

## Interview with Dr. Daniel Burnett of TheraNova LLC



*Wilson Sonsini Goodrich & Rosati partner James Huie recently interviewed Dr. Daniel Burnett, president and CEO of TheraNova. TheraNova is an*

*experienced medical device developer with a track record of creating innovative and practical solutions to large markets with unmet needs. During the interview, Dan touches on a number of topics, including TheraNova's mission, what he's learned since starting the company, and factors that are fueling innovation in the medtech sector. He also offers helpful advice to start-ups and entrepreneurs.*

**James:** Tell us about TheraNova and the incubator's business plan and overall value proposition.

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**Dan:** TheraNova started as an IP holding company when I joined MedVenture Associates, the venture capital firm. MedVenture invested in my first company, but at the time, I also had patents unrelated to that company, so I formed TheraNova to hold them. In 2005, I left MedVenture Associates when I realized I liked building companies more than investing in them.

I started to create some structure around TheraNova, moving it beyond being an IP holding company, because it was no longer possible to get a company funded based on just a patent. You needed either some sort of benchtop or preclinical data. The first company I had funded was based on just the patent application and business plan. The second one was based on preclinical data. Every one after that required human clinical data. So we formed TheraNova to provide the level of support needed to get that first in man data. In order to hit this critical milestone we started to bring in engineering expertise, and then clinical expertise. As we spun out more companies, we started to get this critical mass where the portfolio companies could collectively support a patent person, a grant writer, and a regulatory person. We ended up bolting on more and more expertise, and now we essentially have all the expertise in-house that a startup would typically need to outsource with variable results. Other than reimbursement, we have dedicated and high-quality in-house personnel in all the key areas.

**James:** Those are valuable resources for your incubating companies and potential spin-offs. At last check, I believe TheraNova had spun off 14 companies that have raised more than \$280 million in venture funding. What factors have been important to their success, and what

considerations go into deciding whether or not to spin off a company?

**Dan:** It's about \$300 million now that Potrero Medical just raised close to \$27 million. What we do is, we take a technology and we do benchtop and preclinical work. Usually TheraNova pays for that. Then, if it passes muster, we move toward the clinical data. At any point along the way, if the technology fails, we scrap it.

We did have one technology fail prior to clinical data. It hadn't taken any outside investor capital, which was good, but we just decided to call it a loss and not pursue it further. It was a breast implant that had an inductive sensor that would signal if the implant was leaking. There were two problems. First, we had a partner lined up, but they were acquired at a point when we were far along in talks. This consolidated potential acquirers and resulted in an undesirable duopoly. Second, there was the introduction of a so-called "gummy bear" implant, in which the silicone was a cohesive gel that didn't leak. So the market had evolved underneath us and it essentially erased the value proposition for the technology.

Beyond that, we simply continue marching through the benchtop, preclinical, and clinical stages, then try to get key opinion leader (KOL) support. Once we have KOL support, plus proof of principle and initial demand, we can start testing the waters with investors. One of the bigger risks for medical device companies these days is financial. So, we test the waters with investors and potential acquirers. If we get interest from both, we fast track the project.

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**James:** TheraNova certainly can provide resources that are vertically quite deep. Tell us about the recent partnership with UCSF Surgical Innovations, which we understand is a vehicle for UCSF medtech innovators.

**Dan:** I've worked with them for a while, but we have not worked together as closely as we are now. That may be because of the partnership announcement, but also because we are increasingly reaching out to them to do more clinical studies and get clinical input for what we're doing at TheraNova. Up until recently, TheraNova has had clinical people, but I'm the only M.D. on staff, so broadening our clinical expertise and depth of knowledge was important to us. TheraNova's UCSF Surgical Innovations partnership made a lot of sense to me and their faculty directors, Dr. Shuvo Roy and Dr. Hanmin Lee. I've worked with Dr. Roy extensively as an industry director for the Master of Translational Medicine (MTM) program. He's the academic director. I've also started to work more with Dr. Lee, who is a strong force for innovation at UCSF.

**James:** It's exciting to see the collaboration, especially as Mission Bay and UCSF continue to grow, and great to have a partner that knows how to take technology beyond academia. There has been a lot of progress at TheraNova since you started. What are some of the things that you've learned along the way, if you compare your knowledge and understanding then to what you know now?

**Dan:** I learned a lot on the investor front. When I first started, I was really focused on pre-money valuation and trying to make the financing less dilutive. Then, I began to realize that that's not nearly as important as picking the right investor partner—one that has the same goals and similar views on what a successful arc for the company looks like.

I also learned that it used to be all about improving outcomes and decreasing morbidity and mortality. That's all that mattered. If you came up with something that did both things, and you incentivized the physicians or healthcare systems by being profitable for them, that was a victory. Now, increasingly we've been focusing on the triple aim: we look for technologies that improve outcomes,

reduce costs, and expand access to care. That was based in part on the MTM program that was started by Andy Grove at Intel. He and Dr. Roy came up with that triple aim for their program, for technologies that they were looking for. We adopted it based on the recognition that if you can develop technologies that do all three things, then you have everybody pushing for you—the Food and Drug Administration, Centers for Medicare & Medicaid Services, hospitals, payors, patients, physicians. Everybody.

**James:** That's a great perspective because I come across a number of companies that might have one of those three, or maybe two. But then they get tripped up when they start to talk to investors, or even later as acquirers. What's your view of the medtech sector? Do you see future growth in the near term?

**Dan:** It's interesting. There are a lot of macroeconomic developments taking place right now. The medtech industry is finally turning around. You're starting to see funds surface, like Medtech Venture Partners, as well as others that are either focused only on medtech or have a medtech component. Obviously, predictive health and the digitalization of medical devices are huge. So, it's not just digital health, but also having smarter devices. That includes previously "dumb devices"—like tubes in the body—that now have some kind of functionality to them. That's been one of our big thrusts where we have incubated technologies that extract actionable data from commodity devices like urine drainage systems (Potrero Medical), feeding tubes (Gravitas Medical) and PICC lines (Piccolo Medical). We are confident that by generating clinically useful algorithms from proprietary data streams we will have the potential to create the next medtech unicorns.

I also think that medicine will become much easier for doctors. For example, many of these technologies will be used as an adjunct in caring for the patient, to alert them of situations that they wouldn't be aware of clinically, but that can be detected by sensors in combination with artificial intelligence. These technologies are processing data streams that would be impossible for a human to take into account.

**James:** That's quite interesting, and it highlights something that's always been part of medtech: adoption by doctors, physicians, and surgeons. Do you see this new wave of medical devices having similar adoption hurdles?

**Dan:** That's a good question. I think it's going to be similar based on the technology. If you have a technology that is what we call a "missionary sell"—meaning you're taking a technology that the hospital or doctor has to believe in to do something new or different—then you end up with a market that needs to be convinced. This is especially true if the need your technology is satisfying isn't clearly identified or it's not a glaring need for the physician in a hospital system. But if you have a technology that provides actionable data, that is useful and valuable to the physician healthcare system as it is, then you can drive adoption.

For example, at Potrero Medical, we originally set out to fix urine output. Along the way, we added a temperature sensor and a pressure sensor to the device, so they now provide urine output with accuracy and frequency that was previously impossible. Although hospitals are buying the device based mainly on the urine output aspect, we're also collecting the other two data streams and we think it will help revolutionize ICUs. That is, by tracking those data and using machine learning and analytics, we can detect illnesses in the ICU much earlier. We have already shown this in a study of acute kidney injury that we presented at the Military Health System Research Symposium and expect the correlations to continue to strengthen and broaden.

