Article

Crowdfunding: A New Untapped Opportunity for Biotechnology Start-ups?

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ABSTRACT
Crowdfunding is an evolving popular Internet-based process used to raise funding that has been employed by a few start-ups in the biotechnology industry. To solicit funding, companies profile their case on a specialized web platform (generally called a "crowdfunding portal") to ask the site members (i.e., the "crowd") who then choose which projects they would like to fund, in exchange for financial and nonfinancial inducements. In this paper we examine the evolving commercial and regulatory crowdfunding landscape and also identify case studies of biotechnology industry use. We find that a variety of crowdfunding mechanisms have been used and this alternative financing strategy may represent a viable option for biotechnology start-ups during early stage research or early stage clinical trials. A successful crowdfunding campaign may pave the way for the enterprise's future capital formation phases by attracting angel investors or venture capital because it shows that the business or project is viable. However, crowdfunding, like all other forms of capital formation, requires careful planning and execution before, during, and after a campaign. Strategies that appropriately tap into this innovative and disruptive use of technology and social networks may prove to be a unique capital formation niche for biotechnology start-ups; one that has yet to be fully leveraged.

Journal of Commercial Biotechnology (2015) 21(4), 15–14. doi: 10.5912/jcb717
Keywords: crowdfunding; angel investors; biotechnology financing; start-ups; social media marketing

BACKGROUND

Crowdfunding is a fairly new phenomenon. Companies and individuals post on the Internet to ask the public to fund ideas, projects, and new ventures. It is now utilized as a worldwide funding strategy across a wide spectrum of industries and economic sectors, specifically including the biotechnology sector. Although a relatively nascent instance of technology combined with financing, its use is growing rapidly; Deloitte Touche Tohmatsu Limited estimated that over $3 billion was raised through donation or reward crowdfunding in 2013.[1] Despite this market potential, the current exercise by, applicability to, and future impact of crowdfunding on the biotechnology industry remain relatively unknown. Taking this into account, this article examines the evolving commercial and regulatory landscape of crowdfunding and also identifies case studies of its use by biotechnology firms. Our findings can help guide the biotechnology industry to determine the potential opportunities and challenges faced by this disruptive form of financing technology.

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UNDERSTANDING CROWD–FUNDING

To understand its potential implications for biotechnology, the concept of crowdfunding must first be explored. It is unique from other forms of financing in that crowdfunding creates an ecosystem—an environment that facilitates capital formation in an organic and self-perpetuating manner by which small amounts of money are raised from a large number of people, typically through the Internet.[2] The ecosystem integral to crowdfunding can be efficient, effective, and faster than traditional forms of financing that rely on personal resources, funding by venture capital firms (VCs), or by accessing loans.

In contrast to traditional forms of capital formation, crowdfunding relies on the Internet as a medium on which innovators market their projects and solicit funds from the public as investors. Capital formation over the Internet leverages the ability to access a large number of people who may choose to contribute to an innovator's project. Crowdfunding portals are Internet-based businesses that operate specialized web platforms (generally called portals) to facilitate transactions between entities asking for funding and the crowd that provides financing. These websites also act as a space to present projects and ask for funds and to provide information about the progress of projects underway. Typically, the size of individual investments is small to minimize the investors' potential financial risks.

Crowdfunding is also the title of Title III of the Jumpstart Our Business Startups Act (JOBS Act) that was signed into law on April 5, 2012.[3] The JOBS Act required the Securities and Exchange Commission (SEC) to develop regulations by October 2015 that will govern the offering and sale of securities through equity-based crowdfunding.[4] The SEC finalized the crowdfunding regulations on May 25, 2015, the rules allow companies to raise up to $1 million in funds during any 12-month period (subject to capped contributions based on annual income or net worth). All transactions will be required to go through an equity crowdfunding portal that is registered as an intermediary with the SEC.[5]

CROWDFUNDING AND BIOTECHNOLOGY COMPANIES

Crowdfunding has been used predominantly for such entrepreneurial ventures as creative projects (e.g., music productions, concerts, self-publishing), developing consumer goods (e.g., games, hardware, software, and electronic devices), and various causes (e.g., community projects), but has not been widely adopted by biotechnology firms. Nevertheless, the current crowdfunding environment may still represent a potential avenue for small biotechnology firms to raise capital for their early phase research and development (R&D), such as proof-of-concept (POC), or for clinical trials.

