

Consumer Digital Health: Market Shift Is Leading to New Opportunities

By Steve Allan, CFA, Head of SVB Analytics, and Alex Lee, Manager, Life Science and Digital Health, SVB Analytics

The newest wave of consumer digital health investment focuses on applications encouraging consumers to change health-related behaviors, shifting from fitness/wellness to clinically driven solutions that lead to better health outcomes at lower

costs. This trend underscores why there are greater opportunities for companies with technologies that create value for payers, providers, employers, and consumers. SVB Analytics examined these trends in a recent report, *Consumer Digital Health: Market Shift Is Leading to New Opportunities*. This article provides a summary of the report's highlights.

Where in Consumer Digital Health Are Investors Focused?

Since 2011, investment in the digital health ecosystem has nearly quadrupled, with about half of the number of digital health investments made in companies with technologies that interface with the consumer. This reflects the convergence of technologies to drive and measure improved health

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Non-Dilutive Funding Sources for Medical Device and Biotechnology Companies

By Andrew Ellis, Associate (Palo Alto)

Readers of *The Life Sciences Report* are not strangers to the idea that securing investors for medical device and biotechnology companies is never easy. Anecdotal reports from our clients indicate that investors at every stage want more product or process advancement prior to a new investment than they did in past years. Although total dollars invested in the life sciences industries have increased over the last several years, the *MoneyTree Report* from

PricewaterhouseCoopers for the third quarter of 2016 showed a decline of 17 percent by value and 26 percent by volume on a year-over-year basis.¹ Whether or not that decline becomes a trend in 2017 is uncertain, but to help combat any potential fundraising headwinds, companies would benefit from examining (or re-examining) non-dilutive sources of funding to further advance product development and regulatory processes before their next investor pitch.

¹ The *MoneyTree Report* for the third quarter of 2016 is available at <http://pwchealth.com/cgi-local/hregister.cgi/reg/pwc-pharma-life-sciences-money-tree-q3-2016.pdf>.

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Consumer Digital Health: Market Shift Is Leading to New Opportunities

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outcomes and cost savings—and funding is following.

Consumer digital health, mapped in the chart below, includes a wide variety of products and services, from diabetes management applications to telemedicine services to platforms that help consumers find a doctor. In 2015, more than \$2.5 billion was invested in the sector, compared to roughly \$0.5 billion in 2011.

The advent of the quantified-self movement in the early 2010s attracted significant capital, especially in the fitness/wellness category. Today the targets of consumer digital health financing have changed. Investors are shifting from health insurance and provider search, as well as medical education and fitness/wellness applications, to more clinically focused areas. This focus includes disease management, remote monitoring, and patient-provider communications (outlined in blue in the chart below). Notably, the percentage of investment dollars allocated to clinically focused companies grew from 22 percent in

2011 to 49 percent in Q2 2016.

These companies are also seeing growth in early-stage funding: Early-stage financing for clinically focused companies quadrupled from \$79 million to \$329 million in the same period. By comparison, investments in consumer activation and the education and transparency segments have declined.

What Are the Best Clinical Application Opportunities?

Clinically focused areas of disease management and patient provider communications are seeing the largest increase in early-stage funding, indicating new start-up formation. At the same time, consumer activation companies and education and transparency companies are maturing with fewer early-stage rounds raised.

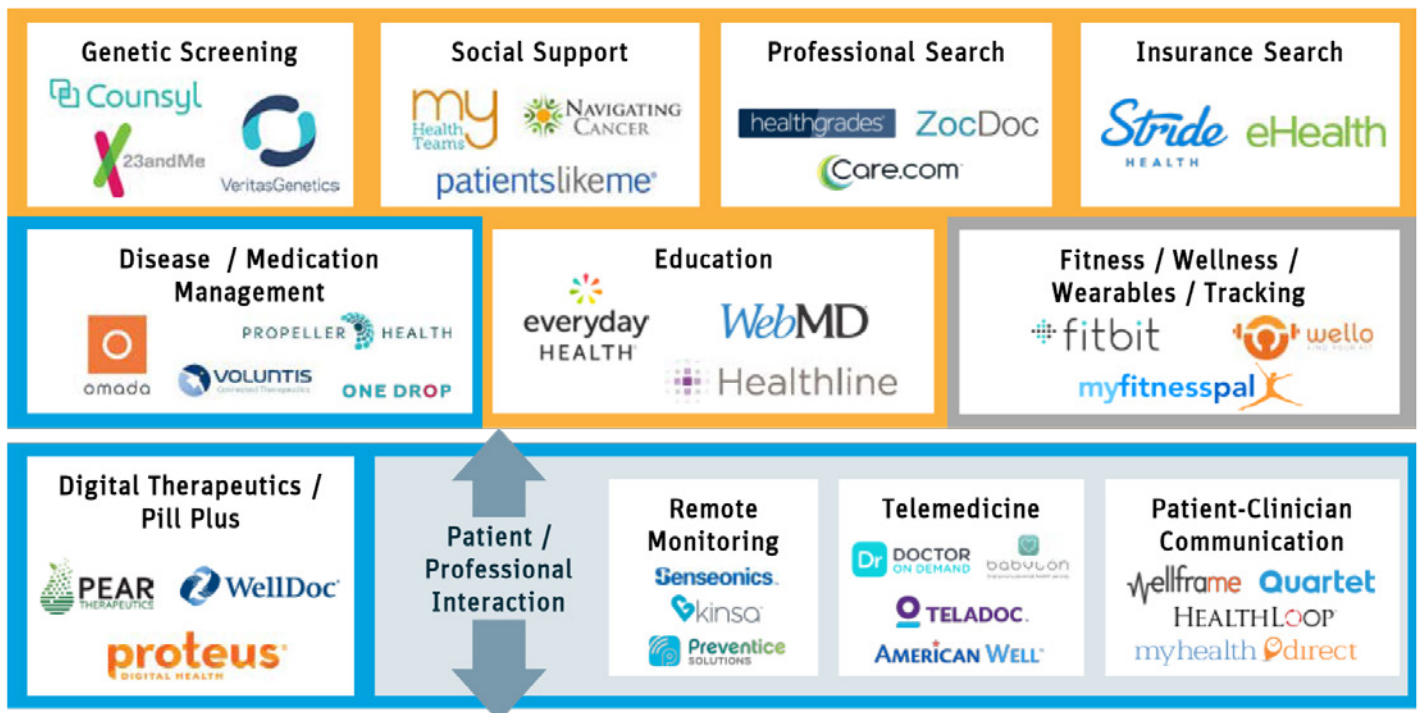
Looking ahead, degenerative and complex diseases, which are difficult to manage and account for a significant portion of U.S. medical expenditures, have received

comparatively lower digital health investment, signaling the space is ripe for disruption.

Since 2011, nearly half of the clinically focused investments have been made in behavioral change technologies (such as treating metabolic or psychiatric conditions). However, only 12 percent of investments have been made in companies focusing on degenerative and complex diseases (such as treating orthopedic, oncologic, and neurologic conditions). Yet in 2013, 33 percent of all medical expenditures were made in this segment. This suggests a potentially lucrative opportunity for technologies developed to treat these diseases, given the novelty of the area and lack of cost-effective solutions to manage them.

What Does the Future Hold for Digital Health Investing?

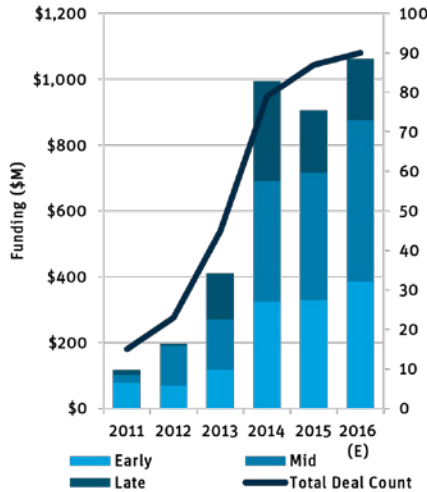
As investors move toward more clinically focused strategies, wearables and wellness companies are executing different strategies to adapt to this shifting landscape, including seeking acquirers and partners.



