# Nanotechnology

Non-traditional Methods for Valuation of Nanotechnology Producers Introducing the Innovest Nanotechnology Index for the Value Investor

Key Issues for Strategic Investors:

- Preparing for the Age of Nanotechnology: In his book, "Quantum Investing", Stephen Waite suggests that quantum physics is the underlying science behind a significant portion of today's Gross National Product. He predicts that the influence of quantum physics, specifically nanotechnology will expand to the extent of fundamentally altering the Dow by 2025.
- For Those Ready to Invest: With products already entering the market and many more to come in the next three to five years, the question becomes which companies will be strong enough to deal with both conventional challenges and those stemming from the perception risk that may be associated with the environmental, health and safety (EHS) profile of nanotechnology going forward.
- **2007 Will be an Important Year:** We expect a number of EHS studies to be complete in that year. Moreover officials in various markets tell us that they have set their sites on that timeframe for establishing a base level of regulation.
- Due Diligence: Investors need to begin educating themselves about which particles, processes and applications represent greater levels of risk than others. We interviewed 12 (early and late stage) venture capital firms many of them do not seem to be doing a thorough review of the EHS risks.
- Strategic Profit Opportunities: Given the diverse range of applications for nanotechnology, the value investor may focus on products rather than nanotechnology itself. Moreover, public perception risks may be mitigated by demonstrating the benefits of using nanotechnology in a timely manner.
- Drawing Parallels: Industry's experience with synthetic chemicals and genetically modified organisms may provide historic lessons for investors interested in the potential impact that perception and other non-traditional issues could have on the advancement of nanotechnology.
- Development Stage Companies: appear to be cognizant of risks and a number of them are conducting themselves in a manner that would be considered favorably in our analysis.

Heather Langsner, Senior Analyst 212 421 2000 ext 212 and Sondra Martinez

Darshana Zaveri Kayoko Iguchi Reka Sumangali Matthew Milcetich

Report prepared by
Innovest
STRATEGIC VALUE ADVISORS

Uncovering hidden value potential for strategic investors

Report prepared by Innovest Strategic Value Advisors, Inc.

Heather Langsner, Senior Analyst Four Times Square 3rd Floor New York, NY 10036 United States P +1-212-421-2000 X 212 F +1-212-421-9663 hlangsner@innovestgroup.com

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### www.innovestgroup.com

Four Times Square 3<sup>rd</sup> Floor New York, NY 10036 United States P +1-212-421-2000 F +1-212-421-9663 225 E. Beaver Creek Road Suite 300 Richmond Hill Ontario L4B 3P4 Canada P +1-905-707-0876 F +1-905-707-9084 4 Royal Mint Court London EC3N 4HJ United Kingdom P +44 (0)20 7073 0470 F +44 (0)20 7073 0473

110 Boulevard de Sébastopol 75003 Paris France P +33 (0)1 44 54 04 89 F +33 (0)1 44 54 02 30

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### 1. The Innovest Nanotechnology Index and Research Group

- Global nanotech R&D investment reached an estimated \$8.6 billion in 2004<sup>1</sup>. Experts agree that nanoscience will enable new technologies across a majority of industry sectors going forward.
- Early testing reveals that some types of engineered nanoparticles may present risk in terms of human health and eco-toxicity.
- Experts in the "nano" space are beginning to warn investors that this could result in perception risks that could affect markets for nanomaterials and end-products.
- In light of this, Innovest has reviewed a set of 200 public companies and a set of 100 private companies listed on NanoInvestorNews.com for qualities that we feel will be appropriate in offsetting potential perception risk and in contributing to responsible nanotechnology development going forward. We have distilled this list down to an index of 15 companies, and a research group (watch list) of an additional 8 companies.

		Product Strategy	Product Risk	Product Stewardship			
Altair Nanotechnologies, Inc.	ALTI	0,		· · · · ·			
ApNano	IPO soon						
BASF AG	BAS-FF						
Biosante Pharmaceuticals, Inc.	BPA						
FEI Company	FEIC						
Flamel Technologies S.A.	FLML						
General Electric Company	GE						
Headwaters, Inc.	HW						
JMAR Technologies, Inc.	JMAR						
Lumera Corporation	LMRA						
Nalco Holding Company	NLC						
Plug Power, Inc.	PLUG						
Spire Corporation	SPIR						
Starpharma Group	SPL						
Veeco Instruments, Inc.	VECO						
		Good St	rategy/Practices				
		Moderate Risk/Average Practices					

Figure 1: Assessment of Risk and Strategic Positioning for 15 Firms Selected for the Innovest Index. For monitoring purposes only. Source: Innovest

Product Risk Not Applicable

<sup>&</sup>lt;sup>1</sup> Lux Research

Research Group	
MEMS USA	Nanosolar
NanoDynamics	Nanosys
Konarka	Ener1
Nanosight	NanoMix

To develop our analysis, we first started with a broad universe of 300 companies (200 public and 100 private) from NanoInvestorNews.com, ranging from a number of pureplay companies to large, diversified manufacturing and chemical companies (see Section 9 for a more detailed description of universe and the analytical process). We then matched this set to the Innovest research universe, primarily large-cap companies, and where rated, we included only those companies with high ratings, AAA or AA. We then subjected the highly-rated companies and the non-rated companies to an intensive search for firms offering *strategic profit opportunities in the fields of water technology, renewable energy resources/technology and innovations relevant to large scale medical needs*, resulting in an analytical set of 75 companies. Within this set, comparative analysis focused on product strategy, product risk, and product stewardship. The process involved product analysis, market review and company interviews, where we achieved a 98% response rate.



Rather than the typical Innovest methodology, which involves a best-in-class comparison *within* an industry sector (See Appendix 11), this report is an assessment of companies in different sectors and their early efforts to offset risk through product strategy, risk management and product stewardship. In each case, the company was evaluated based on a general understanding of risks and opportunities specific to that firm. Going forward, Innovest will conduct *comparative* analysis of strategy and approach within specific industry sectors such as chemicals, pharmaceuticals, personal care products, aerospace/defense, etc.

This index is for monitoring and is not available for investment. Detailed company profiles for each of the index constituents are in Section 7, starting on page 58.

In addition to the index, we have established a watch list of development stage companies (some are privately held) that also rate well on these parameters. Section 7 also includes shorter comments on these companies.

In the following sections of this report:

- **Chapter 2** provides an overview of the investment landscape with particular emphasis on the toxicology issue and its relevance to our analysis.
- **Chapter 3** discusses the market viability issue in light of the possibility that perception issues could play a role in healthy market development and in company performance. The focus is on products with large scale benefits relevant to the average person. These kinds of applications could help to offset any public perception risk issues that may arise.
- Chapter 4 provides a brief overview of early findings on some types of engineered nanoparticles. We survey recently completed work by well-known entities in the nano space and provide a few comments of our own for investors to understand before making investment decisions. Early developments on the regulatory front are discussed. This section also contains a description of the evolving regulatory climate.
- Chapter 5 provides an overview of company best practice and other value indicators.
- Fifteen company profiles are provided in Chapter 7 followed by brief comments on eight companies in our research group.
- **Report appendices** cover characterization of the nanoparticle, detection methods, potential exposure routes, potential for environmental interaction, and an overview of the regulatory landscape in the US and Europe.

### Overview: The potential materiality of public perception risk for Nanotechnology

An article in the Economist last year discusses the potential that nanoscience could experience the same level of product backlash as transgenic agriculture<sup>2</sup>. Given that nanotechnology is widely applied across sectors and that the current level of public awareness is so limited, we do not necessarily concur at this time. However, as investment increases and as more next-stage products become commercialized, the investment community will be required to consider the potential for public perception problems to have share price impact.

Conceptually, it stands to reason that companies attempt to mitigate perception risk now through a two pronged approach: 1) transparency about the potential risks and 2) early demonstration of beneficial applications and results.

# OTHER FORWARD LOOKING INDICATORS ARE ALSO IMPORTANT IN EVALUATING NANOTECHNOLOGY FIRMS

The Innovest methodology is designed to reveal hidden value in uncertain markets through various traditional and non-traditional analytical techniques. This report identifies potentially material factors that are not easily quantifiable by nano-investors and attempts to quantify, whenever possible, the extent to which such issues factor into the competitiveness of publicly traded and soon to be publicly traded stocks. Our analysis includes both historical and forward looking indicators.

This information may be useful whether the investor is making decisions based on stock momentum, growth or value. Regardless of the investment style, we believe that companies that consider these issues today demonstrate that management is more agile and forward thinking in the face of pending external pressures and barriers to entry.

These companies may lead the way in *uncertainty reduction* which could mean the difference between market acceptance and product boycott. The value investor may also find that firms selected for this index are strong on many observable secondary information sources and intangible attributes that can qualify as credible indicators of potential quality over the long-term.

Many investment experts concentrating on nanoscience have begun to speak more forcefully about the need for companies to have a robust business model even at this early stage of development. The factors covered in this analysis may help bring investors closer to an assessment of this issue. Hence we reviewed 75 companies and narrowed that down to an index of fifteen firms that show promise with regard to the factors brought to light in this report.

<sup>&</sup>lt;sup>2</sup> "Much ado about almost nothing." The Economist March 18, 2004 print edition.

# THE INVESTMENT LANDSCAPE AND ITS RELEVANCE TO OUR ANALYSIS

### Counter-intuitive quantum properties

Nanoscience is the study of forces and matter at the scale of 1-100 nanometers. A nanometer is equivalent to 1/80,000 the thickness of a human hair. At this scale, particles may adhere to the properties of quantum physics not present in classical physics. For example, quantum dots emit light in a vacuum. True nanotechnology makes use of these counter-intuitive properties specifically and may yield what we refer to in this report as engineered nanomaterials and particles. *These attributes are part of the reason why nanotech has prompted the attention of regulators and the public. The safety of nanomaterials represents a significant uncertainty factor.* At issue is the ability to identify and characterize the particle based on various factors such as size, chemical composition, and particle surface.

### **Early findings**

Chapter 4 and Appendices provide some brief details regarding what is currently known about certain types of nanoparticles under different scenarios. There is a body of technical literature to rely on but the best resource for the layperson is a report released by global insurance giant SwissRe which outlines risks related to inhalation exposure and describes experiments showing particles passing the blood-brain barrier<sup>3</sup>. Early analysis also demonstrates how certain kinds of particles (particularly those with functionalized surfaces) can exacerbate the mobility and bioaccumulative properties of toxins already present in the environment. Fullerenes, quantum dots, carbon nanotubes, nanowires and dendrimers are being studied at this time. While Rice University's Center for Biological and Environmental Nanotechnologies has been a central force in identifying these issues and devising technological solutions, it is now commonly recognized that product risk is a possibility that will require the financial community to conduct analysis on a case by case basis.

### Not everything that is nanoscale is nanotech

The best example that we have found for the layperson is the following: A nanoscale particle may make a better catalyst at the nanoscale simply because there is more surface area to create a reaction. True nanotechnology relates more to a scenario in which a material that is not a catalyst at the macroscale suddenly takes on catalytic properties at the nanoscale<sup>4</sup>. This analysis focuses on the risks and opportunities involved with the use of *engineered nanoparticles, particularly those that are free as opposed to bound in materials*. This differs from simple nanoparticles that are currently used to make surface coatings reflective and other similar applications.

### **Boom Bust Cycle**

A survey of the ownership of the companies in our analytical set shows a diverse grouping of speculative, growth and even some longer term investors. It is relevant for all types of investors to be aware of certain non-traditional factors that may affect the timeframe for commercialization and which could trigger a binary event.

<sup>&</sup>lt;sup>3</sup> Hett, Annabelle. "Nanotechnology; Small Matter, Many Unknowns". Swiss Reinsurance Company. Zurich. 2004.

<sup>&</sup>lt;sup>4</sup> Brookstein, Darrell.Nanotech Fortunes: Make Yours in the Boom. 2005.

Figure 1 shows a general timeline for various stages of nanotechnology development. Subsequent timelines provided in this report take into consideration the schedule for beneficial technology rollout, the regulatory outlook and a schedule for the release of new scientific findings that may be relevant to the perception risk issue for nanotechnology.

### 20 Year Timeline for Nanotechnology



### Figure 2: 20 Year Timeline for Technological Development

Source: Michael Roco<sup>5</sup>

### **Economies of Scale**

Going from laboratory to commercial level production represents a primary challenge to the nanotech startup. The esoteric equipment required for large scale production is likely to significantly impact the cash burn ratio. Specifically, we are interested in firms that are partnering with equipment manufacturers to incorporate *life cycle* concerns into the production optimization strategy. Many firms provided information about closed loop systems and other solutions.

### Cost and long lead time from technology to application

Given the extreme cost associated with research and development, there is little room in the budget for anything else. With uncertainty arising around the safety of nanoparticles, more companies may feel the need to submit their products for *independent testing* thereby representing an additional factor in the consideration of cost and time

<sup>&</sup>lt;sup>5</sup> Adapted from Roco, M. National Science Foundation

to commercialization. See Chapter 5, Product Stewardship, to learn about how firms are dealing with these issues.

### Large Corporations

Although estimates differ depending on the definition of nanotechnology, NanoInvestorNews.com shows that there are approximately 200 public companies involved in nanotechnology research and development about 77 of which are large corporations. Several of them have nanoscale particle products on the market or are marketing products enhanced with nanoscale particles. These products typically represent the most simplistic stage of development and are used for the enhancement of existing materials. Nanoparticles that impart reflective and strengthening properties for coatings or which make textiles stain resistant would be examples of this. This group includes large chemical manufacturers like Dow (DOW-NYSE) and DuPont (DD – NYSE). *These firms have the resources and capacity to develop techniques to ultimately deliver nanoparticles at commercial production levels.* 

### Pure play

NanoInvestorNews.com lists about 700 private firms. Most of these firms are concentrating on the science and are not close to having a viable product in the near future. Some of them provide information for investors suggesting possible applications for their scientific pursuits. Note that while several companies may be working on the same technology, a firm selected for our index will have been tested for specific traits through our model.

### Academia

University research is an important part of the nanotechnology equation. Several of the venture capital firms and holding companies are working directly with research centers to deliver intellectual property straight to the market. This makes for a complicated risk profile. It is unclear where the accountability for safe nano development would lie in this situation. The role of universities with regard to the toxicology testing issue is examined in Chapter 5.

### **Types of Investors**

In surveying the ownership of the primarily nano-focused companies reviewed in our analytical set (See Chapter 9 for an explanation of the analytical set), we found wide variance in investment styles. The following table indicates the parts of this report that will be most relevant to each category respectively:

VC/Private Equity	Market Viability of Products	Chapter 3
Momentum	Market Viability of Products;	Chapters 3, 6
Growth	Market Viability of Products	Chapters 3
Core Growth	Innovest Rating	Chapter 10
Core Value	Best practices reveal information	Chapter 4
Deep Value	Pure play companies in the Index	Chapter 2
Hedge Fund	Short positions; Timelines	Chapter 6
GARP	Market Viability of Products; Best Practices	Chapter 3, 4

Figure 3: Report Relevance to Various Investment Styles Source: Innovest

### Environmental Health and Safety Risk in the Value Chain

A recent report by the New York-based nanotechnology research firm Lux Research defines the basic landscape for risk with regard to present stage nano development. We use this to begin our evaluation of our analytical set. Figure 2 below provides a rough overview of the nanotech value chain and the most likely areas for environmental health and safety risks to manifest.

While we do not necessarily screen on the basis of a company's nanotechnology product, we take potential toxicology issues into consideration and monitor what programs and strategies are in place to minimize risk. *Comparative analysis reveals that some companies with similar risk profiles may vary with regard to awareness, approach and strategic development.* 



Figure 4: Overview of potential sources of risk in the value chain, Source: Lux Research  $^{\rm 6}$ 

<sup>&</sup>lt;sup>6</sup> Nordan, Matthew M. "A Prudent Approach to Nanotech Environmental, Health and Safety Risks." Lux Research. May 2005





Source: Innovest

### Wide Variation between Firms

Our analytical set includes 75 publicly traded companies ranging in size and business model from Nanophase Technologies (NANX-Nasdaq) to General Electric (GE-NYSE). The level of potential exposure to product risk varies accordingly. Several firms in the analytical set fall into the no-risk category. They produce nanoporous materials (gels, lab test surfaces, etc). Others are also low risk because they serve the nanotechnology research market. These firms supply labs with specialized equipment. In some cases, these firms are of interest because *they will contribute to the ability to characterize and detect nanoparticles in the future – a key factor in reducing the uncertainty of using nanoparticles in production*.

### The Future of Risk Analysis

Microcap, pure play nanotechnology firms are not prevalent on most of the indexes being monitored today, but a host of privately held start-ups are waiting to be acquired and a few are positioning themselves for public offering. Interestingly, these firms appear to be cognizant of the risks and a number of them are conducting themselves in a manner that would be considered favorably in our analysis. Other firms are a cause for concern because in this early stage, *poor handling of risk by any player could result in perception problems that would affect entire markets*.

### Private Companies: More proactive but more risk

We interviewed several private, development stage companies. Most of them are working with particles that would be noteworthy according to the diagram in Figure 2.

While the technologies under development are interesting from an investment perspective, we keep in mind that they may also bear more risk. *Our research revealed that investors should not assume that early or even late stage venture capital firms are conducting appropriate due diligence on the environmental, health and safety risks of the particles used or made by these firms.* This report provides an outline of issues and a framework for analysis that could be used by investors who want to incorporate this into their analysis.

### Where we are headed

This year we take a very broad view of risk, but in subsequent years of this analysis we will track nanotechnology development across many of the more than 80 sectors covered by Innovest. Food, pharmaceuticals and the three sub categories of the chemicals sector (Diversified, Commodity and Specialty) will likely be a starting point for this kind of benchmarking and analysis. In the chemicals sector we have begun a comparative benchmarking of activity and responsible development to be issued in the first quarter of 2006.

### **Four Scenarios**

There has yet to be any real indication of a surge in public awareness of nanotechnology. However, should this occur, experts interviewed for this review outlined four scenarios that could contribute to consumer backlash and product boycott:

<u>Tipping the Scale</u>					
Mounting evidence of negative environ- mental and health impacts	Scant research to date reveals some early yellow light con- cerns				
Continued flow of new nano-based products into the marketplace	Products are generally entering into the market at an esti- mated rate of 12-20 per month				
Existing Frameworks prove inadequate in addressing risk and boosting public confi-	Summary of NGO Responses to the EPA proposal to regulate nanomaterials through a voluntary pilot program				
dence	Docket ID: OPPT-2004-0122. See Chapter 4.				
Nano Incident					
Accidental release and exposure in a devel- oping country	Scant research to date reveals some early yellow light con- cerns				
Accidental release and exposure in a devel- oping country Small business or research lab affected	Scant research to date reveals some early yellow light con- cerns Low risk but something to consider				
Accidental release and exposure in a devel- oping country Small business or research lab affected Poorly handled emergency response fol- lowed by global press coverage	Scant research to date reveals some early yellow light con- cerns Low risk but something to consider Low risk but something to consider				

<u>Popular Media</u>	
Release of film, embedded messages in advertisements offering a negative picture of nanotechnology	Michael Crichton book <u>Prey</u>
Market Reaction	
Radicalized civil society actors raise con- cern	The recent T.H.O.N.G. protest in front of Eddie Bauer www.chicagothong.org
Application of "precautionary principle"	Chapter 3 discusses developments in the UK and Europe
Actionable policy interventions	China establishes first nanotech standards in June
Protective regulatory spheres are established resulting low public confidence in areas where protections are minimal.	If the UK and Europe apply any regulatory weight to the pre- cautionary principle, this would effectively represent the great- est protections in any market. Already, chemicals regulation in Europe is moving to this. European chemicals regulation due to enter into effect in 2006 is a formal application of the precau- tionary principle. See Chapter 3 for further information on this issue.

### Figure 6: Four Scenarios for Product Backlash

Source: David Rejeski<sup>7</sup>

<sup>&</sup>lt;sup>7</sup> Rejeski, David. Adapted from IOM talk 27, May 2004.

### ANALYTICAL FOCUS

For this report we focused on emerging environmental, health and safety information with an emphasis on the possibility that perception problems may arise that could impact companies and markets. The way that firms are planning for this issue is an interesting indicator of management quality -a key indicator of potential stock value.

This report provides an overview of factors that may have potentially material impact on both end-user and pure play nanotechnology companies going forward. We have identified a range of test factors based on mainstream techniques but which approach them from a slightly unorthodox angle. Such secondary information sources are often used when objective indicators of quality are not yet available for a technology in its nascent stage.

While the Innovest analytical model is designed to consider information relevant to the long term investor and while we are finding increasing interest in an extended outlook on the part of our client base, the following analysis may even have relevance for the speculative nano-investor interested in short term objective results. Corporate handling of the *perception risk* issue is the primary condition in our analysis but the factors used to arrive at our conclusions may have relevance to secular factors like cash burn rate and product viability.

