Jim Greenwood Keynote Speech 2009 BIO International Convention Atlanta, Georgia May 19, 2009

Good afternoon.

Well, it has been quite a year since we met in San Diego.

It would be an understatement to say that things have changed.

The change has been profound.

Over the past several weeks I have discussed the impact of these changes with thought leaders in our industry.

And since change has been so on our minds, I actually Googled the word change. I found an interesting quote that I believe applies to us. It reads:

Change has a considerable psychological impact on the human mind.

To the fearful, change is threatening because it means that things may get worse.

To the hopeful, change is encouraging because things may get better.

To the confident, change is inspiring because it challenges us to make things better.

We find ourselves today in the midst of a perfect storm of economic meltdown, political volatility and scientific challenge.

But unlike the characters in the movie, I know we will survive this perfect storm.

Even as the seas of economic, political and scientific uncertainty seem to pound us from all sides, we embrace the challenge – we embrace the change —

and we keep moving forward.

We remain confident.

We remain inspired.

Because we know that we can help make things better.

We can help save and extend lives.

We can help preserve our environment.

And we can help feed the hungry.

This is what we do.

Still, we cannot deny the storms that circle around us.

First let's talk about the economic storm.

I don't have to tell you the outlook has been bleak.

You can see it in the headlines and in your own portfolios as we've slid into the worst economic downturn since the Great Depression.

Every sector of the economy has felt the pain, and biotech is no exception.

Our investors are wary. Globally, venture capital investment in biotech is down 46% in the first quarter of this year compared to 2008.

Our companies are struggling. There was only one biotech IPO in 2008 – but eleven bankruptcies.

Nine more bankruptcies have been filed so far this year, and there are no IPOs on the calendar.

Hundreds of biotech companies have laid off thousands of workers – and dozens have put research projects on ice for lack of funds.

A full forty percent of current publicly-traded biotech companies are down to their last 12 months of cash and about a third of companies ended 2008 with less than six months of cash.

Like the recession itself, this pain is being felt in biotech worldwide--and we can expect things to get worse before they get better.

Sadly, more otherwise good, innovative companies will fail as they capsize in this storm.

Our capacity to finance the innovation of new treatments, cures, food sources, and sustainable fuels is seriously at risk.

No one knows when the economy will turn around. And no one knows how this experience will change our industry.

Big, big changes and great uncertainty, indeed.

On the policy front – the outlook is equally uncertain.

The historic 2008 election here in the U.S. has seen us proudly place the first African American President in the White House.

In the Congress, the Democrats increased their lead over Republicans in the House and Senate.

The Obama administration has enacted a massive 787 billion dollar stimulus package that includes ten billion dollars in additional NIH funding, more than a billion dollars for comparative effectiveness programs, and twenty billion dollars to spur progress in health information technology.

Congress and the President have expanded the State Children's Health Insurance Program, extending health benefits to an additional four million American children.

President Obama has reversed the Bush policy on federally funded embryonic stem cell research.

And thanks to BIO's leadership, Congress has added 325 million dollars to the FDA's budget.

But the big policy threats to biotech innovation still lie dead ahead.

Bio-similar proposals in the House and Senate that would severely limit the period of data exclusivity put at mortal risk the entire enterprise of discovering and developing biologics.

Think about what a tragic irony it would be for Congress to have funded the Human Genome Project and the NIH at the cost of billions and billions of dollars – only to cut the legs out from under the dedicated scientists at drug discovery companies who are trying to convert basic research into treatments and cures for patients.

At a time when up to 67% of all prescriptions are generic, many in Congress still remain bent on reducing reimbursement for even the most innovative new drugs and biologics.

The costs of clinical trials and FDA compliance continue to escalate.

Patent reform legislation has threatened to reduce the value of our intellectual property, jeopardizing continued advances in the life sciences.

And that threat is not just here in the United States. This movement against intellectual property has gained traction in countries around the globe.

In Washington, the health reform debate provides both opportunities and real challenges for our industry.

The one thing we all agree upon is that we all want to achieve universal health care coverage. We deeply believe that every man, every woman and every child in America – and, for that matter, the world - should have access to the best health care possible, including our most innovative products.

We intend to work with the Congress and the Administration to achieve this goal.

But we will insist that the critical role of innovation is not overlooked in the health reform debate. Because if Congress and the president enact health reform legislation simply focused on ratcheting down reimbursement for medicines, they will strip away the fragile incentives for innovation that remain.

The reason that health care is so expensive is that cancer is expensive, cardiovascular disease is expensive, and diabetes is expensive.

We envision a world with less disease. If Washington will work with us we will make that vision reality.

There are policy challenges as well in food and agricultural biotechnology.

Opponents of genetically-enhanced crops and animal cloning techniques have mounted campaigns of fear in an effort to accomplish irrational labeling legislation.

Meanwhile, our work to create sustainable biofuels that would dramatically reduce greenhouse gasses and slow global warming are under attack by those who first falsely blamed ethanol production for higher food prices that were actually driven up by the price of petroleum.

And now these opponents make unscientific arguments exaggerating indirect costs to biofuels.

Rarely have we seen so many simultaneously unsettled policy issues of such vital significance to our industry.

That brings us to the scientific front, where the picture is mixed.

Approval of new drugs and biologics continues at a steady, but slow, pace -24 new approvals in 2008.

The FDA and its counterparts worldwide are demanding greater assurances of safety and efficacy.

Some argue that all the low-hanging biotech fruit has been picked and that the multi-genetic bases of disease make the science just too hard, too risky and too expensive.

As we cast about in this perfect storm of economic decline, political volatility and scientific challenge, we couldn't be blamed if we were to become discouraged and see the biotech glass no longer half full, but half empty at best.

But we cannot indulge in such pessimism.

