United States—a very long time that had little to do with the actual study enrollment.

With the data in hand showing the issues and the current state of affairs, we set out to bring the stakeholders together to work on the common problems. Our first effort was a Best Practices Workshop held in Washington at the MDIC offices with 65 participants from leading industry players—both big companies and small companies, clinical site coordinators, principal investigators, the FDA, CMS, and MDIC. Over a day and a half, we discussed the key issues and openly shared best practices to achieve efficient processes. We published the findings and made the information available for everyone.

Then, with the help of all stakeholders and the use of tools developed by MDIC, by 2019 the average IDE approval time was reduced from 68 days to only 53 days, IRB approvals were shaved to 51 days, and the time to first subject enrollment was significantly reduced, from 187 days to only 88 days.

One metric that had not yet improved was the time to contract approval. Therefore, a further key step was to develop a Master Clinical Trial Agreement (MCTA) that streamlined the contract negotiating process between industry sponsors and sites with pre-

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agreed language on the thorniest issues. We believe that the use of the MCTA will significantly improve the time to contract approval once we have transitioned out of the current pandemic.

### **Impressive! Any last thoughts on EFS and the Medical Device Innovation Consortium?**

If you go to the MDIC website at [www.MDIC.org](http://www.MDIC.org) and look under the Initiatives tab, you will find a list of wonderful free tools developed by MDIC to assist companies with the efficient execution of an EFS. The program director for EFS at MDIC is Liliana Rincon Gonzalez and she can be reached at [lrincon-gonzalez@mdic.org](mailto:lrincon-gonzalez@mdic.org). The team at MDIC has done a great job creating these tools and we would like to invite all companies to take advantage of it. Thank you.



## Five Design Mistakes Medical Device Start-Ups Make

By Walt Maclay, President, Voler Systems

Start-ups are the lifeblood of the medical device industry. Large medtech companies depend on start-ups to eliminate some of the risk of new technologies. In addition, start-ups are very efficient in their use of funding, and they move much faster than large companies.

That being said, start-ups are often inexperienced. Here are five common design mistakes they need to avoid:

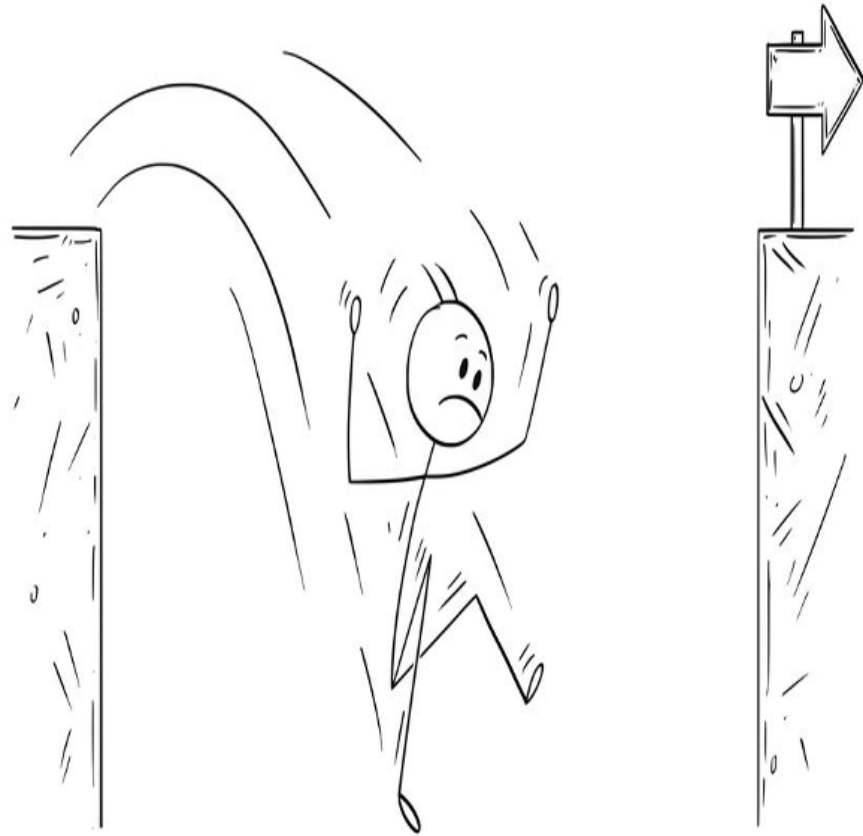
### 1. Feature Creep

The biggest mistake start-ups make is trying to cram too much into that first device. When you start adding bells and whistles, it increases your timeline, it increases your budget, and it opens you up to more scrutiny by the Food and Drug Administration (FDA). We advise them to take a little time and think about the core things that are needed. Those core features are going to drive your minimum viable product (MVP). Get those done, get those right. Keeping the feature list limited keeps your budget needs limited. Requirement creep will be

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the death of your product. On the other hand, make sure you know what is really needed, and put that in.

The best way to get this right is to thoroughly understand your customer and the problem you are solving. This requires interviewing many customers and watching them do their work. You can't just ask them if they want your product and what features they want. You need to experience their pain, then figure out a solution no one else has thought of. When you are tempted to add features, just focus on solving the urgent problem the customer has.

### 2. Not Doing a Feasibility Study

Another big problem is that if you're bringing to market something that

hasn't been done before, you may run into unanticipated problems. The more unprecedented your project is, the longer it's going to take, and the more it's going to cost. As Murphy's Law says, "If anything can go wrong, it will." You have to plan for that. It's important to understand what is risky and what isn't. If the technology is unproven, do a feasibility study, or at least investigate enough to be sure your risk is low.

If you are not thoroughly familiar with the technology, a consulting company that is focused in the space will know what technology is risky and what technology isn't. They can propose feasibility tests that will reduce the risk, or they may show that the risk is very high, and you may not want to proceed.

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## Five Design Mistakes Medical Device Start-Ups Make *(Continued from page 9)*

### 3. Underestimating the Amount of Work Needed to Meet FDA Requirements

The FDA cares that the device is safe. A non-medical commercial device can be just good enough. A medical device has to be safe and effective, and that takes time and money. The FDA requires a lot of documentation to prove it. A good rule of thumb is to plan on a medical device costing about three times as much as a consumer product to develop and prepare to sell. This includes the extra design work, testing work, regulatory work, and quality system work.

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### 4. Ad Hoc Processes

Start-ups often use ad hoc processes to explore the application needs and

develop the product, but to get FDA approval, a proven design control process needs to be used. Product specs must clearly and unambiguously articulate the product's features, functionality, and behavior. Careful writing of the product requirements is the important starting point in a more rapid approval process, and they are essential for the verification process. Here is a white paper titled "Developing Product Requirements for Medical Devices": <https://volersystems.com/design-tips/voler-whitepaper-developing-product-requirements-medical-devices/>.

If you have not done this before, an experienced design consulting firm can make sure your product requirements are done well. The requirements will be adjusted by the risk analysis. You will probably need to mitigate some risks with design changes. The requirements should support the verification testing that will be done at the end of the design process. All of this should be prepared before starting the design. It will save time and money in the end.

### 5. Not Getting the Right Expertise

Find people who know how to build the kind of device you want to build—people who can help you not only develop the product, but get it through the FDA. We work in partnership with start-ups to ensure that the right product is being developed, that it will rapidly get FDA approval, and that it can be manufactured easily to get into the marketplace quickly and at minimum cost.

*Walt Maclay, president and founder of Voler Systems, is recognized as a domain expert in Silicon Valley technical consulting associations. He has spoken on sensors, wearable devices, wireless communication, and low power design. From 2008 to 2010, he was president of the Professional and Technical Consultants Association (PATCA). He is a senior life member of the Institute of Electrical and Electronic Engineers (IEEE) and a member of the Consultants Network of Silicon Valley. Walt has been an instructor at Foothill College in the Product Realization Certificate Program, teaching successful new product introduction skills. He has applied his outstanding leadership to many multidisciplinary teams that have delivered quality electronic devices. Walt holds a B.S.E.E. degree in electrical engineering from Syracuse University.*

*Voler Systems, one of the top electronic design firms in Silicon Valley, is committed to delivering quality electronic products on time and on budget. It provides design, development, risk assessment, and verification of new devices for medical, consumer, and industrial applications. Voler is particularly experienced in designing wearable and IoT devices, using its skill with sensors and wireless technology. The company has developed hundreds of products, including medical devices, wearable devices, home health, products for the aging, and other medical, consumer, and industrial devices.*

## USJMF and JSNC Host MedTech Emerging Growth Companies 2020 Virtual Roadshow



On October 12-14, 2020, US-Japan Medtech Frontiers (USJMF) and the Japan Society of Northern California (JSNC), with the support of founding sponsor Wilson Sonsini Goodrich & Rosati, held the MedTech Emerging Growth Companies 2020 Virtual Roadshow. Featuring keynotes from Andrew Cleeland, CEO of the Fogarty Institute for Innovation, and David Cassak, founder and co-editor-in-chief of iconic industry publication *Medtech Strategist*, and pitch presentations from 22 innovative emerging growth medtech companies, the event attracted more than 500 attendees worldwide, including a large contingent from Japan. The keynote addresses and company presentations were all given simultaneously in both English and Japanese.