**James:** It's interesting to see the convergence of technology. I always wonder whether the digital health craze is just the new flavor of the week for Silicon Valley, or if it's really representing a pivotal time where we see convergence across industries like medtech, software, big data, AI, and sensors. I also think about whether the new technologies weren't available before only because industries weren't talking to each other.

**Dan:** I don't think it's like the dot-com era where it's blowing up bigger than it should, or

that we're in a bubble. I believe there will be technologies that *do* revolutionize healthcare within 10 years. That will come about because of what you just said: less expensive sensors, medtech innovations, big data, machine learning, and analytics. And because of the last piece that's going to be required—evidence-based medicine. So if these technologies improve healthcare to the extent that convinces doctors, they'll be adopted more rapidly. You'll see a lot of victories related to devices that help doctors do their job better.

**James:** It's certainly great just having successful technologies brought to market. Another common challenge for start-ups is the tendency to burn through cash and run out of money. In an article you wrote in October 2014, you noted that the industry average for bringing a concept to market was about \$31 million. What strategies would you recommend to companies that want to stay lean and implement cost-efficiencies?

**Dan:** The best recommendation I can make is to look for synergies. For us, the biggest source of efficiency is when we have a technology that leverages the work from another technology. So, for example, we have a feeding tube that we've developed where we are already in discussions with potential acquirers prior to an equity financing. We got to our first in man with that device for about \$25,000, which is probably close to two orders of magnitude less than the industry average. That was possible because we used the hardware and software library from Potrero Medical and adapted it to provide the readings that we needed for our feeding tube to show that it's in the stomach and not in the lung. And we've got a great electrical engineer and software expert who was able to adapt the technology so that we could get these readings, and then, as a physician, I was able to put the tube in myself and show that it was in the right place. So, that was our clinical data. At TheraNova, we have an expression: "Instead of first in man, it's first in Dan." As long as it's not invasive, I'll usually try it out first.

**James:** That's pretty amazing. We've really seen you evolve throughout your career, and now you're taking on a mentor role—we know that you joined UCSF as an entrepreneur-in-residence with QB3 and you're an adjunct professor in UCSF's bioengineering department. Do you have any advice for young companies and potential entrepreneurs when they're starting their careers with their companies?

**Dan:** Don't focus on the valuation and be careful when picking the firm that's investing in you. It's more important to pick the investor that feels right for the company and has a similar mindset as you. So, my advice is that, when you pick your investor, think of it as getting married because the two of you—the founders and the investors—will be the parents of that spin-out, and if you are in sync in terms of what you want for that company, things will be better in good times and in bad.

**James:** Just seeing the community that you're building there, does TheraNova have a mission statement? I see everyone working together, and I feel like they have a common ethos.

**Dan:** Yes, I think having an ethos of focusing on impact and not just financial return is critical to what we do and critical to us being able to hire talent. We focus on reducing costs, improving outcomes, and expanding access to care which will drive life-saving technologies to market. That's honestly the reason we're able to attract top talent from places like Google and Facebook. Especially in the data analytics world, I think the people who come here like the idea of working in a fun, productive culture, making a decent salary, getting stock that could be worth quite a bit down the road, and just generating the karmic return of doing something that truly is meaningful and impactful.

**James:** I can definitely see TheraNova being a good role model and leading the younger industry by example. I'm looking forward to working more together in the future.

**Dan:** Thanks. Along those lines we've also started a nonprofit. We've begun to assign rights to TheraNova technologies in Africa, India, and Southeast Asia to the nonprofit so that the technologies can be provided at lower costs to some of those areas. The nonprofit's job is to adapt the technologies so they can be used in those much lower-cost areas. As an example of selecting the right investors and building the right board, Potrero Medical is, to my knowledge, the only venture-backed medical device company to assign these rights to the developing world after an equity financing with an institutional investor. This speaks volumes about the ethical alignment of the founders, investors and board members.

**James:** That's great, because I know one of the hurdles with nonprofits is that maybe the intention is good, but the execution is difficult. But if you have technologies that are already doing well in the U.S. market, perhaps there's a higher chance of success in the global market?

**Dan:** Right, and if you start to generate the evidence-based medicine here, but adapt it so that it has fewer bells and whistles but is still very functional and can be provided at really low cost for these very low-resource settings, it could be very impactful.

**James:** Is there anything else you'd like to highlight?

**Dan:** Well, I hope you don't mind me adding that WSGR has been a great partner for us. The firm helped open a lot of doors, and it's been the counsel to all of my spin-offs since Polymorphics in 2000, which was the very first one at MedVenture Associates and, of course, is now called TheraNova. So I'm very appreciative, and just like selecting investors, I would encourage founders to also consider their attorneys to be key, fundamental partners whom they should select wisely. While it's easier to switch legal counsel than investors, attorneys can be equally valuable if you pick the right one.

# Top 10 Frequently Asked Questions Related to Human Factors and Medical Device Design

By Russell J. Branaghan, Ph.D., President and Chief Scientist, Research Collective

Advances in healthcare, medicine, and medical devices continue to improve the health and well-being of our society. Benefits of these technological advances include longer, healthier lives, quicker post-operative recovery times, and less time spent in hospitals. Despite these benefits, new technologies have the potential to introduce new and possibly unforeseen risks. For example, negative pressure wound therapy (NPWT) has been shown to reduce the healing time of wounds and burns. It promotes wound healing by applying a dressing and vacuum that not only draws fluid from the wound, but increases blood flow to the area. However, if the dressing is applied incorrectly, the vacuum can pull blood out of the wound, possibly leading to injury or death. In the case of NPWT, the only difference between improved

healing and possible death is the way the dressing is applied by a human user. Careful consideration must be given to this interaction between the user and the technology.

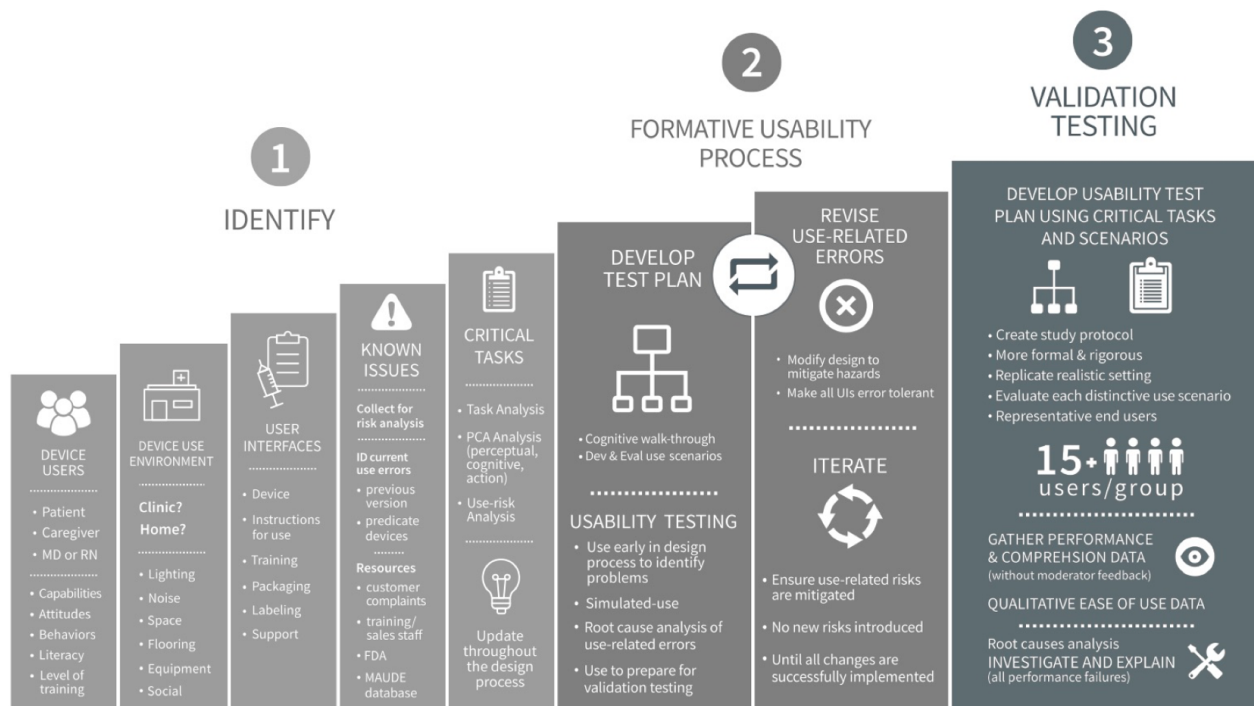
Human factors is the scientific study of how people interact with products, environments, systems, and services. Human factors can also be referred to as usability engineering, ergonomics, or user experience. For medical devices, human factors practitioners are responsible for ensuring that the design of the device, the instructions, and the training all support safe and effective use. (For a detailed description of human factors and its role in medical device design, see Shannon Clark's article in the Summer 2017 edition of *The Life Sciences Report*.)

