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# Biopreneur™

**A quarterly magazine for the entrepreneurs  
with focus in the life sciences businesses**

Published by the California Takshila University/Biopreneur



# BIOPRENEUR

## Tits bits .....

### California Takshila University

Biopreneur immerses into a formal educational Institution beginning June 2008. Biopreneur become a part of California Takshila University, Silicon Valley. Biopreneur now will have the resources and capabilities to offer more entrepreneurial trainings, workshops and boot-camps.

### LARTA Conference

Recently Biopreneur attended LARTA-NIH organized one day conference of biopreneurs. It was a wonderful opportunity to learn potential ground-breaking technologies are in development by fresh and seasoned entrepreneurs.

### Do No Harm: Dr. Anil Bansal, IMA, India

Biopreneur-of California Takshila University launched its bio-business-public health seminar series in June. On June 24, Dr. Anil Bansal, Executive member of Indian Medical Association presented a seminar/colloquium on "Do No Harm: mild, medium, hot" – practice of medicine at the dawn of the 21<sup>st</sup> century.

### AAPIO-25<sup>th</sup> annual convention -

Biopreneur attended 25<sup>th</sup> anniversary convention of American Association of Physician of Indian Origin. Convention's prime message was on metabolic problems on health; and medical practice in California in near future. CEO of California Medical Association, Joe Dunn highlighted the later part in detail.

Biopreneur –is a quarterly magazine published by California Takshila University from Silicon Valley, California with the support offices in India and Japan. Magazine is available for the Biopreneur members and affiliates through emails and downloadable format.

**To authors:** Contributing authors are requested to submit a short 10n-page proposal for articles relevant to the business/sciences audiences. Email: [biopreneur@ymail.com](mailto:biopreneur@ymail.com)

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## Prologue:

We know that every business is related to either inventive or innovative products or services and it must face some ups and downs throughout the phases of its development. Ultimately, and quite fortunately, a stage usually appears in typical development that can offer some comfort and satisfaction to participants of most business ventures. But purists in any field will advocate neither satisfaction, nor comfort alone, for its own sake. It is dedication, business zeal, will power to prove proficiency, and the unforgettable love of a product that entices most people involved to continue serving business goals. Our focus and our prime concern in this book is to explore *bioventure* and the journey of a *bioventurer*.

Bioventure represents a microcosm of the world at large concentrated into the small word of biological *venture capital*. As far as biopreneurs are concerned we have to define a scenario with a different kind of light—a light of a different color and temperature. It is an interesting and exciting a time for people wanting to appreciate the world of bioventure. And this is plainly because biotechnology, with emergent educational, governmental, and industrial support, is moving toward its wave crest.

We can think of *bioventure* being a sleek aerodynamic car racing on three wheels—technology, management, and capital. Each wheel is extremely sophisticated, and must be taken care of appropriately to drive the car to an ultimate and optimal destination. After spending many years learning and teaching, when I joined the practiced field of authentic business, I realized the need for the proper understanding of those three driving *wheels*. As people from the field of research work, and management, we may be aware of the greater issues related to our own unique areas of interest, but to be a truly successful biopreneur we must have a commanding grasp on all three driving wheels in our bio-business.

When we look at the world of *bioventure* we find several cases where people intended to invest heavily, but due to a lack of suitable knowledge they decided to shy away. There are instances where companies having a potential to expand their horizons by meeting a mere few necessities—such as patenting their ideas, and technology. Simply having enough information and facts regarding selling intellectual property or research-based material to pharmaceutical establishments may help some budding bioventures to succeed. But insufficient information also causes comparable ventures to lag behind other more aggressive competitors.

When these realizations struck me, I felt there was a lack of one extraordinary item in our immediate area which could solve our collective problems. That extraordinary item was a quality study curriculum that might be of assistance to all people in the field of bioventure. My intent is that this study material must contain substantial information for all—upcoming entrepreneurs, people from the field of management, and suited investors. This would not only to serve getting people from various fields under the one roof—bioventure—but it would also create a feeling of unanimity within bioventure.

Working together has always been a fun for people like us. Now we have the means to create that same fun—multiplied—by networking our talents, invented drugs, and various other biotechnological products. At the same time there could be an additional benefit waiting for each of us involved, in the form of earned capital. In all honesty, that is simply one future that I dream of for *bioventure*. The best possible future relies on greater understanding among the people associated with this business. This will be possible only if we can integrate our knowledge and experience, and operate within each other's respective fields of expertise. If we can appreciate the views that those among us want to share, and vice versa, then a treasure trove in bioventure is not far off.

~~ *Biopreneur Editorial Board*

## PATRONS

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### **Medzym – [www.medzym.com](http://www.medzym.com)**

Medzym, Inc. is a privately held biotechnology company focused on building molecular therapeutics based on effective platform technologies. Company's current focus is on Age-related eye disorders- (1) eye-diseases, (2) Anti-Inflammatory/Allergy, and (2) Cardio-vascular.



**California Takshila University (CTU)** is located in the center of Silicon Valley, California. The mission of CTU is to provide students with a multidisciplinary and intercultural understanding of the world that enriches their lives while actively participating in the global marketplace of commerce, culture, and technology. CTU offers graduate degree programs, general education, services and activities to enhance the academic and personal

development of students. CTU is a place for global learning.



**tech-edits** is a Silicon Valley based organization that provides technical writing, editing and copywriting services to biotech and high-tech organizations. Biopreneur uses tech-edits for its selective needs and services. For more information contact: [wjspies@technoedits.com](mailto:wjspies@technoedits.com).

# Bioinformatics and the race for the \$1000 genome: How ready are the start-ups?

Natarajan Ganesan, PhD

NIH

## Watson had his genome sequenced – So what?

James. D. Watson recently had his full genome deciphered; he was the co-discoverer of DNA structure in the 50's<sup>1</sup>. In other words, technology has rapidly moved beyond sequencing the 'generic' human genome to sequencing each and every individual's entire genome on a routine basis. To scientists this means a gateway to an era of personalized genomic medicine and to the Pharma this means, marketing those individualized medicines.

What does this mean for Bioinformatics companies? What exactly are bioinformatics companies anyway (in this age of open-source information)? Are they different from Biotech companies? Do they have any markets? If so, how would their globalization plans look like? To understand

this, let us fast forward to 10 years from now (probably even sooner!) – your health care practitioner prescribes a full length report of your genome sequence. Well, what does he do with it then – or for that matter the diagnostic lab he sends the report to?

This is where Bioinformatics companies and their products will step in. These software products/solutions will help process huge amounts of voluminous sequence data and run them against public and private databases to fish out medically relevant information. Simplified interfaces like *Sequerome*<sup>2</sup> will vastly aid research scientists and lab technicians scrutinize data in a seamless fashion. Thus, the **Biotech** and the **Bioinformatics** industry are different in that they involve different scopes. The products of the former help the growth of the latter.

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<sup>1</sup> "DNA pioneer Watson gets own genome map";  
- by Nicholas Wade, Int. Herald Tribune, June 1<sup>st</sup>  
2007  
<http://www.iht.com/articles/2007/06/01/america/dna.php>

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<sup>2</sup> "A web-based interface facilitating sequence to structure analysis of BLAST alignment reports";  
Biotechniques (2005), Vol 39(2), pp186-188

## **Commercializing Bioinformatics! – Where is the market?**

Well...already many Bioinformatics companies have started defining their niche and expanding their markets. The consumers span across institutions from all the countries. The products range from straightforward software suites (e.g. Redasoft<sup>3</sup>), to enhanced content providers (Ingenuity Systems<sup>4</sup>). By early 2000 itself, there were a reported number of 50 companies into the market and the estimate of this industry was in the tune of \$1.4 billion in 2005<sup>5</sup>. They have been estimated to grow at an annual rate of 15.8%. Numbers apart, there has been an explosion in the growth of the Biotech industry over the past few years and consequently the requirement for commercial software for processing the data generated out of this technology. This has been further accentuated by the large scale projects in academic R&D in the last two decades.

Thus, when viewed in terms of market entry modes for a new Bioinformatics start-up there are enough proactive stimuli –

- The products are unique – Each software tool does a specific function and has its own niche. Even if the

market is saturated with all the tools, there will always be new concepts that handle data in many different ways.