The first day of the event featured welcome addresses from Takahide

Akiyama, president of JSNC, and Keith Kirkham, Minister Counselor for Commercial Affairs from the U.S. Embassy Tokyo. USJMF Chairman Jack Moorman then introduced Mr. Cleeland, who delivered his keynote address. Seven cardiovascular-focused emerging companies gave brief presentations to the virtual audience, after which remarks were provided by Dr. Fumiaki Ikeno of Stanford University's Byers Center for Biodesign.

Day Two kicked off with the keynote address from Mr. Cassak, which was followed by presentations from six companies in the neuro or orthopedic sectors and remarks from Mr. Akiyama. The third and final day of the event highlighted presentations from nine companies in the gastrointestinal, surgical, ophthalmology, ENT, or women's health sectors.

The 2020 MedTech Emerging Growth Companies Virtual Roadshow featured presentations from the following:

- Agile Devices
- AiM Medical Robotics
- Centerline Biomedical
- Centese, Inc.
- Eyedaptic
- InformAI, Inc.
- Invenio Imaging
- Ischemia Care
- Mitre Medical
- MITRx, Inc.
- Oracle Health, Inc.
- osteolabs GmbH
- PercAssist, Inc.
- Prescient Surgical
- Qidni Labs
- Quantason, LLC
- Radux Devices LLC
- Regentys
- Shape Memory Medical Inc.
- Slate Therapeutics
- Smartlens, Inc.
- Sway Medical, Inc.

Each day concluded with interactive breakout sessions at which attendees had the opportunity to participate in live Q&A sessions around virtual "tables" with representatives from the presenting companies and bilingual medtech experts facilitating the discussions.

"This would have been our Seventh Annual Medtech Week in Japan, with perhaps 1,000 attendees," said USJMF Chairman Jack Moorman. "Though

*Continued on page 12...*



## USJMF and JSNC Host MedTech Emerging Growth Companies . . . *(Continued from page 11)*

we had to reschedule to 2021, we still wanted to provide an environment where Japanese companies could get to know these exciting early-stage companies despite their inability to travel in person to Japan. The keynotes and presentations were not only given in English, but they had a real-time Japanese interpreter on a parallel Zoom channel. The Q&A was virtual, but felt up close and personal, as interested attendees could

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“We still wanted to provide an environment where Japanese companies could get to know these exciting early-stage companies despite their inability to travel in person to Japan ... Overall, the feedback was very positive, and I think we have a recipe for success we can use for future virtual conferences.”

– USJMF Chairman Jack Moorman

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be at a table with company presenters and a knowledgeable medical device expert fluent in both Japanese and English. Each table was limited to six attendees at a time, so it felt like a small meeting you might have after a typical

conference. Overall, the feedback was very positive, and I think we have a recipe for success we can use for future virtual conferences.”

“The Japan Society of Northern California, with its 115-year history, was delighted to partner with USJMF to deliver this incredibly informative and productive event on medical device innovation. We look forward to jointly hosting similar events with USJMF in the future and bringing this type of industry-specific collaboration to our audience, sponsors, and partners,” said Takahide Akiyama, president of the Japan Society of Northern California.

The 2020 MedTech Emerging Growth Companies Virtual Roadshow was held in lieu of the USJMF/Wilson Sonsini trade mission and roadshow, which was originally scheduled to take place in Kyoto and Tokyo from November 7-13, 2020, but has been postponed until November 2021 due to the global pandemic. Early and growth-stage medical device, diagnostic, and digital health companies will be encouraged to apply to the 2021 trade mission and roadshow. Representatives from 22 such companies attended the Sixth Annual Japan Medical Device Innovation Week via the USJMF/Wilson Sonsini trade mission and roadshow in November 2019.

Founded in 2013, [US-Japan Medtech Frontiers](#) is a Silicon Valley-based nonprofit whose mission is to share



**US-Japan**  
MEDTECH FRONTIERS

best practices for medical device innovation and promote networking and collaboration between U.S. and Japanese medical device organizations.

Wilson Sonsini is a co-founder and sponsor of USJMF, and partners Casey McGlynn and Elton Satusky serve on the organization’s board of directors, along with Chairman Jack Moorman, Dr. Fumiaki Ikeno of the Stanford Byers Center for Biodesign, Kirk Zeller of Silicon Prairie Center and Nichibei MedTech Advisors, LLC, and Masa Ishii of AZCA Venture Partners.



**JAPAN SOCIETY**  
OF NORTHERN CALIFORNIA

Founded in 1905, the [Japan Society of Northern California](#) works to advance U.S.-Japan collaboration and understanding in a global context. The Society offers an array of programs and networking opportunities for people and organizations in the Bay Area with a strong interest in Japan. These programs draw on the diversity of the region, its importance as an exemplar of innovation and economic growth, and its historic ties to Japan across fields including business, technology, and the arts.

## An Interview with Dr. Wasim Malik of Iaso Ventures



Wilson Sonsini partner Mark Solakian recently interviewed Dr. Wasim Malik, the managing partner at Boston-based Iaso Ventures, the nation's first sector-focused neuroscience and mental health venture capital firm. Wasim oversees Iaso Ventures' overall strategy, investments, and partnerships. Below is a selection of highlights from their conversation.

**Mark: Could you provide us with a bit of background on Iaso Ventures?**

Wasim: We launched the firm last year in response to the market gap we noticed related to innovation and early-stage investments in the neuroscience and mental health space. In contrast with generalist investment firms, our strategy revolves around an investor-operator team with deep sector expertise and an innovation ecosystem comprising value-add strategic partners. I am also delighted about the strategic partnership Iaso Ventures has with Wilson Sonsini.

**What was your personal interest in neuroscience, and what drew you to it in your career?**

Many of us are intrigued and inspired by the mysteries that remain unsolved

in whatever age we happen to be born in. For me, the brain represents the next major frontier for exploration and discovery. In my journey through academic training and working in various industry sectors, from telecommunications and software to healthcare, I concluded that the brain and mind have defied human understanding through the eons. Demystifying the brain was something that would motivate me to get out of bed in the morning, so it seemed appropriate to turn this interest into a career.

The human genome project really was when we turned the corner in our understanding of genetics. We have not hit a similar milestone in neuroscience yet; therefore, our understanding of the brain remains rudimentary at best. Even the most basic innovations in brain science can greatly impact human society. This important knowledge gap and the opportunity for social and business impact made it an easy decision for me to jump headfirst into neuroscience innovation and investing.

**Iaso Ventures is a new fund and you have a unique model. You call it the Iaso Ventures Studio. Tell us about the studio model, how it works, how it differs from other models, and any other unique attributes.**

The venture studio model is not a new invention—it goes back 25 years and has been performing well in building high-value start-ups, especially in the tech industry. Rather than providing only investment dollars or hands-off advisory, the studio model pairs up entrepreneurs with experienced operators to roll up their sleeves and co-create new ventures. The success of the studio model can be seen in the recent IPO of Snowflake—the largest software IPO to date. Snowflake was started at Sutter Hill Ventures' studio. The attraction for investors is

obvious, because the returns are far higher than when achieved only with a "lazy-money" approach.

At Iaso, we have adopted the studio model to work with early-stage companies in a hands-on way to help them grow and reach the next value inflection point at an accelerated pace. We also identify market gaps through our extensive landscape analysis, opportunistically ideating and creating new ventures from the ground up. My belief is that this model brings the real value-add the market requires, particularly in specialty markets such as neuroscience, where domain expertise makes all the difference.