Historically, biotechnology start-ups have relied either on debt financing, or equity capital from VCs, or angel investors. However, equity-based funding results in loss of ownership interest, whereas in nonfinancial-return crowdfunding ownership interest can be retained. Furthermore, VCs often are more interested in backing bigger and later-stage deals with less risk, further limiting the attractiveness of equity-based funding for early stage or start-up biotechnology endeavors.[6] The size of the investment also matters, for VCs, which generally invest $2 million and up in a financing round; and for angel investors that may invest much smaller amounts—$5,000 to $100,000—either individually or as a group.[7] In fact, the Angel Capital Association provides a guide for start-ups that are seeking angel investment financing and specifically recommends approaching these investors when a "product is developed or near completion."[8]

For this reason, due to the nature of VCs and angel financing, it is becoming increasingly difficult to approach these investors during the early stages of R&D. This funding dynamic has the potential to change with the passage of the JOBS Act that, according to the SEC, allows crowdfunding to fill the gap for the "very early stage endeavors [that] continue to be squeezed out of the capital markets" by finally offering the option of equity-based financing through regulated crowdfunding.[4] Although it is unknown how attractive crowdfunding for smaller biotechnology firms and investors under the JOBS Act will be, a few cases studies based on different types of crowdfunding models illustrate why and how small biotechnology companies might consider and use crowdfunding to raise capital, which we discuss below.

CROWDFUNDING MODELS

There are generally three models of crowdfunding: (1) donation/reward/pre-purchase, (2) peer-to-peer (P2P) lending; and (3) equity models that can be simplified into the nonfinancial return and financial-return-based funding types.[9] In the donation, reward, or prepurchase models (hereinafter referred to as the "donation/reward model"), funders may receive small rewards as perks, or prepurchase products in exchange for their funds. In contrast, P2P lending and equity crowdfunding models are market-based financing methods. The P2P lending and equity models are collectively referred to as "financial return crowdfunding" and are regulated by the country-of-domicile's financial laws and regulations.[10] Financial-return crowdfunding portals that operate in a foreign country sometimes must also comply with a second country's financial or securities laws and regulations that are applicable to their activities. For example, a United Kingdom (UK)-based financial-return crowdfunding portal intending to operate in the United States (U.S.) must also comply with all applicable U.S. laws and regulations. We further describe these different models in detail in the following subsections and provide specific examples of their use in science and research.

Donation/Reward Model

In the donation/reward crowdfunding model, an entity with an idea or project goes to a crowdfunding portal (a specialized website) to request funding. Individuals or organizations describe their projects and ask the crowd to fund them. Members of the crowd who decide to fund a project then become its backers. They are kept informed about activities related to their project through the project's web page and other identified social networking websites (e.g., LinkedIn, Twitter, Facebook, or a combination) chosen by the project owners. The backers may or may not receive a small reward (e.g., a T-shirt) in return for their donation. The backers may also prepurchase a product to raise funds for its further development. Crowdfunding platforms that provide services related to the donation/reward model currently are subject to little regulation; however, businesses trying to raise funds on these platforms cannot offer their backers equity securities or other types of financial return on investment due to securities laws.

The donation/reward crowdfunding model is not new and, using different media platforms, has essentially been in place for decades. Many organizations have raised millions of dollars from the public through traditional media including mail, television, and radio for causes focused on finding treatments or a cure for a number of diseases (e.g., cancer, cystic fibrosis, and Alzheimer's, among others). As an example, fiscal year 2013 contributions, gifts, grants, and fundraising events resulted in total contributions of $16,472,823 to the Cancer Research Institute (CRI) and $2,106,609 to the Pediatric Cancer Foundation. These organizations now also use the Internet to raise funds, among their other activities.[11,12]

In the donation/reward crowdfunding model, an entity with a project goes to a crowdfunding portal (e.g., Indiegogo) to solicit funding from the public. The crowdfunding portal facilitates all aspects of crowd participation including collection of funds, distribution to projects, necessary record-keeping, and management of communication with the project backers (see Table 1 for a list of popular donation/reward crowdfunding portals). One of these portals, Experiment (formerly called Microryza), is dedicated to scientific projects and includes partners from major academic institutions and nonprofit medical centers. Although no active health-related biotechnology projects are currently posted on the portal, projects have been funded during early stage discovery, basic research, and other types of investigator-driven health-related research. A sampling of projects funded on the Experiment portal is as follows:

- Harvard Medical School researchers, along with the Mind First Foundation, fully funded (100 percent of their targeted $10,000) a research project on partitioning depressed people into groupings that allow determination of the underlying biology of their disease by characterizing their genomes and other biology. The researchers agreed to allow free access worldwide to all of their aggregate data. Other researchers having unfettered access to the data may reveal the biological roots of these different classes of depression.[13]
- Massachusetts General Hospital researchers overfunded (raised 215 percent of their targeted request amounts) their project and raised $17,217. Their project sought to determine, during testing, if using experimental compound anle138b (a protein aggregation inhibitor that is a synthetic oligomer modulator which has shown promise in therapy for neurodegenerative diseases) during treatment can delay the onset of genetic prion disease.[14,15]
- University of North Carolina at Chapel Hill researchers fully funded their project and raised $10,000 to study whether the transmission of BRCA mutations can be prevented.[16]

Peer-to-Peer Lending Model

The peer-to-peer lending crowdfunding model is a market-based financial instrument that provides loans to businesses and individuals. The P2P lending model is a crowdsourcing form of microcredit, a worldwide phenomenon that now acts as a financing vehicle for

Table 1: List of popular donation/reward crowdfunding portals

Crowdfunding Portal (Launch Year, Ownership, Country)	Biotechnology Projects	Crowdfunding Model/ Volume/Website	Fees/Ownership Claims	Project Categories
GoFundMe (2010, Private, U.S.)	None	• Donation/Charity • Open to global backers • No penalty for not reaching targeted amounts • Over $1.1 B raised • www.gofundme.com	• 5% of funds raised • 2.9% + $0.30 nonrefundable payments processing • Claims of ownership: N/A	• 20+ categories: Animals, Business, Charity, Community, Competition, Creative, Events, Faith, Family, National News, Newlyweds, Other, Travel, Wishes, Medical, Volunteer, Education, Memorials, Sports, etc.
Kickstarter (2009, Private, U.S.)	None	• Donation • Open to global backers (certain countries) • All or nothing • $1.8 B raised • www.kickstarter.com	• 5% of funds raised • 3–5% nonrefundable payments processing • Claims no ownership over their projects	• Publishes statistics • 16 categories: Art, Comics, Dance, Design, Fashion, Film and Video, Craft, Food, Games, Music, Design, Journalism, Photography, Publishing, Technology, Theater
Indiegogo (2008, Private with $40 million B-round financing in 2014, U.S.)	6 biotechnology projects listed A project exceeded the targeted amount by selling products	• Donation • Open to global backers • Reach target or keep the raised amount • Volume unknown • www.indiegogo.com	• 4% of funds raised for successful campaigns • 9% of raised fund for failed campaigns that keep raised funds, no charge if all money is refunded to the contributors • 3–5% payments processing • Claims of ownership over their projects not clear	• Publishes statistics on partners • 24 categories: Animals, Art, Comics, Community, Dance, Design, Education, Environment, Fashion, Film, Food, Gaming, Health, Music, Photography, Politics, Religion, Small Business, Sports, Technology, Theater, Transmedia, Video/Web, Writing
Tilt (Formerly Crowdtilt (2008) (Relaunch 2012, Private, U.S.) $12 million A-round financing	None (site is not searchable)	• Donation (U.S., U.K. & Canada)/Fundraising/ Sell (using Shopify) • Open to global backers (requires international credit cards) • Volume unknown • www.tilt.com	• 0–2.5% of funds raised or total sales • 3% payments processing if credit cards used/no fee if debit cards used • No claim of ownership over their projects	• Fundraisers for experience, cause, nonprofit • Preorder or sell products
Crowdrise (2010, Private, U.S.)	None	• Donation/Charity • Open to global backers (requires international credit cards) • Volume unknown • www.crowdrise.com	• 3–5% of funds raised + monthly fee for annual accounts • 2.9% + $0.30 payments processing • No claim of ownership over their projects	• Fundraisers for causes and service organizations (e.g., American Red Cross raised $1,215,566 for Nepal relief, American Cancer Society has raised $522,080 for pediatric cancer research—ongoing) • Animal Welfare, Arts, Civil Rights, Personal Emergencies & Medical Expenses, Education/Tuition, Volunteer projects • Note: no biotechnology projects
Experiment (formerly Microryza) (2012, Private, U.S.) Investors include (Index Ventures & SV Angel are among portal's investors)	6 Biotechnology 50+ Medicine 17 Neuroscience	• Donation • All-or-nothing funding model • Currently only U.S.-based projects, although piloting projects from Australia, Canada, & U.K.	• 5% of funds raised • 3% nonrefundable payments processing • No claim of ownership over their projects • Hands-off policy regarding intellectual property (open access/peer review pledges)	• Includes academic & hospital medical centers as partners • 20 Categories: Anthropology, Art & Design, Biology, Chemistry, Computer Science, Data Science, Earth Science, Ecology, Economics, Education, Engineering, Material Science, Mathematics, Medicine, Neuroscience, Paleontology, Physics, Political Science, Psychology, Social Science • Note: no commercial biotechnology project but early phase projects are funded