In recent years, the agencies that regulate medical devices have increased their demand for human factors to be considered in device design. In 2015, the International

Electrotechnical Commission (IEC) released IEC 62366-1, *Application of usability engineering to medical devices*. A year later, the U.S. Food and Drug Administration (FDA) published its guidance document, *Applying Human Factors and Usability Engineering to Medical Devices*. These two documents describe the human factors activities manufacturers should apply when designing medical devices. Figure 1 provides a three-step approach to complying with IEC 62366-1 and the FDA's human factors guidance.

As human factors consultants working with medical device manufacturers, we find that many manufacturers have similar questions regarding the human factors requirements. The following is a list of the top 10 most frequently asked questions (FAQs) and their answers.

## 1. How many use errors will the FDA accept?



Created by Research Collective (www.research-collective.com)

Figure 1: Summary of recommended human factors practices for medical devices

To quote the FDA directly, “it depends.” It’s an unsatisfying answer, but a number of variables play a role:

- The type of device and potential harm
- The severity of the potential consequences of use errors
- The number of tasks that have use errors
- The number of use errors on a given task
- Whether a design change *can* be made to correct the problem
- Whether a design change *is* made to correct the problem
- The reviewer’s background
- Whether the medical device manufacturer attempted to submit before

Each use error, difficulty, or close call requires an in-depth analysis to determine the root cause. From there, the medical device manufacturer will need to decide whether the residual risk requires additional mitigation, or explain why the residual risk is acceptable as is.

## **2. Do we have to evaluate tasks that aren’t critical? If so, should non-critical task results be included in the report?**

The FDA is primarily interested in the results of critical tasks. However, evaluating every possible task is advisable. Evaluating non-critical tasks provides an opportunity to further understand the use of the medical device and to improve it. It is also prudent to have simulated-use data available for each task, should the FDA request it.

Non-critical task results are not typically provided in detail. Instead, a summary of non-critical task results is appended to the report. This allows the reviewer a high-level view, with the ability to probe further if he/she deems it necessary.

## **3. How do we define critical tasks?**

The FDA’s critical task definition is a good place to start. A critical task is a user task that, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user. In this case, harm is defined to include compromised medical care.

Critical tasks should be determined from severity scores given in a risk analysis or failure modes and effects analysis (FMEA). While the risk analysis or FMEA traditionally gives each user task two scores—severity and probability—critical tasks are not concerned with probability. Any task that could lead to harm, regardless of likelihood of occurrence, should be listed as a critical task.

User tasks related to successful delivery of therapy are often miscategorized as non-critical tasks. The FDA expects to see evidence that a device can be used for its intended purpose. Otherwise, what is the value of that device?

## **4. How realistic does the simulated-use environment need to be?**

The goal of a simulated-use usability study is to observe users interacting with the device interface independently and naturally. The FDA guidance recommends that testing take place in realistic but simulated use scenarios. There are three human factors considerations that interact to produce “device use”: the user, the device interface, and the use environment. Ultimately, the simulated-use environment should be realistic enough to understand how the device, the user, and use environment all interact.

The design of simulated-use usability studies should consider all aspects of the use environment that may influence the user’s interaction with the device. Some of these aspects may include:

- Lighting and ambient noise levels
- Presence of multiple models of the same device (forcing users to identify the correct one)
- Distractions

- Whether the area is busy or cluttered
- How fast- or slow-paced the environment is

## **5. Can we make changes to the device or instructions after the validation usability study?**

Changes can be made after the validation study. However, it is likely the FDA would ask for a reevaluation of the tasks that were affected by the change. Only the tasks affected by the manufacturer’s change would need further evaluation. For example, if the wording of only one step in the instructions were changed, the FDA would likely ask for only that step to be reevaluated.

Completing a reevaluation of only a few tasks is obviously a simpler and quicker affair, but it is important to note that a full 15 new participants would have to be included. Additionally, in order to reevaluate Step 4 of the instructions, participants would be asked to complete Steps 1-9 to ensure proper context.

## **6. What is the purpose of identifying known issues and how do we identify them?**

Known issues refer to usability issues that have already been documented from previous versions of the device, predicate devices, or devices that are similar. Recommending their identification is the FDA’s way of preventing the same mistake from being made twice. By identifying usability issues with current and previous devices, manufacturers can avoid developing medical devices with the same problems.

There are multiple places to look when searching for known issues related to usability, including, but not limited to:

- Internal customer feedback and complaints
- Sales representatives and clinical support staff
- Observing or interviewing current users

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- External databases such as the FDA's Manufacturer and User Facility Device (MAUDE) database, the FDA's MedSun Network, the FDA's Safety Communications, and the FDA's Medical Device Recalls website

## 7. What does the FDA mean by "user groups" for my device?

Many medical devices are used by a diverse group of healthcare providers. For example, an injection device may be used by a nurse, physician, medical assistant, pharmacist, or a layperson with no training. User groups are simply these different roles within healthcare. In the case of an insulin pen, a doctor or nurse might demonstrate proper injection technique to their patient. The patient would then be responsible for performing his or her own injections thereafter. User groups for the insulin pen would be nurses, physicians, and patients (lay users). While performing an injection requires the same technique for each group, nurses, physicians, and lay users vary from one another in that they approach the task with different knowledge, experience, and training.

## 8. Can nurses and physicians be included in one user group?

The FDA recommends that validation usability studies include 15 participants per user group. In an effort to save time and resources, medical device manufacturers often attempt to combine user groups. While there are situations where this may be pertinent, it is not typically appropriate.

Despite working in similar environments, nurses and physicians are distinct from a human factors perspective. In addition to contrasting training and experience, nurses' and physicians' roles within healthcare vary greatly. Responsibilities tasked to a nurse do not typically align with those of a physician, and therefore the two are usually treated separately during validation usability testing.

## 9. How do you recommend that we incorporate user research into our

## design process? How often and when should we conduct user research? What are the best strategies?

Incorporating human factors into the design process is most effective when done in the early stages of the product life cycle. Having the human factors perspective early on promotes informed decisions when the design is still flexible. Fundamental to early human factors' success is the fact that late changes are difficult and expensive, and early ones aren't. Early human-centered design is the most time-, effort-, and resource-efficient strategy. In 2017, the Association for the Advancement of Medical Instrumentation (AAMI) released a technical information report describing methods for incorporating human factors into design controls (see AAMI TIR59:2017 *Integrating human factors into design controls*).

