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WILSON SONSINI

THE LIFE SCIENCES REPORT

USJMF and Wilson Sonsini Host Successful Japan Trade Mission and Roadshow for U.S. Medtech Companies

On November 5-11, 2019, U.S.-Japan Medtech Frontiers (USJMF) and Wilson Sonsini led a group of representatives from 22 U.S. start-up and growth-stage medical device companies to Japan for the Sixth Annual Japan Medical Device Innovation Week, also known as MedTech Week Japan. The week's activities—which took place primarily in Tokyo and Kobe and drew more than 1,000 attendees overall—included various conferences, symposiums, site visits, and social events designed to facilitate access to potential Japanese partners, investors, distributors, customers, and others; help the companies gain visibility; and provide a hands-on introduction to the Japanese medical device ecosystem.

The week's marquee event was USJMF's sixth annual symposium, which was titled "Innovation and Corporate Strategy for Medtech Companies" and took place on November 6 in conjunction with the U.S. Embassy in Tokyo. At the exclusive, invite-only event, the 22 U.S. delegate companies had the opportunity to pitch themselves to the 150 senior executives of large Japanese medtech companies in attendance. The symposium also featured speeches by USJMF Chairman Jack Moorman; Keith Kirkham, Minister Counselor for Commercial Affairs from the U.S. Embassy Tokyo; Elton Satusky, a partner at Wilson Sonsini; and Akihiko Soyama, president and CEO of the Life Science Innovation Network Japan, a co-organizer of the symposium, as well as a keynote address from renowned Johns Hopkins Professor Russell H. Taylor, who provided a 30-year perspective on medical robotics.

"Participating in the U.S.-Japan Medtech Frontiers Symposium was a unique and rewarding opportunity that has resulted in fruitful discussions with several Japanese strategics," said Brett Follmer, CTO and co-founder of Progressive Neuro, one of the U.S. delegate companies.

On November 8, the U.S. delegates attended the Sixth Annual Medtech & Healthtech Innovation Forum, held in Kobe in conjunction with the Kobe Foundation for Biomedical Research and Innovation (FBRI), which drew more than 500 attendees from Japanese medical device companies, academic

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In addition, the trip included a site visit to Vorpal Technologies, a Tokyo-based Japanese market access advisory firm, where the group took part in a well-received educational program on Japanese regulatory approval pathways and national health insurance reimbursement requirements in Japan. The delegates

translational medicine, parties interested in biodesign, and others in the medtech ecosystem. Representatives from a majority of the 22 U.S. companies also participated on panels at the event, which addressed topics such as robotics in healthcare, the development of innovative medical devices to address unmet needs, medtech and healthtech for aging populations, collaboration between the U.S. and Japan, and evaluation criteria for investments by venture investors.

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>
> ***– Elton Satusky***

also participated in a student seminar with University of Kobe students, engaging in a spirited discussion and exchange of ideas regarding the future of medical device development in Japan. Further, participants visited JOHNAN Corporation, a Japanese medical device

factory in Kyoto, where president and CEO Mitsuyo Yamamoto led a private tour.

"For me, the highlight of the trip was making new friends and deepening relationships with old friends," noted Elton Satusky. "Just being there, you make so many connections, as there are only a couple degrees of separation in medtech—and it's amazing how many mutual connections you already have."

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> ***– Kirk Zeller***

"I was absolutely delighted to observe so many Japanese and U.S. companies networking and to hear about the productive discussions that resulted from those new relationships," added USJMF board member Kirk Zeller.

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

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

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

All early and growth-stage medical device, diagnostic, and digital health companies were encouraged to apply to the 2019 USJMF/Wilson Sonsini trade mission and roadshow. USJMF and Wilson Sonsini did not charge or take equity for participation, and there was no application fee involved.