These forward looking indicators of *management quality* include:

Market Viability

The Regulatory Scenario

Product Stewardship

### Analytical Focus

Investors are looking for <i>Revenues</i> and <i>Product</i> <i>Viability,</i> which is defined by Nanotech investment experts as:	This could be restated as:	With regard to Nanotech, Management Quality may be largely defined by how firms deal with:	This can be tested by evaluating how firms strategize for:
Business Model Strategic Development	Management Quality	Perception	Market Viability Product Related Risk and Regulatory Developments Product Stewardship

Figure 7: Innovest Report Focus Source: Innovest Given that the perception factor is deemed to represent a large portion of risk to nanotechnology producers, the companies that are first to offset risk through a comprehensive and proactive management strategy are not only more likely to minimize overall perception risk to the market but may generally be better investments over the long-term.

The following is a list of techniques used by venture capital firms and other investors to test for management quality in uncertain markets. We have modified them focusing on specific ways companies can address actual risks and public perception issues relevant to robust market development:

**Signaling** – Companies know more than investors at this stage of nano investment. Any information that a firm engaged in the research, development, manufacture and marketing of nanotechnology products can provide that differentiates itself from another is useful at this point. In the case of ApNano, the company's provision of data about its efforts to ensure that its product is safe went a long way in our estimation of management quality. In essence, *transparency* is a key indicator in this respect.

**Screening** – The use of a filtering technique based on observable attributes that are associated with the desired unobservable characteristic. If revenues and product viability are the desired characteristic, then a cleantech product strategy is the observable attribute. The first cut of 300 stocks (public and private) was based on our assessment of *products targeted for the clean technology market* as the product viability component.

**Legitimacy** – Creative action that provides symbolic significance of sophistication and quality. In conventional terms this may relate to the reputation of the venture capital firms providing funding and name recognition of the scientists/engineers involved in creating the product. As part of the prestige picture, our research focused specifically on a nano firm's ability to generate partnerships with universities and regulators in the interest of particle characterization and toxicology testing. In some cases companies may be able to take advantage of these opportunities at little or no cost. The benefit of *stakeholder coordination* for nanotechnology companies is considerable. In fact, many companies responded that by teaming up with regulators in order to conduct testing, there was minimal impact to the cash burn rate while simultaneously shedding light on the product liability question – a matter that could save the company money over the long-term.

**Socio-economic** - External drivers that have perceived correlations with true but unobserved drivers of value. In our estimation, *regulation* provides a platform for observing differences between firms. Many of the firms that were interviewed demonstrated an early preparedness and awareness of developing voluntary and regulatory trends that would require them to adapt. These firms are growing with the regulatory picture firmly integrated with the innovation strategy. *Note: We identified several firms that did not seem prepared. In addition, some firms seem to be misinterpreting the rules for regulatory submission, representing possible risk for shareholders.* 

...transparency is a key

indicator

We identified several firms that did not give indication of awareness or appropriate strategy

# WITH ANY NEW TECHNOLOGY, REVENUES MAY NOT HAPPEN RIGHT AWAY...

It may be relevant to consider the long-term value picture for a firm. Investors interested in nanotechnology, like Neil Gordon, President of the Canadian NanoBusiness Alliance<sup>8</sup>, find it important to consider business models and strategy when looking for companies with *long-term revenue generation potential*. The Innovest model is specifically designed to compare firms based on strategy and business model by evaluating more than 120 intangible value assets which stand as a proxy for *overall management quality* – a key factor in the valuation of firms, particularly in uncertain markets.

The results are apparent. Across many sectors, we see that by looking at how companies deal with *macro drivers* and *plan for complex risks and opportunities* that take place over a period of one to three years, investors can understand more about a company's prospects today. For example, the chart below shows the results of an ongoing simulation wherein Innovest ratings were used to modify the actual portfolios of a variety of money managers (employed by a California public pension fund). The modified portfolios overweighted companies with high Innovest ratings and underweighted those with low ratings. The addition of this Innovest information added value ("alpha") to each of the portfolios. For more on this and other research and actual portfolios, please contact Hewson Baltzell (hbaltzell@innovestgroup.com).



## Figure 8: Relative Performance of Innovest Enhanced Portfolios vs. Underlying Portfolios Over the Period 1/02 through 12/03

Source: Innovest

<sup>&</sup>lt;sup>8</sup> Gordon, Neil. "Nanotech Sector Needs Study Business Model." Small Times. January 13, 2005. http://www.smalltimes.com

### CONCLUSION

Innovest has maintained since 1995 that the major portion of a company's value comes not from daily price fluctuations but from an overall picture of the company's long-term competitive prospects. Our methodology is specifically designed to test this aspect of corporate valuation through the assessment of forward looking rather than trailing indicators commonly relied upon by traditional valuation techniques.

More recently, Goldman Sachs has arrived at the same conclusion.....

"...The bulk of the value (60%) of any company is determined by its long-run or sustainable returns, the next 20% by secular or cyclical change observed in the coming 12 months; and the remainder by longer term growth or other issues."<sup>9</sup>



\*market value of major corporations

Figure 9: Growing Importance of Intangible Factors in the Valuation of Companies Source: Innovest

Our evaluation of strategy and business model focused on management's ability to deal with a variety of conventional and non-traditional factors. See Chapter 8 for a detailed explanation of our methodology for determining quality strategy and business model.

<sup>&</sup>lt;sup>9</sup> Goldman Sachs Energy Environmental and Social Report, February 24, 2005, p18

General consensus and common sense holds that investors should focus their research on *revenues* and *products* with real applications, not pure science, in order to determine market viability for nano companies. Management quality may be a key factor in determining a company's ability to generate revenues. Note that the Innovest model serves as a proxy for overall management quality. Part of the screening process involved the use of Innovest AAA and AA scores to identify companies that had already been screened for management quality. In addition, most of the firms analyzed are currently generating returns from other strategic business segments. We favored these firms since this trait is likely to ensure that the company remains a viable investment while the nano product is still under development.

*The remainder of this chapter discusses our approach for assessing products.* Firms that provide product with disruptive and astounding benefits to the average person will have better chances of offsetting the risk related to perception issues as awareness regarding potential risks becomes more well understood by the public. This may include applications such as medical treatments, energy efficient products, water treatment, agricultural productivity, etc.

### VIABLE PRODUCT STRATEGY

Product viability is a critical factor in the valuation of nanotech companies. Many of the investment experts interviewed for this report responded that they liked nanotechnology firms that had *already identified a specific product application and market use as opposed to concentration on pure science*. Interestingly many of the products mentioned involved some breakthrough beneficial application. It is not difficult to envision the possibilities. Innovest believes that markets are moving toward clean technology.

"The Nanosys IPO was rejected for a very simple reason: Where's the product? You've got a bunch of IP [intellectual property] ....So what?"

Tim Harper, President Cientifica

"Investors should try to distinguish between business plans with near-term commercial uses vs. "long-term science projects..."

David Aslin, Director 3i Group

### Consensus timeline for commercialization of products

<ul> <li>Tools and bulk materials (powders, composites).</li> <li>1D (One Dimensional) Sensors, larger MEMS scale devices</li> </ul>	<ul> <li>2D</li> <li>Nanoelectronics: memory, displays, solar cells</li> <li>Hierarchically structured nanomaterials</li> <li>Hybrid Bio-nano, energy, drug delivery &amp; diagnostics</li> </ul>	• 3D Nanoelectronics • <b>Nanomedicine</b> • Machine-phase manufacturing • unknown
Early Revenue	Middle Term	Long Term
		_2011-2020: Environmental Solutions

Figure 10: Consensus timeline for commercialization of products Various sources: Darrell Brookstein<sup>10</sup>, Draper Fischer Jurvetson

<sup>&</sup>lt;sup>10</sup> Brookstein, Darrell.Nanotech Fortunes: Make Yours in the Boom. 2005.

### PERCEPTION RISK MAY CAUSE DELAYS IN LEAD TIMES AND DIMINISHED DEMAND It is not difficult to identify many conventional barriers to market entry for nanoproducts (i.e. the challenge of devicing commercial code menufacturing concerting)

It is not difficult to identify many conventional barriers to market entry for nanoproducts (i.e. the challenge of devising commercial scale manufacturing capacity, long lead times, extreme expense of research and development). However, *perception risk* is considered to have the greatest capacity to impact both products and markets. In essence, the science may show little risk but if the public becomes nervous about the safety of nanotech, demand could be abated.

### Perception risk impact to various types of nano firms

**Diversified/Conglomerate** – All large capitalization diversified and end-user companies surveyed for the development of the index responded that they intended to apply nanoscience across all strategic business units. At least 10 of these firms have a significant portion of their market capitalization invested in "brand value". Consistent with responses for the entire analytical set, these companies responded that they do not plan to specify that products are nano-enabled as part of the marketing strategy.

On one hand, the view may be that these large capitalization companies face very little risk in enhancing their products with nanotechnology. Any given activity represents only a fraction of the overall business. However, we posit that several of the diversified firms may face elevated perception risk. Civil society actors have proven to be very organized and motivated with respect to many of the various industries of interest. A diversified firm with 15 business units ranging from textiles to defense may face 15 different fronts for activism.

We note that a year ago, only a few non-governmental organizations (Environmental Defense, Natural Resources Defense Council, ETC Group, and Greenpeace) had nanoscience on their radar *Last month*, 16 NGO's signed on to the comments that the Natural Resources Defense Council submitted to the United States Environmental Protection Agency on the EPA's proposed voluntary program.

**Pure play** – Depending on the definition, approximately 17 of the companies in our analytical set are solely focused on nanotechnology. A significant number of firms in the set are sufficiently small to the extent that a nano "mishap" could have potentially material repercussions.

At a recent meeting of the Environmental Law Institute in Washington DC, several presentations proposed a scenario in which a small start-up has a production accident which ultimately ends up exacerbating perception problems for large companies like Dow or DuPont. Innovest does not expect that this would be a problem mostly because of the significant expense associated with nanotechnology development. This expense would likely have a repressive effect on entrants with low operating standards. However, representatives of the American Chemistry Council responded that there was enough concern about this issue on the part of their members that the ACC is now trying to create a plan to work with start up nanotechnology firms to assist them with information and best practice.

*Perception is more likely to be a risk to pure-plays*. Biotech is not a perfect analogy to what is happening with nanotechnology, however, there are lessons that can be extracted especially for certain nanotech sectors such as nano agriculture and nano-

"Many public relations crises have short-lived impact on share price, but recently an anecdotal survey shows how reputation problems have caused material destruction of shareholder value; ...Arthur Anderson and Merrill Lynch in the wake of the Enron scandal for example."

- Swiss RE

"Studies of companies that have handled crises affecting their reputation badly have identified longterm and irreparable damage to share price, market share and brand value.... Behind the risk management failure lies a governance failure. By essentially abdicating responsibility for reviewing major risks, the board is not serving the best interests of shareholders"

- AON Insurance

food applications. Investors in these sectors may have to exercise more precaution than those investing in semiconductor applications for example.

In June the United Kingdom failed in its efforts to convince the rest of Europe to lift the ban on genetically modified crops and food. The science, while in dispute, does not at this time appear to be sufficient to support the ban. *Nevertheless, the mere perception that GM crops and food are a risk has resulted in a continuance*. Ministers from the five countries (Austria, Luxembourg, Germany, France and Greece) simply did not accept that GM crops should be released, and the ban drew the backing of a sufficiently large majority of 25 member states to ensure that it remains in place<sup>11</sup>.

The EU ended a six-year moratorium on accepting applications for new genetically modified foods in May 2004, but efforts to bring about labeling rules are ongoing. Approximately 70% of the public is against GM foods and the "GM free" label has become a positive selling point<sup>12</sup>. This is further evidence that once public distrust has been initiated, it is very difficult to sell product even when trade pressures force governments to throw the doors wide open.

The following graph demonstrates the growth and evolution of public discourse on the issue of genetically modified organisms in Europe during the period 1996-2000.

**Debate Intensity Level:** 

#### 0 No Debate

- 1-2 Debate with Small Number of Specialized Arenas
- 3-4 Debate with Greater Number of Arenas including Media, NGOs, and Organized Social Movements
- 5 Debate with Large Number of Arenas that have been significantly influenced by the public debate (High media coverage; mass public awareness)



Figure 3: Intensity Level of GMO Debate in Five Selected European Countries Source: PABE (2001) Public Perceptions of Agricultural Biotechnologies in Europe

<sup>&</sup>lt;sup>11</sup> Brown, Paul. "EU votes to continue ban on GM crops: Britain warns ministers of threat of trade war with US." The Guardian. June 25, 2005.

# DEMONSTRATING THE BENEFITS - A KEY ASPECT OF A VIABLE PRODUCT STRATEGY

Question: What are the biggest challenges for nanotechnology?

Answer: "The perception problem. Because people cannot understand nano, this technology is a little removed from the public domain... Companies and governments need to come together and make people aware of this technology....."

- Tim Harper, chief executive officer and founder of nano technology company Cientifica<sup>13</sup>

### **Risk mitigation**

### Consumers and markets may be more willing to deal with risk if perceived benefits are clearly defined early

Similar to biotechnology, the first applications of nanotechnology offer little in the way of obvious benefit to consumers. The Small Times database of over 500 commercially available products provides an interesting indication of where we currently stand in this regard. In summary, the majority of products are designed to enhance the properties of already existing materials making them stronger, lighter, and more reflective. Others offer advantages for making industrial processes more efficient thereby providing direct benefit to business owners which are not necessarily an obvious benefit to the general public at this time. However many companies we interviewed are targeting markets that we feel will help to offset any perception issues that might arise. How likely is this to be relevant to nanotech?

Experts interviewed for this report felt that some of the same components that created a public backlash against biotechnology are already at work within nanotechnology<sup>14</sup>.

A study conducted by Santa Clara University demonstrates the public's prioritization for nanoscience<sup>1</sup>.

57% of respondents want it to treat illnesses.

16% want it to clean up the environment.

Only 4% want it to produce enhanced products.

 <sup>&</sup>lt;sup>12</sup> Brammer, Marc. "Risk to Investors With Regard to Genetic Engineering." Innovest Strategic Value Advisors. 2004.
 <sup>13</sup> Apares Kriskelsunger PV

<sup>&</sup>lt;sup>13</sup> Aparna Krishnakumar. 'Nano startups can take cues from IT'. The Rediff Interview/Tim Harper, CEO, Cientifica. July 04, 2005. http://inhome.rediff.com/money/2005/jul/04inter.htm

<sup>&</sup>lt;sup>14</sup> "Much ado about almost nothing." The Economist March 18, 2004 print edition.

Clearly, wrinkle-free pants are not high on the list of priorities.

A growing body of literature suggests that nanotech companies need to be considering ways of demonstrating how the science will provide near-term opportunities for satisfying the wish list posted above. Clearly, wrinkle-free pants are not high on the list of priorities. Fortunately, many of the technologies that offer true benefit for the global poor in terms of energy use and storage, water quality and other relevant applications also happen to overlap with viable markets from an investment perspective.

### **Investment Strategy**

## Interestingly, those technologies that offer true benefit may face lower perception risk have an improving investment outlook....

Innovest research is premised on the fact that large scale macro drivers such as carbon mitigation are creating a fundamental shift in economic need that is now relevant to the evaluation of publicly traded stocks. In our evaluation of over 2200 public companies across many indices we have noticed that this trend has led to a surge in cleantech strategy development and investment.

- Cleantech investment rose to a first-quarter record of \$335.9 million, which represents a 4.8 percent increase over the same a year-ago quarter and a 10.3 percent increase over 2003<sup>15</sup>.
- The ten-year cumulative returns on the Vortex-Cleantech Index have beaten the following three indices.





Source: Cleantech Venture Network LLC

<sup>&</sup>lt;sup>15</sup> Cleantech Q1 Funds Grow 4.8% 3, August 2005. On the Internet: http://www.redherring.com/Article.aspx?a=13030&hed=Cleantech+Q1+Funds+Grow+4.8%25

### Macro trends...

- Increasing interest by major corporations in adopting clean technologies. General Electric is a recent example
- Energy price volatility, carbon regulation in Europe
- Advances in science and engineering that make certain clean tech applications more reliable and economically feasible
- Local initiatives: green building standards, procurement strategies, etc

### Institutional investors ...

- The global solar market is growing by more than 30% annually with a current market of more than \$7 billion a year<sup>16</sup>.
- This June, Goldman Sachs and Hudson United Bank entered into an agreement to oversee BP Solar's installation of 25 electric systems on Staples and Whole Foods Market stores.
- In 2004, California State Treasurer Phil Angelides proposed the Green Wave Initiative; a four-pronged program for the state's public pension plans to support environmentally responsible investing. The proposal calls for the California Public Employees' Retirement System (CalPERS) and the California State Teachers' Retirement System (CalSTRS) to funnel \$1.5 billion into environmentally sound investments.
- Shareholder interest has resulted in projects like the Carbon Disclosure Project. Signatories to the Carbon Disclosure Project are institutional investors, representing in excess of \$10 trillion in assets under management,. This number increased by over 250% from 2003.

<sup>&</sup>lt;sup>16</sup> Carey, John; Aston, Adam, Hibbard, Justin and Grover, Ronald. "Alternate Power: A change is in the wind." Business Week. July 4, 2004 print edition.



### The implications of nanotechnology for cleantech development

Figure 12: Cleantech Venture Investment by Industry Segment (Q1 2002 - Q2 2004) Source: Cleantech Venture Network LLC<sup>17</sup>

- Advanced materials and *nanotechnology* investments increased in Q1 2005 to \$83.5 million from \$68.2 million in the same quarter a year ago<sup>18</sup>.
- Energy, materials and *nanotechnology* accounted for more than two thirds of the capital flow into the cleantech industry during 1Q 2002- 2Q 2004<sup>19</sup>.

<sup>&</sup>lt;sup>17</sup> LoGerfo, James. Co-editor Parker, Nicholas. Propper de Callejon, Diana. Cleantech Venture Investing: Patterns and Performance. March 2005. Clean Tech Venture.

<sup>&</sup>lt;sup>18</sup> Ibid.

 <sup>&</sup>lt;sup>19</sup> LoGerfo, James. Co-editor Parker, Nicholas. Propper de Callejon, Diana. Cleantech Venture Investing:
 Patterns and Performance. March 2005. Clean Tech Venture.

### STRATEGIC PROFIT OPPORTUNITY IN THE ANALYTICAL SET

For our index we looked for firms that not only offered a fully conceived and viable product strategy but one that involved a promising clean technology application....

### Market Need: Energy

Over 2 billion people today do not have access to energy services. Growth in demand for renewable energy in industrialized countries is leading to economies of scale facilitating increased access by the developing world. Experts believe that many new markets could sustain even higher rates of renewable energy penetration.

The good news for nanomaterials suppliers is that R&D funding for developing nextgeneration energy sources is on the rise. In the area of fuel cells and the associated hydrogen storage, governments worldwide have pledged more than \$4.5 billion over the next five years for development work that will deliver affordable fuel-cell solutions. Materials technology, and nanomaterials in particular, will play a crucial role in achieving that goal.

A recent report titled Nanomaterials for Next-Generation Energy Sources provides an assessment of the possibilities for nanomaterials and nano-enabled devices for the energy sector<sup>20</sup>. The question is whether these products will truly offer viable benefits over existing energy sources. The report states that energy applications are increasingly popular with venture capitalists. Note that several of the venture capital firms we interviewed either have hired or are planning to hire specialists to help them asses the short and long-term viability of energy technology.

#### Nano applications for The Energy Sector

Photovoltaics inexpensive, light flexible Hydrogen Storage Fuel Fuel Cells **Batteries and Supercapacitors** Photocatalytic reduction of carbon to produce methanol Direct photocoversion of light and water to produce hydrogen

Super-strong, light weight materials Nanoelectronics High current, hyper efficient cabling Thermochemical catalysts to generate hvdroaen Carbon mineralization schemes Organic light emitting diodes

#### Companies listing themselves as having Nano-oriented Energy Applications

Nanergy Inc. (Nasdaq: NNGY)	Headwaters, Inc. (Nasdaq: HW)	US Nanocorp
DayStar Technologies, Inc. (Nasdaq: Dsti)	HERA Hydrogen Storage Systems, Inc.	Texion Solutions
GEMZ Corp. (Otc bb: Gmzp)	Hydrogen Solar Ltd.	Solaronix SA
Hydrocarbon Technologies, Inc.	Kainos Energy Corporation	Quantiam
Nanosolar, Inc	Konarka Technologies	PolyFuel, Inc
Adaptive Materials, Inc.	mPHase Technologies (Otc bb : Xdsl)	Nuclear Solutions
Axion Power Interantional (PS : AXPW)	Spire Corporation	Cymbet

<sup>&</sup>lt;sup>20</sup> "Nanomaterials power next-generation energy devices." Friday, June 24, 2005. On the internet: http: www.technology-tracking.com".

