



Spotlight on Novocell, Inc.

By Greg B. Scott, Managing Editor

We sat down with Dr. Alan Lewis, the new CEO and President of Novocell, Inc., a stem cell company focused on the treatment of diabetes. Its exciting technology promises highly efficacious therapy for this 5th most deadly disease, while avoiding the immune response issues normally associated with the injection of derivative cells. We explore the many challenges – technical, political and sociological – facing stem cell companies today, and how Novocell plans to overcome these to bring its innovative therapy to market.

Editor's Note: The following are highlights of the interview with Dr. Lewis. You may listen to the interview in its entirety at: www.BioBusinessNews.com.

BBN: As the new president and CEO of Novocell, you've obviously facing some big challenges. What are the two or three largest?

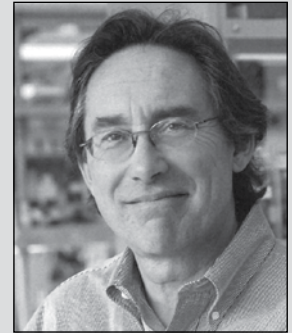
Dr. Lewis: Obviously, the most significant one for any CEO is to raise enough money to ensure you can exploit all of our product opportunities. That's number one, by far. Secondly, [because] we're in the stem cell

field, we need to gain FDA support for our first-in-class cell therapy for diabetes. And we work with embryonic stem cells, so there are certain political and ethical tensions which surround this innovative technology and that's clearly an issue that's on my mind. And then fourthly, the stem cell arena, whilst new, is becoming a busy one from an intellectual property perspective and so we have to avoid the IP minefield as well.

There is a lot of hype surrounding stem cell research today and there are several stem cell companies claiming to be on the leading edge. What makes Novocell different?

We like to refer to Novocell as a stem cell engineering company. What we mean by that is we are able to culture [embryonic stem cells], differentiate them into specific cell types and then produce them in large quantities. We have skill sets in the company of not only stem cell biology, but also developmental biology, so we understand how to take an embryonic cell right through to the end cell, such as a pancreatic islet cell, for example, or a neuronal cell, which is obviously the end game from a therapeutic perspective. As an add-on, we do have some very

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Alan Lewis, PhD
President and CEO

FastFacts

Novocell, Inc.

CEO Profile

Founder/CEO of Signal Pharmaceuticals, divisional President at Celgene, VP of Research at Wyeth-Ayerst. PhD in Pharmacology from University of Wales, Yale postdoc.

Company Focus

Stem cell engineering, developing first-in-class therapies for diabetes and cancer

Funding

\$40MM from Johnson & Johnson Development Corporation, Sanderling Ventures, Asset Management, and others; raising \$30MM Series C

Location

31 Technology Drive, Suite 100, Irvine, CA 92618

www.novocell.com

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FACTOIDS

72% of Americans Support Embryonic Stem Cell Research

In a recent poll by the Coalition for the Advancement of Medical Research (CAMR), nearly three-quarters of Americans support embryonic stem cell research and 70% support federal funding for stem cell research.

A Single Donor Stem Cell Can Generate Billions of New Cells

Embryonic stem cells are functionally immortal – they can keep generating new cells indefinitely. One donor cell can create billions or even trillions of both stem cells and cells that will differentiate.



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Stem Cells: Much Promise, Many Hurdles

By Greg B. Scott, Managing Editor

When California voters approved Proposition 71, the California Stem Cell Research and Cures Initiative, in November, 2004, most believed that a great victory had been won and that \$3 billion would quickly be on its way to fund stem cell research. But politics and bureaucracy have a way of putting a halt to even the best of intentions, and no progress was made for over 17 months.

Finally, in April of this year, two major battles were won: 1) the California courts upheld the constitutionality of Prop 71, in its entirety, and 2) the California Institute for Regenerative Medicine (CIRM) awarded its first scientific grants, providing over \$12 million to 16 different California universities and research institutions. Then more good news came when this July, H.R. 810, The Stem Cell Research Enhancement Act, was passed by both the House and the Senate.

Then a near fatal blow was dealt when President Bush vetoed the bill, declaring that “these boys and girls are not spare parts.” It was surprising and disheartening when this *non sequitur* solicited an extended round of hearty applause. Political conservatism had truly won out over scientific reason.

The Bush administration’s steadfast denial of Federal support for embryonic stem cell research is eroding the fundamental ability of the U.S. to develop stem cell based therapeutics. Many of our most prominent researchers have left the country, seeking opportunities in more politically conducive environments. Others have given up their research or just simply never entered the field, choosing instead to pursue more fundable areas. This undermining trend is certain to worsen as a result of the veto.