The key is iteration. Conduct user research to understand the user's needs. Make design decisions with that information. Implement those designs into something testable. Lastly, have users interact with that prototype and get their thoughts on it. It doesn't matter how crude or developed it is; users will have something to say. Research, design, create, test, repeat.

Many manufacturers find themselves severely confined by years-old engineering or design decisions that wouldn't exist if user research had been included early on. Investing in the human factors perspective earlier, rather than later, is strongly recommended.

## 10. Is there a fast and effective way to get feedback on the usability of my device without having to do an actual study with users?

Usability studies are a powerful means of understanding the usability of a medical device. Accordingly, they tend to be the most time-consuming and expensive option.

There are quicker, more cost-effective methods of evaluating usability. A heuristic analysis completed by a human factors

expert compares a medical device to a set of design principles (often called "heuristics"). A heuristic analysis can be an extremely valuable, cost-effective tool to not only identify usability issues, but begin the process of making design improvements in the device's user interface.

## Conclusion

The human factors discipline is increasingly recognized by the FDA, and is gaining traction within healthcare accordingly. While the FDA's human factors guidance document is intended to provide clarity on the topic, requests for further clarification persist. By understanding the intricacies of the recommended human factors processes, medical device manufacturers can pursue FDA submissions with confidence, efficiency, and an increased likelihood of success.



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*of cognitive psychology and human factors at Arizona State University and a long-standing visiting professor at Northwestern University. He is integrated in the human factors arena, where he currently serves as chair of the Human Factors and Ergonomics Society Product Design Technical Group, on the editorial board of the Journal of Human Factors, and on the advisory board for Mayo Clinic's Center for Innovation. An avid researcher and writer, Russ has authored over 40 articles and one book. He can be reached at [russ@research-collective.com](mailto:russ@research-collective.com).*

*Focusing on human factors and usability testing, Research Collective's network of human factors experts and user experience professionals helps companies make their products easy to learn, efficient to work with, and desirable to use.*

# Reps and Warranties Insurance Coverage in the Life Sciences Sector

*Part One – by Emily Maier, National Group Leader, M&A Insurance, Woodruff-Sawyer & Co.*

The life sciences M&A market shows no signs of slowing down. The total value of 2018 life sciences M&A should once again surpass \$200 billion. The lull in biopharma deal-making last year and the passage of U.S. tax reform have sparked an increase in the desire and need for growth by acquisition.

We are also witnessing the emergence of disruptive firepower in tech leaders Amazon, Alphabet, Apple, Microsoft, Intel, IBM, and Samsung, as well as retail giants CVS, Walgreens, and Walmart, all of which are openly moving into the life sciences and healthcare spaces for the first time. This is fueling M&A in these sectors as these disruptive players seek to purchase existing companies rather than organically develop the healthcare and/or life sciences expertise needed to execute their strategy.

The fight for market share in key areas is affecting growth. We see an attack on pricing power as generic drug approvals surge in the U.S. and new products enter where pricing power had been relatively strong.

The likely increased consolidation activity and new types of buyers will inevitably lead to increased use of representations and warranty insurance (RWI). As the head of the Woodruff Sawyer M&A Insurance Group, I have seen this already at play. RWI is breach-of-contract insurance. It covers the loss associated with discovering a breach of a rep or warranty after the deal has closed. Our experience is that corporate buyers use it more often when entering a new area. If we continue to see consolidation in a seller's environment, it will become a standard request by bidders.

The RWI market has been cautious in life sciences, like most insurance carriers in this sector, because of phase III testing, the storage and usage of data, and the potential for very high payouts in the event of an issue. There are a couple of ways to minimize the risk of adding these exclusions to your reps policy.

The first option is to make sure an exclusion clause is included in the RWI coverage (and I will offer some advice on that). The second form of protection is to understand what insurance coverages already are in place for the target. (My colleague Chad Follmer describes that in part two of this article.) These two strategies can and should go hand-in-hand.

## *Products Liability*

In terms of risk, products liability is the principal insurable risk for most life sciences companies. In almost all reps and warranties policies, the coverage under the reps policy is designed to respond after any existing underlying insurances of the target have paid out. However, for life sciences companies, carriers may still seek to exclude products liability. Make sure that at the quote stage the broker is focusing on markets that are willing to provide coverage in excess of the existing target coverage.

## *Cyber Liability*

This is a significant, ever-evolving concern for all industries, not just life sciences. It is particularly concerning for the life sciences industry because of the potential for large amounts of data protected by the Health Insurance Portability and Accountability Act (HIPAA) and the emerging bodily injury concerns posed by the risk of hacked medical devices. Harmonizing your products liability, medical professional liability, and cyber liability placements with your reps

and warranties placement is of utmost importance to ensure you are getting the coverage you need.

It is important that your underwriter understands exactly what the target does, and how data is used and stored. Don't assume that underwriters understand your business. They are specialists in reps and warranties insurance, not necessarily in life sciences. The more brokers involved who can help them understand the business, the better. We recently had an underwriter who insisted on a HIPAA exclusion. After we explained that the only testing done and the only records kept were for animals, they removed the exclusion.

*Part Two – by Chad Follmer, Healthcare Practice Leader, Woodruff-Sawyer & Co.*

The second way to protect yourself from financial harm in a purchase-sale transaction is to thoroughly understand the risk management measures taken and the insurance program of your target. This can be achieved through a proper risk management and insurance due-diligence analysis performed by a knowledgeable healthcare and life sciences specialist insurance broker. It's important to be sure that the target company has adequate limits and coverage breadth for the traditional areas of life sciences industry risk, such as products liability, clinical trials, privacy liability and network security, supply chain, and inventory risks, including spoilage. Questions to ask and areas to probe regarding these risks include the following:

- Do you have any overseas assets, operations, sales, and/or clinical trials? If so, how have you ensured compliance with any locally required coverages and limits? Have you considered the pros and cons of optional local placements, which may be advantageous even if not required?

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- What steps have you taken to ensure business continuity in the event of a major supply chain disruption? What response measures exist and what coverage limits would apply if a loss is suffered due to a contingent business interruption of a supplier?
- Have you secured proper coverage for stock, both in-warehouse and in-transit globally, regardless of transportation means and contractual hand-offs?
- How did you determine the structure of your coverage limits and retentions? Are they adequate and efficient?

While these traditional sector risks are important considerations, it is also critical to consider the evolving risks facing the life sciences industry, such as:

- the potential for allegations of medical malpractice as genomic medicine and predictive AI modeling advance;
- regulatory liabilities associated with allegations of off-label use and/or False Claims Act allegations as disruptive technologies are potentially prescribed for previously unanticipated applications; and
- ensuring proper coverage for the constantly changing morass of regulatory bodies at several levels of government rushing to enforce alleged HIPAA and network security violations.

Finally, it is critical that your broker work in partnership with knowledgeable counsel to address the management liability risks associated with “the deal” itself, such as pricing, investor concerns, and disclosures, particularly for public companies. Add to this the unique regulatory concerns for the industry, including compliance with the Food and Drug Administration and the Centers for Medicare & Medicaid Services, and it’s clearly integral to have the right team of industry specialist brokers and attorneys on your side.

Right now is a dynamic time in insuring the life sciences, with literally life-changing opportunity in our industry. The scale and impact of successful market adoption is greater than ever before, as are the risks. A well-executed risk management diligence audit in combination with a properly structured reps and warranties insurance placement are important tools for seizing the opportunities presented by strategic transactions.

