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East Coast Biotech Roundup: Sarepta, Zalicus, Alkermes, & More

Written by Ben Fidler on Nov 15, 2013 07:00 am

Ben Fidler

It's been an optimistic year for biotech. IPOs have come fast and furious, and have made a lot of money for investors. The Nasdaq Biotechnology Index is up big. But this week offered a cold reminder of the high risk that comes with those potentially high rewards. Those stories and more below:

—Cambridge, MA-based Sarepta Therapeutics' (NASDAQ: SRPT) chances of getting accelerated approval based on a promising, 12-patient data set of patients with Duchenne Muscular Dystrophy has been one of the year's most closely watched biotech stories. Unfortunately for the company, the FDA squashed those hopes earlier this week. The FDA told the company its new drug application for eteplirsen is "premature." While Sarepta still hopes to change the FDA's mind, it will likely now have to go the traditional route and put together a confirmatory, Phase III, placebo-controlled study that could take a few years to set up, enroll patients in, and complete. With eteplirsen's approval delayed by two years or more, and the uncertainty surrounding the trial design, Sarepta's shares plummeted more than 60 percent.

—Be sure to check out Brad Loncar's guest editorial on Sarepta as well.

—Cambridge-based Zalicus (NASDAQ: ZLCS) had been waiting for years to find out whether the reformulation work it did to a failed pain drug would pay dividends. Its day of reckoning came Monday, and the results weren't good. That drug, Z160, failed both of its mid-stage clinical trials. It's a big setback for Zalicus, which will now turn its attention to another pain drug that is much earlier in development. Investors aren't waiting around to find

out how that turns out—they sent Zalicus stock freefalling by about 75 percent.

—Today, Dublin and Waltham, MA-based Alkermes (NASDAQ: ALKS) is rolling along with an emerging pipeline and a market value approaching $5 billion. But just over 10 years ago, it was on the brink of disaster. Xconomy's National Biotech Editor, Luke Timmerman, spoke to Alkermes CEO Richard Pops about how the company survived its own brush with death in 2002, when the FDA rejected a drug New Brunswick, NJ-based Johnson & Johnson (NYSE: JNJ) developed using the company's drug delivery technology.

—Johnson & Johnson won FDA approval this week of ibrutinib (Imbruvica), a highly-anticipated blood cancer drug it co-developed with Sunnyvale, CA-based Pharmacyclics (NASDAQ: PCYC). Ibrutinib is approved to treat patients with mantle cell lymphoma, a small patient group, but the two companies are also testing the drug in a wide range of cancers. All-told, the expectations for ibrutinib are sky-high. JP Morgan analyst Cory Kasimov is estimating more than $6 billion in potential peak annual sales for the drug.

—Cambridge-based Catabasis Pharmaceuticals is signaling that an IPO is on its long-term to-do list. The biotech has raised a $32.4 million Series B round from its existing investors (SV Life Sciences, Clarus Ventures, MedImmune Ventures, and Advanced Technology Ventures), a new investor (Lightstone Ventures), and importantly, an unspecified public crossover fund. Catabasis CEO Jill Milne acknowledged that an IPO is a possibility, but that the company wants to get its lead drug, CAT-2003, further into clinical trials and develop some of its other assets before it takes the leap.

—New Enterprise Associates has been investing in Boston biotech for many years without having a physical footprint. That changed this week, as the investment firm opened a new office in Kendall Square. General partner David Mott told me that the time was right for such a move, given that NEA is more active now in Boston than at any point in its 36-year history.

—Cambridge-based Zafgen revealed the full results from the Phase II study of its injectable fat-zapping drug, beloranib, and the numbers held up from the top-line figures it announced

earlier this year. Patients taking the highest dose of beloranib (2.4 milligrams) lost an average of about 24 pounds (10.9 kg) over the course of the 12-week study. Patients in the mid-dose group (1.2 mg) shed about 15 pounds on average, while those getting the low dose (0.6) lost an average of about 12.4 pounds over the course of treatment. Zafgen tested 147 patients in the trial—mostly obese women about 48.4 years old—and 122 of them completed the study. The most common side effects seen in patients taking the drug were nausea, vomiting, diarrhea, and trouble sleeping.

—The Broad Institute of MIT and Harvard got a new $100 million gift from philanthropists Eli and Edythe Broad. The Broads have now donated about $700 million to the institute since its founding in 2003. Just a few weeks ago, the Broad Institute got a $74 million gift from the Carlos Slim Foundation to advance research in genomic medicine.