Investment Amount by Stage of Development (2011 – Q2 2016)

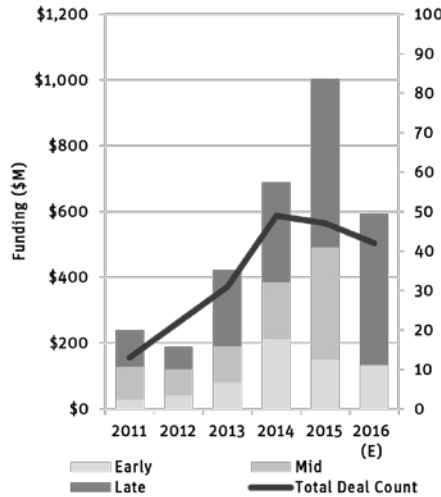
Clinical Enablement

Disease Management
Monitoring
Communications



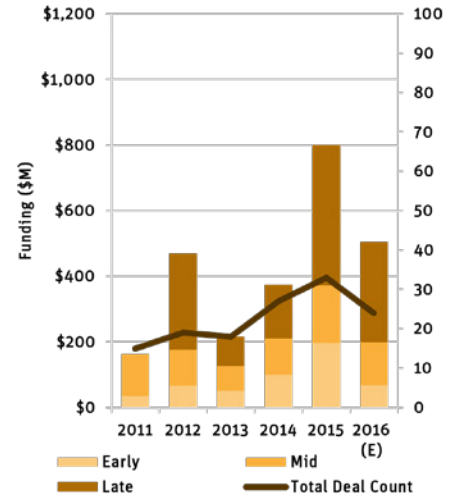
Consumer Activation

Fitness/Wellness



Education and Transparency

Medical Education
Provider Search
Insurance Search



* (E) represents estimated value. This is calculated by doubling the data from the first half of 2016.
Investment data is sourced from Pitchbook and Rock Health 2011-Q2 2016 and based on analysis by SVB Analytics.

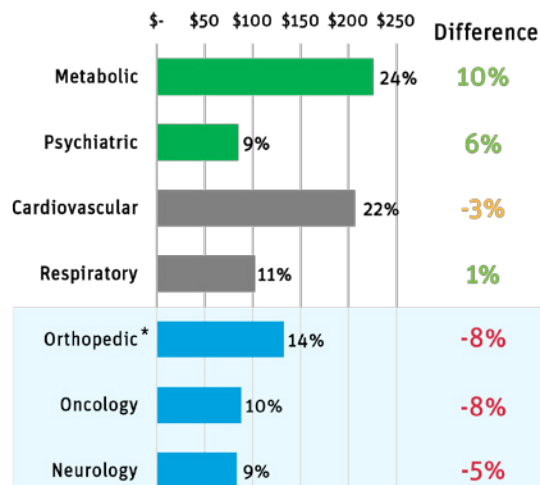
Going forward, as digital health companies create new solutions that target expensive and hard-to-manage diseases, we expect to see improved integration of hardware and software. As these solutions become more clinically focused, we envision the need for growing

coordination with payers, providers, and regulatory bodies. We also anticipate bigger investment opportunities in technologies that provide quantifiably positive health outcomes at lower costs.

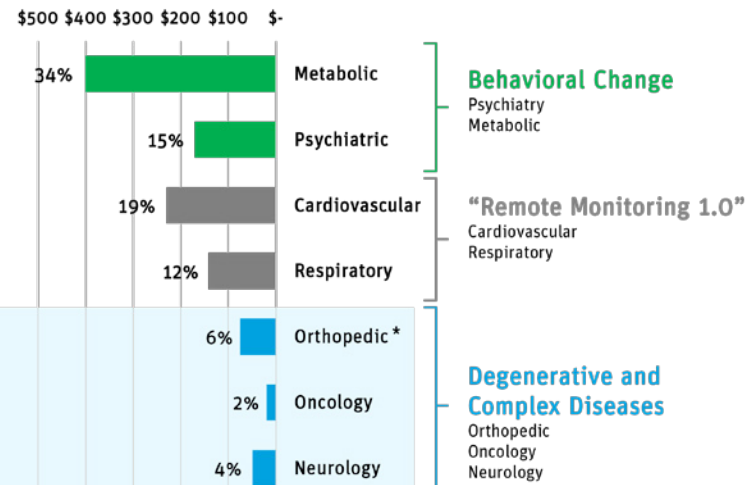
For more information, please see the full SVB Analytics Consumer Digital Health Report at www.svb.com/digital-health-report/. For more about SVB Analytics, please visit our website at www.svb.com/analytics/.

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Total Medical Expenditure, by Chronic Conditions in U.S. 2013 (\$B)



Total Investments in Disease Management and Remote Monitoring Sectors by Chronic Conditions in U.S. 2011-Q2 2016 (\$M)



*Excludes trauma or injury-related conditions

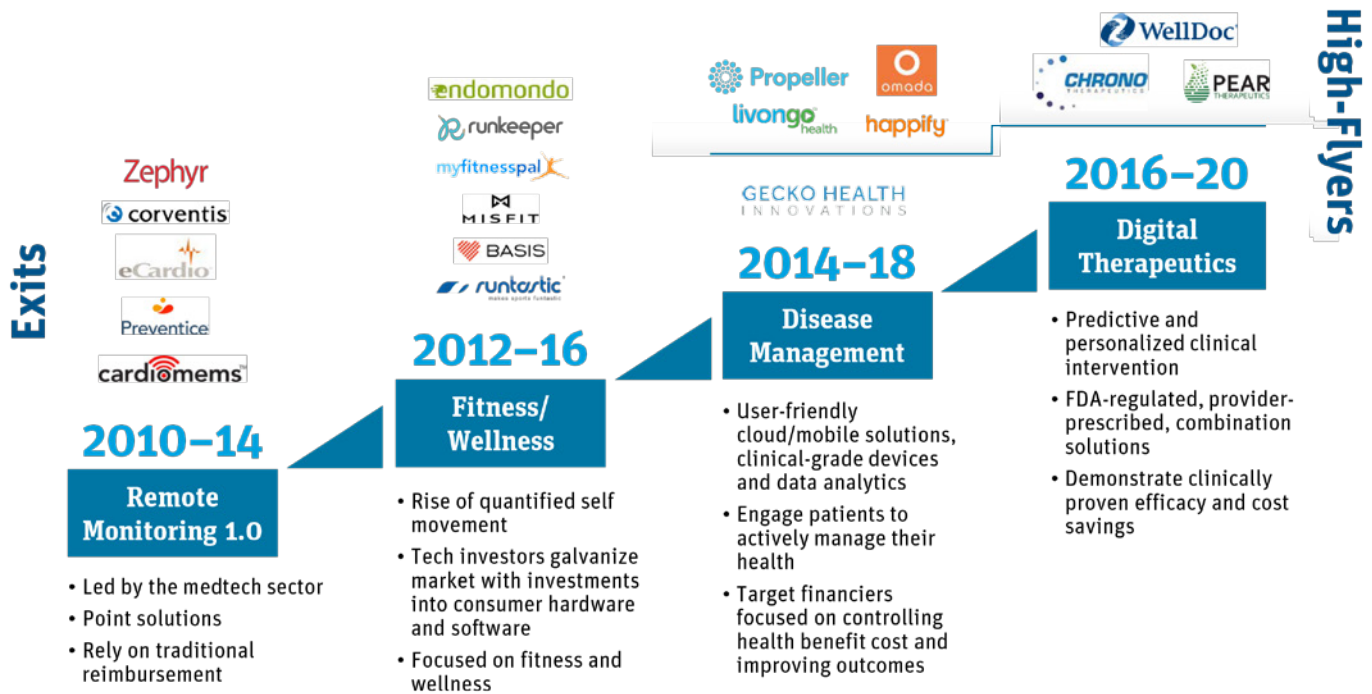
Behavioral Change
Psychiatry
Metabolic

"Remote Monitoring 1.0"
Cardiovascular
Respiratory

Degenerative and Complex Diseases
Orthopedic
Oncology
Neurology

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Steve Allan is the head of SVB Analytics, responsible for the three areas of information services provided to the innovation economy: Strategic Advisory Services, Compliance Valuations, and Insights. Strategic Advisory Services provides consultative guidance around valuations, benchmarking, and inorganic growth strategies. Compliance Valuations issues valuation opinions for private companies. Insight focuses on studying trends and opportunities in the private venture-backed innovation ecosystem. Steve brings a strong financial background and passion for entrepreneurship to his role at SVB Analytics.