### About the Authors



**Chad Follmer, Healthcare Practice Leader, Woodruff-Sawyer & Co.**

For 20 years, Chad has been bringing unique and proactive solutions to clients in the healthcare and life science industry. A leader in his field, Chad has a deep understanding of the complex risks facing these organizations, and knows how to create and deliver the optimal risk management solutions to protect their assets, people, and reputations.

Chad specializes in the risks modern organizations in the healthcare and life science industry face, including: products and professional liability; regulatory risks; data privacy and cyber risks; alternative risk finance structures, such as captives, RRGs, SIRs, and trusts; and global risk management programs.

Chad has led several practices in the area of risk management. He was most recently managing director, health care and life science practice leader for the western region of Marsh. Chad is a “Risk and Insurance” Power Broker award recipient and is a member of, and frequent presenter at, leading industry associations such as ASHRM, CAHF and HFMA. He authors the blog “The Virtual Housecall: Healthcare Trends and Risks.”



**Emily Maier, National Group Leader, M&A Insurance, Woodruff-Sawyer & Co.**

Leading Woodruff Sawyer’s M&A practice group, Emily provides consultation and support to clients who wish to use the insurance market to ring fence the risks that arise from M&A activity. This includes representations and warranties, tax opinion liability, and litigation buyout coverages.

Emily’s deal experience covers both American and European deals. Her clients are as diverse as their locations. She has worked with both strategic and private equity buyers and sellers over a wide range of transaction sizes and industries.

Prior to joining Woodruff Sawyer in the U.S., Emily specialized in M&A insurance transactions in leading brokerage firms in London, including Marsh, Howden and Heath Lambert. Emily is a popular speaker and published author on the topic of M&A insurance.

### About Woodruff-Sawyer & Co.

As one of the largest insurance brokerage and consulting firms in the U.S., Woodruff Sawyer protects the people and assets of more than 4,000 companies. Woodruff Sawyer provides expert counsel and advocacy to protect clients against their most critical risks in property and casualty, management liability, cyber liability, employee benefits, and personal wealth management. An active partner of Assurex Global and International Benefits Network, Woodruff Sawyer has headquarters in San Francisco, offices throughout the U.S., and global reach on six continents.



# Life Sciences Venture Financings for WSGR Clients

By Scott Murano, Partner (Palo Alto)

The table below includes data from life sciences transactions in which Wilson Sonsini Goodrich & Rosati clients participated across the second half of 2017 and the first half of 2018. 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.

Life Sciences Industry Segment	2H 2017 Number of Closings	2H 2017 Total Amount Raised (\$M)	2H 2017 Average Amount Raised (\$M)	1H 2018 Number of Closings	1H 2018 Total Amount Raised (\$M)	1H 2018 Average Amount Raised (\$M)
Biopharmaceuticals	41	1,062.65	25.92	34	413.70	12.17
Genomics	3	3.38	1.13	4	37.23	9.31
Diagnostics	3	69.00	23.00	6	54.32	9.05
Medical Devices & Equipment	39	419.22	10.75	33	277.61	8.41
Health IT	14	184.45	13.18	4	26.92	6.73
Healthcare Services	7	53.70	7.67	11	179.89	16.35
<b>Total</b>	<b>107</b>	<b>1,792.40</b>		<b>92</b>	<b>989.67</b>	

The data demonstrates that venture financing activity decreased from the second half of 2017 to the first half of 2018 with respect to the total amount raised and the total number of closings. Specifically, the total amount raised across all industry segments decreased 44.8 percent, from \$1,792.4 million to \$989.67 million, while the total number of closings across all industry segments decreased 14 percent, from 107 to 92.

Notably, the industry segment with the largest number of closings—biopharmaceuticals—experienced a decrease in both number of closings and total amount raised from the second half of 2017 to the first half of 2018. Specifically, the number of closings in the biopharmaceuticals segment decreased 17.1 percent, from 41 to 34, and the total amount raised decreased 61.1 percent, from \$1,062.65 million to \$413.7 million. Similarly, the

Biopharmaceuticals experienced a decrease in the number of closings and total amount raised during the first half of 2018 compared to the second half of 2017.

industry segment with the second-largest number of closings—medical devices and equipment—experienced a decrease in both number of closings and total amount raised from the second half of 2017 to the first half of 2018. Specifically, the number of closings in medical devices and equipment decreased 15.4 percent, from 39 to 33, and

more significantly, the total amount raised decreased 33.8 percent, from \$419.22 million to \$277.61 million.

Meanwhile, the industry segment with the third-largest number of closings during the second half of 2017—health IT—experienced decreases in both number of closings and total amount raised: the number of closings decreased 71.4 percent, from 14 to 4, while the total amount raised decreased 85.4 percent, from \$184.45 million to \$26.92 million. In contrast, the industry segment with the fourth-largest number of closings during the second half of 2017—healthcare services—experienced increases in both number of closings and total amount raised. Specifically, the number of closings in the healthcare services segment increased 57.1 percent, from 7 to 11, while the total amount raised increased 235 percent, from \$53.7 million to \$179.89 million. The two

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The number of closings and total amount raised in the healthcare services segment both increased from the second half of 2017 to the first half of 2018.

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remaining industry segments—genomics and diagnostics—both experienced increases in number of closings from the second half of 2017 to the first half of 2018. The total amount raised in genomics increased 1,001.5 percent across those same periods, from \$3.38 million to \$37.23 million, while the total amount raised in diagnostics decreased 21.3 percent, from \$69 million to \$54.32 million.

In addition, our data suggests that Series A (including Series Seed) financing activity and Series C and later-stage financing activity, in each case as a percentage of all other financing activity, increased from the second half of 2017 to the first half of 2018, while Series B financing activity as a percentage of all other financing activity, decreased across the same periods. Specifically, the number of Series A (including Series Seed) closings as a percentage of all closings increased from 35.2 percent to 36.6 percent, the number of Series C and later-stage closings as a percentage of all closings increased from 13 percent to 17.2 percent, and the number

of Series B closings as a percentage of all closings decreased from 19.4 percent to 17.2 percent. Bridge financing activity as a percentage of all other financing activity decreased marginally from the second half of 2017 to the first half of 2018, moving from 23.1 percent to 22.6 percent.

Average pre-money valuations for life sciences companies decreased for both Series A and Series B financings but increased for Series C and later-stage financings from the second half of 2017 to the first half of 2018. The average pre-money valuation for Series A financings decreased 56.8 percent, from \$31.17 million to \$13.45 million; the average pre-money valuation for Series B financings decreased 53.6 percent, from \$124.14 million to \$57.64 million; and the average pre-money valuation for Series C and later-stage financings increased 4.4 percent, from \$225.91 million to \$235.95 million.

Other data taken from transactions in which all firm clients participated in the first half of 2018 suggests that life sciences remains the second-most attractive industry for investment. For the first half of 2018, life sciences represented 23 percent of total funds raised by our clients, while the software industry—traditionally the most popular industry for investment—represented 32 percent of total funds raised.

Overall, the data indicates that access to venture capital for the life sciences industry decreased in the first half of 2018 compared to the second half of 2017, with the most active segments—biopharmaceuticals and

medical devices—experiencing significant drops in both number of closings and dollars raised. However, it is worth noting that this decline in activity follows several periods of consistent growth. Because recent exit activity for our life sciences companies remains strong across all industry segments, we are optimistic that the recent slowdown in financing activity represents nothing more

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Data taken from transactions in which all firm clients participated in during the first half of 2018 suggests that life sciences remains the second-most attractive industry for investment, behind software.