Ecoimagination is designed to take advantage of macro drivers such as carbon mitigation through GE's core capabilities such as lighting.

An organic light-emitting diode (OLED) display comprises thin layers of individual carbon-based (hence "organic") elements that emit light when electric current is passed through them (electroluminesence).

These elements, or pixels, can be turned on or off independently and can create multiple colors and a fluid, smooth-edged display. They are self-emitting, requiring no backlight, and therefore are very thin and have low power requirements (in some applications, it will be approximately 2 to 10 volts). For electronics (think televisions) they also provide a wide viewing area, approximately 160 degrees, far superior to other available flat-panel displays. Because OLEDs do not need the backlighting, they do not face endof-life concerns posed by the use of mercury.

Source: Industry Week

**General Electric:** While General Electric states that it does not plan on being able to commercialize a nano-oriented product anytime in the near future and while some non-governmental organization complain that GE appears to be actively opposing regulatory developments, we think the company's recently launched Ecoimagination campaign clearly defines the company's strategy and capacity to deliver nano products that offer significant benefits through cleantech. We count at least nine research platforms from advanced mechanics to polymers where nano is being studied and almost every core technology is a likely candidate for some type of nano application. It is not difficult to identify projects in the pipeline that would fit our requirement. For example, GE's light emitting diodes, which may replace home lighting, could reduce energy consumption by an estimated 10% in the U.S. saving \$100 billion annually<sup>21</sup>. GE may have to address these challenges to its reputation but if it is first to deliver OLED technology at commercial scale, this should go a long way in offsetting public opinion.

**Headwaters:** With a focus on efficient use of the world's natural resources, such as fossil fuels, Headwaters has developed nano-catalyst applications to improve natural resource utilization. The Company is the largest provider of technologies used to produce coal-based solid synthetic fuels, and is the industry leader in managing and marketing coal combustion products in the U.S. Headwaters is developing and commercializing its proprietary nanocatalyst technology, NxCat<sup>TM</sup>, to convert or upgrade fossil fuels into higher-value products, to covert gas to liquid fuels and for use in direct coal liquefaction. The NxCat<sup>TM</sup> technology is also being utilized as a combustion catalyst in coal to reduce the release of nitric oxide by 20-30%.

**Spire:** Targeting the solar electricity market, Spire has been meeting the demand for many years with both solar equipment and solar systems. Using their expertise in materials technologies, Spire has been utilizing nano for thin films and various surface technologies. The company's solar equipment which they develop, manufacture and market can be found in more than 150 factories in 42 countries. In fact, more than 90% of the photovoltaic modules on the market today were manufactured using Spire equipment. As for Spire's solar photovoltaic (PV) systems, they are used both for stand-alone emergency power back-up and for interconnection into the electric power grid. The most successful example of the company's solar PV systems in use is in Chicago, IL where Spire has worked with the City of Chicago, the local utility company and the State of Illinois to provide customers in the metropolitan area with grid-connected distributed photovoltaic systems. In fact, Spire's primary business unit is titled Spire Solar Chicago.

**Plug Power:** Plug power is aligning itself with the general trend away from large facility generation to on-sight renewable energy solutions. The company's research platform is based on a proprietary proton exchange membrane (PEM) fuel cell and fuel processing technologies. Nanotechnology's role in manipulating the atomic building blocks of fundamental matter in a controlled and planned manner results in highly programmable fuel cell membrane technologies that significantly increase efficiency and durability. Plug Power is in collaboration with Albany NanoTech, an academic venture to research the use of nanoscience in providing proton exchange membranes that will be competitive with pre-existing energy solutions. While these appli-

<sup>&</sup>lt;sup>21</sup> "Nanotech and the Poor: Opportunities and Risks." Meridian Institute. January 2005

cations are in development, the company is receiving orders for its GenCore® backup fuel cell systems. Tyco recently ordered 35 systems getting the firm ever closer to reaching its sales goal of 300 this year.

**MEMS USA:** Many of the companies we interviewed do not have a nano product ready for commercialization. However, several of them have identified the energy sector as the target market and are developing non nano-related product to support cash flow while the nano products are in development. MEMS USA fits this description. The company recently announced a joint venture deal with Can-Am Ethanol One and Accelon® Energy System of Canada to establish a system that will convert 800 tons of Canadian wood waste per day into 160,000 gallons of clean burning fuel-grade ethanol. We understand that Merrill Lynch will provide a significant amount of funding upon finalization of the land deal. While the nano application is still in research, the company's current ventures fit well with our environmental strategic profit opportunity requirement. While certain dispersive applications of nano may represent risk (see appendices) we continue to monitor progress in the development of nano-based systems for use in detection and control for the energy sector.

#### Market Need: Clean Water

The current size of the global water market is now \$287 billion and expected to be \$413 billion by 2010<sup>22</sup>. Experts predict that over half the world population will face serious water shortage in the next 30 to 50 years and United Nations statistics show that water shortages could even be a problem in the United States. The industry has entered a period of rapid growth and consolidation not predicted even 10 years ago. The market faces a growing global crisis of an ageing water infrastructure insufficient to meet the needs of the world's swelling population. Regulation and a shift toward privatization have created new markets and investment opportunities are emerging as the global water industry restructures amidst these challenges.

Water purification and management represented only 4% of cleantech venture investment between 2002 and 2004.<sup>23</sup> However it is increasingly obvious that industry is following the lead of companies like Nalco and General Electric in trying to solve this global problem. For example, Seldon Laboratories of Vermont has apparently developed a 'nanomesh' fabric made of fused carbon nanotubes which can filter out all bacteria, viruses and other waterborne pathogens to US Environmental Protection Agency (EPA) potable water standards<sup>24</sup>. While we are concerned about some of the various applications being experimented with (mainly because they involve carbon nanotubes which are being studied for toxicology) we feel that firms who are looking to nanoscience to create inexpensive and highly functional systems for water quality have wisely chosen their target market.

### Nano applications for water:

Photocatalytic materials - water passing through a nanomaterial is subjected to ultraviolet light Nanofiltration based on the electrical charge of particles Membranes and "fabrics" Nanotube filters and porous aggregates Detection systems Soil remediation

**Nalco** Nalco is the market leader in water treatment chemicals with a market share of 19% followed by General Electric at 11%. While nanoscience is likely relevant to almost all of Nalco's various strategic business segments from paper to hydrocarbons, the Colloidal Technologies Group is the most relevant with regard to any future nanooriented product. The nano-oriented water treatment applications (zeolite dendritic polymerization, membranes) are in development, however, given Nalco's strong market position in the industry, the chances are significant that Nalco will have a nano product soon.

**JMAR** JMAR's line of high powered lasers and microscope products is relevant to our analysis for their possible application in bringing nanotechnology production to commercial levels. Moreover, these technologies may also be relevant to the detection and characterization of nanoparticles – an important factor in reducing uncertainty about nanoscience. These products are in various stages of development and when ready will allow for viewing the interiors of very tiny objects at the nanoscale, even

<sup>&</sup>lt;sup>22</sup> UNSTATS. United Nations Statistics Division. Commodity Trade Statistics. <u>http://unstats.un.org/unsd/default.htm June 26</u>, 2005.

http://unstats.un.org/unsd/default.htm June 26, 2005. <sup>23</sup> LoGerfo, James. Co-editor Parker, Nicholas. Propper de Callejon, Diana. Cleantech Venture Investing: Patterns and Performance. March 2005. Clean Tech Venture. Page 21

<sup>&</sup>lt;sup>24</sup> On the internet: August 5, 2005: http://wwwseldontechnolgies.com/products/

organic material. In the interim, JMAR has wisely made water technology its target market. BioSentry<sup>™</sup> line of products this year for the continuous detection of microorganisms in water is not part of the company's nano platform however sales from this product will sustain operations until the soft x-ray equipment is ready. The addressable market for BioSentry is roughly estimated to be \$500 million.

**Argonide** With a focus on water treatment, Argonide has developed a family of water filters developed from nano alumina fibers. The Company's primary product is NanoCeram®, a highly electropositive filter that rapidly adsorbs particles at any size. The filtration technology utilizes attraction based on charges rather than separation through a membrane. The highly electropositive alumina attracts and retains submicron particles and is effective in removing bacteria, virus, cysts, DNA and endotoxins from water. The filters will also remove turbidity whose origin may be natural organic matter, colloidal inorganic or ultra fine metal particles. Applications include industrial water, chemical and pharmaceutical processing, biological sampling, pre-filters for RO membranes, food and beverage manufacture and particulate removal in swimming pools and spas. This technology was developed with backing from the U.S. National Aeronautics and Space Administration (NASA).

## 4. Product Related Risk

The analysis of product related risk can be broken down into two major headings: product safety and regulatory risk.

### **PRODUCT SAFETY**

To date the science remains scant. The analysis of product safety involves a review of hazards and exposure. The following chart is a rough summary of some common particles and potential toxicity implications. While the chart below provides a decent first blush at risk in a simplified format allowing investors to get a quick and basic understanding, note that early findings are more complex than can be adequately covered in this manner. See the following page for a few of our caveats to this representation.

	Weight	Single-walled carbon nanotubes	Muilti-walled carbon nanotubes	Nanoclay particles	Cadmium-selenide quantum dots	Zinc oxide nanoparticles	Titanium dioxide nanoparticles	Dendrimers	Fullernenes	Nanocrystalline drug formulations	Silicon nanowires
Evidence of Toxicity	35%		$\bullet$	0	$\bullet$		0		$\bullet$	0	0
Nanoparticle more reactive than bulk?	15%			0						0	
Bulk material toxic?	5%	0	0	0	$\bullet$	0	0	0	0	0	0
Resists biodegradation?	10%	$\bullet$	$\bullet$	0	$\bullet$		$\bullet$	$\bullet$	J	0	0
Tends not to agglomerate?	5%	0	0	0	0	0	0		0	0	0
Readily purified and characterized?	10%							0	0		
Evidence for specific bodily harm/mobility?	10%			0	0		0			0	0
Evidence for environmental harm/mobility?	10%			0	◀		0	$\bullet$	$\bullet$	0	0
Potential Hazard:											
		•	Yes			Somewh	at	0	No		
	Figure 1	. Charae	terizina	Hazard:	Differer	nt Nanor	oarticle T		orit Diffe	rent	

### Figure 13: Characterizing Hazard: Different Nanoparticle Types Merit Different Levels of Caution

Source: Lux Research25

<sup>&</sup>lt;sup>25</sup> Nordan, Matthew M. "A Prudent Approach to Nanotech Environmental, Health and Safety Risks." Lux Research. May 2005

### **Innovest Analysis on Hazards**

Innovest's perspective on Figure 13 is the following:

- Numerous reports attempt to characterize the environmental, health and safety risks associated with specific types of particles. *This is interesting considering the limited amount of research and scientific review that has been published*. Investors may note that many chemical structures have been approved by regulators and characterized as being safe. Only later do their toxic properties come to light resulting in significant liability.
- 2. We have come across statements in our research on nanotechnology claiming that human exposure risk is measured in terms of volume. In the case of nanotechnology, toxicity is likely to be *affected less by mass and volume and more by surface area, surface chemistry and particle structure*. This provides real challenges for toxicology since many of the models used to predict the toxicity of materials relate toxicity to mass. The mass-based approach is the basis for most U.S. environmental regulations (air and water), which specify thresholds based on mass per unit volume. *See Appendix 1 for further discussion of characterization issues*.
- 3. While titanium dioxide (TiO<sub>2</sub>) has been approved by the Scientific Committee on Cosmetics and Non-food Products (SCCNFP) in Europe and given a green light by the Food and Drug Administration in the United States, we are cautious about these findings for the following reasons:
  - A 1997 study suggests that TiO<sub>2</sub> may cause DNA damage and the science is still uncertain regarding possible effects on damaged skin<sup>26</sup>.
  - The SCCNFP used proprietary *company studies* to determine safety rather than setting preference for independent toxicity testing. Investors may note that the chemicals industry's credibility problem could be partly attributable to this and may explain the existence of programs like the OECD's High Product Volume Challenge which takes proprietary company data and makes it public for peer review.
- 4. There should also be some caution surrounding nano-crystalline and nano composite drugs because many of them are going through the FDA on fast track (discussed later in this report) as an existing drug rather than a new structure that requires a more thorough review.

### Innovest Analysis on Exposure Risk

The following table is a basic guide for incorporating particle risk into fundamental analysis. Note that due diligence will need to be continually updated as the science reveals new information on the risks associated with certain types of engineered particles. We provide a rough timeline on page 39 for completion of studies underway.

This is interesting considering the limited amount of research ...

<sup>&</sup>lt;sup>26</sup> Dunford, Salinaro et al. "Chemical oxidation and DNA damage catalyzed by inorganic sunscreen ingredients," FEBS Letters , volume 418, no. 1-2, 24 November 1997, pp. 87-90.

STAGE	NOTES	QUESTIONS FOR DUE DILIGENCE
Resource Extraction	This is likely a mining situation where, at minimum, there will be high levels of ultra-fine dust particles. Note that the U.S. National Institute of Occupational Safety and Health is currently conducting research on risks related to inhalation of these particles. Nanoclays are a low risk particle however in this scenario workers may have elevated exposure which could necessitate enhanced protection.	
Manufacturing	Manufacturing processes, procedures and equipment are the point of assessment here. Most development stage firms that we interviewed and who work directly with free particles appear to be cognizant of the issues and are taking appropriate precaution. We did identify some variance among firms in the level of awareness and policy development. In some cases, companies appear to be shipping nanopowders in glass vials through overnight shipping services. Systems should be closed loop and involve some way of minimizing the amount of off-site waste that may contain particles. Regulators have not yet established workplace practices. Two chemical companies told us that toxic gas procedures are the most stringent and relevant standard that can be followed in the workplace right now. Keep in mind that some types of particles could potentially pass through most respirators on the market today.	<ul> <li>What is the particle and the risks associated with it? Free or fixed?</li> <li>Have the particles in question been externally tested?</li> <li>Does the company utilize a closed production system?</li> <li>What detection methods are in place? See Appendix 2 for further discussion of detection technologies and companies involved in the detection issue.</li> <li>How well does the company rate with regard to overall operational and environmental management? There are ways to assess this. See Appendices on Innovest Methodology.</li> <li>Has the company conducted a full Life Cycle Assessment (LCA)?</li> </ul>
Use	The application of the nanoparticle is the point for consideration. Applications including cosmetics, food, aerosols, drugs, imaging and medical devices involve direct contact with the body. Common sense dictates that these products may involve a higher exposure risk. Investors may need to determine whether these applications are regulated. Moreover the toxicity of the particle is of significance in determining potential product risk. See page 42 for a timeline of scientific research to be completed over the next several years and <b>See Appendix 3 for details on exposure risk</b> .	<ul> <li>What is the intended use? Will this involve free or fixed particles? If agglomerated what chemicals are used to minimize this?</li> <li>What is the stress to the product during use? Carbon black used in tires is currently being tested.</li> <li>Is there a way for the product to be released through breakage or damage? One company told us that breaking the product would result in a burst of nanoparticles into the atmosphere. The company included this information as part of its marketing pitch. Remember that volume is not necessarily relevant to understanding exposures. Small amounts to could pose risk if inhaled.</li> </ul>
End of Life	At the end of life, investors may consider the potential that nanoparticles will accumulate in the environment. The first level of environmental exposure will be related to applications that involve free nanoparticles i.e. contraception pharmaceuticals have now been identified as an eco-contaminant. Innovest research has identified a number of evolving regulatory and market trends that may indicate that these types of liabilities are becoming increasingly expensive for firms.	<ul> <li>Is the particle free or fixed? If particles are fixed it will be many years before anything is understood about how they succumb to the forces of nature i.e. in landfills.</li> <li>What is the hazard of the particle? Coating may relieve some concerns with reactivity, however there is indication that nanoparticles may readily combine with toxins already present in the environment to enhance bioaccumulative properties. See appendix 4 for further details on particle interaction with the environment.</li> <li>Can the material be recycled if it contains nanoparticles? Auto glass for example?</li> </ul>
Figure au Evenesure and Questions for Due Dilinence		

Figure 14: Exposure and Questions for Due Diligence Source: Innovest
## The Insurer's Perspective

#### Asbestos

There has been an exponential increase in asbestos claims and more than 6,000 independent entities have been named as asbestos liability defendants.

At least one company in every industry has been impacted, including non-producing companies.

An estimated 1.1 million claims have been issued with 75% of the plaintiffs not suffering any negative health impacts.

Approximate total cost to insurers and defendants will be \$200-275 billion.

Approximately 61 companies have filed for bankruptcy due to asbestos litigation.

Takeaways: All companies involved in nano, including end users, may be held liable if nanoparticles are found to cause health or environmental hazards.

Source: American Insurance Association 2002 While most companies we interviewed who are working directly with engineered nanoparticles appeared to be cognizant of the risks, the fact remains that pressure to generate sales could affect responsible nanotechnology development in the future. By most accounts there are already 700 products containing fixed and free nanoparticles in the market. Most of these applications appear to be of low or no risk and our analytical set even includes a few firms with products that have obtained approval from the United States Food and Drug Administration. However, we have identified a number of product applications that raise concern according to early findings. In addition, this scenario leaves the majority of products unregulated. Many firms in the set responded that they are conducting their own tests on the nanoparticles that they are using. *Investors may note that this information is largely proprietary making it unavailable to the public and to the scientific community for review*.

Insurers warn that this is an environment conducive to liability. Clearly European insurers have taken note of the potential for nanotechnology to create latent liability and are concerned about its capacity to create surprise. The four insurers SwissRE, MunichRe, GenRE and Allianz have all issued reports on this issue within the last two years. All are operating under the assumption that dangers will be chronic rather than acute. They are employing loss scenarios and loss limiting measures because "events" are deemed incalculable at this time.

In essence, commercial underwriters are already carrying the risks associated with early commercialization of nanotechnology. As more products are commercialized, insurers are taking on more risk to the extent that a large portion of an underwriter's portfolio could be nano-oriented within a five year period. Note also that companies are currently operating in an unregulated environment; the potential for a product to be brought to market without adequate screening is of concern.

For example underwriters for the chemical industry may initially count only a few companies involved in nano activities in the portfolio. But looking at the larger picture, we note that many of the large capitalization chemical firms are beginning to enter into venture deals with pure-play and micro-cap companies. This makes for a scenario where insurers may bear the burden for the entire supply chain. It is not difficult to make a correlation with an asbestos-like situation where any and all related firms are liable. Moreover, the small-cap, pure-play companies may need to consider whether this will result in a situation where underwriters are already fully loaded with nano-oriented risk from their long-standing relationships with the large-cap companies. These companies could find coverage to be costly under this scenario.

## **INVESTMENT STRATEGY**

Given that Europeans tend to be more emphatic about the precautionary approach and that major insurers are beginning to ask for it, we feel that companies that acknowledge this issue as part of their business model have greater chances for market acceptance and reduced liability over the long-term.

## Investors will need to remain abreast of scientific developments

Our research shows that venture capital firms are not necessarily conducting due diligence regarding the environmental, health and safety implications associated with the use of certain kinds of engineered nanoparticles. Investors concerned about potential liability will need to remain current on scientific developments and should look for companies that are teaming up with regulators and academia to increase the amount of scientific data available. The following is a schedule of U.S. Environmental Protection Agency (EPA) funded research that could have implications for investors going forward.

					Carbon nanopa environ	irticles mental	LCA Nar and Wa Imp	A of nomate Drinki ter pacts of	rials ng
					Absorption & Release of		Car Nar	Carbon Nanotubes in Estuaries	
	Man	ufacturin	g				Est		
					Nanopa	anticles	Stre	ess and	d A
	Ana	Cycle Ivsis			Health	on Impacts	FeC	ammati )	ION OF
						•			
	A	pril			Jun	e Ju	ily A	ugust	September
2005			2006	2007					
						Detern Nanotu Photoc	hinants c ube Toxi catalytic	if city	Nanoparticle Interaction with Skin
						Nanop to micr	article to oorganis	xicity sms	CdSe Quantom Dots
						EHS o <sup>.</sup> Nanop	f articulate	Э	Impact in Water
						Aeroso	ols		Lung Cell Response to
									Metal
									Nanoparticles
		El avera a		dad Dacaar	-h				

Figure 15: EPA Funded Research

Source: U.S. Environmental Protection Agency<sup>27</sup>

 $<sup>^{27} \</sup> http://es.epa.gov/ncer/nano/research/index.html$ 

## EHS Science Funding is Critical to Limiting Uncertainty

- For 2004, \$105.8 million, 11% of the \$961 million research spending budget, was earmarked for health and environmental studies.
  - Only \$8.5 million of the \$105.8 million was used to study potential environmental and health *impacts*<sup>28</sup>.
- For 2005, approximately \$39 million, 4% of funding for the National Nanotechnology Initiative, has been allotted for research to study the potential environmental and health risks<sup>29</sup>.
  - This number may be viewed skeptically since most of this money is only *earmarked* for EHS research.
- Many groups concerned about the lack of sufficient funding have spoken out about their concerns:
  - The American Chemical Council (ACC) and other environmental groups have expressed a need, to the EPA, for more funding.
  - Representatives of the NanoBusiness Alliance have also spoken on the issue and asked for more federal environmental research<sup>30</sup>.
  - The Environmental Defense Fund (EDF) has called for \$100 million to be set aside to study potential health and environmental risks.
  - Lux Research May 2005





Figure 16: National Nanotechnology Initiative Budge for EHS Research 2004 Source: NNI<sup>31</sup>

<sup>&</sup>lt;sup>28</sup> Masci, David. Nanotechnology June 11, 2004 • Volume 14, Number 22

<sup>&</sup>lt;sup>29</sup> National Nanotechnology Initiative. <u>http://www.nni.gov</u>. July 2005.