The U.S. delegate companies for the 2019 USJMF/Wilson Sonsini trade mission and roadshow included the following:

- Atonarp
- Avails Medical
- CarePredict, Inc.
- CellMax Life
- Drawbridge Health
- Galen Robotics
- Gravitas Medical
- HT BioImaging
- Kali Care
- Mitre Medical
- Modulim
- Noctrix Health
- Peach IntelliHealth
- Progressive Neuro
- QT Medical, Inc.
- Shifamed
- Silk Road Medical
- Sisu Global Health
- Spirosure
- Subtle Medical
- Theranova
- Zidan Medical

For those of you planning ahead, the Seventh Annual Japan Medical Device Innovation Week will take place November 7-13, 2020, in Tokyo and Kyoto. Applications to participate in the 2020 USJMF/Wilson Sonsini trade mission and roadshow will open soon, with decisions made later in 2020. As in previous years, selection will be based largely on interest and existing synergies with Japan—for instance, offering a product particularly well suited to the Japanese market, already having a Japanese investor or commercial partner, or looking to Japan as the next logical market to penetrate.

Life Sciences Venture Financings for WSGR Clients

By Scott Murano

The table below includes data from life sciences transactions in which Wilson Sonsini Goodrich & Rosati clients participated during the second half of 2018 and the first half of 2019. Specifically, the table compares—by industry segment—the number of closings, the total amount raised, and the average amount raised per closing across the two six-month periods.

	2H 2018	2H 2018	2H 2018	1H 2019	1H 2019	1H 2019
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	44	$741.77	$16.86	44	$1,203.07	$27.34
Genomics	4	$27.23	$6.81	7	$59.88	$8.55
Diagnostics	7	$33.62	$4.80	10	$140.53	$14.05
Medical Devices & Equipment	25	$369.60	$14.78	50	$591.04	$11.82
Health IT	17	$285.40	$16.79	14	$160.59	$11.47
Healthcare Services	12	$481.89	$40.16	19	$197.92	$10.42
Total	**109**	**$1,939.51**		**144**	**$2,353.03**	

The data demonstrates that venture financing activity increased from the second half of 2018 to the first half of 2019 with respect to the total number of closings and the total amount raised. Specifically, the total number of closings across all industry segments increased 32.1 percent, from 109 to 144, and the total amount raised across all industry segments increased 21.3 percent, from $1,939.51 million to $2,353.03 million.

Notably, the industry segment with the largest number of closings during the first half of 2019—medical devices and equipment—experienced both a significant increase in number of closings and in total amount raised from the second half of 2018 to the first half of 2019. Specifically, the number of closings in the medical devices and equipment segment increased 100 percent, from 25 to 50, while the total amount raised increased 59.9 percent, from $369.60 million to $591.04 million. In contrast, the industry segment with the second-largest number of closings—biopharmaceuticals—experienced no change in number of closings but saw a 62.2 percent increase in total amount raised from the second half of 2018 to the first half of 2019, from $741.77 million to $1,203.07 million.

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Meanwhile, the industry segment with the third-largest number of closings during the first half of 2019— healthcare services—experienced an increase in number of closings but a decrease in total amount raised: the number of closings increased 58.3 percent, from 12 to 19, while the total amount raised decreased 58.9 percent, from $481.89 million to $197.92 million. The industry segment with the fourth-largest number of closings during the first half of 2019—health IT—was unique among others in that it experienced decreases in both number of closings and total amount raised. Specifically, the number of closings in the health IT segment decreased 17.6 percent, from 17 to 14, while the total amount raised decreased 43.7 percent, from $285.4 million to $160.59 million. The two remaining industry segments—genomics and diagnostics—both experienced increases in number of closings and total amounts raised from the second half of 2018 to the first half of 2019. The number of closings in genomics increased 75 percent, from four closings to seven closings, while the total amount raised in genomics increased 119.9 percent, from $27.23 million to $59.88 million. The number of closings in diagnostics increased 42.9 percent, from 7 closings to 10 closings, while the total amount raised in diagnostics increased 318 percent, from $33.62 million to $140.53 million.