Source: portal websites.

entrepreneurs around the world. Crowdsourcing for capital formation (i.e., P2P crowdfunding) provides the necessary funds for small businesses that may not have access to established sources of capital due to a variety of reasons.[17]

In P2P crowdfunding, borrowers ask the crowd for a loan on a lending portal and supply sufficient information about the purpose of the loan, their credit, and other financial information required by the portal. Members of the crowd (that is, backers) decide how to lend money—secured by requiring collateral or unsecured—to a borrower, and under what terms (simple or compounded interest rates). In some cases, unlike traditional lenders, backers may go through a reversed auction to set the lowest interest rate for the loan amounts. A P2P lending portal facilitates loan origination, collection of funds for the loan amounts and distribution of loans, collection of repayments for the lenders, loan servicing, necessary record keeping, and management of communication. These portals charge fees, which comprise a percentage of the loan amounts, for their services.

At its inception, this new financial instrument relied on unrelated people (i.e., peers) as lenders and borrowers to transact business over an Internet lending portal, thereby bypassing traditional financial institutions. The business model for lending portals has changed due to regulatory requirements enacted in various countries. Since 2008, in the United States, P2P portals have been required to register their offerings with the SEC as securities to comply with the Securities Act of 1933.[18] In addition, P2P portals must comply with all applicable laws and regulations pertaining to financial transactions and lending. In the United States, commercially operated P2P lending portals also must comply with the Money Laundering Control Act of 1986, Money Laundering Suppression Act of 1994, and the Bank Secrecy Act of 1970 among others, including consumer protection and privacy laws and regulations. As a result, many lending portals partner with a bank that already has the necessary regulatory compliance mechanisms in place (see Table 2 for a list of well–known P2P lending portals).[19]

P2P lending portals are increasingly lending start-ups up to $500,000 based on creditworthiness. Start-ups, like individual borrowers, are required to make fixed, regular payments to their lenders through the lending platform. Making regular payments might be difficult for some biotechnology start-ups that require a large operating budget before being able to market a product and generate revenue (they may have a negative cash flow); or the biotechnology start-ups may have short operating histories that could impact creditworthiness. In such cases, the P2P loans might be less attractive to start-up businesses because of the difficulty in demonstrating the ability to repay a loan. As a relatively new form of lending, it remains to be seen how the P2P lending market may evolve in the future. It may nevertheless still represent a pathway to access seed money for small biotechnology companies.[4]

Equity Model

The U.S. equity model of crowdfunding resembles traditional investment models that include funding by VCs, angel, or accredited investors. Start-ups issue securities to purchasers by using crowdfunding portals as intermediaries, resulting in a transfer of ownership interest in the business in return for funding. Options for offering equity-based crowdfunding under the SEC's rules include conditional small issues exemption (Regulation A) and the limited offer and sale of securities without registration (Regulation D). Equity crowdfunding portals are registered with the SEC as intermediaries (registered broker/dealer), which allows them to facilitate this equity exchange and receive fees for their services (see Table 3 for a list of popular equity portals). The portals themselves are not currently exempt from Section 15(a)(1) of the Securities Act of 1933, which allows the SEC to allow exemptions from registration for offering equity to small companies because the SEC registration process is cost-prohibitive. Small companies can qualify for an exemption under the Securities Act of 1933 to offer securities through crowdfunding portals without going through the registration process. After the SEC grants the exemption, these companies offer securities only to investors who meet the requirements for purchasing their securities (such as accredited investors).[20]

The equity crowdfunding portals in the United States mostly allow accredited investors to purchase securities in a private transaction through the portals. Accredited investors (revised due to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010) include traditional institutional investors such as banks, insurance companies, hedge funds (but the minimum-asset requirements are generally higher), and individuals who qualify. Individuals or married couples who qualify include those with a net worth in excess of $1 million, and those whose income exceeds $200,000 (for individuals) or $300,000 (for married couples) for the two most recent years and a reasonable expectation of the same income level in the current year.[21] A private transaction means there can be no general advertising or publicity aimed at investors while the offering round is open. The SEC rules require investors to be accredited by the SEC; as a result, a smaller crowd of potential funders is available to businesses hoping to offer equity to the crowd in exchange for financial backing. The participation