**What are you looking for in your portfolio companies? And what are some of the qualities that you have seen in successful portfolio companies?**

Like most investors, we follow a structured and disciplined deal analysis and due diligence process. Some of the key factors are the differentiated technology that a company has developed, the robustness of the intellectual property, and the approach to the regulatory and reimbursement environment.

But perhaps most importantly, we like to look at the team. As early-stage investors, we really invest in teams that are capable of executing, have a track record of innovation and achievement, and are able to perform nimbly under ever-changing market conditions. We even have an in-house organizational psychologist and leadership coach to assess the start-up team dynamics, build upon strengths, and fill any gaps.

We also pay serious attention to the question "Who cares?" Often, we see exciting new technologies, but the

*Continued on page 14...*

## An Interview with Dr. Wasim Malik of Iaso Ventures *(Continued from page 13)*

market may not be ready, the pathway to commercialization may not be clear, or the journey of identifying customers and creating initial traction may not have started. In those cases, we really like to sit down with our entrepreneurs and figure out who should care and how to make them care.

### **How does Iaso Ventures fit into the overall life sciences ecosystem in Boston, and more broadly, throughout the U.S. or internationally?**

We are fortunate to be headquartered in Boston, the global headquarters for life sciences innovation, with the highest concentration of biopharma companies and some of the world's top research powerhouses. This ecosystem provides the best opportunities and resources to build great companies by sourcing technology from top-tier schools, working with well-regarded KOLs, and leveraging a dense cluster of strategics and investors. The Iaso Ventures team spans the major innovation hubs across the U.S. and has cultivated robust international connections.

### **As you look ahead, do you envision any expansion to your industry scope for additional or different vectors that could be of interest?**

Iaso Ventures is charting out a bold agenda to imagine the future of neuroscience and lay out the infrastructure to enable that future. We are philosophically inspired by what the World Economic Forum refers to as the "Fourth Industrial Revolution," where the boundaries between the biological, physical, and digital realms are blurred.

By embracing this transformative vision, we are expanding our mission to push the envelope at the intersection of healthcare and technology as it applies to neuroscience and mental health. As part of this exercise, we see the world

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"Overall, the pandemic hasn't increased the venture market risk profile. In fact, historical data suggests that during recessions, public equities can be up to 13 times riskier than private equity."

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of innovation through the lens of restructuring traditional business models with extensive horizontal and vertical integration.

When applied to the future outlook for venture, we expect that these moving tectonic plates will give rise to unforeseen cross-industry partnerships and exit pathways. As a recent example, we saw that Boston-based Control Labs, a start-up with roots in medtech, was acquired by Facebook for potential use in future human-computer interaction technology.

### **Are you seeing any sectors that might be more attractive due to the current state of the market or other drivers?**

It is no surprise that the healthcare market has experienced massive growth during the pandemic. Certain healthtech applications have seen a significant uptick, prominent among them digital technologies for telehealth, now being used both for care delivery at home and for virtual clinical trials. We expect these industry trends will only grow in the coming years.

In the medium term, we foresee great potential for expansion across the tech-enabled healthcare services spectrum,

especially in digital diagnostics and therapeutics. We can also see the switch from sick care to preventive care, although these are still early days.

### **Do you have any concerns about the market and risk factors related to the pandemic?**

The most significant risk during the pandemic has been the ability to raise capital and maintain sufficient runway. We've seen some degree of correction and consolidation in the private markets. In the early days of the pandemic, investors mostly directed their dry powder toward existing investments rather than making new bets. I read about predictions that 70 percent of start-ups would collapse, but that did not happen. Many overestimated the effects that the pandemic would have on capital markets, as it is typical for capital markets to overreact, but because of various factors, private markets have more or less remained stable.

In the healthcare and life sciences industry, some of the risk factors remain the same as before—primarily due to big bets being made on new, game-changing technology platforms or disease-modifying therapeutics. Overall, the pandemic hasn't increased the venture market risk profile. In fact, historical data suggests that during recessions, public equities can be up to 13 times riskier than private equity, which can partly be attributed to the long time horizon and consequent stability of VC/PE investments.

### **Do you see behavioral health issues developing as an impending crisis? What's your take on why it's a growing concern?**

Currently, one in every five individuals globally suffers from a mental health issue. Several factors suggest that there will be an increase in the mental

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## An Interview with Dr. Wasim Malik of Iaso Ventures *(Continued from page 14)*

health crisis. One reason is that we've succeeded in prolonging life, so we have an aging population, and corresponding age-related diseases and quality-of-life issues. An aging population means higher prevalence of dementia, for example, and higher cost of elder care. There has been a significant rise in behavioral health issues such as addiction, depression, and anxiety, especially among teens and millennials, which can be attributed to increased isolation and the lack of social connectedness. The pandemic has only exacerbated these challenges.

While this sounds ominous, there are also reasons to rejoice. Policy changes, such as the Mental Health Parity Act, have enabled greater access to mental health services. There is a shift toward new pricing models, such as for therapeutic development for rare diseases, which makes it possible to develop new cures in an economically viable way. Value-based reimbursement models are shifting focus toward healthcare outcomes and prevention-based approaches, promoting population health initiatives.

### **What industries do you see advancing in 2021, or in the next five to 10 years? Where do you think the next big disruption will occur?**

In 2021 and beyond, we expect to see advances in more game-changing platforms for therapeutic development. Increased interest in gene editing and stem cell technologies, for example, has spawned vigorous R&D activity. New approaches are being developed for the medical use of naturally existing substances or their synthetic equivalents, such as psychedelic medicines for treating depression and PTSD. And finally, we notice a focus on connected health platforms for patients, caregivers, and providers, which can improve

workflow and ultimately increase the productivity of the overall healthcare system and, in the end, improve patient care and quality of life.

### **Do you see signals that deal flow is trending upward?**

In neuroscience and mental health, deal flow has continued to increase significantly in the last few years. When we first started Iaso Ventures, we were concerned about both the quality and quantity of deal flow. However, our timing coincided perfectly with the upswing in the market interest in neuroscience as a sector, resulting in rich deal activity. Alongside, we see robust interest from investors in this specific sector, both for its societal impact and the potential of outsized returns.

### **Thinking globally, what geographic markets are you and your portfolio companies most interested in?**

Brain health is of course a global issue. It's fair to say it affects emerging markets as much as it affects us here in the U.S., opening up global scaling opportunities. We're also seeing great innovation in neuroscience and mental health in many geographies around the world, such as Israel, Canada, Japan, and certain other countries. In recent weeks, there have been announcements about launching a multibillion-dollar global initiative to promote mental health.

### **Are there any new developments with Iaso Ventures you'd like to share?**

In our quest to build bridges with global and especially emerging markets, we're actively expanding our geographical footprint by leveraging our international networks. This will help us cast a bigger net for deal sourcing, allow our start-ups to access global markets, and open up opportunities for global scaling. We

will be announcing several international partnerships in the coming months.

In addition to an all-star core team that I am most proud of, we are building a stellar advisory group to establish Iaso Ventures at the forefront of thought leadership both in neuroscience R&D and in emerging business models that can support fast-paced innovation.

### **As managing director of a fund, an investor, and with regard to your portfolio companies, how do you plan to apply a diversity and inclusion initiative?**

I am proud to restate our commitment to promoting equal opportunity and ensuring that the core values of diversity and inclusivity are reflected in our team and portfolio composition. By bringing these issues to the forefront, the Black Lives Matter movement [in 2020] has provided tailwind to our efforts. We plan to continue our mission of boosting minority and women's representation in the venture industry. As an immigrant and minority founder myself, I am acutely aware of the many hurdles faced by women and people of color in the venture industry. Through specific firm-wide initiatives, we are taking steps to correct these societal imbalances and promote underrepresented communities as founders, investors, and executives. I want to point out that this focus on equitable representation does not come at a price to our investors. On the contrary, diversity of backgrounds and experiences is known to boost the potential for much higher returns.

### **What is it like being an investor during the pandemic?**

Somewhat counterintuitively, the pandemic is the best time for investing in start-ups aiming to solve real business problems with an eye on generating

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## An Interview with Dr. Wasim Malik of Iaso Ventures *(Continued from page 15)*

traction and profitability. Historically, funds with vintage in down-market years have consistently outperformed. The reason is that market corrections bring valuations down to realistic levels, promote a survival-of-the-fittest environment, and make available larger talent pools.

The timing could not be better for a neuroscience-focused fund. There are now multiple large studies linking COVID-19 to increased incidence of neurological disorders as well as mental health issues. Iaso Ventures is therefore uniquely positioned to invest in market segments at the cusp of rapid expansion due to the pandemic.