In addition, our data suggests that Series A (including Series Seed) financing activity and Series B financing activity, in each case as a percentage of all other financing activity, decreased from the second half of 2018 to the first half of 2019, while Series C and later-stage financing activity and bridge financing activity as a percentage of all other financing activity increased across the same periods. Specifically, the number of Series A (including Series Seed) closings decreased from 37.6 percent to 33.8 percent, the number of Series B closings decreased from 15.6 percent to 12.8 percent, and the number of Series C and later-stage closings increased from 11.9 percent to 16.2 percent. Bridge financing activity increased from 20.2 percent to 24.3 percent over the same period.

> Average pre-money valuations for life sciences companies decreased across the board for Series A (including Series Seed), Series B, and Series C and later-stage financings from the second half of 2018 to the first half of 2019

It was also interesting to note that average pre-money valuations for life sciences companies decreased across the board for Series A (including Series Seed), Series B, and Series C and later-stage financings from the second half of 2018 to the first half of 2019. The average pre-money valuation for Series A (including Series Seed) financings decreased 51 percent, from $24.7 million to $12.11 million; the average pre-money valuation for Series B financings decreased 33.4 percent, from $118.2 million to $78.74 million; and the average pre-money valuation for Series C and later-stage financings decreased 3.3 percent, from $290.96 million to $281.5 million.

Other data taken from transactions in which all firm clients participated in the first half of 2019 suggests that life sciences is the second-most active industry for investment among our clients. For the first six months of 2019, life sciences represented 24 percent of total funds raised by our clients, while the software industry—historically the most popular industry for investment—represented 50 percent of total funds raised.

Overall, the data indicates that access to venture capital for the life sciences industry improved dramatically in the first half of 2019 compared to the second half of 2018. It is worth noting that this is a continuing trend, with the second half of 2018 showing improved access to capital over the first half of 2018. While Series A (including Series Seed) and Series B financing activity was slightly down as a percentage of total financing activity, Series C and later-stage financing and bridge financing activity was up. This may also help to explain the increase in total dollars raised, as later-stage rounds can require more capital, as well as the slightly depressed Series A (including Series Seed) and Series B pre-money valuations, there being less demand and capital available for those deals during the first half of 2019. With exit activity remaining robust across all sectors at the time of this article, we would expect returns on those later-stage investments to get re-circulated into the investment ecosystem. As such, we expect investment activity to remain strong through the end of 2019 and into the new year.

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FDA Finalizes Guidance on Special 510(k) Pathway

By David Hoffmeister, Georgia Ravitz, James Ravitz, and Paul Gadiock

The Food and Drug Administration (FDA) recently finalized its guidance on the Special 510(k) Program—an optional pathway to commercial medical devices that have been modified since their previous 510(k) clearance. The Special 510(k) pathway is available for certain well-defined device modifications where a manufacturer modifies its own legally marketed device, and its design control procedures produce reliable results that can form, in addition to other 510(k) content requirements, the basis for a substantial equivalence determination. Specifically, eligible device changes include certain design and labeling modifications whereby performance data are unnecessary; or, if performance data are necessary, well-established methods are available to evaluate the change, and the results can be sufficiently reviewed in a summary or risk analysis format. Notably, this type of modification can even be a change to the device's indications for use, a type of change previously prohibited for this pathway. Under the new policy, instead of necessarily being converted to a Traditional 510(k) with a 90-day review clock, changes to a device's indications for use may qualify for the quicker Special 510(k) pathway's 30-day review. As described by the FDA, "a Special 510(k) provides an efficient pathway for manufacturers to provide the minimum required information necessary to establish substantial equivalence for a modified device."

To be within the scope of the Special 510(k) Program, the change must be made to the submitter's own legally marketed predicate device for two primary reasons. First, the Special 510(k) Program relies on the FDA's previous review of detailed information in the submitter's prior 510(k). Second, the Special 510(k) Program also leverages design control procedures that must be followed by medical device manufacturers as part of the overall Quality System prescribed under 21 C.F.R. Part 820. Design controls require that manufacturers conduct verification and validation to ensure that design outputs meet design inputs, and that devices conform to defined user needs and intended uses (21 C.F.R. 820.30(f) and (g)). A manufacturer that modifies its own legally marketed device is therefore able to conduct the risk analysis and necessary verification and validation activities to demonstrate to the FDA in a Special 510(k) submission that the design outputs of the modified device meet the design input requirements.

