

AMONG GIANTS:  
OPPORTUNITY ABOUNDS

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By

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“That’s one small step for a man, one giant leap for mankind.”

1969. We sent a man to the moon amidst one of our darkest hours. War, the civil rights struggle...the world was tearing itself apart. Yet out of this chaos, for the briefest of moments, everybody stopped. Hippies, soldiers, workers on the factory floor, cooks in the kitchen, kids in the classroom and farmers in the fields.....all of them just stopped. Froze. Together, they came to know that somehow, in some unbelievable way, things are incredibly bigger than they ever thought they could be. That moment didn’t belong to anyone in particular. Neil Armstrong’s step was not for himself; it was a step symbolic of the sheer possibility and promise of the entire human race. Armstrong was the Magellan of his day. He was Alexander MacKenzie travelling overland in Canada to reach the Pacific Ocean. Jacques Cartier finding the St. Lawrence. He was birthing a new era for humanity. And all who witnessed it, were marked by it and changed.

2002. Today every ocean has been charted and most every square tract of earth has borne the weight of our species. Which frontiers are left? Where are our Magellans and MacKenzies? I submit to you that the greatest uncharted frontier is the human body itself.

Last week NASA announced its cooperative agreement with the biotechnology industry organization. NASA, with space as its laboratory, will test fundamental principles of chemistry and biology. Bio will provide the industry support necessary to maximize the research and move forward its commercial applications. When the space shuttle endeavour docked at the international space station just days ago - Peggy Whitson was not only the second woman to take the post, but she also represents the future of today’s space program. Peggy is not only an astronaut – she is also a renowned biochemist. The marriage of NASA with the biotechnology and the pharmaceutical industries is no coincidence. It is the definitive truth of innovation finding innovation, and together furthering the quest for discovery.

The human eye. The heart. The cell. The single gene. It is these things that make up our undiscovered country - our new Northwest Passage.

A friend recently told me what it was like to visit her mother every Sunday. How it felt to step foot in the building that she dreaded - that edifice organized to contain the whirlwind of Alzheimer’s. She said that after a while she noticed a common look among her fellow visitors. The look of children visiting parents who had forgotten them.

Half the population over 85 has some form of dementia. Our parents are living longer; we will live longer still, thanks to modern medicine. Why should we live to forget all that we spent a lifetime to learn? Alzheimer’s is that undiscovered country, that uncharted sea, that baffles and swallows us up. Why not map it? Why not save our parents and ourselves from that abyss? Why not invest our ingenuity and resources into taking that giant leap for humanity, and finding a cure for Alzheimer’s?

Somehow it’s always easier to talk about a friend.

When I was a kid I played tennis with my dad during summers. We’d play hard. Competitive as we always were. He used to beat me something awful. But I got better as a teenager - and he got slower. I remember hitting shots far away from where he stood. Rather than let them go, and chalk it up to age, he’d run after them as fast as he could...cause that’s who he was. After the shot I remember him turning his back to me, putting something in his mouth. Only years later did I learn that the something was a Nitro Glycerin tablet. That’s all they had to stave off a heart attack in the 1970’s - no knowledge

of diet, or appropriate exercise. No calcium channel blockers, no diuretics, no cholesterol reducers on the market...My dad, a physician, died in the early morning hours of 1977...of a heart attack. I was seventeen. I went to work. As fate would have it I found myself working in the pharmaceutical industry. Found myself immersed in a sea of discovery and promise.

And to bring it full circle for just a minute, Biovail, just last month, released breakthrough clinical data for its newest cardiovascular drug, Cardizem XL, this was announced at the Conference for the American Society of Hypertension. With this new drug we have found the means to improve its delivery in such a way that it works at its peak during the time when individuals are most at risk for a cardiac event – between the hours of 4 am and 10 am. This is the kind of precision that Biovail is moving towards.

The pharmaceutical industry is passionately heeding the call for new discovery. The human genome has been mapped. Personalized medicine is no longer the thing of science fiction, but is becoming a reality.

As Northrop Frye, that great Canadian literary critic broke new ground in the world of literary criticism with his 1957 watershed work, Anatomy of Criticism...We in the pharmaceutical and biotechnology industries are just beginning to break revolutionary ground in the anatomy of the human body.