Table 2: List of top P2P lending portals[32]

Crowdfunding Portal (Launch Year, Ownership, Country)	Crowdfunding Model/ Other Information/Website	Fees for Business Borrowers	Loan Categories and Characteristics
Lending Club (2007, Public–NYSE: LC, U.S.)	• SEC fillings: forms 10-K, 10-Q, 8-K, Sales Reports, Prospectus • Default rate: 4.3% • Over 7 B business loans • Business loans, unsecured personal loans, medical loans • No collateral needed for under $100K loans • No appraisals, business plan or projections • No visit to borrower's business • No appraisals or title insurance • lendingclub.com	• Interest rates: Fixed, 5.9% + • Origination fee: variable 0.99–5.9% • Total Annualized Rate (APR): 8% – 32% • Additional charges for unsuccessful payment fee, late payment, check processing fee • Actual APR depends on credit score, loan amount, loan term, and credit usage & history.	• Business loans: up to $300,000, fixed monthly payment, 1–5 year term, no fee or penalty for payoff • Requirements: 2 years in business, at least $75,000 in annual sales, no recent bankruptcies or tax liens • All loans made by WebBank, a Utah-chartered industrial bank, member FDIC. • Investors do not invest directly in loans; they purchase Member Dependent Notes from Lending Club. • Loans are not issued to borrowers from IA, ID, ME, ND, or NE. • Investor ROI: 5.06% to 8.74%
Prosper (2005, Private, U.S.)	• Prosper Funding LLC is a wholly-owned subsidiary of Prosper Marketplace, Inc. that operates the portal • P2P lending • Small business loans offered as personal loan, unsecured personal loans, auto loans, military loans, green loans • prosper.com	• Origination fee: variable 1–5% taken upfront from loan amount • Interest rates: Fixed, 5.32–35.97% • Actual APR depends on credit score, loan amount, loan term, and credit usage & history • Additional charges for unsuccessful payment fee, late payment, check processing fee • All loans are considered as personal loans to the business owner	• Repayment options are 3 or 5 years • Pre-set rates based on borrower's credit risk. • All borrower loans are fixed-rate, unsecured, fully amortizing loans with simple interest. • Excludes some borrowers from multiple states • All loans made by WebBank, a Utah-chartered industrial bank, member FDIC. • Investor ROI: 8.89% • Notes offered by Prospectus
Funding Circle[33] (2010, Private, U.K.) P2P in U.S. was launched in 2013	• U.S.-based portal lends to established American small businesses • Partnership with VCs, banks, or borrower's referred entity • Businesses can borrow from $25,000 to $500,000 to be repaid over 12 to 60 months • fundingcircle.com (U.S. website)	• Origination fee: variable 2.99–4.5% taken upfront from loan amount • Interest rates: fixed 5.99–20.99% based on business creditworthiness and loan terms • Actual APR depends on credit score, loan amount, loan term, and credit usage & history • Additional charges for nonsufficient funds (NSF), late payment, check processing fee	• Repayment options are 3 or 5 years • Pre-set rates based on borrower's credit risk. • All borrower loans are fixed-rate, unsecured, fully amortizing loans with simple interest. • Excludes some borrowers from multiple states • All loans made by WebBank, a Utah-chartered industrial bank, member FDIC. • Accredited investors only • ROI: 11.2% trailing 12-month return as of April 30, 2015 • Inventors invest in a portfolio of loans or Notes offered by Prospectus Investor Guide

Note: Loans are not searchable by business types.

Source: portal websites.