Steve earned a master's in business administration from Duke University's Fuqua School of Business and a bachelor's degree in finance from the University of Notre Dame.



Alex Lee is a valuation manager at SVB Analytics, responsible for conducting due diligence and financial analysis on valuation engagements for venture-backed companies in the life science sectors.

Prior to joining SVB Analytics, Alex worked as a consultant for biopharmaceutical companies, diagnostic companies, and medical research institutions, assisting in corporate development, product commercialization, and strategic advisory activities. Alex holds a master's degree in bioscience from Keck Graduate Institute and a bachelor's degree in biochemistry from the University of Nebraska-Lincoln.

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Non-Dilutive Funding Sources for Medical Device and Biotechnology Companies

What Are the Benefits of Non-Dilutive Funding?

There are several benefits to obtaining non-dilutive funds, the most obvious of which is that such funds are not given in exchange for an equity stake, so founders are able to retain more voting control of the company. More relevant to companies preparing to raise money from venture capital is that the product or idea could be more mature and de-risked prior to fundraising because of the non-dilutive funds the company received. Utilizing these funds also shows potential investors that the company is resourceful and can accomplish a lot with its invested dollars. Finally, depending on the source of the funds, the company may also find advisors and partners that can help the company through their guidance and connections going forward.

When Should I Look into Non-Dilutive Funding?

It is really never too early to begin looking into potential sources of non-dilutive funding. In fact, non-dilutive funding can start before company formation for some companies. For example, research conducted in an academic setting can utilize basic research grants to de-risk a technology before the company is formed or help define the breadth of the future offering. Another benefit to addressing this issue prior to company formation is that certain government grants, such as specific National Institutes of Health (NIH) grants, can only be made to researchers or academic centers and not to companies. However, there are two primary risks to consider regarding this

pre-formation approach. First, in the academic setting, researchers will need to work with the center's technology transfer office to help ensure that they will be the one to eventually benefit from this grant money and effort. Second, researchers must pay close attention to the terms and limitations attached to the funds, especially as they relate to intellectual property and the use of funds.

One benefit of obtaining non-dilutive funds for companies preparing to raise money from venture capital is that the product or idea could be more mature and de-risked prior to fundraising

For the vast majority of readers who have already founded companies, there is also good news for you: it is almost never too late to be looking into sources of non-dilutive funding. Many funding sources are aimed at commercializing technologies or assisting early- and mid-stage companies during their development processes. Especially in the case of the NIH and other government sources, even large, multibillion-dollar companies apply for and obtain non-dilutive funding for certain research and development initiatives.

What Sources of Non-Dilutive Funding Are Available?

There are many sources of non-dilutive funding from state and federal governments, foundations, and private entities. A few of the most common categories and sources are listed below.

1. Government Grants

- a. NIH Grants. The largest and most well-known source of non-dilutive funds for life sciences companies are grants from the NIH. Despite popular belief, some NIH grants are accessible to companies in addition to academic institutions, especially R01 and R21 grants, and they can range from hundreds of thousands to millions of dollars.²
- b. SBIR/STTR Grants. Another common type of government grants are Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) grants. These grants are administered by several different government agencies, but the health-related grants are most commonly administered by the NIH. NIH-administered SBIR/STTR grants range from approximately \$150,000 for Phase 1 grants to approximately \$1,000,000 for a Phase 2 grant.³ The FDA and the CDC also grant SBIR/STTR funds through a separate application process.
- c. DoD Grants. The Department of Defense (DoD) is another active source

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²More information is available at <https://grants.nih.gov/grants/oeer.htm>.

³More information is available at <https://sbir.nih.gov/funding>.

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of non-dilutive funding for life sciences companies. In contrast to grants from the NIH and other government sources, DoD grants typically take the form of contracts. Many of these contract solicitations can be found at any given time on Grants.gov, and the connection to military uses is not always obvious. For example, a medical device company may be working on a device to be used

Despite popular belief, some NIH grants are accessible to companies in addition to academic institutions, and they can range from hundreds of thousands to millions of dollars

in the ER, and that device may attract DoD dollars because of its potential uses in battlefield applications. Similarly, devices and therapies related to prosthetics and psychology may be relevant to active military and veterans. The DoD also helps fund high-risk, high-reward technologies through the Defense Advanced Research Projects Agency (DARPA)⁴ and has earmarked an aggregate of around \$350 million for biomedical research through the Congressionally Directed Medical Research Programs (CDMRP) in several

areas that are announced annually in February.⁵

2. Private Foundations

Private foundations are increasingly present in life sciences investing, which has been a boon to the industry in recent years as government research dollars have stagnated. Private foundation investments and the terms attached to them vary widely in size, limitations, and disease areas depending on the foundation and its mission. For example, the Michael J. Fox Foundation is focused on finding a cure for Parkinson's Disease and funds researchers and companies through challenges, prizes, and other funding arrangements.⁶ The Bill and Melinda Gates Foundation focuses on global health (infectious disease, vaccines, etc.) through its Grand Challenges Program⁷ and other grant opportunities.⁸ Other active private foundations include Susan G. Komen (breast cancer),⁹ the Juvenile Diabetes Research Foundation (type I diabetes),¹⁰ the Cystic Fibrosis Foundation,¹¹ and the X Prize Foundation (various).¹² As with any source of funding, it is important in each case to carefully examine the terms and limitations that come with the investments; some may ask for intellectual property or may limit the use of funds to one particular project.

3. State Initiatives

States around the country have

announced programs to entice life sciences companies to start in or relocate to their state. Sometimes these take the form of seed or venture-style funds that invest in exchange for a convertible note with favorable terms, while others take the form of grants or tax credits.¹³ These benefits typically come with certain requirements to maintain a nexus to the state, such

Private foundations are increasingly present in life sciences investing, which has been a boon to the industry in recent years as government research dollars have stagnated

as the number of employees the company commits to hire in that state or maintenance of the company's principal place of business in that state. It would be worth a company's time to look into these types of opportunities in any state to which it has a nexus.

4. Incubators, Accelerators, and Innovation Centers

One benefit of the world's increased focus on healthcare in the last several years is the number of biotechnology and medical device incubators and

⁴ More information is available at <http://www.darpa.mil>.

⁵ More information is available at <http://cdmrp.army.mil>.

⁶ More information is available at <https://www.michaeljfox.org/research/apply-for-grant.html?navid=funding-opps>.

⁷ More information is available at <http://grandchallenges.org>.

⁸ More information is available at <http://www.gatesfoundation.org/How-We-Work/General-Information/Grant-Seeking-Resources>.

⁹ More information is available at <http://www5.komen.org/ResearchGrants/FundingOpportunities.html>.

¹⁰ More information is available at <http://grantcenter.jdrf.org>.

¹¹ More information is available at <https://www.cff.org/Our-Research/For-Researchers/Research-Awards/>.

¹² More information is available at <http://www.xprize.org/prizes>.

¹³ For examples of grants and tax credits, see <https://ventures.jhu.edu/tedco-gives-four-200k-grants-to-local-life-sciences-companies/> and <http://califesciences.org/connect2ca/incentives/state-incentives/>, respectively.

accelerators that have been formed around the country. Some offer non-dilutive funding in the form of grants¹⁴ or debt investments,¹⁵ and many offer other resources of value such as access

Some biotechnology and medical device incubators and accelerators offer non-dilutive funding in the form of grants or debt investments, and many offer other resources of value

to equipment, mentors, and providers at no additional cost to the company. The risks and benefits of these programs warrant separate discussion (perhaps in a future article), but great care should be taken to evaluate the terms of the investment, the alumni of the program, the available mentors and advisors, and any opportunity costs before joining one of these programs.

5. Industry Partnerships

Industry partnerships leading to non-dilutive funding sources can take many forms. One such form is granting a license or option to license certain intellectual property to a strategic corporate partner in exchange for a cash investment. Another common scenario is an infusion of cash from a strategic partner in exchange for a right of first negotiation in the event that the company is acquired by a competitor in the future. These transactions can be complex and have a tremendous impact on the future of the company, so competent legal counsel is imperative.