<sup>&</sup>lt;sup>30</sup> Ibid.

This is effectively the first sign of a non-tariff barrier.

...repeating many of the errors that were made with biotechnology

Shareholders are left with potential liability and poor returns.

Current regulatory developments may pose risk to companies and their shareholders

## IMPLICATION OF REGULATION FOR SHAREHOLDERS

China announced in late June that it has developed the first batch of nanotechnology standards and stated its intentions to develop an entire set which could in their words "reshape world nanotech competition."<sup>32</sup> Upon closer inspection the current set only covers first stage nanomaterials already in commercial use, however, the message is clear and relates back to the concept of protective/regulatory spheres impacting the competitive landscape (see page 13). This is effectively the first sign of a non-tariff barrier.

In comparison, the United States, which currently leads in the number and concentration of nanotechnology start ups, appears to be repeating many of the errors that were made with biotechnology. At this stage, the regulatory situation for Genetically Engineered (GE) crops in the U.S., the major market for both developers and sales, consists of a patchwork of outdated regulations and voluntary guidelines which have been widely criticized by the scientific community. Since the first introduction of these new crops in the early 1990s, there have been no new laws passed to regulate GE crops. *Instead, all regulation has fallen under pre-existing laws*. Public groups widely criticized the process because major players like Monsanto appeared to have an inordinate role in the development of controls.

In essence, markets operate properly when there are adequate checks and balances between corporate interests and protection of the public. When this is absent, the result is public distrust in regulators and companies to the extent that demand is abated and *shareholders are left with potential liability and poor returns*.

It appears that all interested parties (both corporations and regulators) are cognizant of trying to avoid past mistakes. However, counter to the intuition that regulation is bad for healthy market development, and given our conversations with companies for the development of this index, we feel that well-conceived science-based regulation may in fact support viable markets. In light of this we feel that current regulatory trends may pose risk to companies and their shareholders as frameworks become solidified:

- 1. In June, the U.S. Environmental Protection Agency proposed a voluntary reporting program. NGOs have written a formal response pointing out a number of faults with the proposal (see Figure 16). There is concerted discussion about the possibility of exhausting *pre-existing* statutes under the Toxic Substances Control Act (TSCA) for nanotech.
- 2. The Food and Drug Administration has already approved several nanotechnology oriented structures and has recently established a new Office of Combination Products for multiple component nano pharmaceuticals. Depending on the type of structure, companies can opt for the lengthy process for submission or a more streamlined process which does not necessarily involve a toxicology review<sup>33</sup>. Several cosmetics and personal care items containing nanoparticles that have been recently targeted for study are already on the market.

<sup>&</sup>lt;sup>31</sup> Ibid.

<sup>&</sup>lt;sup>32</sup> Zheng, Yu. "China Surpasses traditional scientific powers in standardizing nano-tech." Xinhuanet. www.chinaview.cn. http://news.xinhuanet.com/english/2005-06/20/content\_3110882.htm.

<sup>&</sup>lt;sup>33</sup> Till, Marc, Simkin, Michele, Maebius, Stephen. "Nanotech Meets the FDA: A Success Story about the First Nanoparticulate Drugs Approved by the FDA." Nanotechnology Law & Business Volume 2.2 (2005). Page 166.

3. The National Institute of Occupational Health and Safety website states that a set of "best practices" were supposed to have been released in 2004. They have not been released. Moreover the agency's position statement does not result in any actionable guidelines for companies at this time.

Summary of NGO Responses to the EPA proposal to regulate nanomaterials through a voluntary pilot program

- 1. The EPA proposed voluntary program is inadequate and inappropriate: We conclude that <u>all</u> engineered nanomaterials are "new chemical substances" under TSCA because they are new or "organic or inorganic substances of a particular molecular identity,"....therefore the pre-manufacture notice (PMN) reporting requirements under TSCA section 4 are triggered <u>prior</u> to their commercial manufacture or import.
- 2. **Immediate Regulatory Objectives:** EPA should use its authority under the Toxics Substances Control Act (TSCA) section 4 and other authorities to require adequate toxicity testing of engineered nanomaterials and to evaluate these materials so as to prevent unreasonable risk to the population, by preventing the release of potentially harmful nanomaterials into commerce.
- 3. Adequate Information: Testing on nanomaterials should be performed in a transparent manner by a credible independent agent, and all findings made public as required by various statutes under TSCA.
- 4. **Long-term regulatory objectives**: The burden of proof should be reversed essentially requiring the manufacturer to demonstrate that nanomaterials are safe prior to commercialization. Those materials deemed unsafe should be prevented from entering commerce unless they can be used in a highly controlled manner in order to prevent human exposure.

Figure 17: Summary of NGO Responses to Proposed EPA Voluntary Reporting Program

Source: Docket ID: OPPT-2004-0122

## **Relevance of NGO Comments for Shareholders:**

In trying to understand this from the perspective of shareholders, we consider these responses in the following manner:

1. Clearly the NGO community is activated and cognizant of the implications of the science.

2. The EPA is taking a more open approach this time and inviting commentary we feel will favor companies and shareholders over the long-term.

3. We are concerned about the various interpretations of existing regulation and the fairly vague rules that currently govern the way companies submit chemicals for review.

4. Results of focus group studies will be launched in September showing a low level of public support for voluntary approaches by government and industry and desire for more pre-market testing of nanotech-based products and materials. In essence voluntary programs may be useful in providing some initial data, but in light of this, we wonder how useful they will be in instilling public confidence over the long term.

5. If regulators fail to take into consideration the concerns outlined above, nanotech companies could face the same perception and market rejection problems that affected biotechnology companies.

## **Regulators' Reticence to Act, Impact to Firms**

Closer examination of the regulatory environment for genetic engineering in the United States shows *a significant lack of oversight that places the risks taken by the industry squarely onto shareholders*. Regulator's reticence to act with regard to biotechnology resulted in a lack of public trust in government and a chilling effect on the European market for genetically engineered food products. The following table is a sample list of food companies representing in excess of \$450 billion in yearly revenues that have publicly committed to remove GE ingredients from their supply chains in key countries or regions.

Aldi	Соор	Нір	Sapporo
Alpro Soya	Corona	Kirin	Soya Hellas
Amadori	Dannon	Kraft Jacobs Suchard	Spar
Asahi	Delhaize Le Lion	Marks & Spencer	Super Quinn
ASDA	DUC	McCain	Tegel
Barilla	Edeka	McDonald's	Tinglemann
Ben & Jerry's	Esselunga	Migoros	Tesco
Bodin	Ferrero	Nestlé	Trader Joe's
Burger King	Findus	Nutricia	Unilever
Cadburry's	Friki	ParkinShop	VitaSoy
Carrefour	FujiOil	Perdigao	Waitrose
Coca-Cola	Gerber	Sadia	Wiesenhof
Coluryt	Heinz	Safeway	Wimpy Fast Foods

#### Figure 18: Market Rejection of GE foods

This is a sample list of food companies representing in excess of \$450 billion in yearly revenues that have publicly committed to remove GE ingredients from their supply chains in key countries or regions. The scale of rejection by each company varies from those who have removed only GE ingredients from food for human consumption in products sold in one or more countries, to companies who have an international or global policy to remove GE ingredients from their supply chain and also to exclude the use of GE crops as animal feed.

Source: Innovest

## **Market Rejection**

Below is a flowchart showing the development of market rejection for genetically engineered foods. Many of the companies we spoke with believe that a lack of regulation could result in similar situation for nanotech.



#### Flow Chart of GE Market Rejection



## Chinese Standards Announced in May include:

- Nomenclature
- Two testing methods: Gas adsorption BET and the granularity of nano powder
- Four Sets of Specifications for Existing Nano materials currently on the market. This includes: nickel powder, zinc oxide, titanium oxide and calcium carbonate.
- They will be effective from April 1, 2005
- Li Zhonghai, Director of Standard Administration of China, disclosed that research on 15 nano materials standards were underway and the 7 items released this time was only the first batch.
- Liu Zhaobin, spokesman for General Administration of Quality Supervision, Inspection and Quarantine, confirmed that preparation for certification of nano materials has begun. The training of personnel has also been initiated.

## A MODEL TO SUPPORT VIABLE MARKETS: CAMBRIDGE, MA

Wall Street tends to react unfavorably to regulation in most circumstances. However given our findings above, we sought to find examples of situations that demonstrate how regulation could be viewed by the investment community as necessary for supporting viable markets. The following anecdote may be helpful in this regard:

Very early in the national debate about recombinant DNA the Cambridge City Council created the Cambridge Experimentation Review Board (CERB) and developed its own regulatory framework for biotech research including an ordinance regarding the use of rDNA. Counter to intuition, biotech leaders specifically chose to locate their R&D headquarters in Cambridge because the city's established review and regulatory process, and mature understanding of the field, were in fact part of the community's appeal. Regulation there was seen as being clear, predictable. Cambridge is now a haven for biotech research, development and cross-licensing with fifty biotech licenses held by leading firms in the area<sup>34</sup>.

Investors may note that the Cambridge Model worked because the National Institutes of Health (NIH) had already established a scientifically-valid set of biosafety guidelines and continually updated them. The city would never have had the intellectual capacity to develop the guidelines otherwise. As shown on the following pages of this report, nothing remotely similar currently exists for nanotechnology

We interpret this as being a signal that countries like China who are developing standards very early in the game, may see a competitive edge as the international race to win superiority in nanotechnology ensues. China and India are gaining ground. China currently ranks third in the world behind the United States and Japan in terms of nanotech patent applications. An as yet unpublished article in the journal Research Policy, places Chinese researchers second in terms of the number of papers published in nanotechnology journals. It also estimates that the U.S. government spent \$1 billion on nanotech research in 2004, just ahead of China, Europe, and Japan, which each spent about \$900 million<sup>35</sup>.

## Chinese officials believe standards support viable markets

In May the General Administration of Quality Supervision, Inspection and Quarantine and the National Committee for Standards jointly held a news conference to announce the coming debut of China's national standards for nanomaterials. This includes a nanomaterial nomenclature. While it is unclear how binding these standards are and while there are no definitions for subjectivity, rapid action by China should indicate to other countries the competitive reasons for moving quickly to develop their own standards. Chinese officials expressly state that the standards were intentionally designed to support the "healthy development of nanotechnology. *Chinese officials state that these standards might serve as a useful model for international standards*<sup>36</sup>.

<sup>&</sup>lt;sup>34</sup> Lipson, Sam. "The Cambridge Model: How public Oversight of biotech is good for everyone – even business." GeneWatch. Volume 16, Number 5 pg. 7-10.

<sup>&</sup>lt;sup>35</sup> "Developing Global Nanotech" Red Herring. 12 April 2005.

<sup>&</sup>lt;sup>36</sup> Interview with Embassy of China 21 May, 2005 and People's Daily "World's First National Standard for Nanotech to Be Effective in China." On the internet: 2005-03-03http://www.edu.cn/20050303/3130013.shtml.

## **Standards Setting**

We note that several of the firms in our analytical set are in talks with overseas joint venture partners Activities being undertaken by bodies like the International Council on Nanotechnology (ICON), ASTM International, and the International Standards Organization (ISO) will be the tipping point for countries seeking guidance on how to develop their own regulation. Indeed, this factor has a critical role in technological development and market growth of nanotech products and companies. On one hand, the Cambridge Model discussed above suggests that this could spur development in certain markets. Conversely, it could create regional barriers to entry.

The activities of the standards-setting organizations will effectively result in a baseline set of instructions for characterization and nomenclature for nanomaterials. We predict that once this occurs, the basis will be set for the development of regulation and trade industry policy. The chart below indicates the flow of developments toward standardization.

ICON International Council on Nanotechnolo gy (Rice University)	ASTM- Committee E56	ANSI-NSP The American National Standards Institute's Nanotechnology Standards Panel	International Standards Organization ISO
July/August	July	As Needed	First Meeting in November

Figure 20: Schedule of Activity Toward ISO standardization Source: Innovest

## **REGULATORY OUTLOOK: UNITED STATES**

## **Environmental Protection Agency**

On June 23, the U.S. Environmental Protection Agency: EPA conducted a public meeting on nanoscale materials to discuss a potential voluntary pilot program. The pilot would require companies (both large and small) to report toxicological and ecotoxicological data on certain nanoscale particles. Some of the nanoscale materials are new chemical substances subject to notification requirements under section 5 of the Toxic Substances Control Act (TSCA) Industry and non-governmental parties provided comment. At issue is the concern that companies have to guess at whether a certain nanoparticle represents an existing or new structure under this regulation. *We note several instances where firms have made potentially risky judgment calls on this already. Experts predict that the reporting program will be in place by <u>end of year</u>. Certain factions in Washington are proposing that pre-existing EPA statutes under TSCA may already be applicable (See Appendix 5).* 

#### **Issues to consider:**

...reporting program will be

in place by end of year

One carbon nanotube structure was submitted in January for consideration of its exemption status under TSCA 5. This may have implications for other CNT producers but this depends on the specific features of interest listed in the submission document. *More importantly, there could be a more general affect on CNT companies if the analysis leads to negative judgment.* We continue to monitor the progress of this submission.

## Food and Drug Administration

The first approval for a nano-based pharmaceutical went to Merck for Emend® on March 26, 2003. Companies focused on pharmaceutical applications are less subject to speculation over the regulatory issue at this point in that each structure must be evaluated on a product-by-product basis. According to research undertaken by Nano-Biotech News, 61 nanotech-based drugs and delivery systems and 91 devices or diagnostic tests have entered pre-clinical, clinical, or commercial development<sup>37</sup>.

If the nanoparticulate drug has a different pharmacokinetic profile than its larger particle original then it must be submitted as a new chemical entity. However, a drug that is simply the nanoscale version of its larger analog still needs to prove bioequivalency but the process is a more streamlined approach that *does not require firms to submit both the New Drug Application (NDA) and the Investigational New Drug (IND) screening.* Conducting both is a costly and time consuming process<sup>38</sup>

#### **Issues to Consider**

- Drugs involving nanoparticles are taking two forms; nano-crystalline forms of existing drugs and nanoparticle delivery mechanisms for new and existing drugs.
- For nano-crystalline forms of existing drugs investors may need to consider that particles at the nanoscale may not necessarily be identical to their macro analog.

 $<sup>^{37}</sup>$  2005 Nanomedicine, Device and Diagnostics Report National Health Information, LLC http://www.nanobiotechnews.com

<sup>&</sup>lt;sup>38</sup> Till, Mary C.; Simkin, Michele M.; Maebius, Stephen. Nanotechnology Law & Business Volume 2.2 (2005) page 66.

Recognizing this confusion, the FDA has recently created a new Office of Combination Products.

In addition, several companies in our analytical set are utilizing nanoparticles as delivery mechanisms. We identified a significant amount of variance between firms in how they decided to submit (see above). Recognizing this confusion, the FDA has recently created a new Office of Combination Products. Note: we have some concern about the decisions taken by a few firms in our analytical set and are monitoring the potential for risk. Note that studies due for release will show a very low level of trust in the FDA to manage the risks associated with nanotechnology. This may be grounded in perceptions of the agency's record with regard to Vioxx and other drugs that proved harmful once in wide use by the public.

Note that while most companies responded that they do not plan to identify their products as being "nano-enabled" public concern could develop into a demand for labeling. Experts expect the "nanofood" market to rise from US\$ 2.6bn today to US\$7bn next year and to \$20.4bn in 2010. Approximately 200 companies are currently active in research and development. The US is the leader in the sector followed by Japan and China. By 2010 Asian countries are projected to be the sector leader in the market for nanofood<sup>39</sup>.

#### **Companies Engaged in Nano Research and Development**

Nestlé Altria (Kraft Foods) Unilever PepsiCo Cargill General Mills Sara Lee H.J. Heinz Campbell Soup Maruha Associated British Foods Ajinomoto DuPont Food Industry Solutions

McCain Foods Nippon Suisan Kaisha Nichirei BASF United Foods La Doria Goodman Fielder John Lusty Group Plc Northern Foods Astrofina Nutralease Mars, Inc.

Figure 21: Companies Engaged in Nano Research and Development

Source: Food Engineering Magazine and Helmut Kaiser Consultancy<sup>40</sup>

## Uses of Nano in Food:

Companies are using nanotech to change the structure of food and food packaging:

"Interactive" drinks that contain nanocapsules that change color and flavor.

Spreads and ice creams that have improved texture due to nanoparticle emulsions.

Nanocapsules that carry nutrients and flavors into the body increasing the bioavailability of the product.

Nano-sized self assembled structured liquids (NSSL) that integrate free phytosterols into food products. The phytosterols will compete with cholesterol for entry into the micelle, bloodstream.

Nanomaterials that extend food shelf life and signal when a food spoils by changing color.

Clay nanoparticles that make plastic less likely to shatter and seal in carbon dioxide to keep carbonated drinks fresh.

<sup>&</sup>lt;sup>39</sup> "Nanotechnology sales increase to €87.5m in 2004." Food Production Daily. Com <u>http://www.foodproductiondaily.com/news/news-ng.asp?n=60283-nanotechnology-sales-increase</u>. 27 May, 2005.

<sup>&</sup>lt;sup>40</sup> "The World's Top 100 Food and Beverage Companies," Food Engineering Magazine, 1 November, 2003 and Helmut Kaiser Consultancy.

## **Occupational Safety and Health Administration**

The National Institute for Occupational Safety and Health (NIOSH) is the research body serving OSHA, the regulator in charge of workplace standards in the United States. NIOSH is in fact the only agency involved directly in scientific research at this point. All other agencies may utilize funds to sponsor research but *OSHA is likely the first agency to come up with actionable requirements for firms regarding the use of nanoparticles in the workplace*. While there does not appear to be any major developments in the pipeline, we expect a round of NIOSH research to be ready within the next several months and that would result in OSHA rule development. Studies on the propensity for carbon nanotubes to form an aerosol while being handled and the toxicity of nanotubes were recently published. The following is a list of studies underway. Representatives of NIOSH expect a few of these to be *finished in the very near future*.

#### Current Projects of the NIOSH Nanotechnology and Health & Safety Research Program:

- Generation and Characterization of Occupationally Relevant Airborne Nanoparticles
- Pulmonary Toxicity of Carbon Nanotube Particles
- Role of Carbon Nanotubes in Cardio-Pulmonary Inflammation and COPD-Related Diseases
- Particle Surface Area as a Dose Metric
- Ultrafine Aerosols from Diesel-Powered Equipment
- Monitoring nanoparticle exposures with respect to aerosol surface area concentration.
- Risk assessment for nanoparticle exposure
- Bypass leakage, and nanoparticle recirculation in the workplace
- Surface activity of inhaled particles
- Evaluating occupational nanoparticle exposures
- Characterization and control of beryllium ultrafine aerosols
- Characterizing metallic nanoparticles from diesel combustion
- Ultrafine particle intervention studies in automotive plants

# Figure 22: National Institutes of Occupational Health and Safety H&S Studies Underway

Source: NIOSH

OSHA is likely the first agency to come up with actionable requirements for firms regarding the use of nanoparticles in the workplace.

## **REGULATORY OUTLOOK: INTERNATIONAL**

Europe is decidedly more emphatic about the use of precautionary principle in reference to nanotechnology. To date the consensus in Europe appears not to be centered on whether nano-materials should be regulated, but rather when and how they will be regulated. The European Framework Program on Research and Technological development has already developed a formal outline of pre-existing regulation that could applicable to nanoscience. There has already been a formal request to the European Union Senior Toxicology Committee to have nanomaterials regulated and we understand that a response is expected by end of year<sup>41</sup>. We also note that the UK's version of the EPA, Department for Environment, Food and Rural Affairs (DEFRA) held its first stakeholders meeting in July.