### **What is your view on the utility of the scientific advisory board from the perspective of the CEO or CFO, board, and investors?**

The team is one of the foremost things we evaluate in our investment decisions. The scientific advisory board is a critically important segment of the team, especially in life sciences and healthtech start-ups. We talked earlier about the role our firm's location plays in our business strategy. In the East Coast healthcare and life sciences investment market, we tend to be evidence-based and data-driven. We pay attention to the composition of the scientific advisory board, the complementarities of the individuals involved, the ability of those individuals to identify and capture opportunities nimbly, and the ability to adapt in light of new discoveries or challenges along the way.

### **What kinds of questions are you asked most often by entrepreneurs?**

People that aren't shy about asking questions and are capable of active listening make good entrepreneurs.

The most naïve questions are the best ones, as new directions of inquiry can promote outside-the-box thinking and generate paradigm-shifting insights. Candid feedback—and tough love where needed—coupled with the ability to pivot quickly and pivot often, can spell the difference between roaring success and crash-and-burn situations.

I usually advise early-stage entrepreneurs to not be fixated on the uniqueness of their idea or the coolness of their technology, but instead to focus on the business model and the path to profitability. To turn your question around, the question I most often ask of entrepreneurs is, “So what?”

### **Do you have any additional advice for new entrepreneurs?**

A core tenet of entrepreneurship is that it takes a village. My advice for new entrepreneurs is to build a team around themselves that falls in place like pieces of a puzzle. Once you surround yourself with people smarter than yourself, “constructive collisions” start to take place, which generate bold ideas and launch great companies. It's important to surround yourself with differing opinions and encourage disagreement.

### **What are the qualities you look for with respect to your outside attorneys, and what do you encourage entrepreneurs to look for when selecting counsel?**

It goes without saying that having specific expertise within one's industry is a core requirement, but perhaps even more importantly, personal chemistry and trust are critical. Selecting counsel is part of the journey of building a business that lasts for years and years, so the selection of legal partners should be thoughtful.

It is advisable to look at the track record of any legal or other partner an entrepreneur chooses to work with, and develop a comfort level that the partner has relevant subject-specific expertise and a broad market footprint. That often translates into working with firms that are highly reputed within the specific industry, have a global presence, and offer full-service capabilities that can address any sphere of legal needs as they arise. Outstanding law firms such as Wilson Sonsini, which are known for their entrepreneurial DNA and for going to bat for their start-up clients, are the ideal partners for entrepreneurs.

*Prior to becoming the managing partner at Iaso Ventures, Dr. Wasim Malik served as chief digital strategist at Roivant Sciences, a global biopharma company. He also served on the faculty at Harvard Medical School and Massachusetts General Hospital, where he built a research program on tech-enabled clinical research in neuroscience, anesthesia, and critical care. In addition, Dr. Malik taught entrepreneurship, neuroscience, and machine learning at MIT, and served on the visiting faculty at Brown University. He received a Ph.D. in electrical engineering from Oxford, postdoctoral training in neuroscience from MIT, and finance education in venture capital and private equity from Harvard Business School. Learn more about Iaso Ventures and Dr. Malik at <https://iasoventures.com/>.*

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\* This interview was originally published in the Q3 2020 edition of *The Entrepreneurs Report* published by Wilson Sonsini.

## Select Life Sciences Client Highlights

### Hurdle Raises \$5 Million Series Seed Financing

On January 25, 2021, Hurdle, an innovative digital mental health platform company, announced that it has successfully closed a \$5 million Series Seed financing co-led by 406 Ventures and Seae Ventures with participation from F-Prime. Hurdle will use the new capital to strategically scale its evidence-based and tech-enabled platform, designed to support culturally diverse populations' behavioral health needs. Wilson Sonsini advised Hurdle in the transaction. <https://www.prnewswire.com/news-releases/hurdle-raises-5-million-series-seed-to-accelerate-expansion-of-its-mental-health-platform-with-special-focus-on-the-black-community-301213620.html>.

### Pacific Biosciences Announces Multi-Year Collaboration with Invitae Corporation

On January 13, 2021, Pacific Biosciences of California, Inc., a leading provider of high-quality, long-read sequencing platforms, announced a multi-year collaboration with Invitae Corporation, a leading medical genetics company, to begin development of a production-scale high-throughput sequencing platform leveraging the power of PacBio's highly accurate HiFi sequencing to expand Invitae's whole genome testing capabilities. Wilson Sonsini represented PacBio in the transaction. [https://www.pacb.com/press\\_releases/pacific-biosciences-and-invitae-to-develop-ultra-high-throughput-clinical-whole-genome-sequencing-platform/](https://www.pacb.com/press_releases/pacific-biosciences-and-invitae-to-develop-ultra-high-throughput-clinical-whole-genome-sequencing-platform/).

### Earli Raises \$40 Million in Series A Funding

On January 12, 2021, bioengineering firm Earli, which developed in stealth a new platform technology that will allow clinicians to exactly locate early cancers so they can be treated, announced that it has raised \$40 million

in Series A funding. The financing was led by Khosla Ventures, along with Perceptive Advisors, Casdin Capital, Andreessen Horowitz, Sands Capital, and top individuals, including Midas List investors Jim Breyer/Breyer Capital and Rahul Mehta; Goldman Sachs's former CFO and CIO R. Martin Chavez; and biomedical device entrepreneur Shlomo Ben-Haim. Wilson Sonsini advised Earli on IP matters related to the transaction. <https://www.businesswire.com/news/home/20210112005302/en/Earli-Raises-40-Million-Series-A-Funding-Led-by-Khosla-Ventures-With-Perceptive-Advisors-Casdin-Capital-Andreessen-Horowitz-Sands-Capital>.

### Gracell Biotechnologies Announces Pricing of IPO

On January 8, 2021, Gracell Biotechnologies Inc., a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies to address major industry challenges and fulfill unmet medical needs in the treatment of cancer, announced the pricing of its initial public offering of 11,000,000 American Depositary Shares, each representing five ordinary shares, at a public offering price of US\$19 per ADS. The gross proceeds to Gracell from the offering are expected to be US\$209 million. Wilson Sonsini advised Gracell on IP matters related to the transaction. <https://ir.gracellbio.com/news-releases/news-release-details/gracell-biotechnologies-announces-pricing-initial-public>.

### Abbisko Therapeutics Announces \$123 Million Series D Financing

On January 8, 2021, Abbisko Therapeutics Co., Ltd., an oncology-focused biopharmaceutical company, announced the completion of its Series D financing of \$123 million. The proceeds from this round will be used to accelerate the progress of Abbisko's

clinical programs and further expand its preclinical pipeline consisting of multiple programs in discovery to IND-enabling stages. Abbisko is dedicated to the discovery and development of innovative medicines for unmet medical needs in China and around the world. Wilson Sonsini acted as counsel to Warburg Pincus, a lead investor in the financing. [http://www.abbisko.com/page96?l=en&article\\_id=157](http://www.abbisko.com/page96?l=en&article_id=157).

### Blacksmith Medicines Launches with Seed Funding and Research Collaboration with Lilly

On January 8, 2021, Blacksmith Medicines, Inc., a biotechnology company focused on creating novel medicines for immuno-oncology and inflammatory diseases by targeting human metalloenzymes, announced that it has secured seed funding and has entered into a research collaboration with Eli Lilly and Company (Lilly). Lilly joins existing Blacksmith investors Evotec A.G., MP Healthcare Partners, MagnaSci Ventures, and Alexandria Venture Investments. Wilson Sonsini advised Blacksmith Medicines on IP matters related to the transactions. <https://www.prnewswire.com/news-releases/blacksmith-medicines-launches-with-seed-funding-and-a-research-collaboration-with-lilly-301203230.html>.

### DiCE Molecules Announces \$80 Million Series C Financing

On January 8, 2021, DiCE Molecules, a biopharmaceutical company leveraging its proprietary DNA-encoded library platform to discover and develop next-generation therapeutics in immunology, announced the completion of an \$80 million Series C financing. The financing was led by RA Capital Management with participation from new investors including Eventide Asset Management, New Leaf Venture Partners, Soleus Capital, Driehaus Capital Management, Osage University Partners, and

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

Asymmetry Capital Management. Existing investors Northpond Ventures, Sands Capital, Sanofi Ventures, Alexandria Venture Investments, Altitude Life Science Ventures, and Agent Capital also participated. Wilson Sonsini advised DiCE Molecules on IP matters related to the transaction. <https://www.businesswire.com/news/home/20210108005060/en/DiCE-Molecules-Announces-80-Million-Series-C-Financing>.