As described by the FDA, "a Special 510(k) provides an efficient pathway for manufacturers to provide the minimum required information necessary to establish substantial equivalence for a modified device"

In cases where a manufacturer determines under its design control procedures that no additional verification or validation testing is necessary to evaluate a change that otherwise requires submission and clearance of a 510(k), the manufacturer may submit the change as a Special 510(k) with a clear rationale supporting its conclusion that no performance data are necessary. If, however, performance data are required, the change can still qualify for the Special 510(k) Pathway if well-established methods are available to evaluate the change and the results can be sufficiently reviewed in a summary or risk analysis format. Well-established methods are those that have been established for evaluation of the device, device type, or scientific topic area, and are validated according to scientific principles. These may include the submitter's methods, protocols, and acceptance criteria used to support the previously cleared 510(k) that can be applied to the subject 510(k); methods found in an FDA-recognized voluntary consensus standard or FDA guidance document; qualified medical device development tools (MDDTs); or widely available and accepted methods published in the public domain, scientific literature, or found acceptable by the FDA through the submitter's own 510(k)-clearance, a granted De Novo classification request, or premarket application (PMA) approval. Manufacturers should be aware that minor deviations to a well-established method may be acceptable within the context of a Special 510(k),

Manufacturers should be aware that minor deviations to a well-established method may be acceptable within the context of a Special 510(k), but significant deviations to the protocol or acceptance criteria of a well-established method can render the device change ineligible for review as a Special 510(k)

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the device change ineligible for review as a Special 510(k). Additionally, submissions that use methods that rely on clinical studies or animal data to support substantial equivalence are not considered appropriate for the Special 510(k) Program.

The final Special 510(k) criterion requires that the verification and validation results can be sufficiently reviewed by the FDA in a summary or risk analysis format. Put another way, when complete test reports or underlying data such as images, raw graphs, or line item data are necessary to support substantial equivalence, the device modification should not be submitted as a Special 510(k).

In the Special 510(k) guidance, the FDA also provides circumstances under which the agency believes a change would be categorically ineligible for the Special 510(k) Program. Among others, these circumstances include:

- When evaluation of the change(s) to the device generally involve more than three scientific disciplines (e.g., biocompatibility, sterility, electromagnetic compatibility);
- When a recent inspection has resulted in the issuance of a 483 Notice of Observation related to design controls that are relevant to the design changes under review in the 510(k); and
- When Special 510(k)s are submitted for common scenarios that the FDA anticipates a review of complete test reports will be necessary to establish substantial equivalence, such as:

The Special 510(k) Program remains one of the quickest premarket review pathways for medical devices that have been modified and has become even more appealing now that it can apply to changes in indications for use

  - Changes to the indications for use that are supported by clinical, animal, or cadaver data;
  - Use of novel sterilization methods as described in the FDA guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile";
  - Change from single-use to reusable when reprocessing validation or human factors data should be provided; and
  - Use of analytical chemistry testing using ISO 10993-1820 and/or toxicological risk assessment using ISO 10993-17 21 to address biocompatibility.

In addition to providing examples of device changes that would qualify under each of the criteria described above, the Special 510(k) guidance also includes device changes that would fail under each criterion to help illustrate precisely where the FDA considers the threshold for Special 510(k) eligibility to be.

The Special 510(k) Program remains one of the quickest premarket review pathways for medical devices that have been modified and has become even more appealing now that it can apply to changes in indications for use. Manufacturers considering modifications to their devices are urged to evaluate whether this expeditious route to market is available for their device change, while taking into account applicable device-specific guidance, consensus standards, and other regulatory levers.

The FDA hosted a webinar on October 31, 2019, to discuss this latest improvement to the 510(k) Program. For more information on this program, including the Special 510(k) Pathway, please contact one of the authors of this article or any member of the firm's FDA Regulatory, Healthcare, and Consumer Products Compliance practice groups.