- There is exclusive information – Highly processed data is unique to each lab group, scientist and the project involved.
- The market size is virtually untapped – Despite a healthy growing market, there is a vast unmet need among the scientific community. Consequently there is a great potential for profit advantage when the market is utilized strategically.
- Economies of scale – The demands for creation and maintenance of software/enterprise solutions parallels with that of the software industry which is already an industry in its right. The question is that of the market and how it can be strategically tapped.

### **Business and markets in an open-source era**

Initial estimates of the market in 2000 were more than \$ 2 billion and the market was not even tapped. Yet, all the promises held by the industry have not seen its fruition in fullest in all these years and this has been in part due to the emergence of open-source projects. Practically all the major databases and crucial software is available for free to the

<sup>3</sup> Redasoft - <http://www.redasoft.com/>

<sup>4</sup> Ingenuity Systems - <http://www.ingenuity.com/>

<sup>5</sup> “Global Bioinformatics market ...\$3 billion by 2010” – Medical informatics news - <http://www.medinfonews.com/ar/1h.htm>

researchers. Some of them are even fully open-source in that it is possible to download the source code and modify it to suit the needs. So, why would one want to purchase software when a public domain makes it an open access?

In short, the challenges faced are virtually identical to the software industry with the exception that the concept of open-source is more recognized and appreciated (for the sake of science, of course). This has left the industry scampering for new ways to generate revenue. Software solutions have started looking to enterprise solutions and funded projects. However, there exist R&D areas like drug discovery, modeling and simulation which continue to command their market. Dedicated bio-software companies like Accelrys<sup>6</sup> are the main players in this market. Pharma and Biotech

have their own in house projects that are often proprietary. Another area is academic and institutional licensing. Some of the key drivers in this area are the cutting edge research carried out that rely crucially on Bioinformatics solutions, while proper funding remains one of the chief constraints.

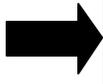
### **Blueprint for market entry and further growth**

It is well known that globalization has become one of the most strategic issues for marketing managers, and nothing could be truer than the case of a bioinformatics start-up. The industry is such that cost-input simply involves covering the programming and maintenance, while profits are there to be reaped from every corner of the world.

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<sup>6</sup> Accelrys Inc - <http://www.accelrys.com/>

**Table 1 Adapted from Ex 6.1 - "International marketing" - by Czinkota and Ronkainen**

| Pressure to globalize in the industry | Competitive Assets                                                     |                                                                                   |                                                              |
|---------------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------------------------|
|                                       |                                                                        | <u>Customized to home market</u>                                                  | <u>Transferable abroad</u>                                   |
| <u>High</u>                           | <b>Dodger</b><br>Sells out to a bigger player                          |  | <b>Contender</b><br>Upgrades to match global niches          |
| <u>Low</u>                            | <b>Defender</b><br>Leverages local assets where global assets are weak |                                                                                   | <b>Extender</b><br>Expands into markets similar to home base |

However, if it were indeed so, why is it that the industry has not grown the way it could have OR why don't we have any major players (besides the offshoots from R&D of big companies)? Could it be possible to overcome the open-source environment and look at a good model to capture the world market? Or is it simply that industry is so nascent that the time is not yet ripe to aim global? At best, there are players like Accelrys who have to crucially depend upon heavily funded groups with big projects. In other words, no other players have come up to pick all the low hanging fruits.

The following matrix depicts the competitive strategies for new

start-ups in Bioinformatics products.

The strikeouts represent the cases not applicable to any Bioinformatics company at present (given the nature of the business) and the arrow represents the direction in which startups and midsize companies should aim to move. The market is such that pressure/incentive to globalize is high, given the inherently international user base of the industry. Hence the natural evolution of a small company or a startup should be to switch very quickly from *Dodger* to the *Contender* status.

# Global Business Accelerator

Your **SUCCESS** in this Global Economy might require **AVOIDING** Two **MISTAKES ...**

**JUST 2!**

- 1. Acting when you should not act.**
- 2. Not acting when you should act**

All businesses are **GLOBAL** in the 21<sup>st</sup> century whether one wants to **BE** or **NOT**.

GBA is here to support and be catalyst for those who are already global and those who are still pondering upon the facts of globalization. GBA brings wealth of information, knowledge and wisdom – hands-on and strategic.

GBA specializes in the Field of high-tech-IT-software, biotech-pharmaceuticals including medical devices and DNA-technologies.



Geographically GBA actively works in India, Japan, South Korea and USA. GBA located in the heart of Silicon Valley where it operates Global Business Center (GBC) that houses domestic and International companies those are to penetrate USA market and develop cross access to S. Korea, India and Japan.

Global Business Accelerator (GBA) is an organization that facilitates large, small and medium sized companies' globalization strategies. We arrive at twenty first century much faster than that of our entry to 20<sup>th</sup> century from the 19<sup>th</sup> century. This fast moving entrance to the new century brought many advantages while left some corporations in strategic-scrambles. Many well-proven, time-tested, doctrines and paradigms have made very dramatic shifts.

# Global Business Accelerator

## SERVICES

### **Physical Presence-at the GBDC**

Physical Office space  
Laboratory Space (if needed)  
Monthly PR Access  
Management Counseling  
Market Research & Market Communications

### **Setting Up**

Registration of a corporation  
IRS –EIN number  
Local Registration  
Business License

### **Corporate representation**

Acting Executive/representative  
Preliminary communication  
Business Development  
(NOT SALE – GBA does not engage in SALES)

### **Off-source Representation**

Physical presence without being at GBDC  
Acting representation  
Official correspondences and forwarding

### **Management Related Services:**

Specifically for early stage and start-up companies:

Entrepreneurship, Biopreneurship and Technopreneurship  
Understanding the cultural-ingredients in dealing with global partners and alliances  
Fundamentals of negotiation,  
Funding and fund raising,  
Communication with VCs and corporate partners.  
Strategic IP-Management  
Value creation through pro-active IP strategy

### **For SMEs and large corporations:**

Intrapreneurship,  
Strategic corporate management, and culture based marketing,  
Strategic Global marketing  
Turn-around strategy  
Selective Market-entrance  
Dodging Competitor while curving new market-shares  
Branding Strategy in a Global Business Environment  
Strategic IP-Management

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kzaiusa@yahoo.com



excitement of the entrepreneurs at this event.

This year the Venture Forum was dedicated to the life sciences primarily because of a large numbers of early stage innovators in the life sciences through the exclusive partnership of LARTA with the National Institutes of Health (NIH). This year Venture forum attracted entrepreneurs from several other countries. There were 80 companies exhibited, showing their inventions at the conference – from USA NIH-funded forty eight (48), from affiliates program twenty-four (24), and International – eight (8). It was a highly coordinated and dedicated effort of the Larta team (as show above).

Prior to founding Burrill & Company in 1994, **Mr. G. Steven Burrill** spent almost three decades with Ernst & Young. He was recognized as the biotech investment visionary by the Scientific American magazine. He currently serves on the Boards of Directors for the Bay Area Science Infrastructure Consortium, BayBio, the California Healthcare Institute, the Exploratorium, The Kellogg Center for Biotechnology, Research!America, Campaign for Medical Research, The National Health Museum, and the University of California, San Francisco (UCSF) Foundation.

Keynote speaker Steve Burrill of Burrill and Company shared his vision of the life-sciences in the coming decades. Mr. Burrill pointed



## VENTURE FORUM 2008

Larta Institute organized its yearly venture forum on May 30, 2008 at Santa Clara Convention Center, Silicon Valley, CA. Biopreneur of the California Takshila University is one of the affiliates of the program promoter and had the privilege to witness the

out the opportunities and challenges for the sector. According to him memory and metabolic-diseases related area will receive the highest attention from the market. He also indicated that more and more people were gravitating toward the staying well concept – thus the market opportunities for the wellness industry are undisputable. Just to give a quantitative feeling of his statement – Current drug market is about US\$240 billion while size of the wellness product market is US\$300 billion and growing.

BURRILL NUTRACEUTICALS, 2003–2007



Source: Burrill & Company

On the financial market stocks of nutraceuticals product companies consistently did better than the both the indexes for past five years.

One of his encouraging statements for the entrepreneur was “big company is not an innovator, small company is”. Taking string of that statement we discussed with Mr. Burrill and his associate Mr. Peter Winter regarding possible working association with Biopreneur of the California Takshila University. He had one piece of advice for our forum members – “when seeking investment entrepreneur must realize that the use of investment capital comes with the change in strategy.”