—The FDA has given a fast-track designation to Cambridge-based Alnylam Pharmaceuticals's (NASDAQ: ALNY) experimental RNA-based drug, patisiran, for transthyretin familial amyloid polyneuropathy, meaning it will get a speedier review from the agency than it would have otherwise. Alnylam is currently enrolling patients in a Phase III trial.

—Waltham-based GeNo Healthcare this week became the latest biotech to file for an IPO. The company, which is developing a new way to deliver inhaled nitric oxide, plans to raise up to $50 million from public investors. Founder, executive chairman and chief scientific officer David Fine is by far the company's largest shareholder, owning 58.2 percent of GeNo's stock. Jefferies LLC, Stifel, Nicolaus & Co., and Canaccord Genuity are underwriting the offering.

—The FDA has approved Marlborough, MA-based Sunovion Pharmaceuticals's anti-seizure drug, eslicarbazepine (Aptiom), as an add-on therapy for patients with epilepsy. Sunovion is a unit of Dainippon Sumitomo Pharma. When known as Sepracor, the company was acquired by the Japanese pharma giant for $2.6 billion.

UNDERWRITERS AND PARTNERS

Catabasis Scores $32M Series B Round With IPO in Sight

Written by Ben Fidler on Nov 15, 2013 12:01 am

Ben Fidler

When investors better known for backing public companies jump into a startup's private financing round, it's typically a signal that an IPO is on the way. That looks to be the case for Cambridge, MA-based Catabasis Pharmaceuticals.

Catabasis is announcing today that it has raised $32.4 million in equity financing through a Series B round from existing investors and new ones, including an unspecified public crossover fund. New backer Lightstone Ventures joined Catabasis' existing funding syndicate, which is comprised of SV Life Sciences, Clarus Ventures, MedImmune Ventures, and Advanced Technology Ventures. Catabasis CEO Jill Milne wouldn't disclose the name of the new public crossover investor, but says that Catabasis has now raised $83 million since its inception in 2008. That figure includes the new round, a $40 million Series A in April 2010 that investors have since boosted to $46 million, and the original angel investment that got the company going five years ago, according to CFO Ian Sanderson.

Today's cash haul is significant for two reasons: first, it will give Catabasis the juice to get its lead drug candidate, known as CAT-2003, through Phase II studies and—assuming all goes well—begin thinking about a confirmatory trial. But in adding a public investor into its syndicate, Catabasis is also signaling an IPO could be on the horizon if it can continue to progress and get the mid-stage clinical data it is hoping for.

Jill Milne, CEO of Catabasis Pharmaceuticals

"That is a possibility," Milne says. "[But] we'd like to get deeper into the clinic with [CAT-2003] and develop some of the earlier assets as well before we start to approach the public markets."

That's where the new cash comes in. Catabasis already has two Phase II studies up and running for CAT-2003, and is considering finding a partner to bring a second drug, CAT-1004, into a mid-stage study of its own. With the $32.4 million in the bank, Catabasis now has cash to get it "deep into 2015," which should allow it to get through those two studies and begin "Phase III enabling activities," according to Milne.

Both drug candidates are the products of Catabasis' in-house "SMART-Linker" technology, which it uses to attach two compounds together with a proprietary linker to form a new chemical entity that is supposed hit two targets in a disease pathway at once. The most advanced drug candidate to emerge from that approach is CAT-2003, a chemically-linked combination of niacin and the Omega 3 fatty acid called eicosapentaenoic acid, or EPA.

Catabasis believes this combination approach differentiates CAT-2003 from … Next Page »

Seattle E-Commerce Startup Zulily Raises $253M in IPO

Written by Benjamin Romano on Nov 14, 2013 11:32 pm

Benjamin Romano

Seattle is home to another multi-billion-dollar tech company with the initial public offering of Zulily, which sold 11.5 million shares for $22 each today.

The IPO raised $253 million for the company and selling stockholders, and gives the four-year-old daily deals site for moms and kids a market value of $2.6 billion before trading

begins on the NASDAQ Friday under the ticker symbol ZU.

Zulily adds about $140.3 million to the corporate treasury as a result of the IPO, with the remainder going to inside sellers, including Maveron, the venture capital firm co-founded by Starbucks CEO Howard Schultz.

The company walked up its offering price from a range of $16 to $18 a share at the beginning of the month to $18 to $20 earlier this week. We will see how much they left on the table as the shares hit the open market.