Investors may note that the European chemical regulation known as REACH (Registration, Evaluation, and Authorization of Chemicals) will *require companies to prove safety as a condition of market entrance*. This will be applicable to imports as well as European manufacturers. Given that there is no data it is not unreasonable to envision a "no data, no market scenario". See Appendix 5 for an overview of both US and European regulation and the issues that we feel will be of relevance to investors.

#### **Issues to Consider**

 REACH has not been finalized but our conversations with regulators indicate that companies have had only minimal success in negotiating alterations and refinements that would weaken certain aspects of the regulation. Under the proposed law, *companies* would be required to prove the safety of certain high-priority chemicals. Under pre-existing regulation in the U.S. and Europe *agencies* must prove harm, often long after the product has been commercialized. For further information on this market condition (See Innovest Diversified, Commodity and Specialty Chemicals reports).

[REACH]... will require companies to prove safety as a condition of market entrance

REACH shifts the burden of proof

<sup>&</sup>lt;sup>41</sup> "Scientific Committee on Emerging and Newly Identified Health Risks: Request for a scientific opinion: on the products of nanotechnologies." On the Internet: http://europa.eu.int/comm/ph\_risk/committees/o4\_scenihr\_questions\_en.htm

## **UNANSWERED QUESTIONS**

	• We understand that one company has submitted a carbon nanotube structure for review as a new chemical under EPA TSCA Section 5. We think that this may have implications for other CNT companies but it will depend significantly on the specific characteristics being submitted for and this could leave room for speculation.
Fundamentally new characteristics	• It is widely recognized that particles at the nanoscale do not adhere to the principles of classical physics. This suggests the existence of a particle with fundamentally new characteristics that need to be screened as <i>new chemicals</i> . We continue to identify firms that appear to be interpreting their product as being a preexisting chemical and we wonder what liability this may represent should research underway reveal a specific risk regarding nanoparticles that have been submitted in this way as opposed to the new chemical review process.
	<ul> <li>Investors may consider that regulation may not be the only necessary protection for firms, particularly given the number of cases like MTBE (methyl tertiary bu- tyl ether) that have occurred over the years. Hazards were identified in 1954 but MTBE was approved by the US Environmental Protection Agency in 1991. The clean up of MTBE in water systems has been estimated to be in the range of \$25- \$85 billion according to American Water Works Association (AWWA). We iden- tified a few firms that set their own internal moratoriums on certain types of par-</li> </ul>

ticles because early analysis led them to believe there would be risk. It may be

relevant to inquire about this when conducting due diligence.

50

## 5. Product Stewardship

The following list of best practices that may be of relevance in evaluating a firm's ability to prepare for potential perception issues and new developments in the scientific and regulatory landscape.

## TESTING

Testing of the nanoparticle in question may represent the most proactive and given the extreme expense of providing "extra" particles for research, perhaps the most costly option that can be undertaken by a firm.

**Agency**: Some companies are teaming up with the National Institutes of Occupational Health and Safety (NIOSH) to take part in the establishment of regulation and standards. This may involve the donation of nanoparticles for use in research and some companies are providing information to NIOSH and/or other agencies about lab and operational procedures for study and evaluation.

**University**: Companies that team up with universities may have the opportunity to offset the expense that might otherwise be incurred by contracting with an independent testing laboratory. The results are mutually beneficial and help to build the body of publicly available data on the EHS implications of nanotechnology – something that ultimately benefits all companies. Some companies that we interviewed explained that working with universities may also have the side benefit of reducing toxicity testing costs. In this case the primary cost is related to providing batch particles for study.

**Independent**: A few firms have paid independent laboratories to analyze the particle in question. Our research shows that this is indeed a costly option and the results are private. Given the expense, this may be relevant to the evaluation of cash flow for a pure-play company. This may also indicate the level of priority that a firm has placed on responsible development. Companies targeting sensitive markets such as the UK and European Union may feel added pressure to submit structures to a lab even if they are relatively certain that there are minimal risks. Examples of two firms that are providing these services are Harlan Laboratories and Intertek Group plc.

#### Companies that have had their products tested include:

AltairNanotechnologies Carbon Nanotechnologies Nalco ApNano Starpharma DuPont

## DISCLOSURE

A variety of laws and regulations in both Europe and the United States could be interpreted as being relevant to the enforcement of disclosure about nano related risks. Sarbanes Oxley's Management Discussion and Analysis, Rule S-K 303 is a likely candidate in this respect. Under S-K 303, companies are:

- Required to provide historical and prospective analysis of the financial condition and results of operations
- Required to disclose any known event or uncertainties known to management reasonably likely to have a material effect on the financial condition or operating results.

It is widely recognized that SK 101, 103 and 303 require the reporting of information about operational risk such as environmental issues. This may include information on climate change, site contamination or chemical product liability. The large majority of firms across all three sub-sectors of the chemicals industry have begun to comply.

At this early stage, any level of transparency about nanoparticles in use would be considered highly proactive. Investors may note that several companies have opted to provide basic chemical composition, structure and size information relating to the particles in use. Going forward, the scenario could change, particularly if there is an incident (note that certain nano powders can be explosive) or dramatic finding. We heard from several stakeholders that it would be desirable for firms to provide information about the entire life cycle of the product in question.

#### Companies currently disclosing particle information:

BASF AG Altairnanotechnologies Headwaters Most of the carbon Nanotube companies

## LIFE CYCLE ANALYSIS

In the case of nanotech, a notable benefit stems from a detailed understanding of where potential liabilities may lay in production, use and disposal. In certain markets such as Japan and the European Union this is an increasingly relevant concern as new statutes require companies to take responsibility for their products at all stages. Innovest specializes in assessing the financial exposure to companies related to these regulatory changes.

To date, only a few life cycle assessments (LCAs) on nanotechnologies have been completed. Although few LCAs have been completed, others are underway or are in the early stages of development<sup>42</sup>.

Stakeholders request a full disclosure of life cycle implications.

<sup>&</sup>lt;sup>42</sup>" Analysis of Nanotechnology from an Industrial Ecology Perspective." Lekas, Deanna. Yale School of Forestry & Environmental Studies.26 May 2005.

We note that the NGO community is placing a particular priority on encouraging firms to disclose the results of the LCA to the public as part of their fiduciary reporting requirements. Discussion has centered on whether aspects of Sarbanes-Oxley could be interpreted as requiring this.

We have identified approximately 11 companies in our analytical set who are likely to have conducted some sort of LCA on their products. In some cases this is because the company has a standing policy to conduct an LCA as an inherent aspect of the innovation strategy. Contact the analyst for further information.

## **OPERATIONAL QUALITY**

We noticed that a few companies in our analytical set appear to be announcing their affiliation with the Good Laboratory Practice standards of the European Union as part of their nanotechnology marketing platform. The GLP is essentially a "seal of approval" that certifies the results of lab data. This will be particularly important for companies that may need to submit structures to European regulators. A few examples of GLP certified companies include: ApNano and BASF AG.

## SMALL BUSINESS INNOVATION RESEARCH

Investors may want to look for pure-play companies that are recipients of the Small Business Innovation Research grant. The program is competitive and is designed for innovative projects that have strong commercialization potential. So far, of the 75 companies that we reviewed, Altair Nanotechnologies is the one recipient of an SBIR grant. The company was awarded both a Phase I and Phase II grant that in total provide an estimated \$550,000. At minimum, the SBIR indicates that a set of government selected reviewers consider the company's efforts to be scientifically and economically promising.

## TEAMING UP WITH ENVIRONMENTAL DEFENSE

At a recent conference in Washington DC, the NGO Environmental Defense announced the inception of a new cooperative program similar to those it has developed with the chemicals and paper sectors. This will enable the collaboration between Environmental Defense and nanotech companies interested in identification of risk, establishing best practice and monitoring of performance for responsible nanotechnology development. We understand that there are a number of corporate partners getting ready to announce their alignment with this initiative; however, there are no formal members yet. We suspect that DuPont is already involved. Environmental Defense is a highly respected organization offering technical solutions for industry's environmental challenges. We continue to monitor the membership list.

While we are encouraged that some of the large corporations are engaged, not all NGOs are supportive of this kind of voluntary program. Some believe that such agreements fundamentally undermine the ability to push through more formal regulations. At a recent conference in Washington of the Environmental Law institute, concerns were raised about the ability of such programs to reach all players. Such one-off agreements can only reach a small fraction of the existing and potential manufacturing base. Note that these types of agreements are time and resource intensive making them far less attractive to small businesses and start-ups.

## HPV

A company's faithful adherence to the High Product Volume (HPV) program can be an indication of how transparent a firm will be with regard to nanomaterials manufacture. HPV is a voluntary reporting system established in 1998 to encourage companies to submit structures in order to increase scientific understanding of the toxicity implications of the more than 2,200 chemicals currently on the market. At the time, more than 70% of top-volume commercial chemicals lacked publicly available screening data. Companies make voluntary commitments to the program in order to contribute to the body of knowledge regarding inorganic chemicals and their toxicology profiles.

There is wide variance in on-time submission of robust summaries to the HPV program and there are many "orphaned" chemicals. Note that BASF was rated by Environmental Defense as being in the top ten performers in submitting robust summaries on time in 2003 while 3M and General Electric were classified among the 10 worst submitters<sup>43</sup>.

## **Environmental Certification**

Nanophase Technologies Corporation (NANX-Nasdaq) which specializes in nanomaterials and nanoengineered products and which is a major supplier of titanium dioxide nanoparticles to BASF recently announced that it has been certified as having met the international standards of ISO 14001:2004. This is a very general audit of overall environmental managerial capacity. It is highly unlikely that the audit was conditioned to be specific to nano-oriented production. However we understand that ISO is in the process of forming convention on responsible nanotechnology development. When this happens, companies like Nanophase will be in good standing with regard to their next audit.

<sup>&</sup>lt;sup>43</sup> Environmental Defense On the internet:

http://www.environmentaldefense.org/documents/2685\_HPVBestandWorstFinal.htm

## 6. Conclusions

#### Knowledge is Power

Investors are gearing up and venture capital spending is expected to recover by end of 2005. Comparisons between nanotech and the advent of the information technology era abound. But the analogy is not exact. Product safety was not a concern for software. Investors need more information.

- Most companies we spoke with expressed concern over the fact that so little priority has been placed on toxicity research by the National Nanotechnology Initiative.
- What we do know is that a number of toxicology studies are scheduled for completion in 2007. The results will hopefully provide better information allowing investors to make more informed decisions about which technologies are safe for investment. At minimum, the information may point to questions that need to be asked.
- Currently the focus is on fullerenes, carbon nanotubes, dendrimers, quantum dots and nanowires. The analysis of risk is complex involving many parameters. It should be undertaken on case by case basis with an understanding of production processes, product use and end disposal.
- In many instances there are mitigating factors that reduce the relative risk of a product. For example, Rice University's Center for Biological and Environmental Nanotechnology (CBEN) has revealed that it can minimize the reactivity of particles with functionalized surfaces by coating the particle<sup>44</sup>.
- Detection of particles in production is critical to the safety issue. Companies engaged in providing detection technologies will be sound investments.

#### Perception and Market Development

Perception of the risks of nanotechnology is mostly limited to the academic community and policy makers at this stage but the possibility of public backlash cannot be completely discounted.

- Companies have a role in working to offset the potential for perception issues to impact markets.
- Transparency, involvement in the science and a commitment to product stewardship are important indicators of corporate quality.
- People may be more willing to accept risk if nanoscience yields the right products now. This means renewable and clean energy technology, resource efficiency, clean water, vaccinations.

<sup>&</sup>lt;sup>44</sup> "Rice University Researchers Reduce Toxicity of Water Soluble Buckyballs by 10 Million Times." On the Internet: http://www.Azonano.com. Posted 24 September 2004. Retrieved 6 June 2005.

#### Regulation

- A significant portion of the more than 60 companies we interviewed indicated an interest in having some sort of standards in place. In many cases, they felt that science-based regulation would provide a more level playing field. The lack of adequate funding for toxicology research is, again, an issue here.
- Looking at the international picture, the rapid response to the possible risks of nanoscience has prompted a movement toward standards development and establishment of nomenclature.
- Off the record conversations with regulators indicate that Europe, the UK and China are expecting to have some sort of binding requirement for companies within the next 2 to 4 years. China clearly states that its standards were designed to create a robust foundation for nanotechnology development in that region and they expect their standards to impact the competitive landscape for nanotechnology.
- A regulatory timeline for the US is less certain given what appears to be a concerted effort by the legal community to exhaust all existing statutes. This is very similar to the way that U.S. regulators dealt with genetically modified crops and food. With regard to nanotechnology, the U.S. is gearing up for the initiation of a voluntary reporting scheme. Investors may note a growing level of discord regarding this option.
- We continue to monitor the possibilities for risk related to the fact that a few nanotechnology companies may have already improperly interpreted existing law.

#### Investors Play a Role

- We strongly support calls made my others in the investment community for increased government funding of toxicology research. The NNI's lack of priority for this issue represents a missed opportunity to minimize uncertainty.
- There is always a fine line between lax policy development and market chilling risk aversion. Counter to intuition, our research shows that robust, science-based regulation can contribute to healthy market development.
- We interviewed 12 venture capital firms specializing in nanotechnology. Very few of them indicated adequate attention to this aspect of due diligence. To the extent that a given environmental, health or safety issue can delay commercialization or result in perception issues and/or latent product liability, we believe that asking the right questions will be important.
- Responses to these questions may reveal hidden value, particularly for development stage firms.

7. Profiles of Index Constituents

## ALTAIR NANOTECHNOLOGIES, INC.

Country:		United States	
Ticker Syn	nbol:	ALTI	
Industrial Sector:		Specialty Chemicals	
Combined IVA Rating:		N/A	
Sub-Facto	rs:		
Market Viability:		4.4	
Product Saf	ety:	3.1	
Product Stewardship:		5.0	
Analyst:	Heather 646-237 hlangsn	r Langsner -0212 er@innovestgroup.com	

#### SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

While we continue to monitor the possibility that toxicology studies on nanoparticulate metal oxides underway could impact Altair's model and while certain applications ready for commercialization give us pause, we note the company's standard setting performance in the area of transparency, risk management and product stewardship. The company's business model is based on a diverse range of product platforms (too many in our estimation) but the company has revenue coming from research grants and Department of Defense funding and is one of the few public nano pure-play companies focusing on CleanTech product applications. ALTI provided complete particle information and has submitted particles for testing

through academic institutions and governmental agencies. Finally, the company displays a competitive approach to operational quality and information sharing regarding possible nano-oriented risks relative to other companies in the analytical set.

#### **COMPANY OVERVIEW**

ALTI is an industrial nanotechnology company that specializes in developing and commercializing nanomaterial and titanium dioxide pigment technologies. It also has collaborative ventures with industry partners and leading academic centers which have allowed them to pioneer an array of intellectual property and products. Most of the company's existing products, potential products and contract research services are built upon its proprietary nanomaterials and titanium dioxide pigment technology.

ALTI is applying its proprietary development platform to two divisions: life sciences and performance materials. The Life Sciences division is pursuing market applications in pharmaceuticals, drug delivery, dental materials and other medical markets. The Performance Materials Division is pursuing market applications in advanced materials for paints and coatings; titanium metal manufacturing, catalysts, air and water treatment, and alternative energy including advanced battery electrode materials.

Currently the company has three different revenue streams; research contracts and grants, commercial collaborations, and licenses, royalties and product sales. Year 2004 sales of \$1.15 million increased due in part to a commercial collaboration with Titanium Metals Corporation funded by the Department of Defense, a license agreement with Western Oil Sands and a grant from the National Science Foundation (NSF). The top institutional investors with positions in ALTI are Barclay's Global Investors, Hussman Econometrics Advisors, Hauck & Aufhäuser Investment Gesellschaft S.A., Merrill Lynch & Company, Inc., Vanguard Group, Inc., and Gabriel Capital L.P. ALTI holds over 30 patents and has more than 50 pending. The company has 43 employees.

#### MARKET VIABILITY

ALTI has the ability to minimize perception risk for nanotechnology products because of management's focus on environmental applications and an above average commitment to sourcing manufacturing technology that minimize environmental impact. ALTI has six platforms that are divided evenly between the two divisions. In the Life Sciences division, ALTI's three platforms include: pharmaceutical drug candidates, controlled chemical delivery systems, and biocompatible materials. The Performance Materials division has many applications targeting the CleanTech market. The three platforms include: advance materials, water and air purification, and materials for advanced energy. The current status of the market viability for each division is described below.

#### Pharmaceutical Drug Candidates:

The Company has licensed a drug candidate, RenaZorb<sup>TM</sup>, to Spectrum Pharmaceuticals and states that it is receiving milestone payments. The target market for this drug is patients with end-stage renal disease (ESRD), a \$600 million market, which is expected to grow to over \$1billion in the next four years because of increasing evidence that earlier prevention of high blood phosphate slows the progress of renal failure. Spectrum Pharmaceuticals is completing testing and seeking approval from the FDA for commercial use in humans. The drug may also be used for cats and

dogs as 21 million suffer from renal disease worldwide. This untapped market is estimated to be in excess of \$100M per year. The licensing and commercialization of Renalan for animal indications is currently underway.

**Chemical Delivery Products:** For the chemical delivery platform, ALTI's TiNanoSphere<sup>TM</sup> product is targeting drugs with (a) poor bioavailability and (b) which need to be introduced into cells to effect their therapeutic action. Treatments that require targeted delivery are cancer therapies and vaccines. This platform is being tested by 3rd parties and is expected to be a long term project for the company.

**Biocompatible Materials:** This platform consists of dental materials and prosthetic coating materials. The dental material, made of a nanozirconia, is expected to be commercial by next year where as the orthopedic implant coating materials that stimulate osteoblast growth should be commercialized within 3 years.

Advanced Materials: This platform has applications for paints, coatings, sensors, and the production of titanium dioxide pigment utilizing the Altair Hydrochloric Pigment Process (AHP). The company is completing a Phase I feasibility study for Western Oil Sands to produce titanium dioxide from tar sand tailings. They are also in discussions with other companies and should have licensing agreements by year's end. ALTI has a collaboration agreement with Titanium Metals Corporation, TIMET. (NYSE:TIE) which requires them to supply their TiO<sub>2</sub> micro porous electrodes for titanium metal production using the FFC process. They are currently shipping materials to TIMET. Finally, ALTI produces thermal spray grade powders. They are currently supplying nominal amounts of their  $TiO_2$  coating materials to F.W. Gartner and are in early stage discussions with several companies for their yttria stabilized zirconia coating powders.

Air and Water Purification Systems: Air: ALTI has a strategic alliance with Genesis Air to supply specialized surface activated nanosized titanium dioxide compounds for use in HVAC air cleaning systems, specifically Genesis Air's GAP Photocatalysis technology. This system is currently in 12 beta sites worldwide and is expected to be commercialized in the fourth quarter 2005. This application addresses a new, unique solution in the \$45 billion HVAC market.

Water: ALTI's water purification system, NanoCheck<sup>TM</sup>, removes phosphate (the food for algae) from water and has been in field trials for over one year. This product represents some potential for risk in our estimation and this would not be a relevant application for our index. However, the company demonstrates a leading approach to product stewardship and we will continue to monitor the potential for risk. Applications for this product include swimming pools and aquariums as it is effective in providing an algae-free environment. The company is currently in contract negotiations and expects to launch NanoCheck<sup>TM</sup> by the end of the year. This first NanoCheck product addresses a key problem of the 10 million plus installed recreational pools. Additional applications for NanoCheck range from treatment of aquariums to municipal water systems.

#### Materials for Alternative Energy

ALTI is targeting the alternative energy market by producing 1<sup>st</sup> and 2<sup>nd</sup> generation Lithium Ion Battery Electrode Materials and Hydrogen Generation Electrode Materials. The company has a development part-

nership with Advanced Battery Technologies where the batteries are in Phase II testing. ALTI expects its partner, Advanced Battery to have the batteries using Altair's battery materials commercialized within Q4 2005 to Q1 2006 and in road test in electric sedans and buses by the end of 2005. The company is also in discussions with battery manufacturers, providers of battery material, and companies within the automotive industry concerning their technology. The company is halfway through a Department of Energy (DOE) sponsored program with UNLV on a hydrogen filling station project and has produced nanometer scale metal oxide electrode films for use in a photochemical hydrogen generation device. These materials are a fundamental building block for the multibillion dollar electric vehicle market.

## PRODUCT SAFETY

ALTI is cognizant of the potential risks and impact of regulation on their business and the company is taking a proactive approach by working with government agencies such as National Institute for Occupational Safety and Health (NIOSH) and the DOE as well as teaming with academic institutions to develop "best in class" documentation and procedures for nanomaterial production and handling.