Table 3: List of popular equity crowdfunding portals

Crowdfunding Portal (Launch Year, Ownership, Country)	Biotechnology Projects	Crowdfunding Model/ Other Information/ Website	Fees/Ownership Claims	Investment Categories and Characteristics
Fundable (2012, Private, U.S.)	• More than 7 health-related biotechnology companies (click to see list) • Selected companies: Genome Profiling LLC (GenPro), Levolta Pharmaceuticals, Enzium, MH Systems, Inc. works in association with UC San Diego's Scripps Institution of Oceanography (SIO); UBDoc (fee-based interactive health information portal providing diagnosis, testing, and treatment)	• Software as a service crowdfunding platform • The portal offers both rewards-based and equity-based options for small businesses • All or nothing model • Private companies offer securities to investors under Rule 506 of Regulation D on CircleUp and through Fundme Securities LLC • Supports both Regulation D 506(b) and 506(c) offerings • $179 M in funding • www.fundable.com	• Monthly subscription fee, platform fees, and consulting fee • Project owners agree to pay all royalties and other amounts owed to any person or entity due to their submission or any user submissions service • Claim of ownership rights of the project content based on legal agreements; IP might be impacted unless user has secured its IP	• Allows both reward- and equity-based • Equity-based offered to institutional or accredited investors only • Minimum investment amount is $1,000 and there is no maximum • All securities-related activity is conducted through Fundme Securities
AngelList (2010, Private, U.S.) The portal was originally founded in UK, also operates in U.S.	• 25+ Biotechnology start-ups • 10+ Pharmaceuticals • 25+ Medical devices • 15+ Health technology	• Equity investment for accredited investors and institutions • Supports both Regulation D 506(b) and 506(c) offerings • Syndicate investors do not invest directly in a company. They invest in a special purpose fund that is created specifically for the investment. This fund then invests in the company. The corporate form of the fund is an LLC. • angel.co	• Investors pay 0–25% deal carry to lead, 5%, to platform • Investors receive a profit, if any, when the company is acquired or has an IPO	• Startups offering rounds A, B, C, ... • Syndicated investment funds led by an angel or VC investor • 16,9904 of 53,0814 companies claimed funds
CircleUp (2011, Private, U.S.)	• None	• Private companies offer securities to investors under Rule 506 of Regulation D on CircleUp and through Fundme Securities LLC. • Supports both Regulation D 506(b) and 506(c) offerings • Accredited investors only • All securities related activity is conducted through Fundme Securities LLC, a wholly owned subsidiary of CircleUp Network, Inc. Fundme Securities LLC is a registered Broker/Dealer and member FINRA/SIPC • circleup.com	• Commission case by case—% of the total amount • Investors include USV, Canaan Partners, Google Ventures, Maveron, Rose Park Advisors • Partners: General Mills, P&G, and SPINs • The issuers set the valuation of their companies. Valuations on CircleUp are intended to be in line with industry comparable on a revenue and net profit basis • Ownership claims: not clear	• Currently 144 companies are on the portal, focus on mostly consumer products companies, no biotech companies • Entrepreneurs screen interested investors and select which investors to participate in their round; also, structure the terms of their raises through an Investors Rights Agreement • Average funding time is 2–3 months
Seedrs (2012, Commercial, UK) Note: Plans to expand into the U.S. market	• Medical device start-up (IRISS Medical)	• Equity, Fund, Convertible Campaigns: investment in multiple early and growth-stage finance for businesses • All or nothing • Angel investors & VCs • Open to retail investor (not U.S. residents) from throughout Europe • Investors have to provide investor questionnaire, or self-certify as a "high net-worth individual" or a "sophisticated investor." Institutions provide "high net worth company, unincorporated association, etc.") forms. • www.seedrs.com	• One-off fee of up to 7.5% from successfully funded businesses • Investor fee of 7.5% carry (of the profits investors) • All-or-nothing basis but successful campaigns have the option to overfund • Referral fees paid for successful cases	• Investment in early– and growth–stage finance for businesses • Funds businesses in 48 countries • Business categorizing: N/A

Source: portal websites.

criteria for all parties seeking to offer equity-based securities through crowdfunding are provided in Table 4.

CROWDFUNDING BIOTECHNOLOGY CASE STUDIES

Few biotechnology firms have used crowdfunding to actively raise capital. Despite there being only a few case studies available for review, some firms have been successful in raising capital for their projects by way of different types of crowdfunding platforms. Successful biotechnology firms generally used crowdfunding during early stages of their R&D, and some used a multi-prong strategy to market and raise funds for their innovations. The case studies also reveal that crowdfunding for biotechnology start-ups appears to attract a diverse group of angel investors, patients, and ordinary people who are interested in funding a project for a variety of reasons beyond investment purposes. A start-up biotechnology firm must tell a good story for the crowd to attract support. Not only must the story be made available on a crowdfunding platform, but a communications campaign must also be mounted to inform members of the public who have the potential to become members of the crowd that funds the project. In this sense, crowdfunding for biotechnology projects is functionally similar to communication campaigns for political office; better campaigns have higher chances for success and garner greater funding opportunities.

Exogen Biotechnology Inc.