Attendees enjoyed an wonderful lunch session with the President of ResearchAmerica, Ms. Mary Woolley. She asked the state to take much larger role in advancing research and lack of coordination and attention in the U.S.



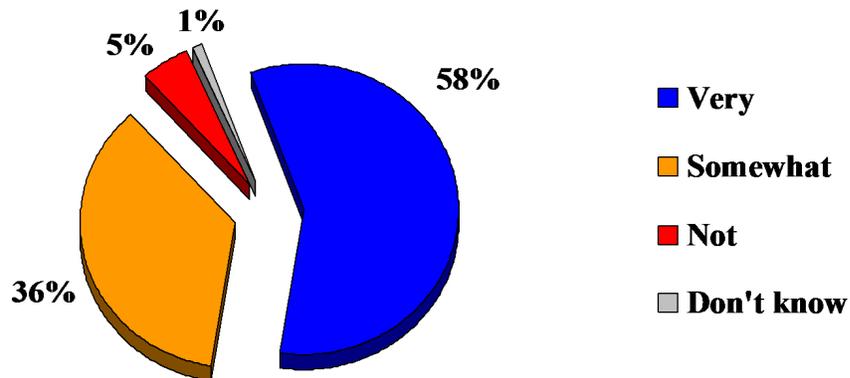
**Mary Woolley** is the president of Research!America. Ms. Woolley is an elected member of the Institute of Medicine and a fellow of the American Association for the Advancement of Science (AAAS). She serves on several boards and committees, including the Institute of Medicine Health Sciences Policy Board, the National Council for Johns Hopkins Nursing, and the Children's Research Institute of Children's National Medical Center. Ms. Woolley has served as a reviewer for the National Institutes of Health and National Science Foundation and as a consultant to several research organizations

We all anticipate and work for *science fiction-like* breakthroughs.

What we need now more than ever is an *advocacy* breakthrough, particularly

## Investment in Research Important for Job Creation and Higher Incomes

In terms of job creation and higher incomes, how important do you think it is to invest in scientific research?



Source: Bridging the Sciences Survey, 2006  
Charlton Research Company for Research!America

Research!America  
AN ALLIANCE FOR INVESTMENT IN HEALTH

advocacy by innovators and entrepreneurs. She explained the need of public investments in both the fundamental research as well as in technology commercialization. These investment in-turn created jobs and stimulated the nation's economy.

She further emphasized the need for regenerative research in order to stay



ahead of the global competition. Countries like Singapore, South Korea, India and EU nations are implementing more of the current knowledge of the regenerative technologies than that of USA.

Clearly we need more public awareness and

governmental support in this area.



**Boris Nikolic** is a Senior Program Officer in Global Health Discovery at the Bill & Melinda Gates Foundation. He is the inventor of the symptom based diagnostic methodology based on comprehensive nucleic acid and protein testing for major medical conditions such as pneumonia, meningitis, septicemia and malaria. He served as an advisor to private equity and venture capital firms evaluating numerous medical diagnostics, medical devices and biotechnology companies worldwide. Dr. Nikolic is an Assistant Professor in Medicine at Massachusetts General Hospital/Harvard Medical School.

We ended the forum with an extraordinary speech on human health crisis in developing countries by Mr. Boris Nikolic, Senior Program Officer, at Global Health Discovery, Bill and Melinda Gates

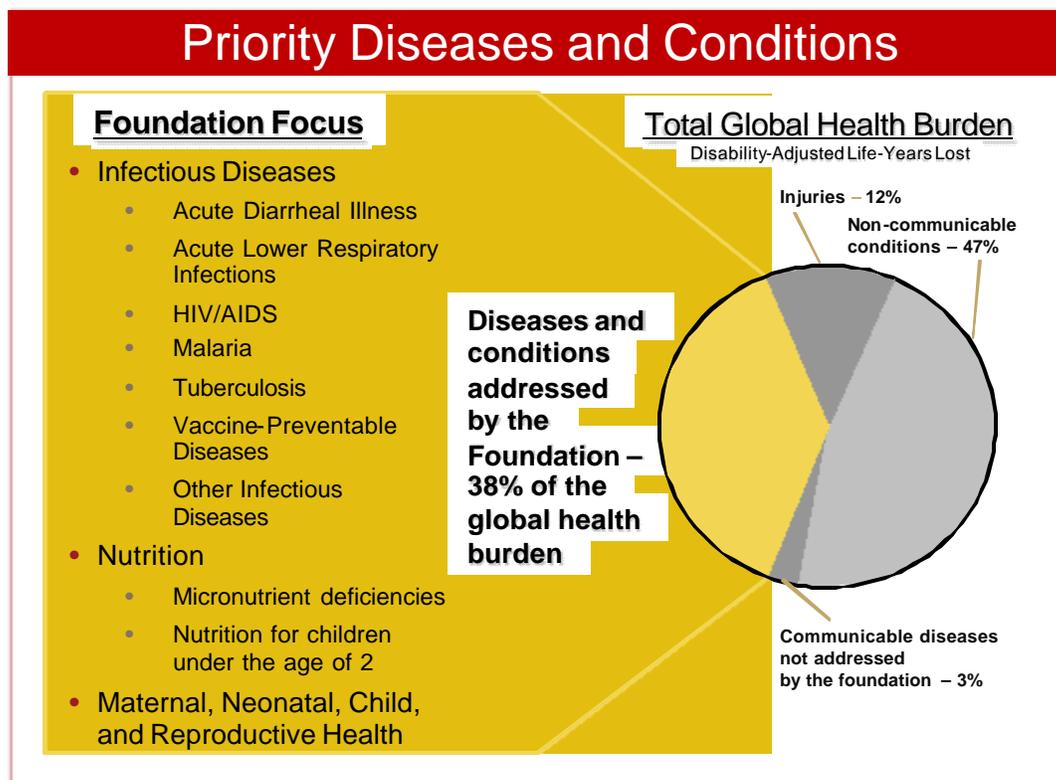
Foundation. Dr. Nikolic challenged every entrepreneur in the audience citing the current inequality of health that exist in the world. Guiding principles of the Bill and Melinda Gates foundation is –All lives – no matter where they are – have equal value. It is foundation’s goal to reduce inequality of lives.

**Where does the inequity lie?**

**With the 2/3 of the world’s 6 billion people that live in the developing world. The greatest need is among the 1 in 6 that lives on less than \$1 per day.**

- Millions die unnecessarily each year from diseases that are currently treatable or preventable
  - » AIDS, TB and malaria alone kill 6 million people annually
  - » Vaccine-preventable diseases kill more than 2 million children annually
- Access to existing, effective health interventions is severely limited for most of those in need
  - » Systems for delivery of vaccines don’t regularly reach all of those in need
  - » Vaccines available for many years in wealthy countries, but are not used widely in the developing world

**The Result: a global health problem that undermines economic development, social and political stability**



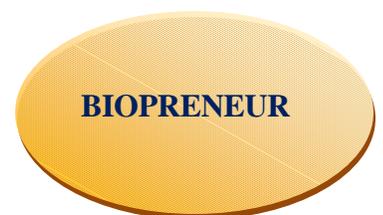
He concluded his callings with the vision of the Gates foundation – *"There is no bigger test for humanity than the crisis of global health. Solving it will require the full commitment of our hearts and minds. We need both. Without compassion, we won't do anything. Without science, we can't do anything. So far, we have not applied all we have of either."* Bill Gates, World Health Assembly, May 2005



I had the opportunities to meet some of the entrepreneurs who have made exceptional technological advancements in their field. I also met a professor—biopreneur, like myself from Brazil, who not only teaches entrepreneurship to his life sciences students but is also a founder of a positive cash-flow bio-business in Brazil. Above you see him explaining to me his peptide technology for metabolic syndrome.

More information on Larta and Venture forum can be found at [www.Larta.com](http://www.Larta.com). Also stay tuned for the up-coming events by Larta and its affiliates including TIP, Biopreneur/ California Takshila University.

**Ryan Baidya**  
**California Takshila University**



# InvivoSciences

The nature and properties of chemical mechanisms cannot be effectively assessed independent of the systems in which they are to function. Therein lies the impetus for our work.

As our name implies, the core of the InvivoSciences mission is the research and development of engineered-tissue based assays that are different and better because they mimic functions of living organisms, specifically, those of animals and humans. Designed to meet increasing demand for efficacy and productivity in the areas of drug discovery and life science research, we provide automated, real-time, high-content and highly sensitive detection systems that are as predictive and cost effective as they are revolutionary.