The company has submitted particles opting for a new chemical designation under EPA chemicals regulation. This is critical as we founhd several firms that seem to be misinterpreting existing rules for submission. We continue to monitor the potential for risk those firms since those products are now commercially available and have not undergone a thorough review.

#### **PRODUCT STEWARDSHIP**

ALTI appears to be a market leader in the area of product stewardship, representing one of the few transparent companies we screened. Their proactive approach towards product stewardship is likely to yield real value in the future as they are better prepared to deal with a possible binary event, market freeze, or regulatory change. They also stand to have global acceptance and market reach due to the use of the precautionary principle. When interviewed, CEO Dr. Alan Gotcher spoke to every issue; disclosure, life cycle analysis, testing, operational quality, and small business grants, we examined in this area of our due diligence.

#### **Disclosure:**

Altair Nanotechnologies sets the standard for disclosure. The company provided the chemical formula, structure, and particle size for each of their platforms. While many pure plays selling particles such as carbon nanotubes provide particle characteristics, the companies applying particles to products were reluctant to provide this information. More importantly, ALTI is also providing particles and characterization information to governmental agencies and academic institutions.

#### Life Cycle Analysis:

While ALTI is cognizant of the need for Life Cycle Analysis (LCA), this remains an area for improvement as the company is currently relying heavily on its partner companies to perform this task. Innovest research heavily weights for LCA performance and will be looking for ALTI to enhance operations in the future by conducting thorough LCA's on their products. We do note that the company is working with partner firms to conduct efficiency review in the supply chain.

#### **Testing:**

ALTI has opted to submit particles to NIOSH for exposure and toxicity testing. By doing this the company may be bypassing the added costs associated with contracting with independent testing facilities.

#### **Operational Quality:**

ALTI has invested in closed system manufacturing to produce high quality, controlled particles. Note that other companies in the analytical set are struggling with these issues. CEO, Dr. Alan Gotcher, is staying abreast of any potential problems with worker and customer safety and industrial hygiene through collaborations with academic institutions. Due to the company's concern for industrial hygiene and the nature of the manufacturing process, the exposure risk to employees should be minimal. Given the company's proactive approach to stewardship and an operational quality, it is expected that the company can minimize any general exposure issues that may be specific to commercial production of nanomaterials.

#### Small Business Innovation Research:

ALTI was just awarded its second SBIR grant for over \$470,000 provided by the NSF. The company is using the grant money for continue development of nano-structured electrodes for the next generation batteries and super capacitors

#### APNANO

Country:		United States	
Ticker Sym	bol:		
Industrial S	sector:		
Combined Rating:	IVA	N/A	
Sub-Factor	s:		
Market Viab	ility:	4.5	
Product Safe	ety:	3.2	
Product Stewardship	:	5.0	
Analyst: Heather 646-23 hlangsi		er Langsner 37-0212 ner@innovestgroup.com	

#### SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

Of the 75 companies we reviewed, ApNano stands out as having one of the most proactive approaches to product stewardship of any in the set. The company has been recognized by Red Herring and Innovation World 21 for management quality and product concept and the recently launched industrial lubricant NanoLub<sup>TM</sup> fits our requirement for a cleantech application.

#### **COMPANY OVERVIEW**

In January ApNano announced that it raised \$5 million in its second round of financing to a total of \$6 million. The money raised will be used to construct a pilot manufacturing plant, designed to produce 150 kg a day of the company's first product - NanoLub<sup>TM</sup>. The company states that it plans to go public in 2006 in order to raise funds to establish the plant. ApNano Materials is a private company incorporated in the US in 2002. The company was granted an exclusive license by Yeda Research and Development Co. Ltd., the commercial arm of the Weizmann Institute of Science, Israel, to manufacture, commercialize and sell nanotechnology products based on inorganic nanostructures. Prior to the group's discovery it was commonly held that fullerenes could only consist of carbon atoms. ApNano is headquartered in New York with an R&D center in Rehovot, Israel.

#### MARKET VIABILITY

ApNano states that it has already received indicated demand for 1.000 tons annually of its NanoLub<sup>TM</sup> industrial lubricant. The company values this level of demand at approximately \$50 million. The novel properties of ApNano's inorganic nano structures have application for catalysts for the refining industry and composite materials with excellent energy absorption capabilities. The durability and thermal stability of these materials would make sense for an array of applications from semiconductors to nano-motors. We suspect that the first clients will be in the aerospace/defense industry: however the company announced in 2004 that The Volkswagen Group, one of the world's leading automobile manufacturers, has included ApNano Materials products in its automotive nanotechnology program. Of importance to this analysis, NanoLub<sup>™</sup> will significantly reduce fuel consumption in industrial processes which will lead to less air pollution and the product can replace existing products which contain free sulfides: some are very toxic and are being banned in several markets.

#### PRODUCT SAFETY

Spherical nanoparticles, particularly fullerenes have been a focus for toxicity research. For example, water-soluble fullerenes have shown to be toxic in small levels in both human skin and liver carcinoma cells and there is no public information available regarding inorganic spherical particles. However studies conducted at Rice University indicate that coating the surface of particles can greatly reduce toxicity. NanoLub<sup>TM</sup> has been found to be non-toxic in testing performed by Harlan Biotech Israel Ltd., an accredited testing laboratory for pharmacological toxicity studies, located in Rehovot, Israel. The nanoparticles are essentially bound in material that would prevent general atmospheric dispersion. Moreover field and beta site tests performed by major global lubricants and automotive manufacturers have also not returned any indication of risk according to the company. The one difficulty of this is that the results of these tests are private and not available for scientific review.

#### **PRODUCT STEWARDSHIP**

Testing: The acute toxicity testing was done in full accordance with European Commission directives for Good Laboratory Practice (GLP). ApNano underwent this process on a voluntary basis.

## **BASF AG**

Country:		Germany		
Ticker Sym	bol:	BAS-FF		
Industrial S	ector:	Diversified Chemicals		
Combined Rating:	IVA	ΑΑΑ		
Sub-Factor	s:			
Market Viab	ility:	3.0		
Product Safe	ty:	2.9		
Product Stewardship:		4.8		
Analyst: Heather 646-237- hlangsne		r Langsner -0212 er@innovestgroup.com		

#### SUB-FACTOR PERFORMANCE



### **RATING OUTLOOK**

Some might consider firms like BASF to have the greatest exposure to any environmental, health or safety issues that may arise with regard to nanotechnology. However, the company has long demonstrated a commitment to green chemistry and exhibits many strengths that bode well for the company's ability to minimize product risk and any related perception problems. BASF ranks AAA relative to peers in Innovest's comparative analysis of managerial capacity and risk management in the Diversified Chemicals sector. Investors may note that we are monitoring scientific developments regarding titanium dioxide and various other nanoparticles being used by BASF. Studies are being conducted on certain particles being applied in food, food packaging

and cosmetics as well. In addition, we would prefer to see BASF put more emphasis on the cleantech applications as described in our report. See Product Safety for further information.

#### **COMPANY OVERVIEW**

BASF is the world's largest chemical company, ahead of Dow and DuPont. With more than 100 major manufacturing facilities, it does business worldwide through five segments: plastics (including polyolefins and polystyrene), performance products (value-added chemicals, coatings, and dyes), basic chemicals (plasticizers, catalysts, solvents), oil & gas exploration and production (through subsidiary Wintershall AG), and agricultural products and nutrition (additives, herbicides, and fertilizers). It employs over 87,000 people worldwide. BASF sold its pharmaceutical operations (Knoll Pharmaceutical) to Abbott Laboratories Inc. to concentrate on its core chemical operations in 2001. BASF sold its fibers unit in 2003 to focus on core chemical operations, and acquired the chemical division of Mine Safety Appliance (MSA) in September. FY 2003 sales were \$42.6 billion, leading to a net income of \$1.1 billion. Sales by geographic regions: Europe, 57.3%, North America, 21.5%, Asia, 15.9%, South America, 5.3%. BASF and Shell combined their petrochemical businesses into joint-venture Basell in 2000 and sold the JV to a private investment group in 2005.

#### **Top Ten Institutional Holders:**

Allianz Dresdner Global Investors Deka Investment GmbH 1 DWS Investment GmbH Union Investment Group Barclays Global Investors, N.A. Capital Research & Management Company Templeton Investment Counsel, LLC, Deutsche Asset Management Investmentgesellschaft; Pioneer Investment Management Ltd.; Cominvest Asset Management GmbH

#### MARKET VIABILITY

BASF has been manufacturing multiple products based on nanostructures and particles for many years. BASF's annual sales of nanotechnology based products currently amount to around  $\in 2$  billion and center around the company's significant market share in coatings, paints, and inks for plastics. In most cases these are less advanced forms of nanotechnology however the company's work in hyperbranched pigments and its new product mincor<sup>TM</sup> which creates a water resistant surface for textiles represent a more advanced use of nanoparticles based on their unique quantum properties.

#### Nanocubes for Hydrogen Storage

More interesting to this analysis is the work that BASF is doing on cube-shaped nanostructures. The conceived end use, hydrogen storage for rechargeable batteries, correlates with our continuing search for nano products that serve energy use, water technology and other beneficial applications. The cubes. consist of three-dimensionally linked biometallic networks that are capable of storing hydrogen. The company's website states that as a rechargeable storage medium for miniaturized fuel cells, nano-cubes could replace conventional rechargeable batteries in mobile electronic devices such as laptops or cell phones.

#### Catalysis

We are also interested in the role of nanoparticles in green chemistry and will be looking for BASF to share more information on specific efforts to utilize the specific surface properties of nanoparticles to reduce the cost and environmental impact of production. The company currently does not provide this kind of information; however, as more investors inquire about green chemistry as a competitive issue in the Diversified Chemicals sector, BASF may find it useful to discuss their activities in this area.

## PRODUCT SAFETY

While most of the particles being used by BASF in various applications are of a relatively large particle size (and some are coated, agglomerated in the application or bound in a matrix), we do note that toxicity research is being conducted on titanium dioxide. Research being done on metal oxides would also be relevant to other aspects of BASF's nano platform. This stated, BASF provides sufficient information to indicate that the nano safety issue has been given top priority by management. Moreover, BASF scored in the top 5 percent of firms on overall product safety management in Innovest's comparative analysis of the diversified chemicals sector (please see Innovest Diversified Chemicals sector report May 2004). Note The Company is highly engaged in pan-European and German efforts to conduct research on the risks of nanoparticles in the work environment and in end consumer products. Examples include the NanoDerm project of the EU or the NanoCare project of the German Federal Ministry of Education and Research (BMBF).

#### Particles

The company is primarily working with dendrimers and nanoparticulate titanium dioxide. Note that Nanophase (NANX- Nasdaq) is BASF's  $TiO_2$  supplier.

#### **Product Notes: Fuel Additives**

BASF's Venture Capital GmbH, a subsidiary of BASF Future Business GmbH invests in Oxonica Ltd., a

British company dedicated to using nanotechnology to solve problems faced by a large number of consumers. Oxonica is currently launching a fuel additive based on nanoparticulate metal oxides which when incorporated in diesel fuel is intended to reduce consumption by up to 10 percent according to the company. This would be relevant to our analysis of technologies that contribute to more efficient use of resources. However, we understand from experts that metal oxides are being studied for possible harmful affects. Moreover as a fuel additive, this represents the kind of dispersive application that could conceivably contribute an incontrovertible release of particles into the environment similar to the MTBE situation. Importantly, BASF has conducted a full Life Cycle Assessment on this product. See following section for information on LCA.

#### **PRODUCT STEWARDSHIP**

#### Life Cycle Assessment

BASF experts are engaged in a project called Nanosafe 2 a European research project with 23 partners from seven EU countries aimed at developing methods for the safe use of nanoparticles. Two aspects of this project set the standard for other firms involved in nano development: the emphasis on LCA and the commitment to transparency. Nanosafe2 looks at the entire lifecycle of nanoparticles, from their production and storage through to transport and use in a finished product. The results of the research will subsequently be made available worldwide in the form of databases. official procedures and workshops. The project will bring together scientists from leading companies in industry, startups, and selected research institutes and universities. Of the total budget of approximately €12.4 million, around €7 million is

being provided by the EU's research funding program and the remainder by the companies involved.

#### **General LCA practice**

BASF has established a method called Eco-efficiency analysis. The aim of the eco-efficiency analysis is to compare similar products or processes. This involves carrying out an overall study of alternative solutions to include a total cost determination and the calculation of ecological impact over the entire lifecycle.

#### One product based on nanomaterial from a costumer was assessed in such an eco-efficiency analysis.

#### Instrumentation/Measurement

As specified in our report, the detection and characterization of particles will be critical to minimizing occupational safety and other production risks. BASF is also involved in developing physical measurement methods and measuring equipment to reliably detect nanoparticles.

#### **Internal Toxicology Work**

BASF does not submit structures for external analysis. The company has a European Good Lab Practice (GLP) certified experimental and toxicology round and there fore does its own testing. For example company officials tell us that they have been performing a study on the cutaneous absorption of titanium dioxide and zinc oxide in sunscreen formulations that have shown that these nanomaterials are not absorbed through the skin, however please refer to the report for a timeline of scientific development on this issue. Inhalation appears to be another focus of research.

## Perception

In dealing with the perception issue, BASF states that it seeks a dialogue with interested - including critical groups to learn from them and better understand their views especially on the risks in the context of nanotechnology To raise awareness BASF supports the NanoTruck Project of the Federal Ministry of Education and Research (BMBF). The NanoTruck is a large truck traveling throughout Germany presenting a variety of experiments and exhibits related to nanotechnology. In addition BASF is an active member of the "European Technology Platform for Sustainable Chemistry" which unites the chemical industry, academia, national governments, EU-Commission and NGOs around a common vision and approach for the development of industrial biotechnology, materials technology, reaction and process design and nanotechnology.

#### Nano-related Affiliations and Initiatives

BASF is involved in nano-related initiatives of the International Council of Chemical Associations (ICCA), the American Chemistry Council (ACC), the European Center for Ecotoxicity and Toxicity of Chemicals (ECETOC), and International Life Sciences Institute (ILSI)

#### **High Product Volume Status**

BASF submitted about 60 substances under the OECD HPV-Program, all identified uses were assessed. Up to now all dossiers have been endorsed by OECD. BASF considers the particles that it is working with to be new in that nanoparticles have fundamentally different properties than their macro scale analogs. This thinking will guide their submissions to European chemicals regulatory regimes.

## BIOSANTE PHARMACEUTICALS, INC.

Country:		Australia		
Ticker Sym	bol:	BPA		
Industrial S	ector:	Pharmaceuticals		
Combined Rating:	IVA	N/A		
Sub-Factor	s:			
Market Viability:		4.1		
Product Safe	ety:	2.3		
Product Stewardship:		3.0		
Analyst: Heather 646-237- hlangsne		r Langsner -0212 er@innovestgroup.com		

#### SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

BioSante has a positive rating outlook as the company's management appears to be able to mitigate most real and perceived risks associated with nano products. The company is cognizant of the potential for liability and negative perception pressures and has chosen a globally beneficial nano-product, a vaccine drug delivery system, to reduce any negative perception issues. Furthermore, the company is choosing to submit their nano-product as a new drug under the FDA to mitigate any real risks associated with the free nanoparticles in the drug delivery product.

#### **COMPANY OVERVIEW**

BioSante Pharmaceuticals is developing a proprietary calcium phosphate (CaP) nanotechnology for use as a vaccine adjuvant, for innovative drug delivery systems and other biotechnology applications. Bio-Sante's technology could improve vaccine efficacy and make vaccines available by mouth or via inhalation. The company receives primary funding for its CaP development program through potential corporate partners such as GlaxoSmithKline and Wyeth Pharmaceuticals which it terms "partner funded feasibility studies". It also receives funding from the U.S. government in various collaborative agreements. The company is an attractive investment target because calcium phosphate particles present a lower risk profile as compared to other types of nano particles. Additionally, while the company does not have any products on the market so far it has a potential near term revenue stream via its hormone replacement therapies (awaiting NDA). The top institutional investors with positions in BioSante are William Harris Investors Inc., JO & Co, Goldman Sachs & Company, Inc., Brandywine Asset Management, Inc. and Rx Capital Management, L.P. The company has 17 employees.

#### MARKET VIABILITY

BioSante's drug delivery application for vaccines represents a perfect example of a product with consumer benefit. For this reason, Bio-Sante should have better global market acceptance even in the face of increased regulation. To mitigate real risk, including cash flow, Bio-Sante has developed more traditional drugs and is working with the FDA to gain approval for all products. The company's target markets include a nanotechnology drug delivery system and more traditional hormone replacement drug delivery systems. The current status of the market viability for each division is described below.

Traditional Drug Delivery: In terms of traditional drug development. BioSante Pharmaceuticals is developing topical hormone therapy gels for delivery of supplemental estrogen, progesterone and testosterone. The company's leading product candidate Bio-E-Gel will treat women suffering from hot flashes and other menopausal symptoms. On June 5th of this year, Bio-Sante announced significant Phase III safety and efficacy results of Bio-E-Gel<sup>TM</sup> (bioidentical estradiol transdermal gel). A new drug application (NDA) will be filed as soon as possible after completion of the data analyses. The company's NDA is anticipated in September 2005. Other hormone gel products are also being developed to treat female sexual dysfunction (LibiGel) and hypo gonadism as well as the loss of testosterone in men (Bio-T-Gel). These therapies will treat impotence, lack of sex drive, muscle weakness, osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis. The current market in the U.S. for estrogen and testosterone products is approximately \$2.5 billion.

Nanotechnology Drug Delivery: Formulated using BioSante's proprietary CaP nanotechnology, Bio-Vant is being tested as an adjuvant for orally and intra nasally administered anthrax vaccines. While injectable aluminum salt (alum) derivatives are the only adjuvants approved by the FDA, they have been associated with adverse reactions including irritation and inflammation of the injection site. Composed of specially formulated calcium phosphate, BioVant has not been shown to cause inflammation or allergic reaction after administration. BioSante is developing Bio-Vant under a subcontract with Dyn-Port in support of the U.S. Department of Defense Joint Vaccine Acquisition Program (JVAP).

Other CaP Products being developed include:

a. BioVant, a proprietary CAP adjuvant technology in development for vaccines against cancer, viral and bacterial infections, and autoimmune diseases, including biodefense vaccines, such as anthrax and ricin;

b. CAP-Oral, a delivery system for oral administration of proteins and other therapies that must be injected;

c. BioAir, a delivery system using CAP technology for inhalable versions of proteins and other therapies that must be injected; and

d. CAP biotechnology production, which use CAP technology in a patented process for purifying the milk of transgenic animals in order to extract therapeutic proteins.

CAP is a natural constituent of the human body. Thus, CAP is very well tolerated and absorbed. By virtue of the potency of this CAP adjuvant and the relative absence of side effects, we believe that this new CAP formulation has great potential for use as an adjuvant in humans.

#### **PRODUCT SAFETY**

BioSante is aware of the potential risks of nanoparticles and is cooperating with the FDA, seeking new drug approval. The company is also developing products with the US Navy and Army. In a phone interview, CEO Steven Simes, said that he did not expect his nanotechnology products to produce a negative public reaction since the benefits derived from Cap are significant and directly applicable to end users. He also said that these products will not necessarily be sold as nano products and any advertising will emphasize better and more efficient delivery of drugs or in case of adjuvants the superior safety profile of Calcium phosphate as compared to aluminum salt derivatives (current industry standard for adjuvants in vaccines). We will continue to monitor BioSante's products for real health risk considering the invasive nature of the engineered nanoparticles.

#### PRODUCT STEWARDSHIP

Although BioSante was unwilling to fully disclose information about the company's nano product, their willingness to submit as a new drug through the FDA is a sign of proactive management. This approach towards product stewardship is likely to yield real value in the future as they are better prepared to deal with any regulatory change. We will continue to monitor the company's progress in this area with particular interest in their ability to work with the FDA and conduct thorough LCA's on commercialized products.

#### **Disclosure:**

BioSante is providing particle information to the FDA but was not willing to disclose their proprietary technology. This is an area for improvement prior to next year's review.

#### Life Cycle Analysis:

BioSante's strategy is to allow commercialization of their drug delivery mechanism by their corporate partners thus depending on these partners for thorough Life Cycle Analysis (LCA). Innovest research places great importance on a company's LCA performance and will be looking for BioSante to reduce their potential for legal liability in the future by conducting thorough LCA's on their products especially those developed in RnD that will be licensed to corporate partners. If they continue to depend on partnering companies to perform LCA's, we expect them to have a

high level of awareness in regard to their supply chain and partnering companies abilities to conduct thorough due diligence in this area. This is an area of improvement for Bio-Sante prior to their review next year.