In January 2014, Exogen Biotechnology Inc. (Exogen) launched a reward/purchase crowdfunding campaign called "How Damaged is your DNA?" on Indiegogo (a popular crowdfunding platform with 15 million monthly visitors, home to campaigns from 226 countries, which has 310,537 followers on Google+).[22] Exogen is a Berkeley, California-based start-up that has developed blood test kits for measuring damaged DNA. Exogen aimed to raise $50,000, although the campaign actually raised $106,100 from 597 people in two months. The company's slogan was: "Gain access to leading-edge information about the health of your DNA while helping advance science!" Exogen's campaign offered various perks to the crowd, based on different contribution levels, including listing the donor's name on the company website; a T-shirt; and multiple types of scientific packs and self-tracking services available for purchase, with prices ranging from $15 to $1299. By the end of the campaign, not only did Exogen raise 212 percent of its original funding goal through individual contributions, the crowd also provided valuable DNA samples for research to measure DNA damage, which has the potential to advance our understanding of cancer and immunological disorders, among other diseases.[23]

Apta Biosciences

In April 2014, Apta Biosciences (Apta) had a crowdfunding-based equity offering round on SyndicateRoom and raised £1,850,000 by the round's close.[24] Apta is a small biotechnology company (11 to 50 employees) that was founded in 2013 when its technology spun out of Fujitsu. Its offices are in Singapore and the United Kingdom.[25] SyndicateRoom is a UK-based equity crowdfunding platform; its business model allows its retail members to invest alongside angel investors in equity offering rounds that allow the same share class and same price per share.[26] The same criteria were used in Apta's offering round, which allowed Apta to raise capital to undertake the validation process of its adaptamers, a new group of synthetic molecules that mimic the characteristics of proteins such as antibodies, for further product development. The company holds 25 patents for its developed adaptamers. Apta's adaptamers are called Seligos; the synthetic molecules are very stable (they do not require cold storage), easy to produce, and purportedly deliver high performance.[27]

ImPatient

ImPatient is a nonprofit crowdfunding platform that is currently crowdfunding its own creation and launch by soliciting donations.[28] The portal's funders won seed money when they won the top prize during the Lehigh Valley Startup Weekend competition sponsored by the Lehigh University Baker Institute for Entrepreneurship, Creativity and Innovation.[29,30] ImPatient is planning to launch its crowdfunding portal in fall 2015 and operate as a hybrid donations and loans crowdfunding platform that, for a fee, will raise funds for small biotechnology companies. After launching the portal, ImPatient's scientific advisors will select "promising unfunded medical treatments" for the crowd to fund as their favorite medical research. The crowd includes portal's members, who provide a minimum of $25 in the form of a loan to the medical project of their choice. The funded companies may pay back the loaned amounts. The payback amounts are then credited to members' accounts and can be loaned to another project. A loan that is not repaid is considered a donation.

Table 4: Crowdfunding proposed rules criteria for participating[4]

Actor	Requirements
Investor	• The amounts of an individual's investment are capped to: • 5 percent ($2,000) of annual income or net worth when it is less than $100,000 • 10 percent of annual income or net worth when it is more than $100,000 (with an overall cap of $100,000 per individual)
Issuer	• The amounts of capital raised through crowdfunding offerings by a company are capped to aggregate amounts of $1 million sold to all investors during a 12-month period. A company may still raise capital from other sources or use exemptions that do not fall under the Section 4(a)(6) exemption[4] • Need to transact through the SEC-registered intermediaries
Equity Crowdfunding Portal	• Funding portal—a registered broker—acts as an intermediary and facilitates transactions involving the offer or sale of securities under Section 4(a)(6) only over Internet websites (including access through multiple devices) • File certain financial information (including reviewed or audited financial statements, capital structure, depending on the amounts offered and sold during a 12–month period); financial statements should be prepared in accordance with U.S. generally accepted accounting principles (GAAPs) when auditor involvement is required such as for offerings of more than $100,000) • Disclose certain other information about their offers—include description of the business and the use of proceeds; targeted offering amounts, price, and deadline • Additional disclosures[4] • Registered as brokers or funding platforms with the Financial Industry Regulatory Authority (FINRA) • Comply with the requirements of the Securities Act Section 4(a)(6)(C) • Must remain independent and prohibited from providing investment advice, soliciting purchase or sales of securities posted on their portal, compensating employees, agent, or others for soliciting sale of securities on their portal • Must "hold, manage, possess or otherwise handle investor funds or securities" • Must not engage in similar activities[4] • The portal's officers, partners, and directors must not have financial interests in an issuer displayed on their portal, and must have in place "measures to reduce risk of fraud"[4] • Responsible for managing crowdfunding through maintaining issuer information, qualifying investors for opening account, keeping track of investment limitation, facilitating communication, managing fund transfers, and providing appropriate financial recordkeeping for both issuers and investors • Must accept purchases only from individuals who have an account with their portal and provide these individuals with all the required information under Subpart C (educational materials, notices. and transaction confirmations by electronic means)
Non-Qualified Entities (for participating in crowdfunding under Section 4(a)(6))	• Foreign issuers who are not organized under the laws of a state or territory of the United States or the District of Columbia[4] • Investment companies as defined in the Investment Company Act of 1940 (15 U.S.C 80a–1 *et seq.*, 15 U.S.C. 80a–3(b) or (c))[4] • Companies subject to SEC reporting • "Other issuers that the Commission, by rule or regulation, determines appropriate"[4]