### **Harpoon Therapeutics Announces Pricing of Public Offering of Common Stock**

On January 6, 2021, Harpoon Therapeutics, Inc. announced the pricing of an underwritten public offering of 5,882,352 shares of its common stock at a price to the public of \$17 per share. Harpoon expects the gross proceeds from the sale of the shares to be approximately \$100 million, before deducting underwriting discounts and commissions and offering expenses payable by the company. In addition, Harpoon has granted the underwriters in the offering a 30-day option to purchase up to 882,352 additional shares of common stock at the public offering price. Wilson Sonsini advised Harpoon Therapeutics on IP matters related to the transaction. <https://www.globenewswire.com/news-release/2021/01/07/2154613/0/en/Harpoon-Therapeutics-Announces-Pricing-of-Public-Offering-of-Common-Stock.html>.

### **Distributed Bio Acquired by Charles River Laboratories for \$83 Million**

On January 4, 2021, Charles River Laboratories International, Inc. announced that it acquired Distributed Bio, a next-generation antibody discovery company, on December 31, 2020. The purchase price was \$83 million in cash, subject to customary closing adjustments. In addition to the initial purchase price, the transaction includes contingent additional payments of up to

\$21 million based on future performance. The transaction combines Distributed Bio's antibody libraries and immuno-engineering platform with Charles River's extensive drug discovery and non-clinical development expertise to create an integrated, end-to-end platform for therapeutic antibody and cell and gene therapy discovery and development. Wilson Sonsini represented Distributed Bio in the transaction. <https://www.businesswire.com/news/home/20210104005198/en/Charles-River-Laboratories-Acquires-Distributed-Bio>.

### **ONL Therapeutics Closes on \$46.9 Million in Series B Financing**

On December 22, 2020, ONL Therapeutics, Inc., a biopharmaceutical company developing novel therapies for protecting the vision of patients with retinal disease, announced it closed on \$46.9 million in a Series B preferred stock financing. The financing included new investors Bios Partners (which led the round), Johnson & Johnson Innovation-JJDC, Inc., Kaitai Capital, PSQ Capital, and Michigan Capital Network Venture Fund III, as well as existing investors ONL Therapeutics management, InFocus Capital Partners, ExSight Ventures, the University of Michigan's Michigan Investment in New Technology Startups program, Western Michigan University's Biosciences Research & Commercialization Center, and the Capital Community Angels. Wilson Sonsini represented ONL Therapeutics in the transaction. <https://www.onltherapeutics.com/2020/12/22/onl-therapeutics-closes-46-9-million-in-series-b-financing-to-advance-onl1204-into-three-retinal-disease-indications/>.

### **Janux Therapeutics Announces Strategic Collaboration and License Agreement with Merck**

On December 18, 2020, Janux Therapeutics announced a strategic collaboration and license agreement

with Merck to discover, develop, and commercialize innovative, next-generation T cell engager immunotherapies for the treatment of cancer. Under the terms of the agreement, Merck has received an exclusive worldwide license to products and intellectual property developed from this collaboration. In exchange, Janux will be eligible to earn up to \$500.5 million per target in upfront and milestone payments, plus royalties on sales of any product derived from the collaboration. Merck will fund R&D performed under the collaboration. Wilson Sonsini advised Janux on patent matters related to the transaction. <https://www.januxrx.com/janux-therapeutics-announces-collaboration-with-merck-to-develop-novel-drug-candidates-for-immuno-oncology-using-t-cell-engager-tractr-technology/>.

### **Vivace Therapeutics Announces Close of \$30 Million Series C Funding**

On December 16, 2020, Vivace Therapeutics, Inc., a small-molecule drug discovery and development company focused on targeting the Hippo pathway, announced the closing of a \$30 million Series C financing. The financing was led by Boxer Capital with participation from new investor RA Capital Management and existing investor Canaan Partners. Vivace anticipates advancing its clinical candidate into first-in-human studies in early 2021, targeting tumors dependent on activated YAP. Wilson Sonsini advised Vivace on patent matters related to the financing. <https://vivacetherapeutics.com/wp-content/uploads/Vivace-press-release-20201211-FINAL.pdf>.

### **Atsena Therapeutics Closes \$55 Million Series A Financing**

On December 16, 2020, Atsena Therapeutics, a clinical-stage gene therapy company developing novel treatments for inherited forms of blindness, announced it has closed an

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oversubscribed \$55 million Series A financing. The proceeds will be used to advance Atsena's ongoing Phase I/II clinical trial evaluating a gene therapy for patients with GUCY2D-associated Leber congenital amaurosis, as well as complete manufacturing development for Phase III. Wilson Sonsini advised Atsena Therapeutics on IP matters related to the financing. <https://atsenatx.com/press-release/atsena-therapeutics-raises-55-million-series-a-financing-to-advance-lca1-gene-therapy-clinical-program-two-preclinical-assets-and-novel-capsid-development-for-ocular-diseases/>.

### **Ripple Therapeutics Announces Licensing Agreement, Series A Financing**

On December 15, 2020, Ripple Therapeutics Corporation, a clinical-stage, ophthalmology-focused developer of novel therapeutics, announced the signing of an exclusive licensing agreement for the rights to their lead product, IBE-814, for North America and Europe with Théa Open Innovation (TOI), a wholly owned subsidiary of Laboratoires Théa, the leading independent ophthalmology pharmaceutical company in Europe. In addition, Ripple announced that TOI is leading its Series A financing, which raised \$14.8 million. Wilson Sonsini is advising Ripple on both transactions. <https://www.accesswire.com/viewarticle.aspx?id=620401>.

### **ALX Oncology Announces Close of \$208 Million Public Offering**

On December 14, 2020, ALX Oncology Holdings Inc., a clinical-stage immunology company, announced the closing of its previously announced underwritten public offering of 2,737,000 shares of its common stock, which includes the exercise in full of the underwriters' option to purchase

357,000 additional shares of its common stock, at a price to the public of \$76 per share. The aggregate gross proceeds to ALX Oncology from the offering were approximately \$208 million. Wilson Sonsini advised ALX Oncology on the offering. <https://ir.alxoncology.com/news-releases/news-release-details/alx-oncology-announces-closing-public-offering-and-full-exercise>.

### **Locanabio Announces \$100 Million Series B Financing**

On December 14, 2020, Locanabio, Inc., an RNA-targeting gene therapy company focused on developing life-changing therapies for patients with severe neurodegenerative, neuromuscular, and retinal diseases, announced a \$100 million Series B financing. The financing was led by Vida Ventures with participation from new investors including RA Capital Management, Invus, Acuta Capital Partners, and an investment fund associated with SVB Leerink, and prior Locanabio investors ARCH Venture Partners, Temasek, Lightstone Ventures, UCB Ventures, and GV. Wilson Sonsini represented Vida Ventures and Temasek in the transaction. <https://locanabio.com/press-releases/locanabio-announces-100-million-series-b-financing-to-advance-portfolio-of-novel-rnatargeted-gene-therapies-for-neurodegenerative-neuromuscular-and-retinal-diseases/>.

### **IGM Biosciences Announces Closing of \$230 Million Public Offering**

On December 11, 2020, IGM Biosciences, Inc. announced the closing of its upsized underwritten public offering of 1,221,224 shares of its common stock, which includes the exercise of the underwriters' option to purchase additional shares in full, and pre-funded warrants to purchase 1,334,332 shares of its common stock. The public offering price of common stock was \$90 per

share and the public offering price of each pre-funded warrant was \$89.99, with each pre-funded warrant having an exercise price of \$0.01. The aggregate gross proceeds to IGM from the offering were approximately \$230 million. Wilson Sonsini represented IGM in the transaction. <https://investor.igmbio.com/news-releases/news-release-details/igm-announces-closing-230-million-public-offering-and-full>.

### **Opiant Pharmaceuticals Secures \$50 Million in Convertible Debt Financing**

On December 10, 2020, Opiant Pharmaceuticals, Inc., a specialty pharmaceutical company developing medicines to treat addictions and drug overdose, announced that it has entered into a \$50 million convertible note purchase and security agreement with a syndicate of Pontifax Medison Finance, a healthcare-dedicated venture and debt fund, and Kreos Capital, Europe's leading growth debt firm. Opiant plans to use the proceeds to fund the potential future commercialization of OPNT003, nasal nalmefene, an investigational treatment for opioid overdose, which the company aims to file for approval by the FDA at the end of 2021. Wilson Sonsini represented Opiant Pharmaceuticals in the transaction. <https://ir.opiant.com/news-releases/news-release-details/opiant-pharmaceuticals-secures-50-million-convertible-debt>.