Most current in vitro drug testing methods use two-dimensional (2D) cell cultures that do not take all into account the impact of the physical environment in which cells grow. While the 2D cell-culture environment is mostly rock solid, the cells' native environment extracellular matrix will yield to the parameters of the 2D environment. This results in unsatisfactory, sometimes misleading and non-predictive data for in vivo responses. We believe that the key to successful in vitro

testing is to develop models that mimic the in vivo system. The ready-to-use tissues and assay platforms produced by InvivoSciences provide three-dimensional geometrics and physical environment for cells, bridging the gap between cell-based systems and isolated organ tissue systems or animal models, and can therefore act as model systems for chemical screening assays. This provides researchers with screening strategies that can assess the potential toxicity of new drugs—including those for cardiac applications—in accurate, predictive detection environments requiring less time and cost than corresponding studies using animals. Further, our ongoing commitment to research that pushes the boundaries of toxicity assessment in drug discovery helps reduce the risk of late-stage attrition in clinical trials.

## **Drug Testing Against Engineered Tissues with Human Genome**

Decades of scientific research clearly demonstrates that the integration of a human genomics component early on in the drug discovery process increases the potential for success in pharmaceutical development. We have thus introduced a platform technology that incorporates predictive human-cell-based, engineered-tissue models that generate a uniquely informative biological activities signature for each drug candidate. This yields

actionable data that can be used to drive the selection of drug leads that demonstrate best market potential.

We know that by harnessing the predictive power of integrative systems biology on high-content information gathered from engineered tissues that mimic human organ functions, we can significantly reduce time-to-market for new pharmaceuticals without compromising clinical integrity. Thereby, our work can and will improve many aspects of human health.

### **Striding Ahead in Cardiac Therapeutics and Predicting Cardiac Side Effects**

The rapid and ever-increasing incidence of heart attack (myocardial infarction) cases in the U.S. and worldwide has driven the demand for therapeutics in this category. Our most recent research efforts are centered on developing an assay system that can screen and profile drug candidates for treating cardiac muscles damaged after heart attacks.

A heart attack injures the heart muscle forming wounds that seldom heal, leading to cardiac fibrosis and often, death. And while some 38 percent of heart attack survivors will die within one year due to the cardiac fibrosis that manifests itself in altered mechanical performance of the heart and arrhythmogenesis, few therapeutic options exist.

In collaboration with academic laboratories, we are using

miniaturized engineered heart tissues that can maintain their physiological or pathological properties for weeks or even months to better understand the mechanics of fibrosis development. The functional properties of engineered heart tissues assessed by our platforms can sensitively report cardiac side effects of drug candidates. Our platform will assess the altered cardiac contractility and will predict toxic sides of drug candidates in animal tissues.

### **Seeking investors as well as Strategic Partners**

InvivoSciences is interested in collaborating with pharmaceutical and biotech partners to improve the efficiency of their drug discovery programs at many stages, including:

- Compound screening for lead discovery
- Lead optimization and structure-activity relationship studies (SAR) studies
- Characterization of secondary of off-target activities
- Mechanism of action studies
- Re-profiling of stalled clinical-stage compounds
- Cardiac toxicity assessments
- Toxicity on fundamental cellular functions
- Compounds profiling targeting extracellular matrices

Additionally, we are looking all potential customers in pharmaceutical, biotech, cosmetics

and consumer good industries to market our next generation proprietary assay products, device and services worldwide. Please see our web site for the detail information about our bio system and products.

Company contact and investment relationship: Ayla Annac, Co-founder/CEO, [aannac@invivosciences.com](mailto:aannac@invivosciences.com), cell 608 628 8035, [www.invivosciences.com](http://www.invivosciences.com)

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**To authors:** Contributing authors are requested to submit a short 1-2 paragraph proposal for articles relevant to the bio-business audiences. Email: [biopreneur@ymail.com](mailto:biopreneur@ymail.com)

# Product Launch and Lifecycle Management: A View From the Field

**Sherri Dohemann**

Ortho-McNeil Neurologics, Inc

For a successful product launch now, it includes early and often collaboration across clinical and commercial departments of a life science organization. That will separate the winners from the losers. When we look at commercialization, for the sake of common language for all functions, whether we are in marketing of R&D, let's focus on 6 basic stages:

Preclinical, Phase 1, Phase 2, Phase 3, Submission, and Launch

There are several aspects to good marketing, however the highest ROI early in a product's cycle are detailing and physician relations. This article will focus on that. Having a good advisory board helps you understand your physicians' needs, thus enhancing and maintaining physician relations while identifying unmet needs and areas for future growth. It also provides the opportunity for

advocacy on behalf of your product for reimbursement, for example, when needed. For context, Here are the balance of the suggested launch and cycle activities by Phase, source Best Practices, LLC.

## **Invest marketing dollars targeted and early:**

According to Best Practices benchmarking research firm, the top performing companies in Biotech and Pharma allocate marketing resources as early as the preclinical phase as a low percentage of spend, however still important to shape market-relevant clinical trials by gaining thought leader input and ensuring commercial alignment with clinical practice in the marketplace. Some companies don't start until phase 2. It's interesting to note that DTC was found to have the lowest ROI as well as associated regulatory scrutiny.

**Product Launch and Lifecycle Management**

|                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b><u>Pre-Clinical</u></b><br/>         Market Needs Analysis<br/>         Market Size Research<br/>         Competitive Analysis<br/>         Commercial Potential Analysis</p>                                                                                          | <p><b><u>Phase I</u></b><br/>         Concept Testing<br/>         Initial Profile Testing<br/>         Therapeutic Area<br/>         Competitor Research<br/>         Thought Leader Identification<br/>         Market Needs Analysis<br/>         Market Size Research</p> | <p><b><u>Phase II</u></b><br/>         Positioning Studies<br/>         Focus Groups on Market<br/>         Analysis<br/>         Concept Testing<br/>         Initial Profile Testing<br/>         Therapeutic Area<br/>         Competitor Research<br/>         Thought Leader Identification<br/>         Market Needs Analysis<br/>         Market Size Research</p> | <p><b><u>Phase III</u></b><br/>         Branding and Naming Study<br/>         Conjoint Analysis<br/>         Positioning Studies<br/>         Focus Groups on Market<br/>         Analysis<br/>         Concept Testing<br/>         Initial Profile Testing<br/>         Therapeutic Area<br/>         Competitor Research<br/>         Thought Leader Identification<br/>         Market Needs Analysis<br/>         Market Size Research</p> |
| <p><b><u>Submission</u></b><br/>         Market Attitude and Acceptance Study<br/>         Promotional Piece<br/>         Development &amp; Testing<br/>         Refine Positioning &amp; Message<br/>         Pricing Study<br/>         Payer/Advocate Advisory Boards</p> | <p><b><u>Launch</u></b><br/>         Market Tracking<br/>         Sales Uptake Tracking<br/>         Sales Force Feedback<br/>         Position &amp; Message Refinement<br/>         Physician Awareness Research</p>                                                        | <p><b><u>Pre-Launch</u></b><br/>         activities: Pre-Launch:<br/><br/>         Thought leader and advocacy group development<br/>         • Scientific meetings and symposia<br/>         • Medical publications<br/>         • CME programs<br/>         • Public relations<br/>         • Disease awareness programs</p>                                            | <p><b><u>Post Launch:</u></b><br/>         Field force detailing and sampling<br/>         • DTC marketing<br/>         • CME programs<br/>         • Professional journal advertising</p>                                                                                                                                                                                                                                                       |

The use of an advisory board of several members from different geographic areas ensures diverse perspectives and market needs will be represented.

For example, a Southern California based company looking for national or international success wouldn't want every member of its advisory board to be solely based out of UCLA, USC, and UCSD out of convenience just because that's where the headquarters is. Due to larger market demands, they'd ideally have thought leader development in the identified regions of high market potential, difficulty, and/or innovation potential. From the perspective of the field, targeting the most respected physicians for early education and collaboration is a "win-win-win" since they influence their peers and your customers are likely to ask, "What does Dr. Jones think?" or worse, "Dr. Jones doesn't do that, he does and uses product y." The work needs to be done to get the right physicians on board first as a credibility issue, which bears the next point.

**Bringing a strategic focus to a thought leader development plan brings credibility to your product and organization in the medical and scientific communities.**

Understanding who to include, can be gained through market research, which helps to align R&D

goals with early commercial input through this critical process.