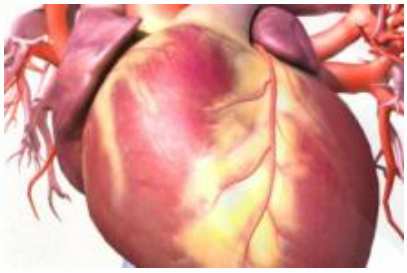
Fortune's Dan Primack noted earlier this evening that the IPO pricing was being largely ignored by the tech press outside of Seattle, and offers some theories as to why.

One of those: "Not too many tech reporters have kids," so they aren't likely aware of Zulily, his argument goes. Oddly enough, most of the tech reporters I know in Seattle actually do have kids. But having kids might also be a reason to ignore the news, at least temporarily. I'm posting this relatively late after spending a happy afternoon with mine, who definitely sports some gear from Zulily…

Primack notes another interesting angle on the news: Schultz and Maveron crushing it lately with back-to-back portfolio company IPOs. As with Zulily, Maveron was the largest pre-IPO shareholder in Potbelly (NASDAQ: PBPB), the Chicago-based sandwich chain that went public at $14 last month and closed today at $29.65.

San Diego's Celladon Postpones IPO, Cites "Poor Market Conditions"

Written by Bruce V. Bigelow on Nov 14, 2013 06:29 pm



Bruce V. Bigelow

Maybe that IPO wasn't such a good idea after all.

San Diego's Celladon, on the fast track to advance clinical development of its first-in-class gene therapy for patients with systolic heart failure, postponed its IPO Wednesday, according to Renaissance Capital, an institutional research firm that specializes in IPOs.

The company cited poor market conditions.

Celladon set the terms for its IPO in a Nov. 1 filing that set a price range of $14 to $16 per share. The initial stock offering of 5 million shares was intended to raise about $75 million.

The company's decision to postpone its offering came on the same day that Tandem Diabetes Care, a San Diego medical device company, completed a bigger-than-expected IPO at the top of its price range. Life sciences companies represent the biggest segment of IPOs this year, which have been happening at a near-record pace. Tandem Diabetes was San Diego's seventh life sciences company to go public this year.

On the other hand, Palo Alto, CA-based CardioDx, which sells a diagnostic test for coronary artery disease, also postponed its planned IPO, according to Renaissance Capital. CardioDx also cited poor market conditions. Redwood City, CA-based Relypsa, which is developing a treatment for hyperkalemia, reduced the terms of its IPO, which was planned for today.

Celladon initially filed confidentially for its IPO in early September. J.P. Morgan and Barclays were set to be the joint bookrunners on the deal.

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Austin's MapMyFitness Charts Digital Fitness Course to $150M Exit

Written by Angela Shah on Nov 14, 2013 05:42 pm

Angela Shah

2007 wasn't that long ago, but at that time when Robin Thurston and Kevin Callahan founded what was then called MapMyRun, using digital devices to enhance one's fitness routine was still largely the domain of ultra-athletes. Smartphones were new and everyday use of GPS was uncommon.

Six years later, the rechristened MapMyFitness has gone from a stand-alone fitness website to a suite of apps with a community of 20 million users who employ 400 different fitness tracking devices, sensors, and wearable technologies. And, earlier today, athletic apparel company Under Armour (NYSE: UA), announced it was buying the Austin, TX-based, startup for $150 million.

Chris Glode, MapMyFitness's general manager, says the company wasn't looking for a partner when Under Armour first came calling in the early summer. But he says he and his team ultimately were won over because of the Baltimore-based apparel maker's commitment to building an open platform. That platform allows users to use nearly any fitness monitoring device offered from dozens of manufacturers in order to track their workouts—say, the map

of your Sunday 5-mile run—and compare it with other routes, as well as sharing the information with family and friends on social media.

"This means something that is always free for users that provides consumers with the widest range of choice in devices, programs, and fitness equipment," he says. "That's important to us. We've spent time and energy working with our partners to get them integrated into our platform."

Both Under Armour and MapMyFitness share the belief that some of the best innovations come from outside their own walls, Glode added.

"This partnership is about Under Armour … Next Page »

Redfin Raises $50M From Tiger Global, T. Rowe Price, Others

Written by Benjamin Romano on Nov 14, 2013 01:44 pm

Benjamin Romano

Redfin just raised $50 million, more than double what the Seattle-based online real estate brokerage had raised from venture capitalists in its prior 11 years in business.