The adverse political climate has also generated some wide-spread fallout that is affecting the pharmaceutical and biotech industries. Companies are shying away from the controversy and limiting themselves to less contentious areas of drug development. This repression of business and science in the name of a political cause can only spell trouble in the future.

There are very real moral and ethical issues surrounding the use of human embryo stem cells that must be acknowledged. But blocking or ignoring this significant avenue for research will prevent scientific breakthroughs and life saving therapies from being developed for decades to come. This harkens back to “The Lysenko Affair” of the 1950s, when the former USSR banned all genetic research, a decision Russia has yet to recover from 55 years later. If the President’s veto is not overturned, the U.S. could be in the same situation – left out of the stem cell revolution and missing out on the contributions currently on hold in our universities, research institutes and biotechnology companies.

It is our fervent hope that pioneering companies like Novocell, our Spotlight Company this month, find the political, societal and financial support necessary to fully develop this exciting technology and make good on the promise to revolutionize the practice of medicine as we know it.

For more information see www.BioBusinessNews.com.

Have an opinion regarding this or another topic affecting biotechnology or medical device companies? We welcome reader opinions. Send yours to editor@BioBusinessNews.com.



How to Set a Patent Strategy

By Cooley Godward LLP | www.cooleygodward.com

Getting a new drug to market can cost as much as \$800 million or more. With this type of investment, patents are vital to protect a company's intellectual property and market exclusivity.

But patents provide a company with much more than the opportunity to protect a market space or product franchise. They are also attractive assets to potential investors, collaborators and acquiring companies. And they can help remove roadblocks set by third-party patents through cross-licensing.

The maximization of IP value requires a strategic approach by the company and its patent counsel, and that approach needs to be much more sophisticated than simply filing patent applications early and often. The patent strategy must be based on the company's business model and its business plan. It also must take into account the larger picture of the company's business environment and its endgame.

Consider the example of a startup biotechnology company. The company begins by obtaining a license for its initial core technology from a university. It then develops and enhances that technology through its own research and development efforts. Eventually, the company seeks to partner with a large pharmaceutical company for further research, development, regulatory approvals and marketing. What should the company do to develop a patent strategy to maximize the value of its intellectual property?

Due Diligence

The first step in developing the patent strategy comes when the company begins negotiations to license its core technology from the university. It starts with a strategic analysis of the patent rights supporting that technology, typically through a due diligence process.

For reasons of cost and time, senior management may be tempted to settle for only a limited due diligence. The company's transactional counsel might also see this as something that patent counsel does near the end of the deal with a simple checklist to complete. But in view of the importance of the asset being acquired, the significant upfront fees and other considerations often associated with technology license agreements, senior management should work with its patent counsel to start the patent strategy development process early and devote sufficient resources to it.

While the due diligence itself is fairly straightforward, there are many elements to consider. The ownership and chain of title for the patent rights need to be confirmed. Any potential restrictions must be identified, including not only financing liens filed under the Uniform Commercial Code but also restrictions arising under other license agreements that may be related to the technology.

Moreover, the patent rights need to be examined to assess their realistic scope and significance. Obviously, the company has already decided that the rights are critical to its business strategy. But the company's understanding of these rights is all too often based on cursory readings of the titles and abstracts by management and scientists, rather than on a careful analysis of the claims by patent counsel. That legal analysis should also include an analysis of the patent application file histories to identify any potential impairment.

Finally, patent counsel should conduct a "freedom to operate" assessment of the technology. Any third-party patent rights that might be infringed by the use of the technology must be identified and analyzed. Often, this analysis is rejected for cost reasons, although the cost for the search and initial review of third-party patents is not great compared with the total legal costs for the licensing transaction.

Entrepreneurs may also have a misguided notion that, as a startup company, they can operate under the radar. But any future big pharma collaborator or venture investor will insist on doing in-depth due diligence on the company's technology, and thus the company can never hope to escape scrutiny on these issues.

Of course, a sound understanding of the value of the intellectual property rights being licensed provides a basis for rational pricing of the deal and offers leverage in negotiating with the licensor for a reasonable price. But strong due diligence, now coupled with a well thought-out patent strategy, will also pay dividends over the life of the asset.

Developing The Strategy

Transactional due diligence leads naturally to the development of a detailed patent strategy, which will, in turn, guide

“To maximize IP value, companies must do more than file early and often.”

Jayme Huleatt, Cooley Godward LLP

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Why Use an Investment Banker to Sell Your Company?