6. Venture Debt

Although it does not take the form of a grant and is by no means “free money,” venture debt can be a useful source of non-dilutive funding for companies. There are times when a bit more financial runway is needed to achieve a key milestone before a priced equity round should be pursued, and venture debt can be an effective means of getting there.

7. Other Sources

There are many other sources of non-dilutive funds that include grants from hospitals¹⁶ or cities¹⁷ and cash prizes for start-up competitions such as the MedTech Innovators Program¹⁸ that WSGR has partnered with for the last several years at our annual Medical Device Conference.¹⁹

The above represents only a few of the many sources of non-dilutive funding that are available to companies. If you would like to discuss any of the above issues further or need assistance structuring a financing of any type, please feel free to contact a member of Wilson Sonsini Goodrich & Rosati’s life sciences practice.



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¹⁴ For example, see <http://onestart.co/about>.

¹⁵ For example, see <http://www.fogartyinstitute.org/innovation-faq.php>.

¹⁶ For example, see <http://www.childrensinnovations.org/Pages/TechnologyDevelopmentFund/ProofofConceptGrant.aspx>.

¹⁷ For example, see <http://www.nycedc.com/industry/life-sciences>.

¹⁸ More information is available at <http://medtechinnovator.org>.

¹⁹ Our 25th Annual Medical Device Conference is on Friday, June 2, 2017, at the Palace Hotel in San Francisco. For more information, please contact Michelle Watkins at mnwatkins@wsgr.com.

Utility Models and Design Patents: What You Should Know

*By Darby Chan, Associate (Palo Alto), and
Doug Portnow, Partner (Palo Alto)*

Most inventors are aware of the importance of filing utility patent applications, through which protection of devices, methods, compounds, software, and so on is pursued and obtained. While there are many advantages to utility patent applications, there are also other types of patent applications that can provide a different set of advantages for protecting an invention. Two such commonly overlooked types of patent applications are utility models and design patents.

Utility Model Patents

Utility model patents protect the structure and/or function of an invention much like traditional utility patents. They are more quickly and less stringently examined, often only needing to undergo a registration-like process. In exchange for faster examination and issuance, patent term is much shorter, and while utility models are available in many important international markets, they are not available in the U.S. Despite these limitations, utility model patents remain very powerful in specific circumstances.

While not available in the U.S., utility model patents are available in key international markets such as Australia, China, France, Germany, Italy, Japan, and Korea. If significant commercial activity (e.g., product development, sales, and manufacturing) is anticipated in these countries, utility model patent filings may be worth considering. Because a key advantage of the utility model is a short examination process, such filings should be considered particularly if the commercial activity is ongoing or anticipated shortly and enforceable patent rights are desired sooner rather than later.

In terms of content, the requirements for utility model patents and traditional patents are essentially the same. There needs to be a written description of the invention, accompanying drawings, and a set of claims that define the legal right of the patent. Hence, the cost of preparing the utility model filing is often in the same range as the cost for a traditional utility patent application—\$15,000 to \$25,000. However, rather than undergoing a lengthy and stringent examination process as with utility patent applications, utility model patent applications are more loosely examined and typically undergo only a registration-like process. With lower costs of examination, the aggregate cost of obtaining a utility model patent is much less—low five figures or less versus mid-to-high five figures or more (in U.S. dollars).

Once a utility model patent is obtained, it can be enforced for approximately the next six to fifteen years, depending on where it was granted and the amount of time examination had required. The patent term available is much less than the typical 20 years available from utility patents. Therefore, utility model patents may not be appropriate for inventions where longer patent term is important, such as biopharmaceuticals and significant medical innovations. On the other hand, the lower cost, quicker examination, and shorter patent term may be justified for incremental innovations, such as improvements to manufacturing processes and ancillary features in products and processes, or for industries where product cycles are very short.

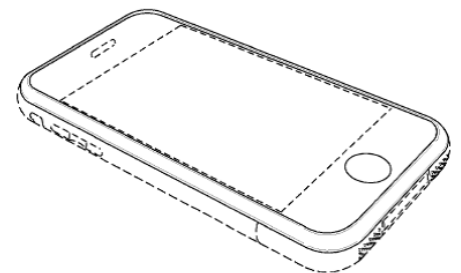
There are also differences in the enforcement of utility model patents and utility patents. Because utility patents have undergone a lengthy and stringent examination process, they are presumed valid. And, the alleged infringer of the patent has the burden of

showing that the patent is invalid. This concept does not apply completely to utility model patents. If an owner of a utility model patent sues an alleged infringer, they typically will have the burden of proving that the invention protected is novel, non-obvious, and therefore patentable. In other words, the burden and costs of establishing patentability for utility model patents are back-loaded but optional in a sense. As a result, it is often recommended that inventors and their patent counsel carefully research and evaluate the merits of their invention prior to the initial preparation and filing of a utility model patent application.

The table on page 9 summarizes some of the key aspects of a utility model.

Design Patents

Design patents are patents that protect the appearance or ornamental design of an object. Some well-known examples are the Apple iPhone in Figure 1 below and the Coca-Cola contour bottle in Figure 2 on page 10.



**Figure 1: Apple iPhone,
U.S. Design Patent No. D593,087**

Utility Models and Design Patents: What You Should Know

Patent Types – Utility vs. Utility Model vs. Design

	Utility Patent	Utility Model Patent	Design Patent
Rights Provided	Structural and/or functional aspects of an invention	Structural and/or functional aspects of an invention	Appearance and/or ornamental design of an invention
Term	Generally 20 years from filing date	6-15 years from filing date, typically 10	U.S.: 14-15 years from grant, depending on filing date Others: 5-25 years
Cost	Approximately \$25,000 to \$75,000 (~\$15,000 to \$25,000 to prepare the original filing)	Approximately \$15,000 to \$30,000 (~\$15,000 to \$30,000 to prepare the original filing)	Approximately \$3,000 to \$5,000 to prepare and file the application Nominal prosecution costs Annuity and maintenance fees may apply
Availability	Generally worldwide	Many jurisdictions (e.g., Australia, China, France, Germany, Italy, Japan, South Korea, Spain, Taiwan) Non-available: U.S.	Many jurisdictions (e.g., U.S., China, Japan, South Korea, Europe, Canada, South Africa)
Examination Requirements	Strictly examined for subject matter eligibility, utility, novelty, and inventiveness/obviousness of invention	Registration-like process with a focus on formalities Greater restrictions on eligible subject matter	Examined for novelty and non-obviousness of design
Time to Process Through Patent Office	Generally 2-5 years	Generally 6-12 months	Approximately 1-2 years (U.S.)
Applying from PCT	Generally available worldwide (notable exception: Taiwan)	Generally available worldwide, but in fewer jurisdictions Some jurisdictions (e.g., China) may require a binary choice between utility and utility model applications from single PCT	Generally available
Enforcement	Presumed valid Burden of proof (for invalidity) on alleged infringer	Patent owner may be required to show novelty and inventiveness Burden of proof (validity) generally on patent owner	Infringed if an ordinary observer believes the allegedly infringing design is “substantially the same” design Burden of proof (for invalidity) on alleged infringer
Consider Filing If:	Longer patent term important (e.g., technology core to the business or business space, medical device inventions, biopharmaceutical/bio-technology inventions) Significant activity in U.S. Issued patent not immediately desired (but consider programs for accelerated/prioritized examination)	Longer patent term unimportant (e.g., consumer products, manufacturing) Issued patent immediately desired (e.g., competitors are acting in your space already, need to show investors issued IP) Cost-consciousness Insignificant activity in U.S.	Ornamental/aesthetic aspect of invention is key commercial advantage Quick patent protection desired Low cost desired Consider filing with utility/utility model patent applications concurrently

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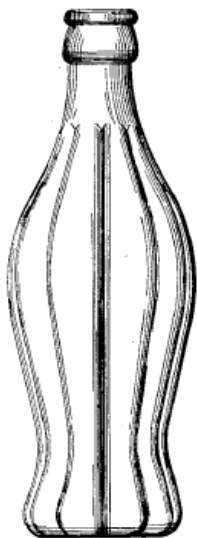


Figure 2: Coca-Cola contour bottle, U.S. Design Patent No. D48,160

It is important to emphasize that a design patent only protects the aesthetics of the design, and not any of the functional aspects of an invention. An example of this might be a new aerodynamically shaped component of an aircraft. Because the shape of this component was designed for aerodynamic purposes, it is functional and therefore would not be protectable with a design patent. On the other hand, the shape of the Coca-Cola contour bottle was designed for aesthetic reasons, not functional reasons, and therefore the bottle was patentable. Functional aspects are protected with a traditional utility patent application or a utility model patent. Thus, if the shape or look of the product is related to a functional aspect, a design patent cannot be pursued.