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2019 Phoenix Conference Convenes Medical Device CEOs, Senior Executives

On October 16-18, 2019, the 26th Annual Phoenix Conference was held at The Ritz-Carlton in Half Moon Bay, California. Co-organized by Wilson Sonsini Goodrich & Rosati, the exclusive event brought together 180 senior executives from large healthcare companies and CEOs of small, venture-backed firms for an opportunity to discuss critical issues of interest to the medical device sector today, as well as to network and gain valuable insights from both industry leaders and peers.

The two-day conference featured presentations on a broad range of topics, including the impact of artificial intelligence on the future of medical devices, the ability of large medtech companies to reinvent their businesses to accelerate growth and sustain leadership roles, the current state of medtech investment, and innovation in medical device reimbursement. The event also featured a lively discussion with Silk Road Medical CEO Erica Rogers in which she provided a candid perspective on her career path and the road to the company's IPO, which raised over $100 million. In addition, as part of the conference's Corporate Spotlight series, Ashley McAvoy, EVP and worldwide chairman of Johnson & Johnson's medical device business, offered insight into the medical device industry generally and J&J's businesses in particular.

In connection with the event, the Phoenix Hall of Fame for Medical Device & Diagnostic Leadership celebrated the accomplishments of companies and individuals at a reception, dinner, and awards ceremony on the evening of October 17. Inari Medical's FlowTriever, the first mechanical thrombectomy device indicated for pulmonary embolism, was honored with the "Most Promising New Product" award, and Silk Road Medical, a medical device company focused on reducing the risk of stroke and its devastating impact, was presented with the "Emerging Growth Company" award. Prominent inventor and medical device industry veteran Csaba Truckai received the Phoenix Innovator Award, while Tom Prescott, the former president and CEO of both Align Technology and Cardiac Pathways, was named the Lifetime Achievement Award recipient.

Select Life Sciences Client Highlights

Rheos Medicines Enters Collaboration with Roche to Discover and Develop Novel Immunometabolism Medicines
On December 19, Rheos Medicines, a biopharmaceutical company harnessing insights in immunometabolism to create a new class of therapeutics for patients with severe autoimmune disorders, inflammatory diseases, and cancer, announced that it has entered into a worldwide exclusive collaboration, option, and license agreement with Roche to discover, develop, and commercialize novel therapeutics in the field of immunometabolism. Wilson Sonsini is representing Rheos Medicines in the agreement. More information is available at https://rheosrx.com/news/press-releases/rheos-medicines-announces-worldwide-collaboration-with-roche-to-discover-and-develop-novel-medicines-in-the-field-of-immunometabolism/.

Alphamab Oncology Lists on HKSE
On December 12, Alphamab Oncology listed on the Main Board of the Stock Exchange of Hong Kong, raising HK$1.8 billion ($230 million). Alphamab Oncology is a leading clinical-stage biopharmaceutical company in China with a fully integrated proprietary biologics platform in biospecifics and protein engineering. Four drug candidates in the company's pipeline have advanced to clinical development phase, including a PD-L1 antibody and two bispecific antibodies, PD-L1/CTLA4 and HER2. Wilson Sonsini represented Alphamab Oncology in related intellectual property matters.

Sanofi to Acquire Synthorx for $2.5 Billion
On December 9, global biopharmaceutical company Sanofi and Synthorx, a clinical-stage biotechnology company focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders, entered into a definitive agreement under which Sanofi will acquire all of the outstanding shares of Synthorx for $68 per share in cash, which represents an aggregate equity value of approximately $2.5 billion. The transaction was unanimously approved by both the Sanofi and Synthorx boards of directors. Wilson Sonsini has served as patent counsel to Synthorx since the company's inception and was responsible for its patent diligence in this transaction. For further details, see https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/media-room/press-releases/2019/2019-12-09-07-00-00-1957603-en.pdf.