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than a natural cooling-off period after the recent growth, and should not serve as an indicator of things to come.



**Scott Murano**  
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# Select Recent Life Sciences Client Highlights

## **IRIDEX Announces Pricing of Public Offering of Common Stock**

On September 14, IRIDEX, an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures used to treat sight-threatening eye conditions, announced the pricing of its underwritten public offering of 1,666,667 shares of its common stock at a price to the public of \$6.00 per share. In addition, the company has granted the underwriters a 30-day option to purchase up to 250,000 additional shares of its common stock in the public offering. The offering is expected to close on September 18, 2018, subject to customary closing conditions. Gross proceeds to the company from the offering are expected to be approximately \$10 million before deducting the underwriting discount and other offering expenses payable by the company and excluding any exercise of the underwriters' option. WSGR is representing IRIDEX in the offering. For additional information, visit <https://globenewswire.com/news-release/2018/09/14/1571046/0/en/IRIDEX-Announces-Pricing-of-Public-Offering-of-Common-Stock.html>.

## **Invuity Announces Definitive Agreement to Be Acquired by Stryker**

Invuity, a leading medical technology company focused on advanced surgical devices to enable better visualization, announced on September 11 that it has entered into a definitive agreement with Stryker Corporation, pursuant to which Stryker will acquire all of the outstanding shares of Invuity for \$7.40 per share in cash, implying a total equity value of approximately \$190 million. The tender offer is expected to be completed in the fourth quarter of 2018, subject to the satisfaction or waiver of the transaction conditions. WSGR is representing Invuity in the transaction. For more details, please see <https://globenewswire.com/news-release/2018/09/11/1569100/0/en/Invuity-Announces-Definitive-Agreement-to-Be-Acquired-by-Stryker-Corporation-for-7-40-Per-Share-in-Cash.html>.

## **Kodiak Sciences Files Registration Statement for Proposed IPO**

On September 7, Kodiak Sciences, a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases, announced that it has filed a registration statement on Form S-1 with the U.S. SEC relating to a proposed initial public offering of its common stock. The number of shares to be offered and the price range for the proposed offering have not yet been determined. Kodiak intends to list its common stock on the Nasdaq Global Market under the ticker symbol "KOD." WSGR is representing Kodiak in the offering. More information is available at <https://www.prnewswire.com/news-releases/kodiak-sciences-files-registration-statement-for-proposed-initial-public-offering-300709072.html>.

## **Outset Medical Raises \$132 Million in Series D Financing**

Outset Medical, a Silicon Valley-based commercial-stage company delivering first-of-its-kind technology into the growing global dialysis market, announced on August 28 that it has raised \$132 million in a Series D round of equity financing led by new investor Mubadala Investment Company, Abu Dhabi's leading investment company, with participation from existing investors Baxter Ventures, the venture capital arm of Baxter International, Fidelity Management and Research Company, Partner Fund Management, Perceptive Advisors, funds advised by T. Rowe Price Associates, and Warburg Pincus. WSGR represented Outset Medical in the transaction. For more information, please visit <https://www.businesswire.com/news/home/20180828005589/en/Outset-Medical-Closes-132-Million-Financing-Accelerate>.

## **China Biologic Announces Strategic Private Placement**

China Biologic Products Holdings, a leading fully integrated plasma-based biopharmaceutical company in China, announced on August 24 that it has entered into definitive agreements for the issuance

and sale of an aggregate of 5,850,000 ordinary shares of the company, which represents 14.9 percent of the enlarged share capital post the issuance and is expected to raise gross proceeds of approximately US\$590 million. Under the agreement, Centurium Capital, CITIC, Hillhouse Capital Management, and PW Medtech Group will subscribe for and purchase 3,050,000, 1,000,000, 1,000,000, and 800,000, respectively, newly issued ordinary shares of the company at a per share purchase price of US\$100.90. WSGR is representing Centurium Capital and PW Medtech in the transaction. More information is available at <https://www.prnewswire.com/news-releases/china-biologic-announces-updates-on-unsolicited-acquisition-proposals-and-strategic-private-placement-300701999.html>.

## **Federal Circuit Reverses Judgment Against Otonomy Ear Treatment Patent**

On August 1, the U.S. Court of Appeals for the First Circuit reversed a judgment from the Patent Trial and Appeal Board (PTAB) in a patent interference against biotechnology company Otonomy. The judgment arose from a patent interference between Otonomy and Auris Medical over competing claims to an otic treatment method. The PTAB had held all but one Auris claim unpatentable, but had held that Auris had invented the method before Otonomy. The contested invention is directed to a less-invasive method of delivering antibiotics locally to the middle and inner ear. Auris claimed to have invented the method before Otonomy based on its disclosure of a different treatment method. The PTAB held that the Auris disclosure did not anticipate Otonomy's claims and that Auris had not disclosed the invention at issue until 2014, but inconsistently held that Auris had invented it first despite crediting Otonomy with an earlier filing date. On appeal, the court reversed the decision that Auris had invented first and affirmed that Otonomy's claims were not anticipated. Rather than simply remand for a new trial, the court directed the PTAB to enter judgment for Otonomy. WSGR represented Otonomy in the matter. For additional details, please refer to <https://www.wsgr.com/WSGR/>

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## Select Recent Life Sciences Client Highlights

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[Display.aspx?SectionName=clients/0818-otonomy.htm](#).

### **Savara Announces Pricing of Public Offering of Common Stock**

On July 27, Savara, an orphan lung disease company, announced the pricing of an underwritten public offering of 4,250,000 shares of its common stock at a price to the public of \$11.50 per share. The expected gross proceeds of the offering were approximately \$48.9 million. The offering closed on July 30. WSGR represented Savara in the offering. For additional information, visit <https://savapharma.com/investors/press-releases/release/?id=2360308>.

### **Allakos Announces Closing of Initial Public Offering**

Allakos, a clinical-stage biotechnology company focused on the development of antibodies for the treatment of various eosinophil and mast cell-related diseases, announced on July 24 that it has closed its initial public offering of 8,203,332 shares of its common stock at a public offering price of \$18.00 per share, which includes the full exercise of the underwriters' option to purchase up to 1,069,999 additional shares. The company estimates net proceeds from the offering to be approximately \$134.4 million, after deducting the underwriting discounts and commissions and estimated offering expenses. The shares began trading on Nasdaq Global Select Market under the symbol "ALLK" on July 19 and closed at \$31.23 per share on the first day of trading. WSGR represented Allakos in the offering. For more information, please visit <https://globenewswire.com/news-release/2018/07/24/1541135/0/en/Allakos-Announces-Closing-of-Initial-Public-Offering-and-Full-Exercise-of-Underwriters-Option-to-Purchase-Additional-Shares.html>.

### **Establishment Labs Announces Closing of Initial Public Offering**

On July 23, Establishment Labs, a global medical technology company focused on breast aesthetics and reconstruction technologies, announced the closing of its initial public offering of 4,272,568 common shares at a public offering price of \$18.00

per share, which includes the full exercise of the underwriters' option to purchase 557,291 additional shares. The gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses payable by Establishment Labs, were approximately \$76.9 million. The shares began trading on the Nasdaq Capital Market under the ticker symbol "ESTA" on July 19. WSGR represented Establishment Labs in the offering. For more details, please see <https://investors.establishmentlabs.com/news-releases/news-release-details/establishment-labs-announces-closing-initial-public-offering-and>.