We cannot succumb to self doubt.

And we dare not yield to frustration.

We cannot accept even a pause in biotech innovation.

Not while brutal enemies continue to stalk and attack our loved ones - enemies that target the health, the vital organs, the very lives of our sons and daughters, our husbands and wives, our mothers and fathers, our brothers and sisters.

Not while 16 thousand children die of hunger every day.

And not while greenhouse gases are melting the polar ice caps and threatening to render hundreds of species extinct.

The innovative spirit that lies at the heart and soul of every biotech company can and will provide solutions to disease, hunger, pollution, and global warming.

These are tasks at which we dare not fail.

And I have every confidence that we will not fail – but that we will succeed beyond even our wildest imagination.

I know this to be true.

I take this confidence from the dedication of the bench scientists, the tenacity and commitment of management, and the indomitable vision and passion of our industry's leaders.

Throughout the history of biotechnology it has been the science and the business that have driven the pace of advancement. Now, more than ever, it will be public policy that will determine our future.

Our political leaders in the United States and across the planet must come to understand, to appreciate, and to encourage the astonishing potential of biotechnology.

We need them to share our well-founded optimism.

We're optimistic because this isn't the first biotech downturn that we've been through.

After all, the bubble has burst before. But our fundamentals are sound.

Our entrepreneurial drive and skills are undiminished.

The yet-to-be-discovered information about human, animal and plant biology is virtually infinite.

And the need and desire for our innovative applications of this knowledge is immeasurable.

Financially, even amid the gloom, there are rays of light.

Recently, BIO and Reuters surveyed 80 individuals from all parts of the Wall Street investment community, with 2.3 trillion dollars in assets under management.

Seventy percent told us that they expect the biotechnology industry to rebound and to outperform healthcare and the rest of the market this year.

The fact is, biotech has weathered this storm better than the Dow average.

Even more remarkable, the U.S. biotechnology industry as a whole actually became profitable for the first time in 2008!

In all this economic doom and gloom, we forgot to celebrate that moment.

Societies will pay for real game-changing value.

We have no choice but to be more creative, more innovative, more adventurous and more passionate than ever.

In the policy arena, we also have good reasons for confidence and optimism.

While the policy battles will be ferocious and our adversaries tenacious, our story and our vision are more compelling.

We have out-wrestled our patent legislation opponents. We are making steady progress on biosimilars legislation. And we are fully engaged in the health reform debate.

While we can't promise to win every battle, rest assured we are pledged to winning the war on behalf of the patients, the hungry, and for the sake of our planet.

On the scientific front, the men and women of biotech continue to astound the world with new discoveries and newly developed products.

The science of biotechnology isn't easy. Nature does not readily yield her secrets.

Still, every day in nearly every country on Earth our brilliant scientists decode a bit more of the language of life.

Our researchers continue to make significant progress in identifying the genetic mutations that cause cancer, understanding how proteins bind to their targets, and developing faster and less expensive genome-sequencing technologies.

BIO member company Geron is about to commence the first human trial of embryonic stem cell therapy.

The trial will treat patients with severe acute spinal cord injury.

You know what?

We believe these paralyzed patients will walk again.

Just two weeks ago the FDA approved Vanda's new product for the treatment of schizophrenia.

With it, patients will gain freedom from debilitating hallucinations and delusions.

And an FDA Advisory Panel just recommended approval of Genentech's Avastin for glioblastoma brain tumors, the terrible disease from which Senator Kennedy suffers.

These scientific advances are singular because they are entirely innovative.

The companies that weather this perfect storm of economic, policy and scientific pressures will be the companies who are most innovative -- innovative in their science and innovative in their business.

Now is the time for us to be more nimble and adaptive than ever.

The public cannot afford and will not pay for just incremental progress.

They rightfully insist on game changing and life-saving revolutionary progress.

That is what we must and will deliver.

Our capacity to keep generations of children from hunger and starvation relies on crops that can resist pests, disease and climate change; and provide higher yields and greater nutrition.

We're confident that we can provide those crops.

In fact, we already are developing biotech plants and trees that can resist the stresses of drought or flooding, biotech crops that are nutrient-enhanced and even allergen-free, and biotech oils that are more healthful and contain fewer saturated fats.

Today a record 13.3 million farmers in 25 countries are using agricultural biotechnology.

And in the emerging field of animal biotechnology, the FDA recently announced the first approval under brand new regulations for which BIO fought hard -- a product derived from a genetically enhanced animal -- a blood thinning therapeutic protein produced in the milk of genetically engineered goats.

The very sustainability of life as we know it on this planet relies on our ability to derive not only food, but fiber and fuel from renewable plants and algae.

We're confident we can meet that challenge as well.

Global energy companies like BP and Shell are partnering with industrial biotech companies like Verenium and Codexis to build commercial scale cellulosic biofuels facilities in the U.S.

Metabolix and ADM have partnered to market a line of bio-plastics, while a flurry of new start ups are developing a range of chemicals and plastics from renewable feedstocks.

Our companies do amazing science.

So do the government-funded researchers in the U.S. and abroad.

But the connection between academic basic research and commercial private science must be strengthened.

These enterprises must become more synergistic so that the basic science provides clearer and sharper guidance to the nature of human disease. That knowledge must be consistently transferred to and translated by our companies large and small.

This perfect storm of economic, political and scientific challenges may at times seem to be too massive for us to weather, but this storm, too, shall pass.

The biotechnology industry that emerges when the skies clear will be leaner,

stronger, wiser and more innovative than ever.

As the quote I began with said, "To the confident change is inspiring because it challenges us to make things better."

Now, I call on each of you to continue to accept that challenge to make things better, to keep innovating so that we continue to grow, continue to offer hope and continue to heal, fuel, and feed the world.

Thank you.