The company brought on new investors Tiger Global Management and T. Rowe Price Associates' portfolios for this "mezzanine investment." Previous investors Greylock Partners, Globespan Capital Partners, Draper Fisher Jurvetson, Vulcan Capital, and The Hillman

Company also re-upped in this round, which brings Redfin's total venture financing to $95.7 million.

Redfin last raised money in 2011, landing $14.8 million.

The financing was revealed in corporate documents dug up by GeekWire's John Cook last night, prompting the company to release its official announcement.

Redfin says the new capital will allow it to invest in new technology for each stage of the home sales process.

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In Defense of Sarepta's Chris Garabedian

Written by Brad Loncar on Nov 14, 2013 01:21 pm

Brad Loncar

Anyone who follows the biotechnology industry surely is aware of the setback Cambridge, MA-based Sarepta Therapeutics (NASDAQ: SRPT) experienced this week after FDA changed their mind about the company's ability to request early approval for its Duchenne Muscular Dystrophy drug, eteplirsen, on the basis of an encouraging Phase IIb study of 12 patients. However, the news appears to be considerably worse than the headline because there is also new doubt about what FDA will require of Sarepta's Phase III study, the one needed to truly confirm the signal seen in the prior study.

The agency appears to be asking for new additional endpoints, a longer study duration, and a larger study population than what most people were expecting going into this. In other words, the company unfortunately has in many ways been sent back to the drawing board. Sarepta and FDA expect to formally discuss those things in the coming weeks, and hopefully will

come to a speedy agreement.

Before getting to the main point I would like to make here, it is first important to recognize that there are no words to express how rightfully disappointed the Duchenne Muscular Dystrophy patient community must feel about this news. They currently have no good treatment options, and these patients undergo a steady decline before they typically die in their 20s. They deserve nothing less than urgency and clarity, yet seem to have come up on the short end of both of those things. That is particularly disappointing in this case because I have seen how they worked with all parties on this issue with dignity, class, and professionalism. Their contribution to this debate has truly been meaningful. I have the utmost confidence that all parties do place the highest importance on patients' interests, and can only hope that will somehow bear itself out over the coming weeks and months in their favor.

Chris Garabedian, CEO of Sarepta Therapeutics

With that being said, what I wanted to write about today is the job Sarepta CEO Chris Garabedian has done getting us to this point. No matter what the outcome, big news events like this bring out the "I told you so" crowd in full force, so it is only natural that some of those types of people will point the finger at him for this setback. The issue here is that some have said he should not have pushed for accelerated approval of eteplirsen as hard or openly as he did. While I don't normally think those types of things are worth responding to, in this case I have also seen a handful of journalists, investors, and other commentators who I have the highest regard for say similar things, so I felt compelled to write something in his defense.

First of all, I think it is important to remember how we got here in the first place. Luke Timmerman has already done a great job here reporting about how Mr. Garabedian brought this company back from the brink a few years ago. Without his leadership, there arguably would have never been a phase IIb study to begin with. Therefore, I think it is important to put into context any debate we are having today about FDA decisions or early approvals, because they likely are a moot point without him. He and his team deserve a lot of credit and appreciation for even getting us here.

I do recognize that all of those previous accomplishments don't change the fact that today we are left with a company that has suffered a significant setback, a DMD community that is sorely disappointed, and investors who have experienced a substantial decline of over 65 percent in one day (two quick disclosures: 1. I'm one of them and 2. investment losses PALE in comparison to what families of these kids are feeling right now). Add the fact that some critics are crowing loudly and you can see why a company's leader will naturally be one of the first people to take some flack when news like this happens. However, take it from an investor who is usually one of the first people to loudly dish it in a case like this…I strongly believe any criticism is misplaced here. I'd like to offer three reasons why:

First, while many people have argued … Next Page »

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San Diego Life Sciences Roundup: Tandem, Sorrento, Volcano, & More

Written by Bruce V. Bigelow on Nov 14, 2013 11:31 am

Bruce V. Bigelow

[*Updated 11/14/13 3:40 pm to show that Celladon postponed its IPO.*] Another San Diego life sciences company completed its IPO, and at least one more local IPO (Biocept) is waiting in the wings for its moment in the spotlight. (San Diego's Celladon has postponed its IPO.) We have details, along with the rest of the news.