#### **Testing:**

BioSante has not submitted their particles or products for independent testing however, the company plans on submitting all of their nano drug delivery products through the FDA as new drugs. Innovest sees this as a company acting proactively to assure product safety considering the new drug application requires full toxicity screening prior to the start of human trials. BioSante's willingness to submit their products as new drugs to the FDA is a sign of management quality as they are mitigating any real health and safety risks associated with their products.

## **Operational Quality:**

BioSante stands to mitigate operational risk in two ways; their RnD space is virology ready (BL3) and the company's licensing partners will be manufacturing the nanoparticle drug delivery product. While BioSante has not prepared for nanoparticle detection, the exposure risk to employees should be minimal considering the BL3 status of the RnD space. Currently, the CaP particles are produced in house as part of the RnD effort however, as the nano products approach the large scale synthesis stage, their production will be outsourced to a cGMP certified US manufacturer. Based on management quality it is expected that the company can minimize any operational risk and effectively control accidental exposure.

## **FEI COMPANY**

Country:		United States		
Ticker Sym	bol:	FEIC		
Industrial S	Sector:	Industrial Technology		
Combined Rating:	IVA	ΑΑΑ		
Sub-Factor	s:			
Market Viab	oility:	5.0		
Product Safe	ety:	N/A		
Product Stewardship:		N/A		
Analyst: Heather 646-237- hlangsne		r Langsner -0212 er@innovestgroup.com		

#### SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

At this point it is well understood that the instrumentation companies are critical players in taking nanotech to the next level. Investors are looking at these firms for their contribution to innovation and their potential role in the scaling up of production to commercial levels. Moreover, the companies focusing on the development of visualization equipment play an important part in the detection and characterization of nanoparticles. This is important to reducing uncertainty regarding their use. It is not entirely unreasonable to consider the possibility that FEI and VEECO will eventually merge. The technologies of both firms are complimentary. One specializes in the ability to view the interior of the particle while the other specializes in viewing the exterior particle. There is literally no particle related

risk to investors when investing in the instrumentation companies.

#### **COMPANY OVERVIEW**

FEI Company's 3D characterization, analysis and modification equipment can enhance visualization at resolutions down to the sub-Angstrom level. Formed in 1971 FEI shares began trading on the Nasdaq National Market in 1995. Revenue by end market in 2004 (2003) was derived as follows: semiconductor 46% (43%), scientific research and industrial 46% (50%), and data storage 8% (7%). Revenue by product segment in 2004 (2003) was as follows: microelectronics 45% (41%), electron optics 33% (34%), components 2% (3%), and service 20% (22%). The company designs, manufactures, markets and services products and systems used in research, development and manufacturing of very small objects specializing in the analysis of three-dimensional shape using particle beam technology. Products include transmission electron microscopes ("TEMs"), scanning electron microscopes ("SEMs"), focused ion-beam systems ("FIBs") and DualBeam systems that combine a FIB column and a SEM column on a single platform, ion mass spectrometers ("SIMS"), stylus nanoprofilometers ("SNPs") and software systems for computer aided design ("CAD") navigation and semiconductor yield improvement. FEI boasts approximately 124 patents in the U.S. and approximately 161 patents outside of the U.S. with more than 1,000 employees including 398 research and development personnel worldwide. FEI has 6,230 systems installed globally. The company recently had to revise estimates and underwent a major reorganization. Revenues for the second quarter of 2005 are now projected to be in the range of \$109 million to \$111 million, compared with earlier guidance of \$114 million to \$120 million. Earnings in 2004 more than doubled to \$465,705 million in over previous year's revenues. Revenues are evenly distributed between North America, Europe and Asia Pacific. Consensus is currently at hold for FEI.

#### Top 10 institutional shareholders

Koninklijke Philips Electronics N.V.

Mazama Capital Management, Inc. Fidelity Management & Research Brown Capital Management, Inc. Barclays Global Investors, N.A. Credit Suisse First Boston LLC T. Rowe Price Associates, Inc. TCW Asset Management Company Kalmar Investments Inc. U.S. Trust Company N.A. MARKET VIABILITY

In July FEI announced a major realignment of its business to capitalize and focus on growth in nanotechnology. The company will realign sales, marketing and R&D to focus on NanoElectronics, NanoResearch and NanoBiology. Massive growth and investment in nanotechnology research and development has contributed greatly to market expansion in these segments of FEI's business. The company's sales and service to the semiconductor industry continue to provide a base for revenue.

#### **PRODUCT SAFETY**

Instrumentation providers are not subject to analysis of particle risk. However, these firms are selected for the index for the very fact that their products will contribute to the reduction of any uncertainty that may be associated with the use of certain types of engineered nanoparticles in the future.

## PRODUCT STEWARDSHIP

Instrumentation providers are not subject to analysis of product stewardship.

## FLAMEL TECHNOLOGIES S.A.

Country:		France			
Ticker Sym	bol:	FLML			
Industrial 3	Sector:	Pharmaceuticals			
Combined Rating:	IVA	N/A			
Sub-Factor	Sub-Factors:				
Market Viability:		4.0			
Product Safety:		3.6			
Product Stewardship:		3.0			
Analyst: Heather 646-237- hlangsne		r Langsner -0212 er@innovestgroup.com			

## SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

Flamel is focused on drug delivery technology that will help patients with Diabetes and Hepatitis. Flamel has chosen to submit its product to the FDA as a new pharmaceutical meaning that it will undergo a complete review as opposed to the more streamlined process undertaken by several firms we analyzed. This is a demonstration of commitment to product stewardship and may demonstrate that the company is sufficiently in control that it will be able to navigate any regulatory developments both in Europe and in the However, the outlook is US. mixed with regard to overall product stewardship. We will be looking for the new management to follow proactive nanopharma leaders such as Starpharma to make

improvements in the future. We encourage companies like Flamel to inform consumers about the benefits and be transparent about potential risks.

#### **COMPANY OVERVIEW**

Flamel is a biopharmaceutical company focused on developing two unique polymer based drug delivery systems. Based on these two systems, the company has two primary platforms: Micropump® and Medusa<sup>®</sup>. Micropump<sup>®</sup> is not based on nanotechnology and is used for delivery of small molecule drugs. The technology controls the release, enhances bioavailability and helps to mask the taste for oral delivery. It is especially good for drug delivery to pediatric and geriatric patients. Flamel's Medusa® technology does incorporate nanotechnology and is designed to deliver controlled-release formulations of therapeutic proteins and peptides. The Company also has photochromic sunsensors in the market, the first product based on their polymer technology to be commercialized, but it does not incorporate nanotechnology and was therefore not reviewed for this index. Despite decreased revenues this year compared to the same time last year, revenues have been steadily increasing for the last three years. Flamel's beneficial technology combined with its FDA compliance will likely yield increased value in the future.

#### **Top Institutional Investors:**

Biotechnology Value Fund, Inc., Knoll Capital Management, L.L.C., Glenhill Overseas Management, L.L.C., Morgan Stanley Investment Management Inc. (US), OSS Capital Management, L.L.C., Staro Asset Management, L.L.C., Selz Capital, Deutsche Investment Management Americas, Inc., Charter Oak Partners, and P.A.W. Partners

#### MARKET VIABILITY

Medusa® is a nano-particulate technology designed to deliver therapeutic proteins, peptides and small molecules. This versatile protein carrier technology allows for the development of novel and second-generation long-acting native protein drugs which are of significant importance to pharmaceutical companies looking to replace lost market share and revenues as first generation drugs come off patent. The Medusa<sup>®</sup> platform has many advantages in that it enables the controlled delivery of fully-human, non-denatured proteins that offer greater effectiveness, fewer side effects and reduced toxicity. The market for protein drugs is approximately \$50 billion. The current status of the market viability for each product is described below.

**Basulin:** Basulin represents the initial application of Flamel's Medusa® polymer technology for drug delivery. It is long-acting insulin for the treatment of Type I Diabetes and is human not analog. Basulin being a new formulation of insulin will be important to pharmaceutical companies wishing to extend their product line as first generation drugs come off patent. Basulin has recently completed human clinical IIa trials. The market for long-acting insulin is approximately \$4.4 billion, as of 2004.

**IL-2 XL:** IL-2 XL, is a secondgeneration long-acting interleukin-2 used in the treatment of renal cancer. It is in phase I of human clinical trials and has not yet received proof of concept. The market for this product is approximately \$250 million but will be substantially larger if the product is also approved for new indications (cancer and HIV) due to expected lower toxicity and side effects.

**IFN a-2b XL:** IFN alpha-2b XL is a long-acting native interferon alpha-2b for the treatment of Hepatitis B and C and some cancers. It is currently in human clinical trials I for the treatment of Hepatitis B and C and has not yet received proof of concept by the FDA. The potential market for this drug is in excess of \$3 billion.

#### Note: The Company is also working to formulate a beta-interferon.

**EPO XL:** EPO is a long-acting native erythropoietin for the treatment of anemia. This drug is a long term product that is only in preclinical trials.

**hGH XL:** hGH, a long-acting native human Growth Hormone for the treatment of growth disorders. It is also a long term product which is in preclinical trials.

## **PRODUCT SAFETY**

Flamel's products in its Medusa® division appear to represent some risk at this time. While the Company is using a self-assembled polyaminoacid nanoparticle system for protein delivery and does not appear to use any engineered nanoparticles at this time, the risk associated with this system was not disclosed. Even though the aminoacids are nano in size, a drug delivery technology based on naturally occurring amino acids and water has less risk than one with engineered nanoparticles. Furthermore, we are pleased that Flamel, like Starpharma and Bio-Sante, is conducting full IND's on its nano product lines for approval as a new drug through the FDA. We will continue to monitor Flamel's progress in this area and feel management can mitigate risk due to the benefits of the products. We encourage Flamel and all companies with nano products to be transparent in regard to product risk especially

in the area of nanopharma where the products are invasive.

## **PRODUCT STEWARDSHIP**

Flamel was chosen for our index based on the company's strategic profit opportunities which are targeting drug markets such as diabetes, cancer and Hepatitis. The company's management does appear to be concerned with product stewardship however; Flamel does not appear at this time to be as proactive as some other pharmaceutical firms in our index in regard to the areas examined for product stewardship.

#### **Disclosure:**

Flamel did provide some information and a description of the amino acids used in their drug delivery technology and as required has fully disclosed its technology to the FDA for the approval process. In the future, we would like to see Flamel be more transparent about the potential risks of its aminoacid nanoparticle system.

#### Life Cycle Analysis:

Flamel is not currently conducting LCA's on their product lines and will likely rely on pharmaceutical licensing and manufacturing partners to complete LCA's on the products.

## **Testing:**

Flamel is submitting its products to the requisite regulatory processes such as the FDA. Due to the pharmaceutical nature of their products, we can expect that each product candidate will undergo thorough toxicity testing as part of the process of bringing it to market. Other than required testing, Flamel is not participating in any additional university or independent testing for its nano products.

## **Operational Quality:**

Flamel scored well on operational quality. It is a biopharmaceutical

company and therefore must comply with operational standards and regulations including Good Lab Practices, Good Clinical Practices, and others requirements from the FDA. Furthermore, the company only uses its plant to produce product for animal and first stage human clinical trials. Once proof of concept is achieved, the product is licensed to a large corporate partner for completion of clinical trials, filing of the NDA and manufacturing.

## GENERAL ELECTRIC COMPANY

Country:		United States		
Ticker Sym	bol:	GE		
Industrial S	Sector:	Industrial Conglomerates		
Combined Rating:	IVA	AAA		
Sub-Factor	s:			
Market Viability:		4.9		
Product Safety:		3.4		
Product Stewardship:		4.2		
Analyst:	/st: Heather Langsner 646-237-0212 hlangsner@innovestgroup.com			

#### SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

The outlook is mixed. While we understand that General Electric is not well regarded by the NGO community for its chosen tack with regard to future nano-regulation, we feel that General Electric's new prioritization for cleantech is a signal that the company is intent on solving big problems and providing technology more meaningful than other companies surveyed for this analysis. General Electric does not anticipate being able to commercialize a nano-based product in the near future, however the chances are good that GE has the resources and has placed significant priority on nanotechnology to make strategic acquisitions and licensing agreements. It is also likely that relative to other companies in the analytical set, GE has greater capacity to be at the forefront of scaling up production to commercial levels. Organic Light Emitting Diodes may be ready in 3-5 years and confidence is high that GE has the managerial and intellectual capacity to use nanotechnology wisely to develop many disruptive applications in the areas of advanced mechanics, materials science, etc. GE has one of the most rigorous product safety oversight programs in the Industrial Conglomerates sector (see sector report 2004). The company receives AAA rating for overall management quality and risk management capacity.

## **COMPANY OVERVIEW**

In June 2004, General Electric announced that the Company would be reorganizing its 11 businesses into six broader units, in its largest sweep of changes since Jeffrey Immelt became chief executive in 2001. General Electric's commercial finance and insurance businesses will become part of GE Commercial Financial Service. GE Industrial, another new unit, will include plastics, automation, equipment services and six other businesses. A third new unit known as GE Infrastructure will include businesses like aircraft engines, rail and energy and will push toward developing markets like China. India and the Middle East. Consumer Finance, and NBC Universal, and GE Healthcare will remain unchanged. 2003 was the biggest acquisition year in General Electric's history, with total commitments exceeding \$30 billion. GE is shifting its focus to more profitable enterprises such as consumer finance and healthcare. Its businesses include Advanced Materials, Commercial Finance, Consumer Finance, Consumer & Industrial Products, Energy, Equipment Services, Healthcare, Infrastructure, NBC, and Transportation. GE's financial arm accounts for nearly half of GE's revenues. Revenues in 2004

were \$152.4 billion (2003 \$134.2 billion). International revenues were \$71.8 billion or ~47% of total revenues.

GE's top institutional holders include Barclays, State Street Global Advisors, Fidelity Vanguard and others. The company operates in more than 100 countries and employs over 300,000 people worldwide.

Nanotechnology is a core research focus and the company has approximately 50 researchers in six labs working on various applications. Lux Research applies a weighting system in order to discount for GE's presence in their nanotechnology index.

## MARKET VIABILITY

Understandably, GE is reticent to provide too many details regarding its research and development activities however the website lists current nano-related initiatives which include nanotubes and nanorods, nanostructured metal alloys, nano ceramics, self-assembled block copolymers, and other nanoparticles. The company has 50 full time researchers working in advanced mechanics, bioscience, combinatorial chemistry, photonics and electronics, ceramics, metallurgy and polymers/specialty chemicals. Moreover, we understand that the company is registering for patents. In 2003, the company registered for 28 patents in nanotechnology according to company documentation. The following are technologies that we know about that are relevant to our selection for environmental or homeland safety oriented application:

#### **Organic Light Emitting Diodes**

Analysts project OLEDs to be a \$1 billion business by 2008. Made of thin, nanostructured polymer films, OLEDS are expected to be ready for application in notebook computers

and eventually into television sets in the next year. However, GE is setting its sights on the far more interesting and difficult goal of general illumination. The company envisions wall –paper like lighting systems with flexibility and low energy use. In fact, GE's light emitting diodes, which may replace home lighting, could reduce energy consumption by an estimated 10% in the U.S. saving \$100 billion annually.

#### **Biodetection:**

Biodetection is an estimated \$500 million segment of the security industry that is growing at more than 10% annually. This year the company introduced a suite of biodetection products which includes a nanotechnology-based sampler and analyzer that decreases the average response time to minutes while minimizing false alarms. In 2005, GE will to add these biodetection capabilities to GE StreetLab®, a portable device that detects both drugs and explosives.

#### PRODUCT SAFETY

General Electric declined to discuss particles in use or under development. The website states only that research is being conducted on nanotubes, nanorods, nanostructured metal alloys, nanoceramics self-assembled block co-polymers and other particles. Investors may note that nanotubes are under study for potential toxicity concerns. While coating certain nano particles has been found to reduce reactivity at the nanoscale, others may pose problems due to the size and shape of the particle. Please refer to the appendices of the Nanotechnology Report to view details on research being conducted on this issue. Ouantum dots. dendrimers. nanowires and fullerenes are also being studied for toxicology.

General Electric scores in the top 1% of firms in the industrial conglomerates sector for risk management and product safety oversight (Please see Innovest's 2004 Industrial Conglomerates sector report).

#### **PRODUCT STEWARDSHIP**

General Electric did not provide as much information about nanotechnology related product stewardship activities as other large capitalization firms such as BASF and Du-Pont. However we know that the company is active on many technical committees and is in discussion with experts at Rice University to increase understanding about possible risk associated with certain types of engineered nanoparticles. The company is receiving some negative attention from the NGO community about its role in helping to shape nanotechnology policy. The company recently submitted as part a group of firms represented by the American Chemistry Council supporting a proposed voluntary reporting system for companies involved in nanotechnology research. We continue to monitor the possibility that NGO perception of GE's actions will contribute to problems however we hold our original position that the right products will be critical to offsetting any future misgivings the public may have about nanoscience.

#### Life Cycle Assessment

The company does not appear to be engaged in or supporting such research.

#### **General LCA practice**

GE's Session E platform includes a mandate to conduct life cycle assessments as part of the innovation strategy. There are a few examples of the company's efforts in this area. However, unlike competitors the company does not demonstrate a strong emphasis on this issue. GE may need to consider the NGO community's strong request for full LCA information on nano-products.

#### Instrumentation/Measurement

We understand from our interview that GE may be in the early stages of supporting research into technologies that help to characterize and detect nanoparticles. This is relevant to our analysis in that the testing of particles will be critical to reducing uncertainty associated with their use.

#### Internal Toxicology Work

No information provided

#### Nano-related Affiliations and Initiatives

American Chemistry Council, National Pollution and Toxicology Advisory Committee

#### High Product Volume Status

While our analysis shows that General Electric has excellent programs in product safety management, GE did not fair well in Environmental Defense's 2003 comparative analysis of 100 firms' performance in submitting their initial test plans and robust summaries on time to the HPV Challenge program.

(http://www.environmentaldefense. org/documents/2685\_HPVBestand WorstFinal.htm).
## HEADWATERS INCORPORATED

Country:		United States
Ticker Sym	bol:	HW
Industrial Sector:		Specialty Chemicals
Combined IVA Rating:		N/A
Sub-Factors	s:	
Market Viability:		5.0
Product Safe	ty:	2.8
Product Stewardship		3.2
Analyst:	Heather 646-237 hlangsne	<sup>r</sup> Langsner -0212 er@innovestgroup.com

#### SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

Headwaters is positioned to be a leader in clean coal technology development. The company has achieved record revenue, operating income, and earnings per share for five consecutive years and while the company has yet to clear certain benchmarks set by other firms in this analysis, environmental management and product stewardship appear to be on management's radar.

## **COMPANY OVERVIEW**

Headwaters is committed to making efficient use of the world's resources. The company provides technologies used to produce coalbased solid synthetic fuels and also manages and markets coal combustion products (CCPs) in the U.S. Headwaters is developing and commercializing proprietary technologies to convert or upgrade fossil fuels into higher-value products and is developing nanocatalyst technologies that promise to greatly reduce by-products of combustion among other applications. Headwaters' focuses on the coal value chain which can be categorized into three major phases: Pre-Combustion (mining, preparation and treatment); Combustion; and Post-Combustion (emissions control and the utilization and disposal of CCPs which are created when coal is burned, such as fly ash and bottom ash). The company's reagents are used to convert coal into a solid synthetic fuel that serve the requirements of Section 29(a) of the U.S. tax code which provides credit for producing fuel from a non-conventional source, measured in barrel-of-oil equivalent ("OBE") of qualified fuels. The credit period will soon end for the company. Headwaters is phasing out their Section 29 exposure and expecting commercialization of one of their nanocatalysts by 2007 to replace the lost revenue. The most commercially advanced catalyst is the heavy oil upgrade catalyst ( $HC_3^{TM}$ ). Currently, Headwaters has 4 business units: construction materials. resources, energy services and the technology innovation group contributing to revenues which have grown consistently from \$6.7 million in 1999 to pro forma revenue of \$892 million in 2004. Nanotechnology is being developed in the technology innovation group and will initially be applied to the resources and energy services divisions.

#### **Top Institutional Investors:**

Waddell & Reed Investment Management Company, Friess Associates, Inc., Barclays Global Investors, N.A., Mazama Capital Management, Inc., Franklin Advisers, Inc., Babson Capital Management LLC, Provident Investment Counsel, Inc., EARNEST Partners, LLC and RS Investments.

## MARKET VIABILITY

Headwaters has developed a proprietary technology for producing nanocatalysts called NxCat<sup>™</sup>. This technology allows the company to align, space, and adhere atoms of precious metals, such as platinum, to support materials. The support materials are then used to make high performance catalysts for specific applications. Furthermore, the technology offers 100% selectivity, simplifies the manufacturing process and requires less precious metal, thus minimizing material resource input costs for clients. The company expects to use the NxCat<sup>™</sup> to create selective catalysts for many applications across every division. The following catalysts should generate revenue in the next three years: homogenous catalysts, reforming catalysts, combustion catalysts and hydrogen peroxide  $(H_2O_2)$  catalysts. The current status of the market viability for each product is described below.