The United States and many other jurisdictions such as China, Japan, South Korea, Europe, Canada, and South Africa provide for design patents. Design patents often can be obtained faster and at significantly less cost than traditional utility patents. For example, in the United States, a design patent may be obtained in approximately one to two years, and the cost for filing the application may range from about \$3,000 to \$5,000, with the majority of the cost coming from obtaining high-quality illustrations of the various views of the product. This

amount is in contrast to the \$15,000 to \$25,000 it may cost to prepare and file a traditional utility patent. Examination of a design patent is typically based on novelty and non-obviousness of the design.

Infringement of a design patent in the United States is based on whether an ordinary observer believes that the allegedly infringing design is substantially the same as the patented design. Therefore, design patents generally provide protection against knock-off products, but a competitor may make simple ornamental feature changes in order to easily get around a design patent. As a result, protection can be somewhat limited. Nevertheless, historically a design patent still could be a powerful form of protection because damages were calculated differently than in a utility patent infringement case. Until recently, damages in a design patent case were based on the entire profits of the infringing design, as opposed to only a portion of the profits that are covered by an invention in a utility patent infringement case. As an example, Apple was previously awarded approximately \$400 million in a lawsuit with Samsung based on the enforcement of several design patents. However, just recently, the U.S. Supreme Court rejected this traditional view of design patent damages, and the Samsung award was tossed out. The Supreme Court ruled that damages may be based on individual components covered by a design patent rather than the entire product. The Court failed to provide further specifics on the issue, and it will now take additional court rulings to clarify the ambiguity.

While these factors certainly are in favor of filing design patents, it is important to note that the term of a design patent is typically shorter than that of a utility patent. For example, in the United States, a design patent is valid for 14 or 15 years from the time of grant, depending on when it was filed. In other countries, a design patent may be valid for as short as five years and as long as 25 years.

The preparation of a design patent is fairly straightforward. A design patent application includes a single claim and a series of

drawings to show the various views of the design (e.g., top, bottom, sides, and perspective). In the United States, there is a six-month grace period to file a design patent after a public disclosure, but an inventor should not rely on this grace period since it may not be applicable in foreign jurisdictions.

In sum, inventors should consider pursuing design patents in order to protect the ornamental features of their designs. Design patents can be obtained relatively quickly and at lower cost than traditional utility patents. While design patents potentially may provide less protection than utility patent applications, damages can be significantly higher. Inventors should therefore consider both utility patent applications to protect the functional aspects of their invention and design patents to protect the ornamental features of their invention.

The table on page 9 summarizes some of the key features of a design patent.

Conclusion

Inventors and businesses should consult with their legal counsel to determine the commercially significant aspects of their innovations, discuss market entry and commercial partnership strategies, and ultimately align their patent filing strategy with these business needs. Utility model patents and design patents may be considered in addition to utility patents, and the countries that are selected for patent filings should be carefully considered as well.



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Effective Regulatory Strategies: Tapping into FDA Expedited Review Programs

By David Hoffmeister, Partner (Palo Alto), and Charles Andres, Associate (Washington, D.C.)

Effective regulatory strategies are important success drivers for drug and medical device companies. They have several components and:

- sync seamlessly and synergistically with patent strategies;
- realize all available U.S. Food and Drug Administration (FDA) regulatory exclusivities;
- play a significant role in maximizing product life span (as part of lifecycle management);
- minimize costs, resources, and time devoted to clinical development; and
- shorten FDA review times and result in successful FDA clearance or allowance.

In this article, we provide an introduction to four important FDA programs that are designed to help expedite drug and medical device development and market entry.¹ These programs should always be evaluated when designing effective regulatory strategies.

Fast Track Designation (Applies to Drugs)

There are two ways for a drug to qualify for Fast Track designation: (1) a drug candidate must be intended to treat a serious medical condition and have associated data (clinical or non-clinical) that demonstrates the drug's potential to address an unmet medical need, or (2) a drug candidate must have been

designated as a qualified infectious disease product (QIDP).²

Fast Track designation comes with several advantages, including frequent interactions with the FDA's designated product review team to discuss clinical study design, dose-response concerns, biomarker use, and the extent of data required to show safety for the drug candidate. Based on a preliminary evaluation of clinical data, the FDA may additionally determine that the drug candidate is eligible for Priority Review (see below discussion). For the period 1998-2010, approximately 36 Fast Track-designated drugs were approved in the FDA's Center for Drug Evaluation and Research (CDER).³ Included among these approvals are the drugs darunavir (for treating AIDS), sorafenib tosylate (for treating renal cell carcinoma), and levofloxacin (for treating post-inhalation anthrax exposure).⁴ Based on their clinical data, Fast Track-designated drugs may also be eligible for rolling review—where the FDA reviews each section of a non-disclosure agreement (NDA) or biologics license application (BLA) as it is ready—rather than waiting for the whole NDA or BLA to be assembled and submitted.

Fast Track designation does not change the standard required for approval, which is substantial evidence of safety and effectiveness from two Phase 3 well-controlled clinical trials, or one large, well-controlled Phase 3 study (usually reserved for biological products).

Priority Review Program (Applies to Drugs)

Similar to the Fast Track Program, a drug candidate may qualify for Priority Review, under which the FDA sets the target date for FDA action on an NDA or BLA at six months after the FDA accepts the application for filing. Priority Review is granted when there is evidence that the drug candidate would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for Priority Review, the application is subject to the standard FDA review period of 10 months after the FDA accepts the application for filing. Priority Review designation does not change the scientific/medical standard for approval or the quality of the evidence necessary to support approval. In 2015, 24 novel drugs approved by the FDA were given Priority Review.⁵ These drugs included alectinib (for treating non-small cell lung cancer) and eftazidime/avibactam (a fixed-dose combination drug containing a novel non- β -lactam β -lactamase inhibitor for treating bacterial infections).^{6,7}

Accelerated Approval Program (Applies to Drugs)

To qualify for the Accelerated Approval Program, a drug candidate must treat a serious or life-threatening disease or condition and such treatment must provide a meaningful advantage over available therapy. Drugs approved under the Accelerated

Continued on page 12...

¹ The FDA has issued guidance for these four expedited programs. See <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>.

² QIDP designation comes out of the Generating Antibiotic Incentives Now Act (The GAIN Act). The GAIN Act incentivizes the development of antibiotics and recites specific strains of bacteria. If an antibiotic in development targets one of the recited bacterial strains, the antibiotic can get QIDP designation. However, designation is not limited to drugs targeting these bacterial strains. Thus, if a company is developing an antibiotic or antiviral drug, it is worth determining whether the drug can be QIDP designated and therefore automatically put on the FDA's Fast Track.

³ See <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/UCM216527.pdf>.

⁴ *Id.*

⁵ See <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm>. A small number of these drugs were granted Priority Review through redemption of a Priority Review voucher and thus may have been exempt from the requirement to provide a significant advance.

⁶ *Id.*

⁷ Fixed-dose combination drugs containing a novel active ingredient (i.e., an active ingredient not previously approved under the Federal Food, Drug, and Cosmetic Act (FDCA)) are now eligible for new chemical entity (NCE) five-year FDA regulatory exclusivity upon FDA approval.