By John J. Taylor, Vice President, Fairview Advisors
www.fairviewadvisors.com

Executives embarking on a major transaction, such as selling their company, buying other companies, raising capital or going public, usually give some thought to hiring an investment banker. Within the biomedical market, M&A transactions are increasing in number and value while IPO transactions are decreasing. So this article will focus on the prevalent trend in liquidity events – selling your company.

SELLING YOUR COMPANY

You're ready for a liquidity event and the timing's right. You're probably thinking, "No one can present my company better than I can. Why pay a fee when I can probably do a better job myself?" But then, you also know colleagues that have chosen to use investment bankers, so there must be something to it.

This dilemma – to use an investment banker or to manage the sale process yourself – is one that successful companies must face at some point. The right decision for some companies may be the wrong decision for others. But, there are a number of considerations each company should evaluate before selecting a course. Some of the more important ones follow.

1. Am I and my staff willing and able to dedicate the time necessary to conduct a professionally organized sale process? The process of selling your company is incredibly time consuming and disruptive, involving myriad details, and, typically, consuming at least six months of dedicated effort.

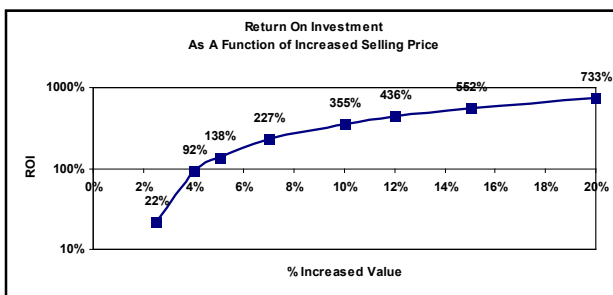
A partial list of typical activities in the sale process is shown at the upper right of this page. Depending on the company and situation, this could expand dramatically. You will need to dedicate your most critical people to work on the sale of the company at the exact time when demonstrating the value and effectiveness of your business is most important. In addition, extra management time will need to be allocated to maintain your customer and supplier relationships during this critical time.

2. How do I maximize my company's sales proceeds net of the investment banking fee? At the end of the day, maximizing the liquidity event is probably the single,

most important reason you're selling your company; and the single, most important element in determining a company's value is recent success. Buyers don't give much value for plans, projections and expectations – they pay for performance. If management is fully engaged by the sale process, they run the risk of letting the business suffer or missing a critical milestone, possibly jeopardizing the sale. An invest-

Selected Sale Activities
• Develop the sale strategy
• Identify qualified potential buyers
• Prepare the Summary, Sales Memorandum and Presentation
• Prepare financial models
• Contact buyers and negotiate NDAs
• Distribute sales memorandums
• Receive Indication of Interest Letters
• Develop due diligence binders
• Present to interested parties
• Solicit proposals and review submissions
• Select most attractive candidates
• Complete due diligence
• Negotiate legal documents
• Close transaction

ment banking success fee can amount to a lot of money, and should be analyzed as any investment would: Will hiring an experienced investment banker provide sufficient return for the risk? Success fees and their structures vary, ranging from 1% to 5%, depending on the size of the transaction. Say the investment banking fee is 2% and you're confident you can sell your company for \$50 million, without any help. If your company sells for only 2% more (or \$51 million), the fee is \$1.02 million and you've lost \$20 thousand. But if your company sells for 5%, or \$2.5 million more, then your return on investment is 138%. So if a banker can add more than 2% in value, the ROI is very high. (See the chart below.)



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the company by setting goals and priorities. One of the first outcomes of due diligence is the identification of gaps in the patent portfolio or of potential blocking patents that may impede the company's ability to exploit its technology. The gaps may be filled through additional licensing or the company's research and subsequent patenting. The problem patents can also be addressed through licensing or other legal strategies.

Another outcome of due diligence may be the identification of weaknesses in the patent applications themselves. Applications from universities can be especially problematic. Since patent filing decisions are often made before a licensee has been identified, there is significant pressure to keep costs down. Moreover, there may have been limited time to prepare the application. Many a tech transfer person has had to scramble to get an application filed after learning that a professor will be speaking at a conference the next day. The company may choose to overlook these weaknesses to get the deal done, but they still must be addressed going forward.

Beyond the initial results of the due diligence, a strategic plan represents an ongoing process that evolves as the company's business plan evolves.