—San Diego-based **Sorrento Therapeutics** (NASDAQ: SRNE) is taking another step in a turnaround saga that began four years ago when the biotherapeutics company merged with an inactive public company, Florida-based QuikByte Software. In a statement today, Sorrento says it is acquiring San Diego's Concortis Biosystems in a stock deal valued at roughly $12 million. The buyout gives Sorrento proprietary linkers and toxins for creating antibody-drug conjugates. As part of its transformation, Sorrento has completed a $35 million financing in recent months, acquired the late stage cancer drug Cynviloq (a new formulation of Abraxan) and acquired resiniferatoxin, an early stage, non-opiate painkiller.

—Shares of San Diego's **Tandem Diabetes Care** (NASDAQ: TNDM) began trading sharply higher on the Nasdaq exchange this morning, after the medical device maker became the seventh life sciences company in the region to go public this year. Tandem Diabetes Care, which makes a next-generation insulin pump, increased the size of its initial public stock offering yesterday, from 7.1 million shares to 8 million shares, and sold at $15 a share—at the high end of its expected range. Early trading today was above $19 a share.

—Engaged Capital, a Newport Beach investment firm headed by former Relational Investors partner Glenn Welling, has acquired a 5.1 percent stake in San Diego medical device company **Volcano** (NASDAQ: VOLC), according to a regulatory filing—and encouraging

buyout speculation. In a recent interview with Bloomberg, Welling said Volcano "is a very attractive acquisition candidate for the large medical device players within the cardiac space." Potential buyers include Abbott and Medtronic. Welling said his firm has been talking with Volcano about ways to increase the stock's value. Volcano makes products that help improve cardiac procedures.

—I got a chance to talk with **Arena Pharmaceuticals** CEO Jack Lief a few days after the San Diego diabetes drug developer said it had expanded its drug commercialization agreement with the Japanese drug giant Eisai. The revised deal enables Arena to work more broadly with Esai to evaluate other potential uses of lorcaserin, Arena's weight-loss drug, such as helping smokers to quit.

—San Diego-based **Illumina** (NASDAQ: ILMN) named Francis deSouza as president, a new executive position. DeSouza, who was previously the president of products and services at Symantec, will lead Illumina's business units and "core functions that envision, develop, and produce the company's products." He will report to Illumina CEO Jay Flatley, and also be responsible for directing the company's strategy, planning, and operations.

Saxena, Hirschtick, Wolfram to Talk Big Data and Devices on 11/21

Written by Gregory T. Huang on Nov 14, 2013 11:00 am

Gregory T. Huang

What can we learn about big data from the founders of Netezza, SolidWorks, and Wolfram Research? Quite a bit, I wager.

And we will, one week from today, at our "D^2: The Future of Data and Devices" conference. It's all going down on Thursday, Nov. 21, at the Fidelity Center for Applied Technology in Boston, near South Station. We only have a few tickets left, so you should get yours today if you want to attend. (See full agenda here.)

Just a few highlights to preview:

—**Jit Saxena**, the founder and former CEO of Netezza (acquired by IBM in 2010), will join a panel with Actifio CEO **Ash Ashutosh** and DataGravity President **John Joseph** (an EqualLogic veteran) to talk about the enterprise of the future. Moderator **Bob Hower** from G20 Ventures will draw out lessons about analytics, business intelligence, and realizing value from big data.

—**Jon Hirschtick**, the founder of SolidWorks and former MIT Blackjack team leader (now with Belmont Technology), will speak on a panel about cloud-based disruption in design and data. He is joined by GrabCAD CEO **Hardi Meybaum**, Salsify co-founder **Rob Gonzalez**, and moderator **Ric Fulop** from North Bridge Venture Partners. This is about how data flow in the cloud is transforming product design, development, and distribution.

—Computational guru **Stephen Wolfram**, the creator of Mathematica and Wolfram Alpha, will kick things off with a keynote about his vision for big data analytics. Be ready for anything.

We will be ready on the 21st. See you there.

Qloo, Now Out of Beta, Wants to Learn Your Different Cultural Tastes

Written by João-Pierre S. Ruth on Nov 14, 2013 10:52 am

João-Pierre S. Ruth

Lots of apps try to tell people where to find stuff they like. New York's Qloo came out of private beta Thursday promising deeply personal recommendations for multiple interests.