Modern medicine changed the Twentieth Century. The Polio vaccine, our ability to fight Tuberculosis, Malaria...and in just the last decade, our incredible progress in our fight against Aids. There is a lot to be proud of...but this is no time to rest.

New strains and variations of diseases are springing up all around us, bio-terrorism is an all too real proposition, and the cures to too many existing diseases still elude us. And though we praise big pharma for all the work they have carried on to date, we recognize too that the road ahead is a long one and remains largely uncharted.

I have been in the very fortunate position over the past decade to be able to surround myself with some of the greatest scientific minds on the planet. From them I have learned to do one thing very well – to listen! To just listen to them as they show me their discoveries and explain to me where the pharmaceutical industry, and hence the state of healthcare, can be in 5, 10, even 50 years from now. So I watch, listen, and exchange ideas with these revolutionary thinkers, and I get a little glimpse of the future.

And what do we see?

With all due respect to the multinationals, an interview with Nathan Myhrvold in the May issue of BIO- I. T. World, was entitled “Big Pharmas are Dinosaurs.” Nathan Myhrvold was with Microsoft for 14 years; his last post was as Head of Research. He had the ear of Bill Gates, who deeply respected his vision. What is this I.T. star who is a Princeton trained mathematician and a UCLA trained physicist doing in biotech? His answer: “I’m excited about biotech in the way I was excited about the PC industry. My analogy is that biotech is in the same stage when Intel shipped the first microprocessor in 1971...the drugs out there are not even the tip of the iceberg.” When questioned specifically about big pharmas, Myhrvold again returns to a computer analogy. “The big pharmas today are like mainframe companies 20 years ago... the mainstream market is about personal computers. That was a radical shift.”

Remember, I didn't make that analogy, Myhrvold did...though I have to tell you...he's right.

Big pharma, for the most part, is still trying to attack a disease with a broad frontal assault when in fact what is needed is a tactical approach to the medicinal treatment of individual patients. The mapping of the human genome will completely revamp the industry. Many more kinds of medicines will be available over the next 20 years.

Let's look at one very simple change, that when it occurs, will turn the industry on its head. This change involves the area of pharmacogenomics – the study of why individuals respond differently to drugs. Companies like the Connecticut based Genassaince use sequencing to find genetic variations called single nucleotide polymorphisms in human DNA. Genassaince applies proprietary algorithms to find sets of SNPS, called haplotypes. Once these sets of haplotypes, which are inherited, are discovered, the goal is to find the sets that are centers for disease susceptibility or drug response. Once found, the personalized treatment that matches the genetic make-up of the patient can be applied. Direct personalized results – no drug jumping, no side-effects, no guessing – we move into exact science.

This kind of technology, according to Larry Ellison, a visionary in the converging world of Information Technology with biotech applications, and the Chairman of Oracle Corporation, says this will produce a new age at the FDA. Potentially life-saving medicines will no longer have to be rejected time and time again at the FDA. When they work for 90% of the people but cause negative side-effects for 10%, the drug is generally rejected for approval - which is today's standard procedure. In this new age of pharmaceuticals, medicines will be tested for specific genetic make-ups. What may work well for 40% of the patients, may be a disaster for 60%...but so what, if you know exactly who the 40% are!!

The future of the best in biotech and I.T., being integrated with the best in the pharmaceutical industry - will bring with it the removal of the blindfold. Testing medicines to see if they can potentially work on everybody will quickly become a crude and outdated practice. What do we do to be ready to meet this coming revolution which will change the face of the pharmaceutical industry, and if embraced widely, will radically alter how healthcare is practiced around the globe? We watch, we listen, and we remain open.

It is no coincidence that the largest international gathering of biotechnology firms is going on this week right here in Toronto. It is rather a beckoning. A calling to our homeland investors to seize the opportunities before them. I invite you to please join me in the halls of the BIO 2002 Conference. See what it is I am talking about. Talk to the new visionaries - They are here and want to share their enthusiasm and expertise...go and see what Voltaire would have called the best of all possible worlds.