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Approval Program are conditionally approved by the FDA based on surrogate endpoint, which is an endpoint that is considered reasonably likely to predict clinical benefit or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit.⁸ An example of a surrogate endpoint for a cancer drug candidate would be a reduction in tumor mass or volume. For drugs granted Accelerated Approval, post-marketing clinical trials (Phase IV trials) are required to be completed with due diligence to show drug effect on IMM or other clinical benefit. The FDA may withdraw approval of an Accelerated Approval drug if the post-marketing trials fail to verify the expected effect on IMM or expected clinical trial benefit. According to one study, five drugs were withdrawn over the period 2005-2011 after having been approved as Accelerated Approval drugs.⁹ Drugs approved under the Accelerated Approval Program in 2015 include venetoclax (a small-molecule drug for treating chronic lymphocytic leukemia in a specific patient population) and atezolizumab (an anti-cancer antibody).¹⁰

Breakthrough Therapy Designation (Applies to Both Drugs and Medical Devices)

In order to qualify as a Breakthrough Therapy drug candidate, a product must demonstrate preliminary clinical evidence (alone or in combination with other drugs) of substantial improvement over existing therapies on one or more clinically significant endpoints. After receiving the request, the FDA has 60 calendar days to either grant or deny the request.

A Breakthrough Therapy designation conveys all of the Fast Track Program features, provides

more intensive FDA personnel interaction, and includes an organizational commitment by the FDA to involve its senior management in the development program, and eligibility for rolling and Priority Review. Specifically, the following actions, where appropriate, are required by the agency:

- Holding meetings with the sponsor and the review team throughout the development of the drug
- Providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program is as efficient as practicable
- Taking steps to ensure that the design of the clinical trials is as efficient as practicable, including minimizing the number of patients exposed to a potentially less efficacious treatment
- Assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the cross-discipline members of the review team for coordinated internal communications
- Involving senior managers and experienced review staff in a collaborative, cross-disciplinary review

Drugs approved under Breakthrough Therapy designation in 2016 include nivolumab (an anti-cancer antibody) and atezolizumab (an anti-cancer antibody checkpoint inhibitor).¹¹

With President Obama's signing of the 21st Century Cures Act into law in December 2016, medical devices are also eligible for Breakthrough designation. Section 3051 of the act creates priority review for Breakthrough-designated¹² medical devices. To qualify, a

medical device must: (1) provide for more effective treatment or diagnosis¹³ of a life-threatening or irreversibly debilitating human disease or condition, and (2) represent a breakthrough technology: (a) for which no approved or cleared alternatives exist; (b) that offers significant advantages over existing approved or cleared alternatives;¹⁴ or (c) where availability of the device is in the best interests of patients. These qualification criteria give the FDA broad latitude in assigning Breakthrough designation.

Breakthrough designation for medical devices comes with a variety of benefits, including: assigning an experienced FDA team to the review, providing for team oversight by senior agency personnel, adopting efficient processes for timely dispute resolution, and providing for timely, interactive communication with the FDA during device development and review.

Conclusion

Today more than ever, it is important that drug and medical device developers craft efficient and effective regulatory strategies. An important part of this process is to properly utilize FDA programs for expediting development and approval.



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⁸ See <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>.

⁹ See [http://www.valueinhealthjournal.com/article/S1098-3015\(14\)00137-5/abstract](http://www.valueinhealthjournal.com/article/S1098-3015(14)00137-5/abstract).

¹⁰ See <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM404466.pdf>.

¹¹ See <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM494010.pdf>.

¹² Designation requests may be made before application submission, notification, or a petition for classification. The act specifies that the FDA should make a designation determination no later than 60 days after submission of a request.

¹³ 510(k), *de novo*, and premarket approval devices may be eligible for Breakthrough designation and Priority Review.

¹⁴ Significant advantages can include: reducing or eliminating hospitalization; improving patient quality of life; facilitating patients' ability to manage their own care; and establishing long-term clinical efficiencies.

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 2015 and the first half of 2016. 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 2015 Number of Closings	2H 2015 Total Amount Raised (\$M)	2H 2015 Average Amount Raised (\$M)	1H 2016 Number of Closings	1H 2016 Total Amount Raised (\$M)	1H 2016 Average Amount Raised (\$M)
Biopharmaceuticals	20	181.21	9.06	31	420.39	13.56
Genomics	4	32.64	8.16	5	31.01	6.20
Diagnostics	4	33.02	8.25	8	37.84	4.73
Medical Devices & Equipment	27	215.73	7.47	48	309.39	6.45
Digital Health	7	65.83	3.34	10	40.18	4.02
Healthcare Services	3	97.40	32.47	4	8.24	2.06
Total	65	625.83		106	847.05	

The data demonstrates that venture financing activity increased significantly during the first half of 2016 compared to the second half of 2015 with respect to the total amount raised and the number of closings. Specifically, the total amount raised across all industry segments increased 35.3 percent from the second half of 2015 to the first half of 2016, from \$625.83 million to \$847.05 million, while the total number of closings across all industry segments increased 63.1 percent, from 65 closings to 106 closings.

Notably, the industry segment with the largest number of closings—medical devices and equipment—experienced an increase in both number of closings and total amount raised during the first half of 2016 compared to the second half of 2015. Specifically, the number of closings in medical devices and

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equipment increased 77.8 percent, from 27 closings to 48 closings, while the total amount raised in the segment increased 43.4 percent, from \$215.73 million to

\$309.39 million. Similarly, the industry segment with the second-largest number of closings—biopharmaceuticals—experienced an increase in both number of closings and total amount raised: the number of closings increased 55 percent, from 20 closings to 31 closings, and the total amount raised increased 132 percent, from \$181.21 million to \$420.39 million. Meanwhile, the industry segment with the fourth-largest number of closings—diagnostics—also experienced an increase in both number of closings and total amount raised. Specifically, diagnostics experienced a 100 percent increase in number of closings, from four closings to eight closings, and a 14.6 percent increase in total amount raised, from \$33.02 million to \$37.84 million. All remaining industry segments (in descending order of number of closings)—digital health, genomics, and

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Our data suggests that Series A financing and bridge financing activity compared to Series B and later-stage equity financings and recapitalization financings increased during 1H 2016 compared to 2H 2015

healthcare services—were up in number of closings but down in total amount raised during the first half of 2016 compared to the second half of 2015.

In addition, our data suggests that Series A financing and bridge financing activity compared to Series B and later-stage equity financings and recapitalization financings increased during the first half of 2016 compared to the second half of 2015. Specifically, the number of Series A closings as a percentage of all closings increased from 29.2 percent to 31.8 percent, while the number of bridge financing closings as a percentage of all closings increased from 26.2 percent to 31.8 percent. Offsetting those gains, Series B financing, Series C and later-stage financing, and recapitalization financing activity compared to all other financings decreased during the first half of 2016. The number of Series B closings as a

percentage of all closings decreased from 18.5 percent to 15.9 percent; the number of Series C and later-stage financing closings as a percentage of all closings decreased from 21.5 percent to 15 percent; and the number of recapitalization financing closings as a percentage of all closings decreased from 4.6 percent to 1.9 percent.

Average pre-money valuations for life sciences companies decreased for Series A financings, but increased at later stages of financing during the first half of 2016 compared to the second half of 2015. The average pre-money valuation for Series A financings decreased 50.7 percent, from \$22.04 million to \$10.86 million; the average pre-money valuation for Series B financings increased 197.5 percent, from \$35.36 million to \$105.2 million; and the average pre-money valuation for Series C and later-stage financings increased 43.9 percent, from \$84.07 million to \$120.97 million.

Other data taken from transactions in which all firm clients participated in the first half of 2016 suggests that life sciences is the third-most attractive industry for investment. For the first half of 2016, life sciences represented 22 percent of total funds raised by our clients, while the software industry—traditionally the most popular industry for investment—represented 23 percent of total funds raised. Services represented 28 percent of total funds raised.

Overall, the data indicates that access to venture capital for the life sciences industry increased during the first half of 2016 compared to the second half of 2015. It is also worth noting that financing activity

The first half of 2016 marked the second straight six-month period of improved financing

during the second half of 2015 had increased marginally over the first half of 2015, so the first half of 2016 marked the second straight six-month period of improved financing activity. Moreover, while activity during the second half of 2015 was concentrated around later-stage financings, activity during the first half of 2016 was concentrated around Series A and bridge financings—a welcome change for entrepreneurs who for so long have struggled to raise capital at the earlier stages. Of course, the improved early-stage financing activity does not come free, as evidenced by the decline in Series A pre-money valuations to more traditional levels.