The company already has $3 million in seed funding in pocket from backers including Kindler Capital, as well as individual investors such as comedian Cedric the Entertainer, actor Danny Masterson from "That '70s Show," and movie producer Tommy Thompson. Unlike discovery platforms that focus on one topic, such as food, Qloo covers eight categories. The idea, says CEO Alex Elias, is to feed some clues to the system and let it learn about users' tastes in books, dining, movies, music, travel, TV shows, fashion, and nightlife.

By absorbing multiple data points, Qloo's founders Elias and COO Jay Alger believe their platform offers a more complete picture of what appeals to each person.

Elias says Qloo was born from his frustration at making decisions on vacations. Picking a travel destination, hotels to stay in, and restaurants to dine at, he says, can be a hassle. "I found myself wishing there was a tool that understood my tastes," he says.

Wanting something to offer him intelligent, personalized suggestions, Elias says such information was available, but across different sources and channels. "Goodreads can suggest books based on my taste in books," he says. "Pandora does music."

Tying those different aspects together, he says, can lead to more useful recommendations. So Qloo takes a holistic view of various points of appeal. The engine compares personal preferences with what appeals to others with similar tastes, Elias says, to offer suggestions. Nearly 30,000 folks—including artists, musicians, and chefs—contributed their tastes during the platform's beta phase, he says, to form the foundation for Qloo's public launch.

Alger says the app needs just five points of preference to start forming a picture of each person's tastes. "It could be one of your favorite movies, favorite music artists, or restaurants, or books," he says. Users can also offer additional layers of detail, such as subcategories in dining. That could be favorite places to eat brunch or take the family, he says.

The startup put in extra sweat structuring data, Alger says, on such content as every film ever made, every book in print, restaurants across the country, and hotels around the world. "We're wrestling an enormous amount of data," he says.

The platform's algorithm processes that data, Elias says, in relation to responses from the Qloo community to make recommendations. The suggestions can be tailored to reflect one's mood or specific occasion as well. "You can find movies to watch with the kids or with a date," he says. As users express opinions on the recommendations, giving thumbs up or thumbs down, Elias says the engine develops a more detailed picture of their tastes.

Armed with their curated suggestions, users can then click through to content channels, he says, such as Amazon, Netflix, and iTunes. "We're going to be integrating Rdio and Spotify very soon," Elias says. The platform also connects users to the suggested restaurants and hotels to book reservations.

Though Qloo covers diverse areas of culture and entertainment, Elias says it is focused enough to not glut users with too many ideas. "We could have gone broader and included things like wine and cars," he says. The company decided to stick to things that have some correlation to each other. "There's a plausible connection between people's preferences within music and their preferences within fashion," Elias says. Literature and film choices can

be mutually informative, he says, as well as dining and nightlife interests.

Before Qloo was founded in 2012, Elias was a principal with private investment fund APE Capital; Alger ran a New York-based a digital design agency. They drafted staff from Alger's agency to be Qloo's CTO, design director, and fill other roles.

Now that Qloo has opened up to the public, Elias has grander plans in mind. He believes the startup's big play will be the creation of a new ecosystem that other apps can be built on top of. "Our goal is to open this up for personalization, the same way Google Maps works," Elias says.

Clot-Busting Inventor Breaks Barriers for Medtech Entrepreneurs

Written by Bernadette Tansey on Nov 14, 2013 10:30 am

Bernadette Tansey

A typical entrepreneur accepted into the competitive startup incubator at the Fogarty Institute for Innovation in Mountain View, CA might be an engineer from the Stanford Biodesign Program, a formal academic program that trains students to invent medical devices. But Dr. Thomas J. Fogarty, who founded the Fogarty Institute in 2007, says he'd be equally open to a great idea that came from a hospital nurse, or even an orderly.

"It could be anybody," says Fogarty, the cardiovascular surgeon who invented the groundbreaking balloon catheter for clot removal in 1960. "Great ideas do not reside within

any given institution—it resides within the person," he says.

Over the past five years, the Fogarty Institute has nurtured more than a dozen fledgling companies with ideas for cardiovascular diagnostics, blood clot treatments, ear care tools, a miniature sewing machine for surgical stitching, baby monitoring devices during childbirth, and other innovations. One of the current entrepreneurs in residence is Peter Coelho, a family practitioner from Hollister, CA who felt he didn't have the tools he needed during tricky home births.

The institute's resident innovators are all kept in close touch with nurses, doctors and other hospital staffers who deal with unsolved medical problems every day.

"It's very important that we pay attention to those people," Fogarty says.