NanoString Announces Exclusive License of nCounter Diagnostic Assets and Rights to Veracyte
On December 3, NanoString Technologies, a leading provider of life science tools for translational research, announced a strategic transaction to exclusively license select nCounter-based diagnostic assets and rights to Veracyte for $50 million in cash and Veracyte stock, plus up to $10 million in cash upon satisfaction of future potential milestones. Wilson Sonsini acted as legal counsel to NanoString in the transaction. For more information, see http://investors.nanostring.com/news-releases/news-release-details/nanostring-announces-exclusive-license-ncounter-diagnostic.

Elevar Therapeutics Completes Merger Transaction with South Korean Company HLB
On November 27, Elevar Therapeutics completed its merger transaction with HLB, a South Korean company whose shares are publicly traded on the Korean stock exchange, pursuant to which Elevar became a wholly owned subsidiary of HLB. Elevar is a pharmaceutical company based primarily in Utah specializing in clinical development of promising therapies for unmet medical needs in cancer. Wilson Sonsini acts as patent, corporate, and technology transactions counsel for Elevar, including in connection with this merger transaction. To learn more about Elevar Therapeutics, visit https://elevartherapeutics.com/.

Federal Circuit Upholds Mylan PTAB Ruling
On November 19, Wilson Sonsini secured a win for Mylan as the U.S. Court of Appeals for the Federal Circuit invalidated two Sanofi patents relating to Sanofi's Lantus vial product, upholding December 2018 decisions from the Patent Trial and Appeal Board (PTAB). In a 2-1 opinion, the majority determined that the PTAB's findings were detailed and well supported by substantial evidence. The Federal Circuit's decision clears the legal hurdle towards marketing of Mylan's proposed insulin glargine vial product. For additional details, see the Federal Circuit's opinion at https://www.wsgr.com/images/content/1/9/19198/mylan-1119.pdf.

Oyster Point Pharma Announces Closing of IPO
On November 5, Oyster Point Pharma, a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of first-in-class pharmaceutical therapies to treat ocular surface diseases, announced the closing of its initial public offering of 5,750,000 shares of its common stock at a price to the public of $16.00 per share. Wilson Sonsini represented Oyster Point Pharma in the offering. Further information is available at https://investors.oysterpointrx.com/news-releases/news-release-details/oyster-point-pharma-announces-closing-initial-public-offering.

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Select Life Sciences Client Highlights *(Continued from page 9)*

Ascentage Pharma Completes Initial Public Offering
On October 28, Ascentage Pharma Group International, a globally focused, clinical-stage biotechnology company engaged in developing novel therapies for cancers, Hepatitis B virus, and age-related diseases, completed its IPO and listing on the Main Board of the Stock Exchange of Hong Kong, raising HK$416 million after issuing 12,180,900 shares at HK$34.20 per share. Wilson Sonsini acted as Hong Kong counsel to Ascentage Pharma in the transaction. Additional details are available at https://www.bloomberg.com/news/articles/2019-10-28/hong-kong-s-biotech-ipo-craze-continues-as-ascentage-soars-57.

Mesoblast and Lonza Enter Agreement for Commercial Manufacture of Mesoblast's Potential First U.S. Allogeneic Cell Therapy
On October 16, Mesoblast and Lonza announced that they have entered into an agreement for commercial manufacture of Mesoblast's lead alogeneic (off-the-shelf) cell therapy product candidate, remestemcel-L for pediatric steroid-refractory acute graft versus host disease (aGVHD). The agreement will facilitate inventory build ahead of the planned U.S. market launch and commercial supply of the product candidate to meet Mesoblast's long-term market projections. Wilson Sonsini represented Mesoblast in the agreement. For further details, see http://investorsmedia.mesoblast.com/static-files/89c9419a-1899-4c49-afb7-a901fee6f2d7.