One basic issue is what to patent. The plan should define categories of technologies that are specific to the particular company and, starting with core products, determine how aggressively to pursue patent protection for each category. With respect to tangential technology, for example, the company may be interested only in protecting its own freedom to operate; therefore, it may file only a limited number of "defensive" patent applications and, perhaps, only in the United States.

The plan should also set decision-making criteria for each point in the process of obtaining a patent. For example, what factors will the company consider before filing a provisional application in the United States, and before filing counterpart applications in multiple foreign countries?

In addition, the plan should provide a long-term approach for identifying and neutralizing third-party patent rights that may block research, development, or marketing of the biotech's products.

One of the most important tasks in developing a patent strategy is to obtain management buy-in. The patent strategy must reflect the larger business plan. This sounds obvious, but is often given insufficient attention.

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interesting encapsulating technology which allows us to encapsulate these cells so that they're protected from the immune response of the patient. That's a unique feature of Novocell – no other stem cell company has that kind of technology.

Your first focus is on diabetes. Why was that chosen? It seems like a complex area.

It may seem like a complex area, but it's actually the low hanging fruit to the stem cell biologists that want to get into therapies. All we intend to do is to replace the insulin producing cells in the body, and we believe that the stem cell derived islets can do that. There are other areas that people are working on today, for example, cardiovascular disease and CNS diseases. In both of those situations you have to put cells into patients so that they have to integrate into the organ in question – in the brain or in the heart. We're able to put our stem cell derived islets subcutaneously into a patient – we don't have to put it into the pancreas – and so we don't have any invasive surgery and there needs to be no integration. All we need [to be effective] is to ensure there will be an adequate blood supply which will take the blood sugar to the islet and that will cause a release of insulin.

That's very exciting. So when do you expect to be in the clinic?

We've already done the proof of principle clinical trials with our primary islets, but the stem derived islets, which is the ultimate product, of course, will happen in the first quarter of 2009.

I know you're doing some research in areas other than diabetes, so what's next?

Absolutely. Because of our knowledge of the science of stem cell culturing and differentiation, we've identified certain targets which we believe will be perfect for evaluation in drug discovery, whether it's with antibodies to actually modify the target, or even small molecules that could do so. So I think that the cancer stem cell area is an area that you will see Novocell developing over the next few years as well.

You raised \$20 million in March from a who's who of VC firms...

Yeah, we're very fortunate that we've certainly got a number of key investment groups from Sanderling Ventures to Asset Management and Johnson & Johnson. We were fortunate that the Johnson & Johnson Development Corporation led the series B and obviously J&J has a particular interest in diabetes – it's a strategic area for them – so their investment was one of great value to us. And we have a very experienced board of directors and they [all] under-

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Stem Cells to Treat Diabetes

By Frank H. Eeckman, MD, PhD, Science Editor

Dr. E. Edward Baetge, Novocell's Chief Scientific Officer, is passionate about Novocell's stem cell technologies. "This is the most innovative combination of technologies in the world," he stated.

Novocell has developed three key technologies to: 1) grow and replicate human embryonic stem cells (hESC), 2) differentiate these cells into insulin-producing islet cells, and 3) protect implanted islets from the body's immune response. A single injection of these special islets promises to combat diabetes for years before another injection is needed.

"For islet transplants, you can't rely on adult stem cells," said Dr. Baetge, "you need to use embryonic stem cell lines." Novocell's new cell line "will be all-human, fully GMP, and functionally immortalized. It will be an unlimited source of cells prepared using state of the art methods."

Novocell's new and exciting approach has the potential to provide a true blockbuster therapy, and literally change the way diabetes is treated. Novocell hints that it may even provide a cure.

Dr. Baetge has worked in developmental biology for Bristol-Myers Squibb, Cytotherapeutics and Modex Therapeutics in Switzerland. He holds a PhD in molecular neurobiology from Cornell University.

Dr. Eeckman's interview with Dr. Baetge and analysis of Novocell's science is available at www.BioBusinessNews.com

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3. Does my company possess the specialized knowledge necessary to successfully sell the business? All successful businesses have a trusted lawyer, CPA and strong management team. But, ask yourself, “Does my team...”

- Know which buyers would likely be interested in buying my company?
- Have the ability and experience to conduct a competitive selling process and generate multiple purchase offers?
- Have the ability and experience to fairly and objectively value my company versus industry “comps” and to determine the right “comps” to use?
- Have an up-to-date understanding of capital markets and the current financial structures used by acquiring companies in the biomedical industry?
- Have experience in dealing with acquirer objections and issues?
- Have the requisite, prior experience negotiating sale transactions?
- Have the ability to represent my company with the objectivity and fairness necessary to command the respect of the acquiring companies?