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WSGR Hosts 23rd Annual Phoenix Conference

On October 5-7, 2016, Wilson Sonsini Goodrich & Rosati hosted the 23rd annual Phoenix Conference at the Montage Laguna Beach in Laguna Beach, California. The exclusive event brought together 170 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, as well as to network and gain valuable insights from industry leaders and peers.

The two-day conference featured presentations on a broad range of topics, including new sources of medtech funding, the identification of commercialization strategies, vulnerabilities in medical device companies' risk assessment, medtech company exit strategies, and the 2016 election's implications for investors. The event also included a lunch featuring Bob Pearson, president of W2O Group, who discussed a new form of marketing called "storytizing" that enables companies to identify target audiences—whether they're medical providers, advocates, patients, caregivers, or journalists—with precision. In addition, as part of the conference's Corporate Spotlight series, Bryan Hanson, EVP and president of Medtronic's Minimally

Invasive Therapies Group, offered insight into the opportunities and challenges that device companies currently face and the dynamics driving the industry.



on the evening of October 6. NeoTract's UroLift System, which treats benign prostatic hyperplasia (BPH), was honored with the "Most Promising New Product" award, and Glaukos, an ophthalmic medical technology company focused on the development of products and procedures designed to treat glaucoma, was presented

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

with the "Emerging Growth Company" award. Fred Khosravi, a Silicon Valley medical device entrepreneur, received the Phoenix Innovator Award, while William Link, Ph.D., co-founder and managing director at Versant Ventures, was named the Lifetime Achievement Award recipient.



Recent Life Sciences Client Highlights

Sumitomo Dainippon Pharma to Acquire Tolero Pharmaceuticals

On December 21, Japan-based Sumitomo Dainippon Pharma Co., Ltd. announced that it has reached an agreement with Utah-based Tolero Pharmaceuticals to acquire the company. Under the terms of the agreement, Sumitomo Dainippon Pharma will make an upfront payment of \$200 million to Tolero shareholders upon the closing of the acquisition, and thereafter will make development milestone payments up to \$430 million related to the compounds under development by Tolero based on its progress. Further, after the launch, Sumitomo Dainippon Pharma will make commercial milestone payments up to \$150 million based on the net sales of the compounds. WSGR is representing Tolero in the transaction. For more information, please visit http://www.ds-pharma.com/pdf_view.php?id=523.

Response Biomedical Completes Going-Private Transaction

On November 29, Response Biomedical, a developer and manufacturer of rapid on-site diagnostic tests, announced that the previously announced acquisition of all the issued and outstanding common shares of Response by 1077801 B.C. has been completed. Response shareholders will receive \$1.12 per share and Response will become a wholly owned subsidiary of 1077801 B.C. WSGR represented Response Biomedical in the transaction. For further details, visit <http://www.marketwired.com/press-release/response-biomedical-corp-completes-going-private-transaction-tsx-rbm-2179316.htm>.

Shockwave Medical Raises \$45 Million in Series C Financing

Shockwave Medical, a pioneer in the treatment of calcified cardiovascular

disease, announced on November 22 the closing of \$45 million in Series C financing led by Sectoral Asset Management with participation from mutual funds advised by T. Rowe Price Associates and returning investors including Sofinnova Partners, Venrock, RA Capital, Deerfield, Ally Bridge Group, and others. The proceeds will be used to advance the development of the company's Lithoplasty balloon catheter platform and to expand commercialization of the technology for the treatment of peripheral vascular disease in both the U.S. and the European Union. WSGR represented Shockwave Medical in the transaction. For more information, see <http://shockwavemedical.com/wp-content/uploads/2016/11/Shockwave-Medical-Series-C-FINAL.pdf>.

PTAB Confirms Patentability of Paragon's Claims in Post-Grant Review

On November 14, the Patent Trial and Appeal Board confirmed in a post-grant review (PGR) that all claims of Paragon BioTeck's U.S. Patent No. 8,859,623 are patentable—the first final written decision in a PGR determining that the challenged claims are patentable. The '623 patent is directed to ophthalmic preparations of phenylephrine and, in particular, to a method for ensuring that patients receive phenylephrine solutions that are both chirally pure and free of phenylephrine degradation products. Paragon submitted a New Drug Application to the FDA for these previously grandfathered preparations, which included the claimed method and was approved, leading to an Orange Book listing for the '623 patent. Altaire Pharmaceuticals had previously petitioned for PGR of all claims of the '623 patent, alleging that they are unpatentable as obvious. WSGR is representing Paragon BioTeck in the matter. For more information,

please see <https://www.wsg.com/WSGR/Display.aspx?SectionName=clients/1116-paragon.htm>.

Zipline Raises \$25 Million in Series B Financing

Zipline International, a start-up that builds drones and runs delivery services dropping crucial medical supplies to clinics or hospitals in areas that aren't accessible by land, announced on November 9 that it has raised \$25 million in a Series B round of financing to expand its humanitarian delivery drone business in Rwanda, the U.S., and beyond. WSGR represented Zipline in the transaction. Additional information is available at <http://venturebeat.com/2016/11/09/drone-delivery-startup-zipline-raises-25-million-from-sequoia-andreessen-horowitz/>.

iRhythm Technologies Announces Pricing of Initial Public Offering

iRhythm Technologies, a leading digital health care solutions company focused on the advancement of cardiac care, announced the pricing of its initial public offering of 6,294,118 shares of its common stock at a price to the public of \$17.00 per share on October 19. The company's shares began trading on the Nasdaq Global Select Market on October 20 under the ticker symbol "IRTC." Wilson Sonsini Goodrich & Rosati advised iRhythm in the offering. For more information, please see <http://www.irhythmtech.com/news/iRhythm-Technologies-Announces-Pricing-of-Initial-Public-Offering.php>.

Rici Healthcare Completes IPO and Listing on the HKSE

On October 6, Rici Healthcare Holdings Limited, a leading private general medical services group in China's Yangtze River Delta

region, announced that it has completed its IPO and has been listed on the Main Board of the Stock Exchange of Hong Kong. The offering included a total of 397,600,000 shares, comprised of 318,080,000 new shares and 79,520,000 sale shares, subject to the overallotment option, with gross proceeds of approximately \$104 million. WSGR acted as Hong Kong and U.S. legal counsel to Rici Healthcare in connection with the transaction. Please see <https://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/1016-rici.htm> for additional details.

Akarna Therapeutics Acquired by Allergan

Akarna Therapeutics, a biopharmaceutical company focused on developing novel small molecule therapeutics that target inflammatory and fibrotic diseases, announced on September 20 that it has been acquired by Allergan, a leading global pharmaceutical company. Under the terms of the agreement, Allergan acquired Akarna for an upfront payment of \$50 million, as well as potential clinical, regulatory, and commercial milestone payments. WSGR represented Akarna in the transaction. More information is available at <http://www.allergan.com/news/news/thomson-reuters/allergan-acquires-akarna-therapeutics-adding-to-it>.

Hebei Welcome and NCPG Prevail in Closely Watched Vitamin C Antitrust Litigation

On September 20, the U.S. Court of Appeals for the Second Circuit issued its decision in a closely watched dispute that may be the largest-ever antitrust case involving Chinese companies. The plaintiffs alleged that two Chinese companies, Hebei Welcome Pharmaceutical Co. and North China Pharmaceutical Group (NCPG), along with several alleged co-conspirators, had engaged in price-fixing in violation of U.S.

antitrust laws in connection with vitamin C exported from China. The primary issue was whether the Chinese government had required the challenged conduct. The Second Circuit said that because the Chinese government filed a formal statement in the district court asserting that Chinese law required the defendants to set prices and reduce the quantities of vitamin C sold abroad, and because the Chinese companies could not simultaneously comply with Chinese law and U.S. antitrust laws, the district court should not have exercised jurisdiction of the case. The Second Circuit therefore vacated the district court judgment, reversed the district court's denial of the defendants' motion to dismiss on international comity grounds, and remanded the case with instructions to dismiss the plaintiffs' complaint with prejudice. WSGR represented Hebei Welcome and NCPG before the Second Circuit. For more details, see <https://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/0916-hebei.htm>.