The program is based at El Camino Hospital, a non-profit community medical center founded more than 50 years ago. Each inventor is assigned to work with a physician who provides guidance and feedback, says Anne Fyfe, CEO of the institute.

Fogarty, 79, holds that inspiration comes from close observation of a practical problem. It's not a surprising belief, given his biography. The veteran of many humble jobs before he was out of his teens—grocery store clerk, machine shop assistant, and hospital scrub technician at 5 cents an hour—Fogarty started on the path toward his seminal invention when he witnessed the invasive and often unsuccessful clot removal surgeries performed by the experienced physicians of the time.

As a 26-year old medical student, he faced an initial backlash from traditional surgeons in 1960, when he offered an alternative—an invention now known as the Fogarty balloon embolectomy catheter. As he recalls in a video on the institute's website, the device was inspired by his observation that a balloon will conform to the varying shape of a soda bottle's neck when the balloon is pushed into the bottle. The same thing would happen, he concluded, if a balloon were pushed through an artery to clear out a clot. He made the first conceptual

model with a balloon made of a surgical glove fingertip, tied to a hollow tube with fishing line.

In the final version used in patients, a tiny deflated balloon is enclosed in a catheter. The catheter is threaded into a blood vessel until it has passed the location of a clot. Then the balloon is inflated, using air that flows from the hollow core of the catheter. As the catheter is then pulled back out, the inflated balloon pushes the deposits in the clot out with it.

The invention, later widely adopted and commercialized by Edwards Lifesciences of Irvine, CA, launched Fogarty's long career as an entrepreneurial surgeon, device company founder, venture capital firm executive, and co-founder of a winery.

Fogarty sees a host of obstacles for the US innovators of today—regulatory hurdles, academic inertia, funding bottlenecks, and high startup costs that are driving entrepreneurship to other countries. But innovative individuals and industry also need to aim higher, he says, and try to create significant improvements that also save money for the health care system.

"Small improvements can cost an awful lot of money," Fogarty says. Applicants to the Fogarty Institute must demonstrate that their inventions could cut costs.

One of the institute's earliest portfolio companies, HeartFlow of Redwood City, could save the US health care system billions of dollars on unnecessary diagnostic tests, says Fyfe.

HeartFlow, founded by a vascular surgeon and an engineer from Stanford University, is developing a non-invasive test to improve the diagnostic power of a standard imaging test, the coronary CT scan or coronary computed tomography. This Xray scan collects data that is assembled into a 3-D image of the heart and coronary arteries. HeartFlow's test uses computer algorithms on the CT data to calculate the flow of blood through each vessel and identify patients who may have a significant obstruction that requires further testing or treatment. It can also rule out patients who don't need further invasive procedures, the company says.

Among the other alumni of the Fogarty Institute is PQ Bypass of Sunnyvale, CA, which is testing a less invasive form of surgery to improve blood flow in the limbs.

The incubator program has a rolling admissions policy. New startups are invited … Next Page »

Ovuline Takes Geeky Approach to Pregnancy Tracking with Ovia App

Written by Curt Woodward on Nov 14, 2013 09:45 am

Curt Woodward

For a lot of people who get pregnant, the freak-out-and-gather-information phase still looks a lot like it did decades ago: stockpiling thousands of pages of advice books, and trying to burn through them all without gagging on all the conflicting pointers.

It's not a terribly efficient way to gather information. But anyone who's tried to simply collect all of their medical records in one place can tell you that the healthcare industry isn't exactly on the cutting edge of the Web age.

Entrepreneurs have noticed. The medical category in the iOS app store, for example, is chock full of paid and free pregnancy and fertility apps, all racing to build a better way of helping women navigate the most important time in their lives.

One of those startups—Cambridge, MA-based TechStars graduate Ovuline—is taking a big leap forward this week with the debut of its new pregnancy-tracking app, Ovia.

Ovia is the second app from Ovuline, which started out with a fertility-tracking app released last year. That product attracted about 150,000 users, who have given it great reviews and kept it ranked in the top 10 of free medical apps.

And, as you might expect, that's led to some ready-made customer demand for the new pregnancy app.

"We have a list of tens of thousands of women who we've gotten pregnant, who have said `Yeah, please help me track my pregnancy,'" CEO Paris Wallace says. "And we've said, `We're working on it!'"

Ovia is, as Wallace says, "jam-packed" with features that a mom-to-be might want at her disposal.