If you can’t answer the majority of these questions with a resounding “Yes,” then your company’s ability to conduct a successful sale without the help of an investment banker is likely to be at risk.

4. If I have all of these skills and abilities should I run the sale process myself? Even if you have the ability to run a sale process, a third party is still in a position to do a better job of it. Often times, the key to maximizing the value of a company is to run a process whereby all of the potential buyers make proposals and walk through the process concurrently. In the real world, getting multiple buyers to step through a process together is not easy. The banker is in the best position to manage the process while maintaining the confidence of the buyers that the process is being conducted in a fair and reasonable manner.

5. Who are the potential buyers for my company and how do I reach them? Most selling companies consider only strategic buyers (companies operating in the same or similar market as the seller) or the larger players. But, as the biomedical market has enjoyed increasing prosperity, new classes of buyers have surfaced and should be contacted as part of the selling process – private equity firms, foreign buyers, or smaller firms with strong backing. If your company doesn’t possess the broad network of contacts in each of these classes of buyers then you should consider hiring an investment banker.

6. Can I produce compelling marketing materials and conduct persuasive management presentations?

Producing professional marketing materials is an important part of the sale process. It begins with an Executive Summary that’s short but tells your company’s story and captures the reader’s interest. It progresses to the Sale Memorandum, a detailed book about your firm that may run to 100 pages. Management presentations come next and must address buyer expectations that can vary by the type of buyer: strategic, financial or foreign.

7. Can I optimize the transaction structure? Just as every company is unique, every transaction is unique, and each deal must be structured to meet the specific objectives set by both the buyer and the seller. Transaction structures also change due to many factors including deal pricing, terms and conditions, valuation, earn-outs, fluctuations in market conditions, liability concerns and employment contracts, to name a few. Often, an objective third party is necessary for management to properly sort through these myriad, complex issues.

8. When should I not use an investment banker?

- Is the expected deal size large enough to afford a reasonable banking fee? Generally, an investment bank can’t afford to work on a transaction producing less than a \$300 to \$500 thousand fee. So, unless the transaction is well north of \$5 million, it generally doesn’t work.
- Is there an existing shareholder, board member or insider who will buy your company? If you have direct access to a buyer who will pay a fair price, then it may not make sense to hire a banker and conduct an organized sale. On the other hand, how do you know it’s a fair price? We’ve already shown in the ROI graph that a small (2%+) increase in selling price, can generate a very large ROI.

IN SUMMARY

Selling your company requires a broad range of abilities including specialized knowledge, a very large time commitment, extensive contacts and industry knowledge, and a proven track record of negotiating successfully and getting deals done. Although a banker’s success fee can be large, it can generate a very high return on investment by successfully concluding your sale at the highest price and allowing you and your management team to focus on what you do best – successfully running your company.

For more information, please contact John J. Taylor, Vice President, FairView Advisors, LLC | (650) 347-1815, john@fairviewadvisors.com



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A more difficult step is assessing certain intangible aspects of management's attitude toward intellectual property. For example, how willing is management to litigate or take other steps to enforce the company's patent rights? A litigation-averse management may require the development of quite a different strategy from that willing to aggressively enforce its rights.

Implementing The Plan

Great strategy is useless without implementation. One effective implementation tool is an intellectual property committee comprising senior scientists and management along with patent counsel. This committee should meet regularly to consider matters such as potential new patent filings and maintenance of existing rights. Patent counsel can also consult the committee as larger issues arise in developing the general strategy.

Another useful tool is a yearly review of the patent portfolio for purposes of overall planning and weeding out marginal applications. In this context, it is helpful to have historical cost figures for each patent family and to develop projected costs for the next one to three years.

A few additional points are worth noting. First, while consensus is fine, a cost-effective strategy should be based upon final approvals by management or the head scientist responsible for the product or area of research. If such a person cannot see the value added by a particular patent application, for example, it probably should not be pursued.

Second, it is important to look at the total estimated cost of securing the patents on a particular invention. Too often, the focus rests instead on the cost of the very next filing -- for example, the \$5,000 to file an initial Patent Cooperation Treaty application -- instead of the \$200,000 to \$300,000 that will ultimately be required to obtain reasonable foreign protection on a single biotech invention.

Third, it is usually a mistake to pursue marginal applications under the notion that someday the patent rights could be licensed to another company. In a small biotech company, that is highly unlikely to happen, despite the best of intentions, because the business development people have time only for major transactions.

If a biotech company has developed and implemented an intelligent patent strategy and has successfully done the

many other tasks necessary to develop its products, then the company is ready for its collaboration with big pharma.