You will need a range of thought leaders to inform you about market needs:

Managed Care, P&T committees  
Payors, outcomes research, address access concerns

Patient advocacy groups

Research, academic based thought leaders-on average, written 7

papers a year in a peer reviewed journal, source Stanford GSB, Nair  
Patient-centered thought leaders

Clinical development

Product positioning

Brand awareness

Market acceptance

**Phase 3 to submission process described as both a qualitative and quantitative iteration by Specialty vs. Primary Care thought Leaders between Market Research Analysis and ad board to validate Positioning and Pricing Research Required**

**Detailed Development Plan from Phase 3 to Submission Inclusive of Disparate issues led by global panel input.**

**Key Questions:**

- What studies are needed for promotional use?
- What competitive products are on the horizon, and what

advantages are they expected to claim?

- **What is the expected response or set of possible responses from the other practicing physician types/settings/customers to the current labeling, dosage and indications?**
- Input from national thought leaders in key Regions( and Types if it will be promoted to multiple specialties), and geographies.
- Successful companies now distinguish research thought leaders from patient thought leaders, involving both in the development process at different stages

### **Partnering with thought leaders:**

Good partnership with thought leaders is a comprehensive effort on the part of a marketing department and leader that is pulled through by a science based field effort, typically MSL's

(medical science liaisons) or possibly highly trained field sales staff with technical backgrounds.

A great partnership with the right mix of thought leaders can help you with the following goals:

**Product development:** focus efforts and reduce cost for trial development

**Launch:** Influence peers and medical societies, officers of (American academy)

**Formulary:** Education, advocacy, health outcomes, quality of life

**Medical community education:** Educate the users regarding epidemiology and diagnosis of the disease state, solution. Lifecycle: Help with additional indications, they have influence with guidelines

**Clinical trials** are conducted as part of a product positioning strategy

***Sherri Dohemann** is a Senior Sales professional at Ortho-McNeil Neurologics, with eight years of experience representing 13 molecular entities to #11 different specialists for a range of 6 disease states. She is a volunteer organizer for the Fountain Blue Life Sciences Forum, an organization that offers education and networking to life science entrepreneurs & their teams such as staff members, advisers, board members, and investors. Sherri completed a BS degree in Combined Sciences, an interdisciplinary natural sciences degree from Santa Clara University and attended Stanford Biodesign's Emerging Entrepreneurs in Biomedical Technology in 2007. .*

# CALIFORNIA TAKSHILA UNIVERSITY

California Takshila University has emerged from nine (9) years' of academic and professional activities in the high-tech and biotech industries. Until recently we offered educational training, workshops, and entrepreneurship boot camps under Biopreneur.



As the programs expanded and the necessity to offer formal degrees, certificates and diplomas have become evident; a new practical talent building think tank concept has been conceived. California Takshila University is the result of that think-tank concept.

The university continues to offer workshops, training, boot-camps to the technology and business entrepreneurs while expanding its higher educational programs in the technology and business disciplines. Programs in progress are: master degree in business management, engineering, software-IT, biotechnology business and public health related fields.

The University offers training workshop and boot-camps for diverse national and international business professionals. A large number of these professionals are either mid-top level executives or senior level dignitaries of different government agencies. California Takshila University is currently an advisor/counselor to Silicon Valley Small business development center/SBA- a USA-government agency. During 2000-2003 Dr. Ryan Baidya provided extensive entrepreneurial seminar-style workshops to the Japanese entrepreneurs, Governmental executives and business professionals in Japan. The following programs are further elaboration of his on-going activities in giving tools, street-knowledge and wisdom to the executives and manager who are to build sustainable business in the 21<sup>st</sup> century's globalization model.

California Takshila University has a team of professors and mentors with versatile experience in business in multiple sectors. Some of them have built their own businesses successfully. Most of the members are currently involved in consulting and educational activities in high-tech, biotech and energy industries.

For further information call 408-561-5123 or email [biopreneur@ymail.com](mailto:biopreneur@ymail.com).

# MBA Program

**Fall-2008**

**Silicon Valley, California, USA**

## **MBA and Integrated MBA Program**

California Takshila University offers two concurrent master degree programs for the professional adult candidates – (i) post baccalaureate master degree and (ii).integrated master degree for the non-baccalaureate professionals.

### **Post baccalaureate MBA**

Offers a comprehensive program designed for the professionals who are pressed for time and need wider flexibility. Programs have allowed students the best use of technologies, mentorship and practical street-learning so they can bring to their profession individual growth as well as corporate productivity.

### **Integrated MBA**

This master degree program is designed for the individuals without a formal bachelor degree and has acquired significant knowledge and understanding in the present field of work, as well as practical knowledge in business. Students will participate in a comprehensive learning system designed by the university, and industry professionals, and solidify a foundation for higher learning. Students will receive both bachelor and master degrees under this program.

Students are encouraged to use distant-learning protocols that are guided by assigned mentors from the University. Class schedule is developed in such a way that the professional can attend live lectures without interrupting their daily work routines.

## **Global Business Acceleration**

Through an affiliation with the Biopreneur

*It is simple and easy and effective - ask how*

# BIOPRENEURS' BITES

One billion people suffer from preventable, treatable diseases around the world

- **Global Health Progress Joins WHO and DNDi to Call For Increased Commitments to Fighting Neglected Tropical Diseases**

The worldwide pharmaceutical industry is joining the World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi) in calling on the G-8 nations the importance of neglected diseases as a global health threat and a major strain on the economic viability and educational development of communities worldwide.

The newly formed Alliance urged G-8 to finance successful treatment and prevention programs, to support innovative strategies that address the challenging health gaps in developing countries, and to fund research and development to develop improved diagnostic, treatment and prevention options.

Most international attention is focused on HIV/AIDS, tuberculosis, malaria and global health security. However, neglected tropical diseases - most of which are preventable and treatable - remain major causes of death and disability worldwide. These diseases receive less funding and less attention while they decrease productivity, negatively affect quality of life and increase poverty throughout the developing world.

- **India's Hepatitis B Virus Drug Market Will Grow Ten-Fold by 2012**

Decision Resources, one of the world's leading research and advisory firms focusing on pharmaceutical and healthcare issues, forecasts that the Indian hepatitis B virus drug market will grow ten-fold by 2012, from \$1.7 million in 2007 to \$17 million in 2012. According to the new Emerging Markets report entitled Hepatitis B Virus in India, this growth will be fueled by a growing awareness of the hepatitis B virus and the growth of individual wealth among India's urban middle and upper class.

Additionally, the report finds that the number of prevalent cases of chronic hepatitis B virus in India (30.6 million in 2007) is three times that of the United States, France, Germany, Italy, Spain, United Kingdom and Japan combined. However, both diagnosis rates and drug treatment rates in India are extremely low.

- **China's Hepatitis B Virus Drug Market Will Grow to \$800 Million by 2012**

Decision Resources also finds that the Chinese hepatitis B virus drug market will more than double by 2012, from \$340 million in 2007 to \$800 million in 2012. Both nucleoside/nucleotide analogues (NAs) and immunomodulators will experience strong double-digit growth, contributing to a robust 18 percent annual growth of the total market.

According to the new Emerging Markets report entitled Hepatitis B Virus in China, the greatest contributor to the growth of the Chinese hepatitis B drug market is the sheer size and nature of the epidemic in China- approximately 80 million Chinese people have chronic hepatitis B. Because treatment with nucleoside/nucleotide analogues is typically long-term (in many cases, lifelong), even steady diagnosis and drug-treatment rates would generate sizable near-term growth in this market. Government-sponsored improvements to the healthcare system and increasing economic prosperity among the Chinese population have also added to this market growth.

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## **NANO TECHNO CITY INSTITUTE OF ADVANCED RESEARCH STUDIES**

Arun Kumar and Ajith Kumar  
[www.iars.in](http://www.iars.in)

In the past ten years, we have seen one of the major advantages in the field of scientific endeavours. The major, Factor in this growth is the Man's revolutionary idea of handling the small world (namely Electrons, Protons & Neutrons) using the advanced branch of physics called Quantum Theory. This had led to vast scale miniaturisation and material development. This is the basic wave for what we called "IT" and Biotechnology. With this view, yet another emerging hi-tech area namely "Nanotech is going to hit the global" arena very soon. This would be the most advanced and the ultimate technology. Indeed many international agencies rendered help in promoting this highly promising area.