Ovia is part pregnancy journal, with details on what size the developing baby might be at each stage and the ability to upload pictures of a growing belly. It's also a medical guidebook, with a huge list of FDA recommendations for medications and a compendium of common pregnancy symptoms. It even connects to a galaxy of "quantified self" devices, like wifi-enabled scales and blood-pressure cuffs, to help measure physical health.

But the heart of Ovia—just like Ovuline's fertility tracker—is its ability to gather, synthesize, and analyze data contributed by its users. Instead of just offering a blunt-force lookup tool that tells women what to do about higher blood pressure or a weird rash that may have cropped up, Ovia responds automatically to the information that expectant moms are adding to the mix.

So, if a woman reports that she's looking pale and feeling fatigued, Ovia will immediately ping her back with an alert—those symptoms could be indicators of anemia, and it's time to check in with the doctor. If she reports something less serious, like an itchy stomach, Ovia

will kick back an article about the symptom and how to treat it.

Ovia also gives pregnant women a sense of how their experience relates to that of other moms, indicating how many other women at a similar stage in pregnancy might have reported a similar mood, for example.

“The fundamental question people are trying to answer is, `Is this normal? Am I normal?’” Wallace says.

Ovuline got its start when Wallace’s co-founder, computer scientist Alex Baron, went the ultra geeky route when he and his wife were trying to conceive.

“The joke there is, he was starting his family and, as opposed to doing what any normal person would do—which is have sex—he started writing algorithms to predict ovulation,” Wallace says with a laugh.

It worked, by the way, and Ovuline was born. Investors have staked the company with about $2.75 million so far to help get Ovia, its marquee product, into the market.

It’s no mistake that Ovuline took its time building a feature-packed pregnancy app—the market for women wanting to track a pregnancy is much larger than those seeking a fertility app, just for the simple fact that many pregnancies aren’t planned, and many more are the result of less-intensive “see what happens” efforts to have a baby.

“We think there’s about 1 million people in the United States every year who are trying to get pregnant, and there’s 4 million pregnancies,” Wallace says. “And we know the vast majority of those people are signing up for pregnancy trackers.”

Ovia is free to users, so it can get the widest possible distribution. Ovuline makes money by collecting lead-generation fees for service providers who are contacted by its users, but the startup goes out of its way to make sure personal data and e-mail addresses aren’t shared with

or sold to outsiders.

That obviously sounds like a good policy, since the key for Ovia's success is women trusting it enough to document very personal moments via the app. On the upside, that means the recommendations that Ovia makes should be pretty specifically targeted, especially compared to most Web advertising.

"If you're based in Boston and you want to go back to work, it turns out that you typically need to sign up for daycare 10 months before," Wallace says. Since Ovia can calculate that lag time based on the baby's due date and other personalized information the mom enters into the app, "We know the exact day and say, `Hey would you like to be connected with one of our partners?'"

If the answer is yes, users are sent to a sign-in page where they submit their contact information again, making the process totally opt-in.

Ovuline employs 13 people now, one of the bigger teams working out of the TechStars office in Cambridge. If the young company can duplicate its fertility app success with the Ovia pregnancy tracker, you might be hearing more from them.

"The biggest determinant of where you fall on the app store is how good your product is and how engaged your users are," Wallace says. "Yeah, there are some ways to goose it, but you need constant success and you need an amazing product.

"If you have that, you actually win, which is exciting."

Austin's MapMyFitness Bought by Under Armour for $150M

Written by Angela Shah on Nov 14, 2013 09:37 am

Angela Shah

MapMyFitness, an Austin, TX-based workout app company, is being acquired by the athletic apparel company Under Armour (NYSE: UA) for $150 million.

The Austin startup, which was founded in 2007, has about 20 million users for its most popular apps, MapMyRun and MapMyRide. By using GPS and other technologies, fitness apps like MapMyFitness help users map, record, compare, and share workouts.

“This partnership is about Under Armour enhancing our digital expertise to drive the future of performance innovation for the global athlete community,” Kevin Plank, founder and CEO of Under Armour in Baltimore, said this morning in a press statement. “We will build on the community of over 20 million registered users that MapMyFitness has cultivated in the connected fitness space, and together we will serve as a destination for the measurement and analytics needs of all athletes.”

MapMyFitness raised $9 million from Austin Ventures last year and has raised a total of $23 million. As a wholly-owned subsidiary of Under Armour, MapMyFitness will continue to operate out of its headquarters in Austin.