It can be certain that a large pharmaceutical company will do a comprehensive, across-the-board due diligence, including a very careful look at all the relevant patent rights. At this point, however, the biotech company should be in an excellent position to address any significant concerns raised by the pharmaceutical company.

A comprehensive and well-implemented patent strategy requires more management involvement and greater expense than a plan that simply focuses on filing and prosecuting applications at the lowest cost. Any sound asset-building activity requires a real investment of time and resources. But when the big pharmaceutical company prices the technology deal or perhaps even offers to buy the company, the biotech's investment in patent strategy will be returned many times over.

“A good solution applied with vigor now is better than a perfect solution applied ten minutes later.”

General George S. Patton, Jr.

For questions on this article, please contact Jayme Huleatt, Special Counsel, Cooley Godward LLP, at 202-842-7842.

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VC Activity on the Rise in California

By Richard Daverman, PhD, Business Editor

California Life Science Fund News

VantagePoint closes on \$756 million of \$1 billion fund (San Bruno); Technology Partners launching eighth fund at \$250 million (Palo Alto); Bailard launches \$40 million fund (Foster City); Okapi closes first fund at \$30 million (Laguna Beach); Life Science Angels closes member-only side fund (Palo Alto)

Fluidigm Raising \$15 Million

Fluidigm of South San Francisco, a maker of integrated fluidic circuit systems, made its first close in a Series E round expected to raise \$15 million. AllianceBernstein LP is the initial investor in the round. Founded in 1999, Fluidigm has raised a total of \$90.5 million.

Allux Closes on \$6.4 Million Series B

Allux, a two-year old company based in Menlo Park that is developing a medical device for hay fever, took in \$6.4 million in a B round. Prospect Venture Partners, Three Arch Partners and Venrock Associates all participated.

Cyntellect Receives \$1.5 Million

Cyntellect, a cellular therapy company based in San Diego, secured \$1.5 million in financing from the National Science Foundation and an angel investor. Cyntellect, founded as Oncosis in 1997, has raised \$27 million to date.

ChimeraCore Gets Seed Money

ChimeraCore closed \$1 million in seed funding, most of it coming from an affiliate of Draper Fisher Jurvetson. The Santa Barbara company will focus on antibodies with lymphoma as the initial target, utilizing its nanocage technology.

Ambrx Raises \$55 Million

Ambrx raised a total of \$55 million in a series C round led by Apposite. The company, based in San Diego, develops technology that substitutes amino acids within a protein. Ambrx expects the money to take the company through 2008.

Ocera Closes \$12 Million Series B

Ocera Therapeutics raised \$12 million to fund an ongoing Phase III trial of its therapy for fistulizing Crohn's disease. New investor Sofinnova Ventures led the B round. Ocera, founded in 2005, is located in San Diego.

Singulex Takes in \$8 Million for Biomarkers

Singulex, a molecular diagnostic company, raised \$8 million in Series C financing from an unnamed investor to launch its lead product, Zeptx, which detects protein and

metabolite biomarkers. The Berkeley company licensed its technology from Stanford University.

Xencor Gets \$6 Million Bridge

Xencor brought in \$6 million as bridge financing to begin trials for a TNF inhibitor for inflammatory diseases. \$3 million came from Novo Nordisk, the rest from existing investors. Xencor, located in Monrovia, has raised \$85 million since its launch in 1997.

Barrx Medical Raises \$27.8 Million

Barrx Medical closed a \$27.8 million Series C round that is expected to take the company to cash-flow positive. Montagu Newhall Associates led the C round. Barrx makes therapies that treat Barrett's esophagus, a precancerous condition of the lining of the esophagus.

Relievent Closes \$5 Million for Device

Relievent Medsystems, which is developing a device for chronic back pain, raised \$5 million in a Series B round. The money will be used to spin the Hayward company out of its incubator, Emerge Medsystems LLC. The round was led by Canaan Partners and Onset Ventures.

Diamics Seeking \$25 Million for Acquisition

Diamics, a Novato-based company that is developing a cervical cancer screening system, is seeking \$25 million to make an acquisition. Diamics did not identify the proposed target but says the company has a complimentary product.

Athenagen to Merge with Zapaq

Athenagen will merge with fellow neurological biotech Zapaq. Both companies have Alzheimer's drugs in the works. Sanderling Ventures is the lead investor in the two San Francisco area companies, and Life Science Angels seeded Athenagen.