Arcellx Raises $85 Million in Series B Financing
On October 3, Arcellx, a privately held biopharmaceutical company, announced that it has raised $85 million in an oversubscribed Series B financing. The proceeds will be used to advance the company's ARC-T + sparX programs, including clinical development of a bivalent BCMA-targeted cell therapy in multiple myeloma, and a CD123-targeted therapy in acute myeloid leukemia. The Series B will also fund earlier stage ARC-T + sparX programs for patients with solid tumors and diseases outside oncology. Wilson Sonsini represented Arcellx in the transaction. For more details, see https://www.globenewswire.com/news-release/2019/10/03/1924589/0/en/Arcellx-Raises-85-Million-in-a-Series-B-Financing-to-Advance-its-Intelligent-Cell-Therapy-Platform.html.

IGM Biosciences Announces Pricing of IPO
On September 17, IGM Biosciences, a biotechnology company focused on creating and developing engineered IgM antibodies for the treatment of cancer patients, announced the pricing of its initial public offering of 10,937,500 shares of its common stock at a price to the public of $16.00 per share. The shares began trading on The Nasdaq Global Select Market on September 18 under the symbol "IGMS." The gross proceeds from the offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by IGM, are expected to be approximately $175 million. Wilson Sonsini represented IGM Biosciences in the offering. Further details are available at https://igmbio.com/2019/09/17/igm-biosciences-announces-pricing-of-initial-public-offering/.

iRhythm Technologies Announces Closing of Public Offering, Collaboration with Verily
On September 10, iRhythm Technologies, a leading digital health care solutions company focused on the advancement of cardiac care, announced the closing of its underwritten public offering of 1,575,342 shares of its common stock at a public offering price of $73.00 per share, which included the exercise in full of the underwriters' option to purchase 205,479 additional shares of common stock on the same terms and conditions. Gross proceeds from the offering to iRhythm Technologies were approximately $115 million. Wilson Sonsini represented iRhythm in the offering. Details are available at https://www.marketwatch.com/press-release/irhythm-technologies-announces-closing-of-follow-on-public-offering-and-full-exercise-of-the-underwriters-option-to-purchase-additional-shares-2019-09-10-16184145.

In addition, on September 4, iRhythm Technologies announced a collaboration with Verily, an Alphabet company focused on the development of solutions aimed at improving the screening, diagnosis, and management of patients with atrial fibrillation (AFib). The collaboration combines iRhythm's expertise in AI-based arrhythmia diagnosis and Verily's advanced health data analytics technologies to address the millions of patients living with undiagnosed AFib. Wilson Sonsini represented iRhythm in the transaction. For more information, see https://www.globenewswire.com/news-release/2019/09/04/1911146/0/en/iRhythm-Announces-Collaboration-with-Verily-to-Develop-Health-Management-Solutions-for-Atrial-Fibrillation-Patients.html.

Grünenthal and Mesoblast Enter Strategic Partnership to Develop and Commercialize Innovative Cell Therapy
On September 9, Grünenthal, a global leader in pain management, and Mesoblast, a world leader in allogeneic cellular medicines for inflammatory diseases, announced that they have

entered into a strategic partnership to develop and commercialize MPC-06-ID, a Phase III allogeneic cell therapy candidate for the treatment of chronic low back pain. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America. Mesoblast will receive up to $150 million in upfront and milestone payments prior to product launch, as well as further milestone payments. Wilson Sonsini represented Mesoblast in the transaction. For more information, refer to https://www.globenewswire.com/news-release/2019/09/09/1913118/0/en/Grünenthal-and-Mesoblast-Enter-Strategic-Partnership-for-Europe-and-Latin-America-to-Develop-and-Commercialise-Innovative-Cell-Therapy-for-the-Treatment-of-Chronic-Low-Back-Pain.html.

Vertex to Acquire Semma Therapeutics

On September 3, Vertex Pharmaceuticals announced that it has entered into a definitive agreement under which it will acquire Semma Therapeutics, a privately held biotechnology company pioneering the use of stem cell-derived human islets as a potentially curative treatment for type 1 diabetes, for $950 million in cash. Wilson Sonsini represented Semma Therapeutics in patent matters related to the acquisition. For further information, see https://investors.vrtx.com/news-releases/news-release-details/vertex-acquire-semma-therapeutics-goal-developing-curative-cell.