### **Reneo Pharmaceuticals Raises \$95 Million in Series B Financing**

On December 9, 2020, Reneo Pharmaceuticals, a clinical-stage company focused on the development of therapies for patients with genetic mitochondrial diseases, announced it has raised \$95 million in a Series B financing. The financing was co-led by Novo Ventures and Abingworth, and was supported by existing investors New Enterprise Associates, RiverVest

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Venture Partners, Pappas Capital, and Lundbeckfonden Ventures, as well as new investors Rock Springs Capital, Aisling Capital, Amzak Health, and other investors. Wilson Sonsini represented lead investors Novo Ventures and Abingworth in the transaction. <https://reneopharma.com/reneo-pharmaceuticals-raises-95-million-in-series-b-financing-co-led-by-novo-ventures-and-abingworth/>.

### **Pear Therapeutics Completes \$80 Million Series D Financing**

On December 8, 2020, Pear Therapeutics, a developer of prescription apps to treat addiction and insomnia, announced that it has successfully closed an \$80 million Series D financing led by SoftBank Vision Fund 2 with participation from existing investors, including Temasek, 5AM Ventures, Arboretum Ventures, JAZZ Venture Partners, Novartis, CrimsoNox, and EDBI, and new investors Forth Management, Pilot House, Sarissa Capital, Shanda Group, and QUAD Investment Management. Wilson Sonsini represented Temasek in the transaction. <https://www.businesswire.com/news/home/20201208005352/en/Pear-Therapeutics-Completes-80M-Series-D-Financing-Led-by-SoftBank-Vision-Fund-2>.

### **RayzeBio Announces \$105 Million Series B Financing**

On December 8, 2020, RayzeBio, a biotechnology company developing a broad pipeline of targeted radiopharmaceuticals against validated solid tumor targets, announced a \$105 million Series B financing. The round was led by Venrock Healthcare Capital Partners alongside new investors OrbiMed, Redmile Group, Viking Global Investors, Logos Capital, Cormorant Asset Management, LifeSci Venture Partners, Alexandria Venture Investments, and others. Also participating were existing investors

venBio Partners, Versant Ventures, and Samsara BioCapital. Wilson Sonsini advised RayzeBio on intellectual property matters related to the financing. <https://www.businesswire.com/news/home/20201208005030/en/RayzeBio-Completes-105M-Series-B-Financing-to-Advance-Targeted-Radiopharmaceuticals-for-Cancer>.

### **Kinnate Biopharma Raises \$276 Million in IPO**

On December 7, 2020, Kinnate Biopharma Inc., a biopharmaceutical company focused on the discovery and development of small-molecule kinase inhibitors for difficult-to-treat, genomically defined cancers, announced the close of its initial public offering, raising \$276 million. The shares began trading on the Nasdaq Global Select Market on December 3 under the symbol “KNTE.” Wilson Sonsini represented Kinnate Biopharma in the transaction. <https://investors.kinnate.com/news-releases/news-release-details/kinnate-biopharma-announces-closing-initial-public-offering-and>.

### **Court Dismisses Federal Securities Class Action Against Invuity**

On November 24, 2020, the U.S. District Court for the Northern District of California issued an order dismissing with prejudice a federal securities class action lawsuit filed against Wilson Sonsini clients Invuity Inc., its former CEO, and its CFO. The complaint was filed following Invuity’s announcement of its Q3 2016 earnings, which fell short of guidance issued in Q1 2016. The complaint alleged that Invuity was aware of, but failed to disclose, a negative sales pattern affecting revenue from existing customers. Judge Jeffrey S. White held that the complaint failed to allege any false or misleading statements and failed to allege scienter. <https://www.wsgr.com/images/content/2/9/29225/invuity-order.pdf>.

### **MedAvail Completes Business Combination with MYOS RENS Technology**

On November 18, 2020, MedAvail, Inc., a healthcare technology company that embeds pharmacy services directly into clinics and other points of care, announced the completion of its previously announced business combination with MYOS RENS Technology, Inc., an advanced nutrition company focused on improving muscle health. Under the terms of the merger agreement, a wholly owned subsidiary of MYOS merged with and into MedAvail, with MedAvail becoming the surviving corporation and a wholly owned subsidiary of MYOS. Wilson Sonsini advised MedAvail in the transaction. <https://www.businesswire.com/news/home/20201118005309/en/MedAvail-and-MYOS-RENS-Technology-Announce-Closing-of-Business-Combination>.

### **ORIC Pharmaceuticals Announces Closing of Public Offering**

On November 17, 2020, ORIC Pharmaceuticals, Inc., a clinical-stage oncology company focused on developing treatments that address mechanisms of therapeutic resistance, announced the closing of its previously announced underwritten public offering of 5,796,000 shares of its common stock, at a price to the public of \$23 per share. The gross proceeds to ORIC from the offering were approximately \$133.3 million. Wilson Sonsini represented ORIC in the transaction. <https://investors.oricpharma.com/news-releases/news-release-details/oric-pharmaceuticals-announces-closing-public-offering-and-full>.

### **D3 Bio Launches with \$200 Million Investment**

On November 17, 2020, D3 Bio, Inc., a global biotechnology company focused on developing and commercializing precision medicines to improve or replace existing standard-of-care

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treatments that do not fully meet patient needs, announced that it has entered into definitive agreements with respect to its US\$200 million Series A financing led by Boyu Capital, Matrix Partners China, Sequoia Capital China, the corporate venture fund of WuXi AppTec, and certain other investors. Wilson Sonsini acted as legal counsel to Boyu Capital, Matrix Partners China, Sequoia Capital China, and the corporate venture fund of WuXi AppTec in the transaction. <https://www.businesswire.com/news/home/20201117005519/en/D3-Bio-Launches-with-US200-Million-Investment-to-Develop-Precision-Medicines-Addressing-Unmet-Patient-Needs-in-Oncology-Immunology>.

### **Metagenomi Completes \$65 Million Series A Financing**

On November 12, 2020, Metagenomi, a next-generation gene editing company launched by UC Berkeley scientists in 2018, emerged from stealth mode and successfully completed a \$65 million Series A financing round. The Series A round was led by Leaps by Bayer and Humboldt Fund. Other investors included Sozo Ventures, Agent Capital, InCube Ventures, and HOF Capital. Wilson Sonsini advised Metagenomi on patent matters related to the transaction and launch of the company. <https://metagenomi.co/press/metagenomi-closes-usd-65-million-series-a-financing-led-by-leaps-by-bayer-and-humboldt-fund/>.

### **Inipharm Announces Close of \$35 Million Series A Financing**

On November 11, 2020, Inipharm announced the close of a \$35 million Series A financing round. Founded in 2018, the company is focused on discovering and developing therapies for liver and related diseases, with its initial program focused on those associated with the genetically defined target HSD17B13. The Series A funding will support the advancement of Inipharm's

lead program through IND filing and into clinical trials. 5AM Ventures and Wu Capital joined existing investors Frazier Healthcare Partners and Jubilant Biosys Limited in the round. Wilson Sonsini advised Inipharm on IP matters related to the transaction. <https://www.businesswire.com/news/home/20201111005234/en/>.

### **Carbon Health Secures \$100 Million in Series C Funding**

On November 10, 2020, Carbon Health Technologies, a technology-enabled healthcare provider, announced that it has secured \$100 million in Series C funding led by Dragoner Investment Group, with participation from existing investors Brookfield Technology Partners (BTP), DCVC, and Builders VC. This investment will allow Carbon Health to further advance its omnichannel care strategy and scale nationally as a primary care provider in a continued mission to bring world-class healthcare to everyone. Wilson Sonsini represented Carbon Health in the transaction. <https://www.businesswire.com/news/home/20201110005767/en/Carbon-Health-Secures-100M-in-Series-C-Funding-to-Become-Leading-National-Healthcare-Provider>.