Gilead Buying Corus for \$365 Million

Gilead Sciences of Foster City exercised an option to buy Seattle-based Corus for \$365 million. Corus has been under a cloud for the past two years because of patent litigation brought by Chiron, which was settled for an undisclosed amount of cash.

Asthmatx Hopes to Raise \$75 Million in IPO

Asthmatx of Mountain View has filed to raise up to \$75 million in an IPO. Asthmatx is developing a medical device that delivers controlled thermal energy to an asthma patient's airway. Asthmatx was spun off from Broncus Technologies in December 2003.



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stand the importance of the technology and they are huge supporters of making sure that Novocell is a success not just from a company perspective but a financial perspective – obviously they would like to see a return on their investment – and I think they see there is clearly an opportunity to achieve that with the kind of programs we have, the IP, the intellectual base and the people base the company has at the present time.

You're trying to raise additional capital right now?

We're actually raising a Series C financing of \$30 million. And that would take us into the clinic and allow us to fertilize additional programs within the organization. We all know you don't want to raise money which leaves you in no man's land, and raising that sum of money would allow us a potential exit such as an IPO, as well.

You had mentioned that this funding would take you to Phase I/II trials in early 2009. How many patients do you see in your trials?

The Phase I/II would be relatively small, approximately 15 patients. And even the Phase III clinical trials would not be a traditional small molecule or even biologics trial – we're probably talking in the 150 range to accomplish that goal. With diabetes, the end points are very straight forward: insulin levels, glucose levels, hemoglobin A1c. There are a variety of well established monitors.

There's an important vote in the Senate this week regarding stem cell research, but President Bush has said he is going to veto the bill if it passes. How will this affect Novocell going forward if the bill passes, or if gets vetoed and fails?

Obviously we're talking about H.R. 810, The Stem Cell Research Enhancement Act. Obviously we think this is a very important act, and it would make a huge difference to research in the United States. And I think it's important to note that a recent poll showed that 72% of Americans support embryonic stem cell research and it's clear that many Republicans are very supportive of this, including people like Nancy Reagan. The benefit to a company like Novocell is that it clearly removes some of the issues that I mentioned earlier, the political tensions, if you will. Obviously, there will always be ethical tensions around the use of these cells for therapies, and rightly so. While we certainly don't take this lightly and it is very important to us, we really believe that the therapeutic potential of embryonic cells will benefit many, many patients and extend their lives dramatically.

Company News



Alphatec Having a Busy Year

Reflecting the high energy orthopedic spine market, San Diego-based Alphatec Spine has been very busy. After their June IPO, which put \$35 million in the bank, Alphatec has announced a licensing deal, multiple new products and an FDA approval – plus their 1st public earnings report. Sales were up 133% to an annual run-rate of about \$75 million/year with a 12% increase in gross margin. Despite this, their stock has declined steadily, losing almost 40% of its value. www.alphatechspine.com

Avera Completes Phase II

Avera Pharma successfully completed its Phase II trial of an anesthesia for rapid intubation of surgery patients. The San Diego company has raised \$72 million to date. www.averapharm.com

Receptor BioLogix Names Glaze as CEO

Tom Glaze has joined Receptor BioLogix as its new CEO. Receptor, based in South San Francisco, has raised \$33.6 million from Skyline and others to develop therapeutics for cancer and inflammatory and autoimmune diseases. | www.rblx.com

Neurocrine Fires Sales Force

Neurocrine continues to face problems related to Indiplon, its new sedative. In May, the FDA refused to approve the drug and Pfizer ended its Indiplon partnership with Neurocrine in June. Now the San Diego company has eliminated its Indiplon sales force. Neurocrine has fallen from \$60 per share before the FDA decision to about \$10. | www.neurocrine.com

CryoCor Tries Again for Cryoablation Approval

CryoCor will add expert opinion to the pre-market approval application for its cryoablation system in response to the FDA's earlier not approvable letter. The San Diego company has developed a minimally invasive procedure using cold energy for treating cardiac arrhythmias. www.cryocor.com

Gilead Gets FDA Approval for HIV Drug

The FDA approved Atripla, an all-in-one HIV therapy developed in a partnership between Gilead of Foster City and Bristol-Myers Squibb. Atripla reduces the once-complicated anti-HIV regimen to a single daily pill. | www.gilead.com

Threshold Prostate Drug Fails Trials

Threshold Pharma, based in Redwood City, announced that its prostate drug, TH-070, failed its Phase II/III trials. Threshold will discontinue development of TH-070 for BPH. | www.thresholdpharm.com



Company News cont.