The project proposal is to create a corridor in Trivandrum, (Kerala) connecting Nanotechnology, Bio technology, IT, allied areas in Engineering, Physics, Chemistry, Biology and Mathematics to involve into a Techno biological global concept so that a large scale inter disciplinary interaction is created which is necessary for this

initiative which will hit the 21st Century by storm. A lot of scope, promise can be created in Kerala and thus in India, not only that, much important hi-zone Economic growth will be enhanced.

The outputs are of wide range including new Enzymes, synthetic Vaccines, transplant tissues, Nanotech software, Nano biotech Pharmaceutical products, Antibodies, New clonal Animals & Breeds using Indian Flora and Fauna, Nano solar fuel cells, Nano chips, Nano Biochips, Nano seeds, Nano gold, Nano silver, Nano robotics for surgery, Nano robotics for Industrial plants & Machinery, Nanodrug therapy Etc., Etc.,

.An insight to Nanotechnology and Biotechnology not only improve and give great chances to take intellectual rights to our own flora and fauna, also it gives an impact to our Natural products along the new globalisation net work.

### **Promoters**

The proposed project is pioneered by two medical doctor brothers, Dr.Arun Kumar and Dr.Ajith Kumar.

### **Foundation of the Project**

The basic foundation of the project is to create an Internationally multi disciplinary platform

incorporating Mainly Nanotechnology, Biotechnology, IT and other allied hi-tech areas, so that it allows a better and more stable platform for new innovative hi-tech products and Investment portfolios. This project will have facilities fort producing certain products of our own and then integrating the scheme connecting various locations World . The above foundation is laid on the basis of the fundamental and pioneering work that has been done by the promoters.

### **"Nanogeneseq Chip Design" NANOGENESEQ**

The key aspects of the technology described by this plan have been developed and are being improved upon. Due to the strategic nature that high-throughput sequencing technology will play in modern drug discovery efforts by pharmaceutical companies.

Since the discovery of the DNA, sequencing DNA has become the most significant routine activity in the field of genetics and drug discovery and their related applications. Year 2000 was the annus mirabilis of biology , the year when scientists announced that their mission to compile the human genome was essentially complete. After 10 years of research mankind's entire DNA was laid bare and its code deciphered, the complete book of instructions that directs the way our bodies grow and how we

respond to illnesses.

The headlines announced that science stood on the threshold of a new era of drug development. The biologists' equivalent of landing man on the moon! However , despite the fanfare, there are still many caveats and science is far away still from translating Genome sequence data in useful preventive or therapeutic remedies for diseases.

The human genome is by no means complete and sequencing alone willot lead to new drugs. It is just one step in a long, very long road to routine and effective use of genetic sequencing data to support drug discovery and development efforts. With the genome sequencing race finished, a new one is on. The new race is in assigning to genes and to variations in genes, a role in disease initiation, progression and drug response. This is a huge task currently being tackeld with modern drug discovery tools (functional genomics, proteomic, bioinformatics, etc.).

The goal will be to identify genes expressed in disease and not in healthy tissues and once such task is accomplished, to design molecules that interact or block the harmful proteins made by these genes. The bottom line is that DNA sequencing, far from being over, now that a rough map of the human genome has been produced, has become a mainstay technique in biomedical research at all levels,

in both academic basic science and commercial environments. And far from being perfect, notwithstanding the enormous progress made in recent years with automated sequencing robots, current DNA sequencing technologies are still complex, time consuming, expensive, relatively inefficient and, henceforth susceptible to substantial improvements and open to innovative approaches.

In the high-throughput sequencing sectors, such as modern drug discovery in Pharma companies and contract research companies, the improvements needed are in the sequencing efficiency and cost of running automated sequencing systems, often operated 24 hours a day every day of the year. At the bench level in academic labs, the market need is for simple –to-use devices that are easy to adapt in “home brew” systems specific for the individual scientist’s needs.

NANOGENESEQ. Technologies address these two needs with a highly innovative and efficient system which optimize DNA sequencing at both the efficiency and cost level.

There are various methods to sequence DNA. The most relevant one are based on electrophoresis, capillary action, capillary gel electrophoresis, ion separation, phase transition etc. The most widely used are based on capillary electrophoresis separation of DNA

strands followed by detection, again by various methods. Capillary electrophoresis separation involves flowing different molecular weight or different size DNA segments through a porous or gel material which allows smooth and easy movement in the presence of an electric field.

The DNA segments are obtained by the use of several restriction enzymes which, acting each as a different chemical scissor, are able to cut the DNA at a specific site along its sequence. The flow patterns, which include the different DNA segments, are then plotted on a particular material in time and scale and the segments are detected using usually lasers (or other detection methods) in combination with certain base-specific fluorescent dyes.

The majority of DNA sequencers available on the market today incorporate the basics of the method described above.

Although capillary electrophoresis sequencers have undergone several evolutionary improvements, they all share the following common disadvantages:

- a) They are plagued by overlapping problems: overlapping of different DNA fragments, as they move across the gel or membrane, makes sequencing and detection inefficient and expensive, since it slows

- down the sequencing process and imposes the use of expensive reagents which brings the commercial cost of sequencing at \$10-12 dollars per base pair.
- b) Only few DNA fragments are flown in the separation columns at any given time.
  - c) Can only sequence up to a maximum of 600 to 700 Base pairs at any given time.
  - d) Use laser detection which severely restricts the use of low molecular weight dyes with fluorescent properties.

NANOGENESEQ has designed a system which reduces or eliminates most of the above mentioned disadvantages, dramatically improves sequencing precision and throughput and, as result, significantly reduces sequencing cost per base pair.

DNA BRAID GENESEQ has designed an innovative sequencing system design consisting of two key components:

- a) The Hardware component
- b) The Software component

The hardware component of NANOGENESEQ design sequencing system is the most critical component since it speeds of the process of DNA sequencing altogether. It has been designed as a silicon chip in which DNA segment separation and detection is much more efficient than currently-used electrophoretic methods.

Separating DNA fragments by length is the single most important step of the sequencing process. The traditional method is to place a “restriction enzyme digested” sample at one end of a column of an organic gel and apply an electric field to the column. The electrical field causes the flow of the DNA fragments through the gel and the rate of flow of each fragment is directly related to its molecular weight. As they slowly make their way through the tiny pores of the material, fragments of different lengths moves at different speeds and eventually collect in a series of bands as a ladder like structure that can be photographed using fluorescent or radioactive tags.

One of the major problems with this conventional scheme is the overlapping of DNA fragments caused by the intense density of the media (gel or membrane) acting as a “viscous” substrate through which the fragments move. DNA fragment overlapping is the first problem that NANOGENESEQ system eliminates.

NANOGENESEQ has designed NANOCHIP as a microelectronic device , a chip-like system , which allows DNA fragments to travel freely without intense density filling . It has been designed through the use of fractal geometrical methods, which are genetical algorithms which can be modeled to develop a porous

geometry architecture which allows DNA samples to move in non-viscous media, such as water and other low/zero resistance media, using an electric field.

In conventional schemes the second rate-limiting step is that only a few DNA fragments can be flown through the columns to avoid overlapping which, acting each as a different chemical scissor, are able to cut the DNA at a specific site along its sequence. The flow patterns, which include the different DNA segments, are then plotted on a particular material in time and scale and the segments are detected using usually lasers (or other detection methods) in combination with certain base-specific fluorescent dyes.

The founders are now seeking qualified Venture Capital to back their licensing efforts and to execute on the plan.

### ***Project Components***

The project envisages a full-fledged Quality Control and R&D laboratory for Product development and has 3 main components viz. QC and R&D Lab, Toxic study centre, and a pilot plant for scale up operations.

### **Intellectual Property of the Promoters**

The efforts of the promoters in identifying one of the high technology area which embraces almost all the exciting fields of science, including life science and

the progress they have achieved in taking up the efforts into a tangible business solution has been considered as the core foundation of the proposed project. This effort has been valued at Rs.150 lakhs by a panel of scientists.

**Nanogeneseq chip design:**  
Patent Published by OFFICIAL PATENT JOURNAL OF GOVERNMENT OF INDIA. {Published 2007-07-27}. Helinaser :  
Patent Published by OFFICAL PATENT JOURNAL OF GOVERNMENT OF INDIA . {Published 2006-04-21}.

The promoters had 8 patent publications in nanotechnology .