### **Stargazer Pharmaceuticals Announces \$57 Million Series A Financing**

On November 9, 2020, Stargazer Pharmaceuticals, Inc., a biopharmaceutical company focused on the development of novel treatment options for rare eye diseases, announced it has completed a Series A financing totaling \$57 million from leading investors Novo Holdings, venBio Partners, Canaan Partners, and Pontifax to develop its proprietary compound STG-001 for treating Stargardt Disease. Stargazer also announced the initiation of a Phase 2a study of STG-001 in Stargardt Disease patients. Wilson Sonsini has advised Stargazer since its formation and represented the company

in the financing. [https://www.prweb.com/releases/stargazer\\_pharmaceuticals\\_inc\\_announces\\_57\\_million\\_series\\_a\\_financing\\_and\\_initiation\\_of\\_a\\_phase\\_2a\\_clinical\\_study\\_of\\_stg\\_001\\_in\\_stargardt\\_disease\\_patients/prweb17524315.htm](https://www.prweb.com/releases/stargazer_pharmaceuticals_inc_announces_57_million_series_a_financing_and_initiation_of_a_phase_2a_clinical_study_of_stg_001_in_stargardt_disease_patients/prweb17524315.htm).

### **Zimmer Biomet Acquires Relign Corp.**

On November 6, 2020, Zimmer Biomet, a leading medical device manufacturer, announced in its earnings report that it has acquired Relign Corp., a privately held start-up in the growing \$1.6 billion arthroscopy market and overall \$5 billion sports medicine market. Relign's offerings include the consolidation of three differentiated arthroscopy tower components into a single system, a first in the industry, and address a key portfolio gap for Zimmer Biomet in the sports medicine and broader ambulatory surgery center markets. Wilson Sonsini represented Relign in the transaction. <https://investor.zimmerbiomet.com/-/media/Files/Z/ZimmerBiomet-IR/press-release/q3-2020-earnings-release.pdf>.

### **Forte Biosciences Announces Pricing of \$40 Million Public Offering**

On October 29, 2020, Forte Biosciences, a clinical-stage biopharmaceutical company, announced the pricing of an underwritten public offering of 1,403,509 shares of its common stock at a price to the public of \$28.50 per share. In addition, Forte has granted the underwriters a 30-day option to purchase up to an additional 210,256 shares of common stock at the public offering price, less underwriting discounts and commissions. Wilson Sonsini provided corporate and intellectual property counsel to Forte Biosciences in the transaction. <https://www.fortebiorx.com/investor-relations/news/news-details/2020/Forte-Biosciences-Announces-Pricing-of-40.0-Million-Public-Offering-of-Common-Stock/default.aspx>.

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### **Azura Ophthalmics Announces \$20 Million Financing**

On October 22, 2020, Azura Ophthalmics Ltd., a clinical-stage company developing innovative therapies for Meibomian gland dysfunction (MGD) and related eye diseases, announced a \$20 million financing. The round was led by a syndicate of existing investors, including OrbiMed, TPG Biotech, Brandon Capital's Medical Research Commercialization Fund, and Ganot Capital. On the back of encouraging Phase 2 data to date, proceeds from the funding round will be used to advance Azura's lead product candidate, AZR-MD-001, through a registration study for the treatment of MGD. Wilson Sonsini advised Azura on intellectual property matters, including patents, related to the transaction. <https://www.businesswire.com/news/home/20201022005332/en/Azura-Ophthalmics-Raises-US20-Million-Registration-Studies>.

### **SparingVision Announces €44.5 Million Fundraise**

On October 21, 2020, SparingVision, a genomic medicine company focused on ocular diseases, announced a €44.5 million financing round. The round was led by 4BIO Capital and UPMC Enterprises, and included Jeito Capital and Ysios Capital. In addition, current investors Bpifrance and Foundation Fighting Blindness participated in the round. Proceeds will be primarily used to advance the development of SparingVision's breakthrough treatment SPVN06 for the mutation-agnostic treatment of retinitis pigmentosa. Wilson Sonsini advised SparingVision on the transaction. [https://sparingvision.com/images/PDF/press\\_releases/2020/201021\\_SparingVision\\_financing.pdf](https://sparingvision.com/images/PDF/press_releases/2020/201021_SparingVision_financing.pdf).

### **InCarda Therapeutics Raises \$30 Million in Series C**

On October 21, 2020, InCarda Therapeutics, Inc., a privately held biopharmaceutical company developing

first-of-their-kind inhaled therapies for cardiovascular diseases, announced that it has raised \$30 million through the first close of a Series C equity financing. The financing was led by an affiliate of Innoviva and also included existing investors Deerfield Management, HealthCap, and Morningside Venture. The proceeds will be used primarily to fund the ongoing clinical development of InRhythm, the company's lead program, for the treatment of a recent-onset episode of paroxysmal atrial fibrillation (PAF). Wilson Sonsini advised InCarda on IP matters related to the financing. <https://incardatherapeutics.com/2020/10/21/incarda-therapeutics-raises-30-million-through-first-close-of-series-c-equity-financing/>.

### **Spruce Biosciences Announces Closing of Initial Public Offering**

On October 14, 2020, Spruce Biosciences Inc., a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet need, announced the closing of its initial public offering of 6,900,000 shares of its common stock at a public offering price of \$15.00 per share. The gross proceeds to Spruce from the offering were \$103.5 million. Spruce's common stock began trading on the Nasdaq Global Select Market on October 9 under the ticker symbol "SPRB." Wilson Sonsini advised Spruce Biosciences on patents and patent strategy related to the IPO. <https://investors.sprucebiosciences.com/news-releases/news-release-details/spruce-biosciences-announces-closing-upsized-initial-public>.

### **Curon Biopharmaceutical and Rhizen Pharmaceuticals Announce Licensing Agreement**

On October 12, 2020, Curon Biopharma, a Shanghai-based clinical-stage biopharmaceutical company, acquired exclusive rights to Tenisib from Rhizen

Pharma of Switzerland for exploitation in greater China. Tenisib is a next-generation dual PI3K  $\delta/\gamma$  inhibitor, which is in Phase 2 clinical development for hematological malignancies. Rhizen Pharma will be eligible to receive upfront and milestone payments worth up to \$149.5 million, as well as tiered royalties on annual net sales of Tenisib. Wilson Sonsini advised Curon Biopharma on licensing matters related to the transaction. <https://www.globenewswire.com/news-release/2020/10/12/2106806/0/en/Rhizen-Pharmaceuticals-S-A-and-Curon-Biopharmaceutical-Limited-Announce-an-Exclusive-Licensing-Agreement-to-Develop-and-Commercialize-Tenisib-a-Dual-PI3K-Delta-and-Gamma-Inhibitor.html>.

### **Avail Medsystems Raises \$100 Million in Series B Funding**

On October 7, 2020, Avail Medsystems, the medical technology company pioneering telemedicine for the procedure room, announced that it has raised \$100 million in Series B funding led by D1 Capital Partners, with participation from 8VC and existing investors. Avail has developed Procedural Telemedicine™ technology that digitizes physical presence and enables HIPAA-compliant collaboration among a network of healthcare professionals and industry experts. Wilson Sonsini represented Avail Medsystems in the transaction. <https://www.businesswire.com/news/home/20201007005707/en/Avail-Medsystems-Raises-100-Million-in-Series-B-Funding-Led-by-D1-Capital-to-Meet-Demand-for-Procedural-Telemedicine%E2%84%A2-Technology-for-the-Operating-Room>.

### **Ligand Completes Acquisition of Pfenex**

On October 1, 2020, Ligand Pharmaceuticals announced that it has completed its tender offer for all outstanding shares of Pfenex Inc. for \$437.5 million in cash, plus one

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non-transferable contingent value right (CVR) per share representing the right to receive a contingent payment of \$78 million in cash if a certain specified milestone is achieved. Pfenex is a development and licensing biotechnology company with commercial products focused on leveraging its proprietary protein production platform, Pfenex Expression Technology®, to develop next-generation and novel protein therapeutics. Wilson Sonsini represented Pfenex in the transaction. <https://investor.ligand.com/press-releases/detail/428/ligand-completes-acquisition-of-pfenex-inc>.