Somaxon Touts Compulsive Behavior Drug

Somaxon Pharma of San Diego reported positive results from a Phase II trial of its smoking cessation drug. The oral compound, an opiate antagonist, produced a higher rate of abstinence. The drug is also being tested for compulsive gambling. | www.somaxon.com

SuperGen Gets Dacogen Milestone

SuperGen, a Dublin (CA) biotech, profited when its partner, MGI Pharma, out-licensed the ex-U.S. rights for Dacogen, its recently approved treatment for myelodysplastic syndrome, to Cilag GmbH, a division of Johnson & Johnson. SuperGen will receive half of the \$10 million upfront payment from the MGI-Cilag agreement plus a royalty. | www.supergen.com

No Early End to Genitope's MyVax Test

Investors in Genitope of Redwood City were disappointed when the data monitoring board failed to recommend an early stop to Phase III trial of MyVax, a therapy for non-Hodgkin's Lymphoma. The trial will now continue to its originally planned conclusion in December 2007. The stock fell almost 50% to under \$3 on the day of the announcement. | www.genitope.com

Aradigm Monetizes Insulin Deal

Aradigm of Hayward received some relief from its financial difficulties when it secured \$27.5 million from Novo Nordisk for the assignment of IP rights to an inhaled insulin drug, currently in Phase III clinical trials. Aradigm has also announced it may spin off its needle-less injection program. | www.aradigm.com

North American Wins FDA Approval

North American Scientific of Chatsworth received FDA approval for its nomosTAT radiation oncology product. The company also closed on a \$24 million private offering led by Three Arch. | www.nomos.com

Cortex Working to Lift Clinical Hold

Cortex Pharmaceuticals, located in Irvine, is on track with its pre-clinical toxicology studies for Ampakine compound CX717, a potential therapy for Alzheimer's disease. The FDA had stopped the trial in April. Cortex expects to complete the work in early September. www.cortexpharm.com

Acologix In-licenses Protein from Japan

Acologix of Hayward has in-licensed a recombinant protein from Toray Industries of Japan. The compound is in pre-clinical development as a therapy for elevated phosphate levels in the blood of dialysis patients. The companies are also partnered on a Phase III drug for "uremic itch" in dialysis patients. | www.acologix.com

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Events Calendar

September 12-13, 2006

Health Care Innovations 2006

DowJones/VentureWire

Redwood City, CA | <http://healthcare.dowjones.com>

Change is coming fast for health care investors, executives and entrepreneurs. Health Care Innovations provides an unmatched program featuring the leading private companies, industry executives and experienced investors.

September 14, 2006

Commercialization of Medical Devices

Medical Device Manufacturers Association (MDMA)

Los Angeles, CA | www.medicaldevices.org

Participants will interact with leading healthcare executives who will share their real-world experience in successfully executing proven strategies for the commercialization of medical device.

October 5, 2006

2006 Entrepreneur Venture Conference

Women's Technology Cluster

Mountain View, CA | www.wtc-sf.org

WTC's Entrepreneur Venture Conference (EVC) is the premier event for women-led companies seeking investment from VCs. Life science and technology companies will be presenting to over 200 venture capitalists.

October 18-19, 2006

2006 BIO InvestorForum

Biotechnology Industry Organization (BIO)

San Francisco, CA | <http://investorforum.bio.org>

The BIO InvestorForum brings together leading industry investors with the management of the top life sciences growth companies. Hosted by BIO, the BIO InvestorForum features corporate presentations as well as panel discussions.

October 19-22, 2006

Phoenix 2006 - The Medical Device & Diagnostic

Conference for CEOs

Wilson Sonsini Goodrich & Rosati

Carefree, AZ | www.wsgr.com

The thirteenth annual Phoenix Conference, an invitation-only event, will provide an outstanding opportunity for top level executives from large healthcare and small venture-backed companies to discuss strategic alliances, financing and other industry issues.

October 24-25, 2006

7th Annual Early Stage Venture Investing Conference

International Business Forum (IBF)

San Jose, CA | www.ibfconferences.com

The Early Stage Venture Capital Alliance event serves as a major industry gathering for over 300 early stage investors. Featuring over 10 in-depth panel discussions over the 2-day program, industry experts will share a wealth of knowledge and exchange insights on the changing climate for funding startups.

November 14-15, 2006

San Diego Investor Conference

BIOCOM

San Diego, CA | www.biocom.org

San Diego's vibrant life science community has over 500 companies. The BIOCUM Investor Conference will highlight investment opportunities in the region's top life science companies to over 300 top institutional and retail investors.



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