As Canadian business people and investors, how do we break into this vast market of ideas, discovery, and unparalleled humanitarian and financial reward? Let me tell you a little bit about what we are trying to do to grow our company. Biovail is an innovative partner to big pharma...an archer working diligently to hit the target more precisely. Our method has been to work alongside big pharma...not against them. The niche we are most well known for carving is one of improved precision. In that sense what we do is really very simple. People often ask me, if it's so simple, why doesn't big pharma do it themselves? My answer is that big pharma is working against a clock. Thankfully, they have the resources to go for the big breakthrough. If a big pharma company found a full proof cure for Aids, they would of course want to rush to get it to market. We all would want them to rush it. But what if

that cure involved the patient having to take an injection eight times a day for two years? So what you say? If it's life or death who cares – eight times a day, sixteen times a day so what? But then look at the quality of a life dominated by injections...it would be difficult.

This is where Biovail would use its drug delivery technology and come up with an innovative approach to make the cure more tolerable, its administration more convenient, and strive to eliminate certain side effects. Biovail has developed an array of oral drug delivery technologies with literally dozens of applications. We have technologies that time the release of a drug in the human body so as to maximize its effect. Our flashdose technologies allow patients, most importantly infants and seniors, to easily swallow tablets as the medication liquefies instantly upon ingestion. Our enhanced absorption technologies ensure medications take effect in a more expedient way than conventional tablets and capsules. There are many multiples of applications for our technologies. Biovail currently is developing over 20 novel formulations. These are medications that will greatly enhance patient compliance, will be clinically superior, and will open up new indications for our patient's use. This niche is our staple, but it is only one aspect of our vision. What we are talking about today is revolutionary innovation...so let me tell you how we intend to participate in this innovation.

We have allocated \$250 million dollars into Biovail Ventures. We are using that money to make minority investments in some of the most exciting biotech companies in the world. We don't want to create an internal "Genaissance," we want to wisely and selectively find those small companies that are doing the great work and invest in them. We can offer these creative companies capital, and a solid administrative, research, regulatory, and legal infrastructure. Above all we can offer these companies freedom. We want them to let their creative spirit soar as we support them, as opposed to dictate to them how to pursue their discoveries. The complaint against the giants of the industry is that their investment in these small biotechs is too slow in their decision making processes, too indecisive in what they are willing to invest in, and unfair when it comes to sharing the wealth with these small companies. Biovail Ventures offers decisive action in a fair and equitable environment. Our aim is to share in prosperity just as we share in discovery. We will make the investment into sales and marketing, which is growing in leaps and bounds, while our biotech partners expertly pursue the purity of science. This kind of venture represents the future of our global economy. It is how Biovail is making it in the lands of the giants.

The days of oil, lumber, and an economy based on the exploitation of natural resources is a relic of the past. The environment cannot withstand it, and besides which, it is no longer economically feasible. The future is in the investment of biotech ideas, not materials. Ideas will turn into breakthrough products. And breakthrough products will turn into cures for disease. This new economy is a win-win. The potential for economic growth is as large as the human mind – the depths of which remain untapped, and the potential for the humanitarian benefit and the public good is as clear as curing cancer, heart disease and Alzheimer's

As Neil Armstrong took his one small step, human beings across the world paused to collectively experience landing in a place that had always seemed eternally distant. The world changed forever with that giant leap. Now embarking on the miraculous small universe of the human gene, we too pause to witness the new miracles of science that extend life, cure disease, and prevent illness. The Magellan's and John Glenn's of the twenty-first century are scattered in laboratories across the world looking deeply into their microscopes in search of the next revolution in healthcare. Let us be there to support these explorers of new frontiers. I have never felt more positive and hopeful about the future of the pharmaceutical industry.

This is an industry that is very visible, often time the cause for much public controversy and misunderstanding. It is also that corridor through which we travel to find the cures we so desperately need.

1969. That one small step silenced us. It wasn't about money or politics or anything else. It was about what human beings could do. We all went to the moon in 1969. Maybe we'll all cure breast cancer in the coming years or Alzheimer's or how about diabetes? Maybe that's what it will take for all of us to pause again. Beholding a discovery much larger and more important than any petty point of view. Let this industry remain strong. In its strength, that one small step in the lab—will forever translate into that giant leap that transforms us all.

Thank you.