Source: SEC Crowdfunding Proposed Rules.

DISCUSSION: CROWDFUNDING OPPORTUNITIES AND CHALLENGES

Biotechnology start-ups generally need to raise $50 to $100 million to have a chance at developing a new drug or medical device. Raising capital through traditional VCs and angel investors has the advantage of allowing the start-up to receive mentoring and guidance. As these sources of capital move toward funding start-ups at later stages of development, biotechnology start-ups have fewer options for raising capital during early stage development. However, various models of crowdfunding may expand options for nontraditional capital formation.

Small companies can quality for exemptions from registration for equity offering through existing SEC rules, such as conditional small issues exemption (Regulation A) and the limited offer and sale of securities without registration (Regulation D). All U.S. equity-based crowdfunding platforms currently operate under Regulation D, because Regulation A was finalized on June 19, 2015. When considering crowdfunding with securities offerings, investors may consider how easily they can exit their securities, an exit strategy that depends on the method of securities offering (for example, securities offerings through Regulation A, Regulation D, or the equity crowdfunding rules finalized by the SEC under the JOBS Act.

In the United Kingdom, where many angel investors actively participate in equity crowdfunding alongside retail investors, the Financial Conduct Authority (FCA) published a statement in its crowdfunding review of its regulatory approach in February 2015. The statement indicated that equity crowdfunding grew by 201 percent in 2014; 25 firms currently are authorized to engage in equity crowdfunding or are appointed representatives, and applications from an additional 10 firms currently are under review.[31] A potential area of concern for the FCA was that negative comments on some crowdfunding portals were deleted; these negative comments might serve to alert potential investors of risks associated with investing in a company. It would be prudent for biotechnology companies to promptly respond to any questions or concerns to prevent negative impressions about the funding opportunity or viability of the venture. However, simplifying information about health, scientific results/processes, medical treatments or devices, while remaining financially and scientifically accurate, can be difficult. Balancing benefits versus risks for *both* financial and scientific or health information may be especially challenging when promoting a project on various media, including social networks. Negative comments on social networks can destroy a company's options for funding in an incredibly short time frame, while positive comments about a company's product or research can attract more investors. Commentary in general might serve as an indicator of the marketability of a company or its product.

CONCLUSION

Crowdfunding may represent a viable funding option for biotechnology start-ups, particularly during the early phases of R&D or for funding clinical trials. However, its potential impact remains unknown, particularly in the evolving crowdfunding regulatory and commercial environment. A successful crowdfunding campaign may also pave the way for future capital formation phases by attracting angel investors or VCs early in the funding process, or by showing that the business or project is viable. However, biotechnology start-ups must keep their multiple, disparate audiences in mind when seeking funding from diverse sources such as VCs, angel investors, or the public. Furthermore, crowdfunding is still in its infancy, and for this reason it is difficult to predict what opportunities or obstacles may lie ahead, especially given the implementation of the JOBS Act. Crowdfunding, like all other forms of capital formation, requires careful planning and execution before, during, and after a campaign. Social media are also a key communications medium by which to successfully solicit funds. The crowd intelligence serves to vet ideas and projects prior to their commercialization. The crowd—the investors—also can be transformed into a marketing engine for the start-up, should both parties have a vested interest in the success of the project.

In conclusion, biotechnology start-ups need to know that (1) crowdfunding is happening *now*, (2) it behooves them to take the time to understand how it works today and in context of the JOBS Act, and (3) they must strategize if they want to appropriately tap into this unique and disruptive opportunity.

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