FEI Company Acquired by Thermo Fisher Scientific

Thermo Fisher Scientific, a world leader in serving science, announced on September 19 that it has completed its \$4.2 billion acquisition of FEI Company, a leader in high-performance electron microscopy. The completion of the transaction followed the receipt of all required regulatory approvals, and the business will become part of Thermo Fisher's Analytical Instruments Segment. WSGR advised FEI Company in the transaction. For more information, visit <http://news.thermofisher.com/press-release/thermo-fisher-scientific-completes-acquisition-fei-company>.

Xenon Pharmaceuticals Prices Follow-On Offering

On September 8, Canadian biotech company Xenon Pharmaceuticals announced that it

has raised \$30 million in an underwritten public offering to support its lead candidate, XEN801, which treats severe acne. The offering sold 4,000,000 shares at \$7.50 each, with 3,000,000 shares being sold by the company and the rest by certain existing shareholders. WSGR represented Xenon Pharmaceuticals in the offering. For further details, refer to <http://investor.xenon-pharma.com/phoenix.zhtml?c=253202&p=irol-newsArticle&ID=2200567>.

Allergan Acquires RetroSense

Allergan announced on September 6 that it has acquired substantially all of the assets of RetroSense Therapeutics, a clinical-stage biotechnology company focused on novel gene therapy approaches to restore vision in patients suffering from blindness. The transaction included a \$60 million upfront payment and future regulatory and commercialization milestone payments related to its lead drug, RST-001. WSGR represented RetroSense in the transaction. For additional information, visit <http://www.allergan.com/NEWS/News/Thomson-Reuters/Allergan-Acquires-Gene-Therapy-Company-RetroSense>.

USPTO Invalidates Three Teva Patents

On August 24, Mylan announced that the U.S. Patent and Trademark Office has ruled in favor of Mylan in its *inter partes* review (IPR) proceeding and found all claims of two related Copaxone patents—which are owned by Yeda Research & Development Co. and licensed to Teva Pharmaceuticals—to be unpatentable. WSGR was part of the team representing Mylan in the matter. Please see <http://newsroom.mylan.com/2016-08-24-Mylan-Invalidates-Two-of-Tevas-Copaxone-40-mg-mL-Patents-Via-U-S-Patent-and-Trademark-Offices-Inter-Partes-Review-Proceeding> for additional details.

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Allergan to Acquire ForSight VISION5

Allergan, a leading global pharmaceutical company, and ForSight VISION5, a privately held, clinical-stage biotechnology company focused on eye care, announced on August 11 that they have entered into an agreement under which Allergan will acquire ForSight VISION5. Under the terms of the agreement, Allergan will acquire ForSight VISION5 for a \$95 million upfront payment and a launch milestone payment related to ForSight's lead development program, a peri-ocular ring designed for extended drug delivery and reducing elevated intraocular pressure in glaucoma patients. WSGR represented ForSight VISION5 in the transaction. For further details, see <http://www.allergan.com/NEWS/News/Thomson-Reuters/Allergan-to-Acquire-Eye-Care-Company-ForSight-VISI>.

Avinger Announces Pricing of Public Offering of Common Stock

On August 11, Avinger, a leading developer of innovative treatments for peripheral artery disease, announced the pricing of its public offering of 8,572,000 shares of its common stock at a price to the public of \$3.50 per share. In addition, the company granted the underwriters a 30-day option to purchase up to 1,285,800 additional shares of its common stock. WSGR represented Avinger in the transaction. To read more, visit <https://globenewswire.com/news-release/2016/08/11/863579/0/en/Avinger-Inc-Announces-Pricing-of-Public-Offering-of-Common-Stock.html>.

Confluent Medical Technologies Acquires ETE Medical

On August 9, Confluent Medical Technologies, a contract manufacturer of Nitinol-based and balloon catheter medical devices, announced that it has completed the acquisition of ETE Medical and its operating subsidiaries, Biomedical Structures, a market leader in the design, development, and manufacturing of medical textiles for device manufacturers, and Modified Polymer Components, a manufacturer of highly precise polymer components for medical device companies. WSGR represented Confluent Medical in the transaction. For more information, please see <http://www.businesswire.com/news/home/20160809005068/en/Confluent-Medical-Technologies-Acquires-Biomedical-Structures-and%C2%A0Modified>.

VytronUS Raises \$49 Million in Series C Financing

VytronUS, a privately held medical device company developing novel technologies for the treatment of cardiac arrhythmias, announced on July 29 that it has raised \$49 million in a Series C round of equity financing. WSGR represented VytronUS in the transaction. For more information, visit <http://www.prnewswire.com/news-releases/vytronus-inc-raises-49-million-in-series-c-financing-300306089.html>.

Invuity Announces Pricing of Public Offering of Common Stock

On July 28, Invuity, a leading surgical photonics company, announced the pricing

of its public offering of 2,800,000 shares of its common stock at a price to the public of \$10.00 per share. In addition, the company granted the underwriters a 30-day option to purchase up to 420,000 additional shares of its common stock. WSGR represented Invuity in the transaction. To read more, visit <http://investors.invuity.com/phoenix.zhtml?c=253978&p=irol-newsArticle&ID=2189561>.

Federal Circuit Overturns Ruling Against Medical Device Companies

On July 21, a three-judge panel of the Federal Circuit reversed a district court judgement awarding AngioScore more than \$20,000,000 in damages based on claims of breach of fiduciary duty, aiding and abetting the breach, and unfair competition against TriReme Medical, Quattro Vascular, QT Vascular, and AngioScore founder Eitan Konstantino. The Federal Circuit held that the district court erred as a matter of law when it exercised subject matter jurisdiction over the claims. Accordingly, the Federal Circuit ordered the district court to dismiss the claims against the medical device companies. WSGR is part of the team representing TriReme Medical, Quattro Vascular, and QT Vascular in the matter. Additional information is available at <http://www.prnewswire.com/news-releases/qt-vascular-announces-federal-circuit-reversal-of-adverse-angioscore-spectranetics-judgment-300303172.html>.

Dow Jones VentureSource and PitchBook Rank WSGR No. 1 for Venture Financings

During the fall of 2016, Dow Jones VentureSource and PitchBook ranked Wilson Sonsini Goodrich & Rosati as the leading law firm for U.S. venture financings in the first three quarters of 2016.

Dow Jones VentureSource's legal rankings for Q1-Q3 2016 issuer-side venture financing deals placed Wilson Sonsini Goodrich & Rosati ahead of all other firms by the total number of rounds of equity financing raised on behalf of clients. WSGR is credited as the legal advisor in 128 rounds of financing, while its nearest competitor advised on 97 rounds of financing. Of particular interest to *The Life Sciences Report*, the firm ranked No. 1 for Q1-Q3 2016 issuer-side U.S. deals in the healthcare and medical devices and equipment industries.

Separately, in PitchBook's Q3 2016 Venture Monitor report, the firm ranked No. 1 for the combined number of issuer- and investor-side venture deals completed in Q3 2016. WSGR was also ranked No. 1 for early-stage financings during the same quarter. For the full PitchBook rankings, visit <https://www.wsgr.com/PDFs/pitchbook-Q316.pdf>.



Past Editions of *The Life Sciences Report*

If you'd like to access any past editions of *The Life Sciences Report*, you can find them on our website. Just visit www.wsgr.com and click on "Insight."

Upcoming Life Sciences Events

Biotech Board of Directors and Senior Executives Reception

January 11, 2017
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 35th Annual Healthcare Conference, is an exclusive networking event geared toward executives and directors of biotechnology companies.

25th Annual Medical Device Conference

June 1-2, 2017
The Palace Hotel
San Francisco, California
<https://www.wsgr.com/news/medicaldevice/>

Wilson Sonsini Goodrich & Rosati's 25th Annual Medical Device Conference, aimed at professionals in the medical device industry, will feature a series of panels and discussions addressing the critical business issues facing the sector today. This year's event will focus on understanding the challenges currently facing the medtech start-up, as well as the strategies that are emerging to respond to these challenges.

Phoenix 2017: The Medical Device and Diagnostic Conference for CEOs

October 18-20, 2017
The Ritz-Carlton, Half Moon Bay
Half Moon Bay, California
<https://www.wsgr.com/news/phoenix>

The 24th Annual Phoenix Conference will convene top-level executives from large healthcare companies and CEOs of small, venture-backed firms to discuss issues of interest to the medical device industry today, as well as to network and gain valuable insights from industry leaders and peers alike.

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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