### **Kite and Gadeta Announce Strategic Collaboration to Advance Gamma Delta T Cell Receptor Technology for Solid Tumors**

Kite, a Gilead Company, and Gadeta, a privately held company focused on the discovery and development of novel cancer immunotherapies, announced on July 19 that they have entered into a strategic collaboration to develop novel gamma delta T cell receptor therapies in various cancers. Under the financial terms, Kite will provide research and development funding for the collaboration and Gadeta will be eligible to receive future payments upon achievement of certain regulatory milestones. In addition, Kite will make an upfront purchase of equity in Gadeta from Gadeta's shareholders and may acquire additional equity in Gadeta upon achievement of certain R&D milestones. Kite will have the exclusive option to acquire Gadeta. WSGR represented Gadeta in intellectual property matters related to the strategic collaboration. For more information, please visit <https://www.gilead.com/news/press-releases/2018/7/kite-and-gadeta-announce-strategic-collaboration-to-advance-gamma-delta-t-cell-receptor-technology-for-solid-tumors>.

### **Avinger Announces Pricing of \$3.55 Million Registered Direct Offering**

On July 12, Avinger, a leading developer of innovative treatments for peripheral artery disease, announced that it entered into a securities purchase agreement with certain institutional investors providing for

the purchase and sale of 2,166,180 shares of common stock at a price of \$1.6425 per share in a registered direct offering, resulting in total gross proceeds of approximately \$3.55 million. WSGR represented Avinger in the offering. For more details, please see <https://globenewswire.com/news-release/2018/07/12/1536539/0/en/Avinger-Announces-Pricing-of-3-55-Million-Registered-Direct-Offering.html>.

### **BD Acquires TVA Medical to Advance Leadership in Solutions for Chronic Kidney Disease**

Becton, Dickinson and Company (BD), a leading global medical technology company, announced on July 9 that it has completed its acquisition of TVA Medical, a company that develops minimally invasive vascular access solutions for patients with chronic kidney disease requiring hemodialysis. Terms of the transaction were not disclosed. WSGR represented TVA Medical in the transaction. For more information, please visit <https://www.prnewswire.com/news-releases/bd-acquires-tva-medical-to-advance-leadership-in-solutions-for-chronic-kidney-disease-300677505.html>.

### **Cryterion Medical to Be Acquired by Boston Scientific**

On July 5, Boston Scientific announced a definitive agreement to acquire Cryterion Medical, a privately held company developing a single-shot cryoablation platform for the treatment of atrial fibrillation. Boston Scientific has been an investor in Cryterion since its inception in 2016, and the transaction price for the approximately 65 percent remaining stake not already owned by Boston Scientific consists of \$202 million in up-front cash. WSGR is representing Cryterion in the transaction. More details are available at <http://news.bostonscientific.com/2018-07-05-Boston-Scientific-to-Acquire-Cryterion-Medical-Inc>.

### **Aerpio Announces Exclusive License Agreement with Gossamer Bio**

On June 25, Aerpio Pharmaceuticals, a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases, announced an exclusive

global license agreement with a wholly owned subsidiary of Gossamer Bio for the development and commercialization of Aerpio's HIF-1 alpha stabilizer, AKB-4924, along with other related compounds. Gossamer will pay Aerpio \$20 million up front, potential development, regulatory, and sales milestones of up to \$400 million, and royalties on worldwide net sales, which range from a high single digit to mid-teen percentage of net sales. WSGR represented Aerpio Pharmaceuticals in intellectual property matters related to the transaction. Additional details are available at <https://www.businesswire.com/news/home/20180625005370/en/Aerpio-Announces-Exclusive-License-Agreement-Gossamer-Bio>.

### **District Court Dismisses Securities Class Action Against Seattle Genetics**

On May 24, the U.S. District Court for the Western District of Washington granted defendant Seattle Genetics' motion to dismiss with prejudice a securities class action filed against the company following the announcement of an FDA-required clinical hold of trials for a drug meant to treat acute myeloid leukemia. A federal judge dismissed the previous version of the case in October 2017, saying that the plaintiffs did not adequately allege that the defendants acted with scienter, or awareness of the wrongful nature of their actions. WSGR represented Seattle Genetics in the matter. Please see <https://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/0618-seattle-genetics.htm> for further details.

### **Zymeworks and Daiichi Sankyo Expand Immuno-Oncology Collaboration Focused on Bispecific Antibodies**

Zymeworks, a clinical-stage biopharmaceutical company developing multifunctional therapeutics, and Daiichi Sankyo Company announced on May 14 that they entered into a new license agreement, building upon their 2016 cross-licensing and collaboration agreement. Under the terms of the second agreement, Daiichi Sankyo will acquire licenses to Zymeworks' Azymetric™ and EFECT™ technology platforms to develop two additional bispecific antibody

therapeutics. In exchange, Zymeworks will receive an upfront technology access fee of \$18 million and may receive up to US\$466.7 million in potential clinical, regulatory, and commercial milestone payments. In addition, Zymeworks will receive up to double-digit tiered royalties on global product sales. WSGR represented Zymeworks in its new license agreement with Daiichi Sankyo. For more details, please see <https://www.businesswire.com/news/home/20180514006244/en/Zymeworks-Daiichi-Sankyo-Expand-Immuno-Oncology-Collaboration-Focused>.

### **WuXi AppTec Completes A-Share IPO on Shanghai Stock Exchange**

On May 8, WuXi AppTec, a leading global pharmaceutical and medical device open-access capability and technology platform company, completed its A-share initial public offering and listing on the Shanghai Stock Exchange. The company issued 104,198,600 shares of common stock in the IPO at a public offering price of RMB21.60 per share. WSGR acted as the lead international counsel to WuXi AppTec in the public offering and related restructuring. Please refer to <https://www.prnewswire.com/news-releases/wuxi-apptec-announces-listing-of-initial-public-offering-of-common-stock-on-shanghai-stock-exchange-300644173.html> for further details.

### **Deerfield Leads Investment of up to \$50 Million in Sollis Therapeutics**

On April 12, Deerfield Management, an investment management firm committed to advancing healthcare through investment, information, and philanthropy, and Sollis Therapeutics, a clinical-stage biotechnology company focused on developing novel non-steroid, non-opioid analgesics, announced a Deerfield-led investment of up to \$50 million in Sollis Therapeutics. The investment will support the development of an innovative non-opioid and non-steroid solution for pain associated with sciatica and other neuropathic pain syndromes. The total equity financing of up to \$50 million was led by Deerfield's commitment of over \$40 million and will fund the company through FDA approval. WSGR represented Sollis in the transaction. Please see <https://markets>.

[businessinsider.com/news/stocks/deerfield-leads-investment-of-up-to-50-million-in-sollis-therapeutics-innovative-solution-for-sciatica-pain-1021298168](https://businessinsider.com/news/stocks/deerfield-leads-investment-of-up-to-50-million-in-sollis-therapeutics-innovative-solution-for-sciatica-pain-1021298168) for more information.

### **Roche Completes \$1.9 Billion Acquisition of Flatiron Health**

On April 6, Roche, a global pharmaceuticals and diagnostics company, announced that it completed its acquisition of Flatiron Health, a privately held healthcare technology and services company. Under the terms of the agreement, the transaction value for the acquisition of Flatiron Health was \$1.9 billion on a fully diluted basis, subject to certain adjustments. WSGR advised Flatiron Health in the transaction. For more details, please see <https://www.roche.com/media/releases/medcor-2018-04-06.htm>.