Research Philosophy: We are introducing a new concept of “**Nano Doctrine Nano shunk works**” concept ie. A nano group will be manipulated for each module/project ultimately for 15 projects.

15 nano shrink works initially and controlling lead network” by the promoters, Dr. Arun Kumar & Dr. ajith Kumar. Simultaneously new nano innovations from each group are teemed to the Commercial production facilities.

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# **BIO-BUSINESSES IN INDIA**

## **Q1-2008**

### **Sun Pharma Received FDA Approval for Generic Fosamax (R) Tablets**

In September, Sun Pharmaceutical Industries Ltd. announced that the company received approval from FDA to market Alendronate sodium tablets (generic Fosamax). Alendronate sodium tablets are indicated for the treatment and prevention of osteoporosis in post menopausal women, to increase bone mass in men with osteoporosis, in the treatment of glucocorticoid induced osteoporosis, and Paget's disease of the bone in men and women.

Fosamax (R) tablets have annual sales of approximately US\$ 560 million in the US alone.

### **Diakron and Orchid Pharma to Develop Anti-coagulant Drug**

In August, Diakron Pharmaceuticals, Inc. announced the signing of an exclusive license agreement for a novel investigational oral anticoagulant drug candidate discovered and developed through Phase I clinical trials by Merck & Co. Inc. Under the terms of the agreement, Diakron has the exclusive rights to develop, and, if approved, market and distribute the compound worldwide.

In a simultaneous transaction, Orchid Chemicals & Pharmaceuticals Ltd., the Chennai (India) based pharmaceutical major ("Orchid Pharma"), has signed an agreement to partner with Diakron as a significant shareholder and developer for the anticoagulant drug candidate. Orchid will be undertaking the next stages of development.

## **Codexis and Arch Pharmed Labs in Strategic partnership**

In August, Codexis, Inc., a leader in biocatalysis technology, and Arch Pharmed Labs Limited, a leading Indian active pharmaceutical ingredients (APIs) and intermediates manufacturer, announced a major new strategic collaboration, expanding their three-year partnership in pharmaceuticals manufacturing.

Codexis, based in Redwood City, CA, will offer multiple pharmaceutical intermediates and active pharmaceutical ingredients (APIs) made with its proprietary biocatalytic processes to both innovator and generic drug manufacturers. Sales in India will be through its subsidiary, Codexis Laboratories India Private Limited. Arch, which is based in Mumbai, India and has ten facilities throughout the country, will be Codexis' exclusive manufacturer for these products. The two companies will also co-market products.

## **Satyam Computer Service Ltd partners with Sciformix, Inc to Provide Comprehensive Drug Safety Management Services.**

In June – Satyam Computer Services Ltd, a leading global consulting and information technology services provider, announced that it formed an strategic partnership with Sciformix, Inc., a Westborough, Massachusetts-based, Life Science Knowledge Process Outsourcing (KPO) company, to data management services in "Pharmacovigilance." Several high-profile withdrawals of popular drugs from the marketplace made this partnership more important. Pharmaceutical companies presently are looking for ways to manage risk and taking a more proactive approach toward collection and assessment of drug safety information.

This partnership addresses the worldwide increase in focus on drug safety, which is leading to increased volumes of adverse events being reported to the regulatory authorities. Satyam and Sciformix will collaborate to enable pharmaceutical and biotechnology companies to better monitor safety of the products they market by offering services across the safety management spectrum, ranging from case intake to international regulatory reporting.

## **Ranbaxy Received a Tentative Approval to Manufacture and Market Valganciclovir Hydrochloride Tablets**

In June - Ranbaxy Laboratories Limited announced that it received a tentative approval from the U.S. Food and Drug Administration (FDA) to manufacture and market Valganciclovir Hydrochloride Tablets, 450 mg. It will be launched by Ranbaxy upon receiving final approval and resolution of litigation currently pending

in Federal District Court, as an affordably priced alternative to the branded product, Valcyte.

Valganciclovir HCl is used for the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS). Valganciclovir HCl is also indicated for the prevention of cytomegalovirus (CMV) disease in kidney, heart and kidney-pancreas transplant patients at high risk.

Ranbaxy believes that it has First-to-File status on Valganciclovir tablets, thereby providing a potential of 180-days of marketing exclusivity, offering a significant opportunity in the future. Total annual market sales for Valganciclovir HCl Tablets were \$239 million (IMS - MAT: March 2008).

Ranbaxy Laboratories Limited, one of the largest pharmaceutical companies in India, manufactures and markets a wide range of generic drugs. The Company is doing businesses in over 125 countries and has extensive international affiliates, joint ventures and alliances, ground operations in 49 countries and manufacturing operations in 11 countries.

#### **FDA Approved Escitalopram Oxalate Tablets (generic)**

In June - Lupin Pharmaceuticals, Inc. (LPI) announced that received a tentative approval for the Company's Abbreviated New Drug Application (ANDA) for Escitalopram Oxalate Tablets 10 mg and 20 mg from the U.S. Food and Drug Administration (FDA).

Lupin's Escitalopram tablets are the AB-rated generic equivalent of Forest Laboratories' Lexapro(R) tablets, used for the treatment of major depressive disorder. According to the IMS-Health Sales data the brand product had annual sales of approximately \$2.6 billion for the twelve months ended March 2008,

Commenting on the approval, Vinita Gupta, President and Managing Director of Lupin Pharmaceuticals, Inc. said, "We are pleased to receive this tentative approval and look forward to bringing Escitalopram tablets to the US market as an affordable generic alternative post patent expiry."

Lupin intends to introduce the products in the market through its network of national wholesalers and drug stores post patent expiry in March 2012. This will strengthen Lupin's presence in the Selective Serotonin Reuptake Inhibitor (SSRI) segment.



### **Carna Biosciences Signs Reagent Supply Agreement with Caliper Life Sciences**

In August, Carna Biosciences, Inc. announced the signing of a collaborative agreement with Caliper Life Sciences, Inc. USA. Carna will supply a set of discrete protein kinases aiding the expansion of Caliper's kinase profiling and assay development services, and ProfilerPro Kinase Selectivity Assay Kits. Caliper's products and services are widely used and highly regarded by leading pharmaceutical and biotech companies. The selection of Carna as a Preferred Provider enhances the visibility and use of Carna's products in the area of kinase inhibitor drug discovery -- a major focus of targeted therapy in the areas of cancer, neurological, and autoimmune diseases.

### **Kowa Company, Ltd. Acquires ProEthic Pharmaceuticals, Inc.**

In August Kowa Company, Ltd., a privately-held company headquartered in Nagoya, Japan, announced the acquisition of ProEthic Pharmaceuticals, Inc., a privately-held specialty pharmaceutical company based in Montgomery, Alabama.

ProEthic will change name to Kowa Pharmaceuticals America and will assume responsibility for all sales and marketing functions currently operating in Montgomery, Alabama. ProEthic's clinical development group will transfer to Kowa Research Institute, which is located in Morrisville, North Carolina.

The first pharmaceutical product to be launched by the new company will be pitavastatin, a novel HMG CoA reductase inhibitor for the treatment of hyperlipidemia. Pitavastatin is sold in Japan, Korea and Thailand under the brand Livalo(R). Pitavastatin has recently completed Phase 3 clinical development in Europe and the United States.

### **Sosei Completed Phase III Trial for NorLevo(R)**

In July Sosei Group Corporation announced the completion of a Japanese Phase III clinical trial for the emergency contraceptive pill (ECP) SOH-075 (NorLevo(R)). Sosei acquired the exclusive distribution rights to the product in Japan from HRA Pharma.

The clinical study was designed to evaluate the safety and prevented pregnancy rate of SOH-075 in Japanese adult female subjects who require emergency contraception. No serious adverse events were reported during the study.

### **Galderma Announced Approval for Differin(R) Gel 0.1% in Japan**

In July, Galderma Pharma S.A., a global specialty pharmaceutical company focused on dermatology, announced that Japan's Ministry of Health, Labor and Welfare has approved Differin(R) Gel 0.1% (adapalene), a novel topical treatment for acne vulgaris in Japan. The drug will be marketed in Japan by Galderma KK, the fully-owned Japanese arm of Galderma, and strategic alliance partner Shionogi.

Differin(R) has been available for over 15 years and is currently marketed in more than 80 countries, where it has become an important therapy for more than 22 million patients. Approval in Japan will reinforce Galderma's presence in the world's second-largest pharmaceutical market. Approval was based on non-clinical and clinical studies, which supported the efficacy and safety of the product for the registration outside Japan and on an extensive local clinical development program, including two phase 3 studies enrolling more than 600 Japanese patients.