### **Flame Biosciences Completes \$100 Million Common Stock Financing**

On September 30, 2020, Flame Biosciences, a clinical-stage biopharmaceutical company developing antibodies to treat cancer and inflammatory diseases, announced the completion of a \$100 million common stock financing. The financing was led by Rock Springs Capital, with participation from funds and accounts advised by T. Rowe Price Associates, Inc., Cormorant Asset Management LP, Janus Henderson Investors, Surveyor Capital, Samsara BioCapital, Adage Capital Management LP, Terra Magnum Capital Partners, Logos Capital, and Acuta Capital Partners. Wilson Sonsini advised Terra Magnum Capital Partners in the financing. [https://flame.bio/news/flame-biosciences-announces-\\$100million-common-stock-financing-to-further-advance-drugs-targeting-inflammasome.php](https://flame.bio/news/flame-biosciences-announces-$100million-common-stock-financing-to-further-advance-drugs-targeting-inflammasome.php).

### **Monte Rosa Therapeutics Raises \$96 Million in Series B Financing**

On September 24, 2020, Monte Rosa Therapeutics, a biotechnology company developing precision medicines to degrade disease-causing proteins, announced the closing of a \$96 million Series B financing. The financing

was led by Aisling Capital with participation from founding investor Versant Ventures and existing investor New Enterprise Associates (NEA). Additional new investors included HBM Healthcare Investments, Cormorant Asset Management, GV, Amzak Health, Casdin Capital, Sixty Degree Capital, and Cambridge Asset Management. Wilson Sonsini advised NEA in the transaction. <https://www.businesswire.com/news/home/20200924005403/en/Monte-Rosa-Therapeutics-Announces-96-Million-Series-B-Financing-to-Advance-Small-Molecule-based-Protein-Degradation-Platform>.

### **Libra Therapeutics Launches with \$29 Million Series A Financing**

On September 23, 2020, Libra Therapeutics launched to develop novel drug candidates focused on restoring the cellular balance lost in neurodegenerative diseases. In conjunction with its launch, Libra Therapeutics has secured \$29 million in Series A financing, co-led by Boehringer Ingelheim Venture Fund (BIVF), Epidarex Capital, and Santé. The round was joined by Yonjin Venture, Dolby Family Ventures, and Sixty Degree Capital. Wilson Sonsini has advised Libra Therapeutics since its formation and represented the company in the Series A transaction. <https://www.libratherapeutics.com/post/libra-launches-with-29m-series-a-to-develop-novel-therapeutics-for-neurodegenerative-diseas>.

### **Athira Pharma Prices Initial Public Offering**

On September 17, 2020, Athira Pharma, Inc., a clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegeneration, priced its initial public offering of 12 million shares of its common stock at \$17.00 per share. The gross proceeds are expected to be \$204

million, before deducting underwriting discounts and commissions and estimated offering expenses. The shares began trading on September 18 on the Nasdaq Global Select Market under the ticker symbol “ATHA.” Wilson Sonsini represented Athira in the offering. <https://www.athira.com/athira-pharma-announces-pricing-of-initial-public-offering/>.

### **Metacrine Announces Pricing of Initial Public Offering**

On September 15, 2020, Metacrine, Inc., a clinical-stage biopharmaceutical company focused on discovering and developing differentiated therapies for patients with liver and gastrointestinal diseases, announced the pricing of its initial public offering of 6,540,000 shares of its common stock at a public offering price of \$13 per share. The shares began trading on the Nasdaq Global Market on September 16 under the ticker symbol “MTCR.” Wilson Sonsini advised Metacrine in patent matters related to the IPO. <https://investors.metacrine.com/news-releases/news-release-details/metacrine-announces-pricing-initial-public-offering>.

### **NiKang Therapeutics Completes \$50 Million Series B Financing**

On September 14, 2020, NiKang Therapeutics, a biotech company focused on developing novel small-molecule oncology drug discovery, announced the completion of a \$50 million Series B financing. The financing was led by RTW Investments, with additional support from existing investor CBC Group and new investors Lilly Asia Ventures, Casdin Capital, HBM Healthcare Investments, Matrix Partners China, and Octagon Capital. NiKang will use the proceeds to support the preclinical and clinical development of several promising oncology programs and further enhance the company’s drug discovery pipeline. Wilson Sonsini

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advised NiKang Therapeutics in the transaction. [https://www.einnews.com/pr\\_news/526165507/nikang-therapeutics-completes-50-million-series-b-financing](https://www.einnews.com/pr_news/526165507/nikang-therapeutics-completes-50-million-series-b-financing).

### **Korro Bio Announces \$91.5 Million Series A Financing**

On September 10, 2020, Korro Bio, Inc., a biotech start-up founded in 2018, announced a \$91.5 million Series A financing to advance its novel platform for precise, single-base, RNA editing to modulate protein function for therapeutic applications. The financing was led by Wu Capital with participation from current investors Atlas Venture and New Enterprise Associates. Wilson Sonsini advised Wu Capital in the financing. <https://www.korrobio.com/press-releases/korro-bio-closes-91-5-million-series-a-financing-to-advance-the-next-frontier-in-rna-therapeutics>.

### **Recursion Announces \$239 Million Series D Financing and Collaboration with Bayer**

On September 9, 2020, Bayer, a global life sciences, healthcare, and nutrition company, and Recursion Pharmaceuticals, Inc., a digital biology company industrializing drug discovery, entered into a strategic collaboration. Under the collaboration, Recursion's purpose-built, AI-guided drug discovery platform and Bayer's small-molecule compound library and deep scientific expertise will be leveraged to discover and develop new treatments for fibrotic diseases. In addition, Leaps by Bayer, the impact investment arm of Bayer AG, is leading Recursion's \$239 million Series D financing with an investment of \$50 million. Wilson Sonsini represented Recursion in both transactions. <https://www.recursion.com/news-and-views>.

### **GI Windows Medical Corp. Announces Series A-1 Financing**

On August 19, 2020, GI Windows Medical Corp, a clinical-stage medical device company, announced a \$16.4 million Series A-1 financing. The financing attracted Johnson & Johnson Innovation – JJDC, Inc., along with Sonder Capital, GT Healthcare, JC Investco, and another strategic investor. In addition to the institutional financing, GI Windows received investments from existing shareholders as well as new investors the Kennedy Trust and Coleman Trust. Wilson Sonsini represented GI Windows in the financing. [https://257e80b3-17d1-4e77-b00b-5db7f134ecb0.filesusr.com/gd/3c37ac\\_620d570415e-14391b5ac536ff9027bof.pdf](https://257e80b3-17d1-4e77-b00b-5db7f134ecb0.filesusr.com/gd/3c37ac_620d570415e-14391b5ac536ff9027bof.pdf).

### **iRhythm Technologies Announces Pricing of Upsized Public Offering of Common Stock**

On August 18, 2020, iRhythm Technologies, Inc., a leading digital health care solutions company focused on the advancement of cardiac care, announced the pricing of its underwritten public offering of 1,093,167 shares of its common stock at a public offering price of \$175 per share before deducting underwriting discounts and commissions. All of the shares are being offered for sale by iRhythm Technologies. The gross proceeds from the offering were expected to be \$191.3 million. Wilson Sonsini represented iRhythm Technologies in the transaction. <https://www.globenewswire.com/news-release/2020/08/19/2080396/0/en/iRhythm-Technologies-Announces-Pricing-of-Upsized-Public-Offering-of-Common-Stock.html>.

### **Tango Therapeutics and Gilead Announce Expanded Strategic Oncology Collaboration**

On August 17, 2020, Gilead Sciences and Tango Therapeutics announced an expanded strategic collaboration focused on the discovery, development, and commercialization of innovative targeted immune evasion therapies for patients with cancer. Gilead will make a \$125 million upfront payment to Tango and a \$20 million equity investment in the company. In addition, Gilead will have the right to option up to 15 programs over the seven-year collaboration for up to \$410 million per program in opt-in, extension, and milestone payments. Wilson Sonsini represented Tango Therapeutics in the agreement. <https://www.tangotx.com/press-releases/gilead-sciences-and-tango-therapeutics-to-expand-strategic-oncology-collaboration/>.

### **Mission Bio Raises \$70 Million in Series C Financing**

On August 13, 2020, Mission Bio, Inc., a pioneer in high-throughput single-cell DNA and multi-omics analysis, announced a \$70 million Series C financing led by Novo Growth, the growth equity arm of Novo Holdings. Soleus Capital also joined the round, along with earlier investors Mayfield, Cota, and Agilent, bringing the company's total funding to more than \$120 million. Wilson Sonsini advised Mission Bio in the transaction. <https://missionbio.com/press/series-c-novo-backed/>.

Casey McGlynn, a leader of the firm's life sciences practice, has editorial oversight of *The Life Sciences Report* and was assisted by Philip Oettinger, Elton Satusky, Scott Murano, and James Huie. 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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