### **Accelerate Diagnostics Announces Pricing of \$150 Million Convertible Notes Offering**

On March 23, Accelerate Diagnostics, an in vitro diagnostics company dedicated to providing solutions for the global challenge of antibiotic resistance and healthcare-associated infections, announced the pricing of \$150 million aggregate principal amount of 2.50 percent convertible senior notes due 2023 in a private placement to qualified institutional buyers. The company also granted the initial purchasers of the notes a 13-day option to purchase up to an additional \$22.5 million aggregate principal amount of the notes. WSGR represented Accelerate Diagnostics as special product counsel in the offering. Please visit <https://globenewswire.com/news-release/2018/03/23/1449173/0/en/Accelerate-Diagnostics-Inc-Announces-Pricing-of-150-Million-Convertible-Notes-Offering.html> for additional details.

### **Medeon Enters into Agreement with Terumo for its Large Bore Vascular Closure System**

Medeon Biodesign, a Taiwan-based publicly traded medical device company, announced on March 5 that it has entered into a definitive asset purchase agreement with Tokyo-based Terumo Corporation for its large bore vascular closure system. The transaction consists of an up-front payment of \$20

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## Select Recent Life Sciences Client Highlights

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million and milestone payments. Medeon will continue to provide its strong expertise in product innovation in collaboration with Terumo for future technical, clinical, and regulatory developments of the closure system. WSGR represented Medeon Biodesign in the transaction. For additional information, please see <https://www.marketwatch.com/press-release/medeon-entering-asset-purchase-agreement-with-terumo-for-its-large-bore-vascular-closure-system-2018-03-05>.

### **Viela Bio Raises \$250 Million in Series A Financing**

Viela Bio, a clinical-stage biotechnology company pioneering and advancing treatments for severe inflammation and autoimmune diseases, announced on February 28 that it has raised \$250 million in a Series A round of financing led by Boyu Capital, 6 Dimensions Capital, and Hillhouse Capital, along with Temasek and Sirona Capital. WSGR represented Boyu Capital, 6 Dimensions Capital, and Temasek in the transaction. For more details, please see <https://www.biospace.com/article/releases/viela-bio-spins-out-of-medimmune-launches-with-up-to-250-million-series-a-financing-from-investor-consortium-led-by-boyu-capital-6-dimensions-capital-and-hillhouse-capital/>.

### **Avinger Announces Closing of \$18 Million Underwritten Public Offering**

Avinger, a leading developer of innovative treatments for peripheral artery disease (PAD), announced on February 16 that it has closed an underwritten public offering of Series B convertible preferred stock, together with warrants, for gross proceeds of approximately \$18 million, prior to deducting underwriting discounts and commissions

and offering expenses payable by Avinger. WSGR represented Avinger in the offering. Please see <https://globenewswire.com/news-release/2018/02/16/1357641/0/en/Avinger-Announces-Closing-of-18-Million-Underwritten-Public-Offering.html> for more details.

### **Alder BioPharmaceuticals Announces Closing of \$250 Million Senior Notes Offering**

On February 1, Alder BioPharmaceuticals, a biopharmaceutical company focused on developing novel therapeutic antibodies for the treatment of migraine, announced the closing of its previously announced underwritten offering of \$250 million aggregate principal amount of 2.50 percent convertible senior notes due 2025. The company also granted the underwriters a 30-day option to purchase up to an additional \$37.5 million aggregate principal amount of notes, solely to cover over-allotments. WSGR represented the underwriters in the offering. Please refer to <https://investor.alderbio.com/news-releases/news-release-details/alder-biopharmaceuticals-inc-announces-closing-250-million-250> for more information.

### **llumina Awarded \$26.7 Million in Patent Suit Against Ariosa Diagnostics**

llumina, a global leader in DNA sequencing and array-based technologies, announced on January 26 that a federal jury in San Francisco has ruled in its favor in a patent infringement suit filed against Ariosa Diagnostics, now owned by Roche. The jury found that both Ariosa's previous and current version of the Harmony non-invasive prenatal test infringe U.S. Patent 8,318,430 and US Patent 7,955,794. The jury awarded Illumina approximately \$26.7 million for past damages. The jury rejected counterclaims

by Ariosa that Illumina had breached a supply agreement between the companies by bringing the lawsuit. The U.S. Patent and Trademark Office previously upheld the validity of the patents rejecting multiple challenges filed by Ariosa. WSGR prosecuted the patent and defended the *inter partes* review on behalf of Illumina in the matter. Please see <https://www.illumina.com/company/news-center/press-releases/press-release-details.html?newsid=2328729> for further details.

### **Millipede Secures Investment from and Enters into Acquisition Option Agreement with Boston Scientific**

On January 24, medical device manufacturer Boston Scientific announced that it has closed an investment and has entered into an acquisition option agreement with Millipede, a privately held company that has developed a system for the treatment of severe mitral regurgitation. WSGR represented Millipede in the transactions. More information is available at <https://www.prnewswire.com/news-releases/boston-scientific-announces-investment-and-acquisition-option-agreement-with-millipede-inc-300587421.html>.

### **Tmunity Announces \$100 Million Financing Round**

On January 23, Tmunity, a private clinical-stage biotherapeutics company focused on delivering the full potential of next-generation T-cell immunotherapy, announced that it has completed a \$100 million Series A round of financing led by Ping An Ventures. WSGR represented Ping An Ventures in the transaction. For additional information, visit <https://www.tmunity.com/copy-of-2017may09-michael-christian>.

## WSGR Named Venture Capital Firm of the Year at the 2018 LMG Life Sciences Awards

On September 12, 2018, Wilson Sonsini Goodrich & Rosati was named the "Venture Capital Firm of the Year" at the sixth annual LMG Life Sciences Awards, besting four other law firm nominees. LMG's annual awards program recognizes the top firms and legal professionals in the life sciences market. WSGR was also a nominee in the "Hatch-Waxman Litigation Firm of the Year—Generic" award category and WSGR partner Doug Carsten was among the six nominees for the "Hatch-Waxman Litigator of the Year—Generic" award.

## Upcoming Life Sciences Events

### Phoenix 2018: The Medical Device and Diagnostic Conference for CEOs

October 17-19, 2018  
Montage Laguna Beach  
Laguna Beach, California  
<https://phoenix.wsgrvents.com/>

The 25th 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.

### Bohemian Medical Device Summit

December 5-7, 2018  
Four Seasons Hotel, Prague,  
Czech Republic  
<http://www.bohemiansummit.com>

This invitation-only conference for senior executives from medical device companies in Europe provides a private and exclusive setting for networking and partnering. The agenda will include high-level panel discussions with keynotes from industry and academic leaders, as well as social networking events. WSGR is one of the three original founding organizations of the Bohemian Medical Device Summit.

### Women in Life Sciences Reception

January 6, 2019  
San Francisco, California

The Women in Life Sciences Reception will host women leaders in the life sciences industry for a lively evening of conversation and networking.

### Biotech Board of Directors and Senior Executives Reception

January 9, 2019  
The San Francisco Museum of Modern Art (SFMOMA)  
San Francisco, California

Wilson Sonsini Goodrich & Rosati's annual Biotech Board of Directors and Senior Executives Reception, held to coincide with the J.P. Morgan 37th Annual Healthcare Conference, is an exclusive networking event geared toward executives and directors of biotechnology companies.

### 27th Annual Medical Device Conference

June 20-21, 2019  
The Palace Hotel  
San Francisco, California

Wilson Sonsini Goodrich and Rosati's 27th Annual Medical Device Conference will feature industry experts discussing key issues facing today's early-stage medical device companies. Through a series of topical panels, attendees will hear from industry CEOs, venture capitalists, industry strategists, investment bankers, and market analysts. The conference will kick off with a dinner on June 20.

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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