### **Rare Indo-Japan Pharma Alliance :**

#### **Ranbaxy to Bring in Daiichi Sankyo as Majority Partner; Strategic partnership Creates Innovator and Generic Pharma Powerhouse in Asia**

In June - Daiichi Sankyo Company, Limited, one of the largest pharmaceutical companies in Japan, and Ranbaxy Laboratories Limited, among the top 10 generic companies in the world and India's largest pharmaceutical company, announced that a binding Share Purchase and Share Subscription Agreement (the "SPSSA") was entered into between Daiichi Sankyo, Ranbaxy and the Singh family, the largest and controlling shareholders of Ranbaxy (the "Sellers").

Pursuant to the Agreement, Daiichi Sankyo will acquire the entire shareholding of the Sellers in Ranbaxy and further seek to acquire the majority of the voting capital

of Ranbaxy at a price of Rs737 per share with the total transaction value expected to be between US\$3.4 to US\$4.6 billion.

If completed, the deal will:

Help Daiichi Sankyo diversify its business within a different segment of the pharmaceutical industry as; following years of divestments in unrelated businesses, Daiichi Sankyo will now participate in a full range of drug product offerings through branded, generic and over-the-counter product lines.

- Allow Daiichi Sankyo to benefit from an upcoming wave of patent expirations in the U.S. and European markets, while also promoting generic products in the under-penetrated Japanese region.
- Support Daiichi Sankyo's geographic expansion plans, particularly in fast-growing emerging markets such as India.
- Leverage Ranbaxy's research resources and manufacturing capabilities, particularly within the Indian market.
- Maintain Ranbaxy's independence as a subsidiary of Daiichi Sankyo by retaining, as is currently proposed, Ranbaxy Chief Executive Officer Malvinder Singh.
- Enable Ranbaxy, through the support of a large globally-established pharmaceutical company, to further implement their own drug development ambitions
- Provide the controlling family of Ranbaxy with an attractive opportunity to monetize their stake in the company

### **Japan's MHLW Approves CyberKnife System for Extracranial Use Robotic Radiosurgery System Offers Non-Invasive Treatment Alternative for Tumors Anywhere in the Body**

In June - Accuray Incorporated, announced that Japan's Ministry of Health, Labor and Welfare (MHLW) granted Shonin approval of the CyberKnife(R) Robotic Radiosurgery System for use in treatment of extracranial tumors, including tumors that move with respiration. This regulatory approval dramatically expands the types of patients that can be treated with radiosurgery. As a result of this approval, the CyberKnife System may be used in Japan to treat tumors anywhere in the body, including those in the spine, lung, liver, pancreas and prostate.

In 1996 the CyberKnife System was first approved in Japan to treat tumors in the head and neck. Currently, there are 20 CyberKnife Systems installed throughout

Japan, making it the second largest installed base of CyberKnife Systems after the United States. The CyberKnife System offers cancer patients worldwide a pain-free, non-invasive alternative to surgery.

Additionally, according to a 2006 report from global research firm, Research and Markets, Japan remains the world's second largest medical device market after the United States. Japan is currently facing a rapidly aging population and the incidence of lung cancer is on the rise. Lung cancer is the leading cause of cancer death among men and women in Japan. In 2003, the number of lung cancer deaths reached 41,615 (22 percent of all cancer-related deaths) in men and 15,086 deaths (12 percent of all cancer-related deaths) in women.

### **Santen and MacuSight Announce Partnership and License Agreement for Sirolimus in Ocular Diseases.**

In June - Santen Pharmaceutical Co., Ltd. and MacuSight, Inc. announced that the two companies entered into a research and development partnership and license agreement for the Japanese and Asian development and commercialization of sirolimus for the treatment of ocular diseases including wet age related macular degeneration (wet AMD) and diabetic macular edema (DME). Sirolimus, originally known as rapamycin, is a highly-potent, broad-acting compound that has demonstrated the ability to combat a broad range of diseases and conditions. MacuSight is presently initiating a Phase 2 clinical trial of sirolimus in DME and preparing to initiate a Phase II study in wet AMD in the third quarter of 2008.

Under terms of the agreement, Santen receives rights to develop and commercialize sirolimus for ocular diseases and conditions in Japan and Asia. MacuSight retains development and commercialization rights to sirolimus in all other markets.

Santen has agreed to provide MacuSight with an initial upfront payment of \$50 million dollars for funding MacuSight's continuing research and development efforts, as well as clinical development of sirolimus. Additionally, Santen will provide MacuSight with milestone payments and a royalty on future sirolimus sales in the Japanese and Asian markets.

Sirolimus is a highly-potent, broad-acting compound that has demonstrated the ability to combat disease through multiple mechanisms of action including immunosuppressive, anti-angiogenic, anti-migratory, anti-proliferative, anti-fibrotic and anti-permeability activity. Based on the versatility associated with these multiple mechanisms of action, MacuSight believes that its sirolimus product may serve as a potentially highly-efficacious therapeutic for a wide range of ocular diseases and conditions, including the treatment and prevention of wet AMD and DME.

## **China Sky One Medical, Inc. Received Chinese Regulatory Approval for Four New Drugs**

In June -- China Sky One Medical, Inc., a China-based life-sciences company for pharmaceutical, medicinal and diagnostic kit products, announced that it obtained approval from the State Food and Drug Administration (SFDA) in the People's Republic of China for four new drugs: Tobramycin Eye Drops, Compound Zinc Sulfate Eye Drops, Ofloxacin Suppositories and Ofloxacin Gels.

Tobramycin Eye Drops have been approved for the treatment of acute infection on eyelids. Compound Zinc Sulfate Eye Drops have been approved for the treatment of acute and chronic conjunctivitis and trachoma. Ofloxacin Suppositories have been approved for the treatment for bactericidal colpitis, and Ofloxacin Gels have been approved for the treatment for bactericidal injection. The Company estimates the size of the each market at approximately \$ 2 million USD to \$2.4 million USD

The new approvals bring the total number of China Sky One's externally used products to 53 and its total marketed products to 102, giving the Company one of the most comprehensive pharmaceutical product portfolios in China.

## **Improved Milk Production in Cows From Cactus Cattle Feed**

In June, China Kangtai Cactus Biotech Inc., a vertically integrated grower, developer, manufacturer and marketer of a variety of cactus-based consumer products in China, announced today test results from studies conducted of cows that received the Company's Cactus Cattle Feed. The studies, which included 30 cows, were conducted in conjunction with the Company's application for a Certificate of National Invention Patent and showed cows that received the Company's Cactus Cattle Feed increased milk production by approximately 15.2% during the twenty-day trial period.

The Company also conducted a second test, evaluating the ability of cattle to produce milk under adverse environmental conditions, including cold temperatures and strong wind conditions. The study selected 100 milk cows between the age of 2.5 to 3 years, and divided them into two groups. The cows in the control group were fed with the normal feed which was made by the ranch. The cows in the experimental group received the same feed, but also added 1kg cactus cattle feed to each ton of the normal feed. The milk production of the experimental group increased to 1,372kg from 1,350kg despite the adverse conditions. The milk production of the control group decreased to 1,286kg from 1,380kg. The results suggest that the use of cactus cattle feed additives could increase milk production by 8.44%.

### **Genesis Pharmaceuticals Closes \$30 Million Private Note Placement**

In June, Genesis Pharmaceuticals Enterprises, Inc., a leading pharmaceutical company in the People's Republic of China, stated that it successfully completed a private placement of \$30,000,000 of its three year convertible notes.

The Notes carry an annual interest rate of 6.0% and are convertible into shares of the Company's Common Stock at a conversion price of \$0.20 per share. In connection with the private placement of the Notes, the Company issued to purchasers of the Notes an aggregate of 75,000,000 five-year warrants to purchase shares of its Common Stock at an exercise price of \$0.25 per share. The lead investor in the private placement was Pope Investments, LLC.

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## **Medzym** – [www.medzym.com](http://www.medzym.com)

Medzym, Inc. is a privately held biotechnology company focused on building molecular therapeutics based on effective platform technologies. Company's current focus is on Age-related eye disorders- (1) eye-diseases, (2) Anti-Inflammatory/Allergy, and (2) Cardio-vascular.

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