Silk Road Medical Announces Closing of Public Offering

On August 13, Silk Road Medical, a company focused on reducing the risk of stroke and its devastating impact, announced the closing of a public offering of 4,200,000 shares of its common stock sold by selling stockholders, and the exercise in full of the underwriters' option to purchase 630,000 additional shares of common stock from certain selling stockholders, at a public offering price of $39.50 per share. Wilson Sonsini represented Silk Road Medical in the offering. For more details, see https://investors.silkroadmed.com/news-releases/news-release-details/silk-road-medical-announces-closing-follow-public-offering-and.

Inogen Acquires New Aera

Inogen, a medical technology company offering innovative respiratory products for use in the homecare setting, announced on August 9 that it acquired New Aera, a developer and manufacturer of portable non-invasive ventilators, for approximately $70.4 million in cash at closing and potential earn-out payments of up to $31.4 million. Wilson Sonsini represented Inogen in the transaction. Further information can be found at http://investor.inogen.com/file/Index?KeyFile=399088316.

Babylon Health Raises $550 Million in Series C Round

Babylon Health, a UK-based start-up that has developed several AI-based health services, announced on August 2 that it has raised $550 million in a Series C round of financing, the largest-ever fundraise in the European or U.S. digital health delivery sector. The company plans to use the proceeds to fund extensive product innovation to cover chronic conditions and international expansion into the U.S. and Asia. The investment values the company at over $2 billion. Wilson Sonsini represented Babylon in the transaction. Additional details are available at https://assets.babylonhealth.com/pdfs/190802-Babylon-Funding-Announcement.pdf.

Wilson Sonsini Ranked Among Top Firms for Q3 2019 VC Healthcare and Pharma Deals

In November 2019, venture capital data company PitchBook ranked Wilson Sonsini among the leading law firms for U.S. venture financings in the third quarter of 2019. Of particular interest to *The Life Sciences Report*, PitchBook's legal rankings for Q3 2019 issuer-side venture financing deals placed Wilson Sonsini ahead of all other firms based on the total number of rounds of equity financing raised on behalf of clients in the healthcare devices and supplies industry and in the pharmaceutical and biotechnology industry. In addition, the firm ranked No. 5 for financings in the healthcare services and systems sector.

Upcoming Life Sciences Events

Wilson Sonsini's Women in Life Sciences Reception
January 12, 2020
San Francisco, California

Held in conjunction with the J.P. Morgan 38th Annual Healthcare Conference, Wilson Sonsini's annual Women in Life Sciences Reception brings together women leaders in the life sciences industry for a lively evening of networking.

Wilson Sonsini's Biotech Reception
January 15, 2020
SFMOMA
San Francisco, California

Wilson Sonsini's annual Biotech Reception, held to coincide with the J.P. Morgan 38th Annual Healthcare Conference, brings together industry leaders and innovators from around the globe for an evening with friends and colleagues in the life sciences sector.

rEVOLUTION Symposium
April 1-3, 2020
The LINE DC
Washington, D.C.
https://revolution.wsgrevents.com/

Now in its 12th year, the rEVOLUTION Symposium has become the place to discuss the most important strategic problems facing pharma and biotech CSOs. We will examine the organization and management of R&D to uncover new disruptive discovery and development models and assess the continued impact of pricing, reimbursement, regulation, and globalization on our industry.

Phoenix 2020: The Medical Device and Diagnostic Conference for CEOs
October 7-9, 2020
The Ritz-Carlton, Laguna Niguel
Dana Point, California
https://phoenix.wsgrevents.com/

The 27th Annual Phoenix Conference will bring together top-level executives from large healthcare companies and CEOs of small, venture-backed firms for an opportunity to discuss critical issues of interest to the medical device industry today, as well as to network and gain valuable insights from both industry leaders and peers. This exclusive, two-day event will provide an unrivaled experience that will help inform and shape company strategy for the years ahead.

Casey McGlynn, a leader of the firm's life sciences practice, has editorial oversight of *The Life Sciences Report* and was assisted by 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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