**Homogenous Catalyst:** The Company has developed the  $(HC)_3^{TM}$  catalyst, a single-molecule nanocatalyst to upgrade heavy oils such as the tar sand bitumen found in Canada and the low-grade crudes exported from South America, Eastern Europe and off-shore sites, into high-quality synthetic crudes, increasing conversion by 10-50%. The product is currently being tested in several major oil refining companies around the world and Headwaters expects to generate

revenues for this product this year. Headwaters has identified more than 25 refineries which could immediately benefit from addition of the  $(HC)_3$  Technology, including about 10 which could utilize the  $(HC)_3$  catalyst with only a minimal capital expenditure,

Coal-to-Liquids: The Company has developed Direct Coal Liquefaction (DCL) technology to convert heavy hydrocarbon molecules in coal into diesel, gasoline, and other fuel and petrochemical components, using a proprietary catalyst developed inhouse. Headwaters has an agreement with the Shenhua Group, China's largest coal company, for the use of this technology at a plant in Inner Mongolia. Increased interest in this technology has been driven by rising crude oil prices, leading to new contracts signed by Headwaters with companies in the Philippines, India and China for commercial project feasibility studies in these countries.

Reforming Catalyst: Headwaters' NxCat technology is being applied to improve an existing refinery catalyst that is used to improve the way that naphtha, the lightest-weight component of crude, is converted ("reformed") into gasoline. Pilot plant studies have confirmed that the NxCat improvement applied to current catalysts can improve net liquid yields while increasing the gasoline octane value by as much as 5 points. A fukk-scale refinery demonstration of this new catalyst is planned for 2006, with commercial sales expected in 2007.

**Combustion Catalyst:** This catalyst has been developed to reduce nitric oxides (NOx), when applied to raw coal, by 20-30%. Headwaters expects this catalyst to be commercialized and generate revenues by 2007. This product will be utilized in coal-fired power plants across the

U.S. but will be especially important in the western states where coal is more commonly utilized and where the environmental standards are tougher.

 $H_2O_2$  Catalyst: Headwaters  $H_2O_2$ catalyst is being used to produce low cost hydrogen peroxide for chemical intermediates such as propylene oxide (PO). The Company has entered into a joint venture with Degussa AG to develop and commercialize Headwaters' technology. The joint venture is in discussions with several potential end-users of the technology regarding worldscale  $H_2O_2$  projects, and expects to be ready to begin basic engineering of such plants by early 2007.

## PRODUCT SAFETY

The majority of Headwaters nanocatalyst product lines do not raise serious safety concerns. For example, the hydrogen peroxide catalyst is produced in a closed system with little risk of worker or environmental exposure. The only issues to note would be any manufacturing waste and end of life disposal issues.

Headwaters' NxCat catalysts for treatment of coal are nanoparticle suspensions in water, which when applied become fixed or anchored to the coal. This anchoring step virtually eliminates any possibility of contamination through coal handling. However, this process for treating raw coal could be relevant to the analysis of potential particle related risk in the processing, use and end use phases due to the beginning free state of the nanoparticles. That stated, Headwaters' application of these nanocatalysts will have significant positive impact on the energy industry and if the benefits of clean fuel are relayed to the public, the company will be able to mitigate most perceived risks from all product lines. We will continue

to monitor Headwaters progress in this area.

## PRODUCT STEWARDSHIP

Headwaters was selected for the index based on the company's strategic alignment with the clean tech market. However, the company rating is average compared with other firms in the index with regard to many of the analytical factors covered in the area of product stewardship.

## **Disclosure:**

Headwaters provided some information and a description of the nanoparticles used in their catalyst technology, including such facts as size and type of particles.

## Life Cycle Analysis:

Headwaters is not currently conducting LCA's on their product lines as they are still in the development stage.

## Testing:

Headwaters has not submitted its particles or products for independent testing. However, the company is considering submitting its nanocatalysts to the EPA as part of the EPA's voluntary program (see Chapter 4 of the Report). Management told us that submission would be contingent on an assessment of commercial viability. Ideally, we would expect Headwaters' entire product line to undergo thorough toxicity testing to mitigate any real risks associated with their nanocatalysts, especially the combustion catalyst.

## **Operational Quality:**

The manufacturing process for the nanocatalysts is a closed system minimizing worker exposure and potential health and safety risks. On the other hand, it is unclear how exposure is being minimized during some of the applications such as, the use of the combustion catalyst in coal.

#### Small Business Innovation Research:

Headwaters has not received an SBIR grant but did receive two grants from the Department of Energy for their nanocatalyst development.

## JMAR TECHNOLOGIES, INC.

Country:		United States
Ticker Symbol:		JMAR
Industrial Sector:		Industrial Technology
Combined IVA Rating:		N/A
Sub-Factor	s:	
Market Viability:		5.0
Product Safety:		N/A
Product Stewardship		N/A
Analyst:	Heather 646-237 hlangsn	r Langsner -0212 er@innovestgroup.com

#### SUB-FACTOR PERFORMANCE



#### **Outlook:**

JMAR has carried out nanoscale research and development for semiconductor fabrication for over 10 years. The company is now positioned to exploit its nanotech expertise by producing instruments and tools for the expanding nanotechnology and biotech industries. In the near-term the company is commercializing its BioSentry<sup>TM</sup> line of products this year for the continuous detection of microorganisms in water - an appropriate application for our index. The addressable market is estimated to be approximately \$500 million and the company intends for BioSentry<sup>TM</sup> to generate revenue while the company works to role out its line of nanotechnology-oriented products which have significance for the characterization and detection issue.

## **Overview:**

JMAR Technologies, Inc. was founded in 1987, went public in 1990, and is currently traded on the NASDAO SmallCap Market under the symbol JMAR. As a leading innovator in the development of laser-based equipment for imaging, analysis, and fabrication at the nanoscale, JMAR applies its technical and development expertise to create esoteric, high value-added equipment for the nanotech market. JMAR develops, manufactures, markets, and supports advanced laser, sensor, and custom systems for applications in the nanotechnology, biotech, semiconductor, homeland security, and water quality markets; however, the company recently restructured to focus entirely on nanotechnolgy development. Revenues in 2004 were \$10 million with net profits of \$1.9 million. Over 92 % of company revenues are derived from military contracts - the U.S. Department of Army Research being the most significant laboratory sponsor. DARPA just recently extended its contract with JMAR valued at \$7,580,000 added to its existing three-year \$10 million contract to continue development of X-ray masks for lithography and optics for NanoProbe. JMAR has approximately 70 employees.

#### **Top Ten Investors:**

JMAR top then investors include two private venture holders, Barclays, Calpers, Highbridge, and Condor Mellon among others.

#### **Strategic Profit Opportunity**

JMAR's line of high powered lasers and microscope products is relevant to our analysis for their possible application in bringing nanotechnology production to commercial levels. Moreover, these technologies may also be relevant to the detection and characterization of nanoparticles – an important factor in reducing uncertainty surrounding their use. These products will enable top-down mechanization of nanoscale features, nano-deposition, and visualization.

X-Ray Nano Probe: JMAR offers an array of related products based on the soft x-ray which has a longer wavelength that can penetrate without destroying biological material. This allows for 3D imaging of cells or polymer down to a spot size measured in 10's of nanometers. This intensely focused X-ray beam creates a nano-plasma in materials of interest that can be used to analyze the chemical structure of materials, or to fabricate materials, all at the nano-scale. The company's promised 20 nm resolution may prove critical to in-lab research, process development, and quality control for nano-materials. For example, a company making a corrosion resistant surface treatment will need to analyze the chemistry of the surface in order to determine if the desired property as been achieved. By adjusting the wavelength of the spot, JMAR can tailor the types of material surface or bulk material that is being surveyed. The plasma can be imaged using spectrometer or optical imaging. We anticipate that this technology has massive scaling up potential and will be relevant for applications like forensics and other unforeseen capabilities. Think the RadioShack Multimeter.

**Compact X-ray:** This prototype can create an x-ray of 3.37 nm. For wavelengths at this scale, light cannot be readily absorbed by oxygen – but they can be absorbed by carbon and other organic matter. This is applicable for internal 3D viewing. By 2006 the company expects to have a Beta version under test mode and has various labs have expressed interest. The company conducted a study to identify the potential addressable market for NanoProbe and identified about 1500 institutions worldwide that would have need of the NanoProbe's 3D imaging of single cells and polymers to 20 nm resolution in the laboratory. Applications in the pipeline include CVD and ablation methodologies.

These technologies will be complimentary to the products being offered by companies like FEI and Veco. Specifically the nano-probe family of products is complimentary to FEI's TEM but with better resolution and the ability to view organic matter.

**BioSentry<sup>TM</sup>** : JMAR is actively negotiating beta test and on sight tests for BioSentry<sup>TM</sup> an earlywarning system that provides continuous, real-time surveillance, detection and classification of waterborne microorganisms. Typical installations will consist of multiple, laser-illuminated sensor units, configured and networked to meet the specific needs of bottled water suppliers, water treatment plants, water distribution systems, and critical facilities.

## Risk

JMAR falls into the category of instrumentation suppliers and would therefore not face the same risk as a company working with and supplying free engineered nanoparticles or intermediates containing nanoparticles.

Importantly the company's products could be applied to the characterization and detection of nanoparticles in research and production - which has relevance to reducing uncertainty about the use of nanoparticles in production. In the near-term these high-powered microscopes will be relevant to quality management concerns which will be critical in creating batch consistency and solving other nano-related large scale production challenges.

## LUMERA CORPORATION

Country:		United States
Ticker Symbol:		LMRA
Industrial Sector:		Specialty Chemicals
Combined Rating:	IVA	N/A
Sub-Factor	rs:	
Market Viability:		4.0
Product Safety:		5.0
Product Stewardship	<b>):</b>	3.7
Analyst:	Heathe 646-237 Hlangsn	r Langsner -0212 er@innovestgroup.com

#### SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

Lumera scored above group average on all three sub-factors and their overall rating outlook is positive. While the company's product platform does not necessarily rate as well in the index relative to companies offering more direct and obvious beneficial applications, the company's "lab on a chip" application should significantly convert pharmaceutical trial time from months to a matter of days and hours reducing costs and lead-times. The company's core technology platform is the basis for several product lines and the company recently sent its first shipment to Raytheon in Q3 2005.

#### **COMPANY OVERVIEW**

Lumera is a development stage company using proprietary methods to develop nano-materials and polymers possessing unique capabilities that significantly improve core technologies of several high growth industries including bioscience, communications and computing and wireless networks. The company also has collaborative ventures with industry partners, governmental agencies and leading academic centers which have allowed them to pioneer an array of intellectual property and products. Most of the company's existing products, potential products and contract research services are built upon its proprietary polymer nanomaterials and process. The company is targeting three markets: bioscience, communications and computing and smart wireless antennas. Currently, the focus on these markets is 50%, 40%, and 10% respectively. The Bioscience platform is pursuing market applications in protein analysis and identification. genomic analysis and diagnostics. The Communications and Computing platform is pursuing market applications in optical modulators for telecom components; high speed signal processing and optical interconnects. The smart Wireless antennas address customer specific niche applications. Currently the company has three different governmental contracts with the Department of Defense and is set to ship product to Raytheon. The company was recently added to the Russell Microcap Index. At end of FY2004 Lumera reported having 40 employees.

**Top institutional investors**: Paulson Capital Corp, Hauck & Aufhäuser Investment Gesellschaft S.A., Vanguard Group, Inc., California Public Employees' Retirement System, Highbridge Capital Management, LLC, Condor Capital Management, Inc.

## MARKET VIABILITY

Lumera has six product lines, three in the bioscience area, two in electro-optic devices and one in wireless antennas. The company's value drivers for these products are high throughput, low cost bioscience devices and faster and low power communication components. Lumera rated well for its efforts to communicate with the technical community and in conducting customer outreach to gain further input and raise awareness about their platform. The current status of the market viability for each division is described below.

**Biosciences:** The Company has three bioscience products: Nano-Capture<sup>TM</sup> Arrays, NanoCapture– HPT<sup>TM</sup> Arrays and Proteomic Processor<sup>TM</sup> Readers. These bioscience products target a \$2.3 billion dollar proteomics market (projection for 2008). The NanoCapture<sup>TM</sup> Arrays are currently being ramped up for full production and the company is expecting to fill orders by the end of O3. The NanoCapture-HPT<sup>TM</sup> Arrays and the Proteomic Processor<sup>TM</sup> Readers are both currently in the prototype phase and are undergoing customer review and evaluation. The bioscience applications are patented and proprietary. They represent a disruptive, beneficial and low risk technology.

**Electro-Optic Devices:** The Company has two product lines in this area: Electric-optic (EO) Modulator and High Speed Optical Interconnects. The current contract with Raytheon is for the EO Modulators while the High Speed Optical Interconnects are still in the prototype phase. Currently, products in this area are being evaluated by one US semiconductor company, a Japanese telecom company, and various government agencies. The market for EO modulators, not including government contracts, is expected to be \$1.2 billion by 2008. The EO applications and devices are also patented and proprietary.

**Smart Wireless Antennas & Systems:** This area of the company only has one product: AccuPath<sup>TM</sup> Smart Antenna that is currently in the prototype phase.

## **PRODUCT SAFETY**

Lumera scores well in the product safety area because their product lines are derived from molecularly modified polymers that represent very little risk at any stage in the lifecycle.

## PRODUCT STEWARDSHIP

Lumera's product stewardship score was slightly above average when compared to other companies in our analytical set. The company spoke to every issue we examined in this area of our due diligence; however, their responses did not suggest a truly proactive or strategic approach to dealing with these issues.

## **Disclosure:**

Lumera disclosed detailed product information. Given that the firm is not working directly with free engineered nanoparticles, the company's level of disclosure was acceptable.

## **Operational Quality:**

The company is not working with free nanoparticles. Forming nanoscale features in polymers requires a significant amount of chemical processing. This issue would be relevant to Innovest's normal review of operational quality – a subfactor in the assessment of the ability to reduce costs and minimize regulatory and other types of operations related risk. Lumera responded that they employ measures to minimize waste and reduce cost by reusing chemicals used in processing.

## NALCO HOLDING COMPANY

Country:		United States
Ticker Sym	nbol:	NLC
Industrial Sector:		Water Utilities
Combined IVA Rating:		AAA
Sub-Factor	rs:	
Market Viability: Product Safety:		5.0 2.8
Analyst:	Heather 646-237 hlangsn	r Langsner -0212 er@innovestgroup.com

## SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

Nanotechnology will be highly relevant to Nalco's water technology and water treatment systems. The company is capitalizing on its superior positioning in this market to advance colloidal, membrane and other relevant technologies and we are generally encouraged by the firm's favorable financial outlook. While the company's disclosure lacks appropriate detail relative to competitors, our discussions with the firm support our moderate estimation that Nalco has the intellectual capital and managerial capacity to reduce nano-oriented risk and deliver beneficial applications to the water treatment market.

#### **COMPANY OVERVIEW**

Nalco is the leading provider of integrated water treatment and

process improvement services, chemicals and equipment programs for industrial and institutional applications. The company currently serves more than 60,000 customer locations (industry, government and institutions) in 130 countries representing a broad range of end markets. It has established a global presence with over 10,000 employees operating in 130 countries, supported by a comprehensive network of manufacturing facilities, sales offices and research centers. In 2004. Nalco achieved sales of \$3 billion. As of 2Q guidance, nominal sales are up with each of the company's four strategic business segments; Energy Services grew 11.3 percent, followed by Paper Services, up 9.4 percent, and Industrial and Institutional Services, up 9.0 percent. Other segment sales nearly doubled. Second quarter earnings statements remain consistent with earlier guidance. Labor relations issues faced by Finnish paper customers slowed business briefly in the second quarter; however the company does not believe that the issue is material. Price increases are expected to offset raw material price increases by year end.

#### MARKET VIABILITY

Nalco is the market leader in water treatment chemicals. Nalco sells a variety of chemicals that help control corrosion and prevent build-up, scaling, and microbial fouling of water-handling equipment. The company is well situated in terms of product viability and the fact that Nalco has long-term relationships with its customers and that more than 80% of the largest customers have been doing business with Nalco for more than 10 years ensure a positive outlook for its water business going forward. The company's Industrial and Institutional Services segment which includes water clarification and wastewater treatment represents 45% of the

company's revenues and currently holds 19% of the global market followed by General Electric at 11%.

The colloidal technologies group is the most relevant with regard to any future nano-oriented development and we note that the company already makes and markets nanoscale silica's and alumina/silica's.

Nalco is strategically aligned with several environmental technology objectives. Among other environmentally relevant applications is a polymer line developed in waterbased salt solutions that keep oils and surfactants from being released into the environment during water treatment. In addition, a new 3D TRASAR® cooling water stress management program automatically adjusts scale, corrosion and microbiological contamination controls to optimize water, energy and chemical use in cooling water operations. The water applications will be particularly critical for the company's Pacific Rim customers. The company has also received a grant by the Spanish government to develop environmentally oriented technologies that may contribute to job growth in that country.

#### PRODUCT SAFETY

While Nalco is only focusing its nano research on the colloidal technologies group right now, it is likely that nanoscience will be relevant to a wide variety of products across many business segments. For now, the relevant applications under study may involve the use of nanoparticles in catalysis, chemical mechanical planarization (CMP) and inorganic/organic composite coatings. Nalco was relatively open about the particles being used and we note that the company is engaged in the movement to contribute to the body of knowledge on the use of nanoparticles.

## PRODUCT STEWARDSHIP

Nalco was one of the first companies to strongly urge the American Chemistry Council to develop a nanotechnology group. And the ACC is now actively engaged with the U.S. EPA to develop appropriate reporting and oversight structures. Nalco is a signatory to the EPA voluntary nano-reporting initiative announced this year and the company received a Green Chemistry Award in 1999 (for the polymer line described above).

Nalco has received several Illinois EPA awards for developing environmentally sensible programs.

Nalco has also received a grant from the Finnish government for technology development related to papermaking including nanoscience-based materials.

## PLUG POWER, INC.

	United States	Country:	
	PLUG	Ticker Symbol:	
	Electrical	Industrial Sector:	
	Components &		
	Equipment		
	N/A	Combined IVA	
			Rating:
		ors:	Sub-Facto
	4.3	Market Viability:	
	4.5	Product Safety:	
	4.2		Product
		nip:	Stewardshi
	Langsner	Heathe	Analyst:
	0212	646-237	-
n	r@innovestgroup.com	hlangsn	
	4.3 4.5 4.2 Langsner o212 r@innovestgroup.cor	ors: ability: afety: hip: Heathe 646-237 hlangsn	Rating: Sub-Facto Market Via Product Saf Product Stewardshi Analyst:

## SUB-FACTOR PERFORMANCE



## **RATING OUTLOOK**

With a stated goal to deliver economic, social, and environmental benefits in terms of reliable, clean. cost-effective power Plug Power Inc is clearly relevant to our analysis. While mass adoption of fuel cell technology is more of a long-term goal, the company has several products on the market today. We are particularly interested in the company's efforts to align itself with the general trend away from large facility generation to on-sight renewable energy solutions. In that vein the company has product on the market and is generating revenue while its nano-specific applications are under development.

Note that the nanotechnology application being studied does not involve working with free nanoparticles. PLUG would be another example in our index of a firm involved in nanotech applications but with minimal risk related to particle exposure.

#### **COMPANY OVERVIEW**

Plug Power Inc. is a development stage enterprise involved in the design, development and manufacture of on-site energy systems for energy consumers worldwide. The company is focused on an architecturebased platform approach to product development, which includes proprietary proton exchange membrane (PEM) fuel cell and fuel processing technologies, from which multiple products are being offered or are under development.

As of Feb. 3, 2005, the company was offering for commercial sale its GenCore product, a back-up power product for telecommunications, broadband, utility and industrial uninterruptible power supply (UPS) applications. The company was also developing additional products, including a continuous power product, with optional combined heat and power capability for remote small commercial and remote residential applications; and an on-site hydrogen generation product for use in a variety of industrial gas applications.

The GenCore product line is focused on providing backup, directcurrent (DC) backup power products in a power range of 2-12 kilowatts for applications in the telecom, broadband, utility and industrial UPS market applications. Its GenCore products are fueled by hydrogen and do not require a fuel processor. In the fourth quarter of 2003, Plug Power began initial shipments of the GenCore 5T product, and shipped 112 units through Dec. 31, 2004.

The company continues to advance the development of its other tech-

nology platforms: Plug Power plans to continue to develop its GenSys into a platform that is expected to support a number of products, including systems fueled by liquefied petroleum gas (LPG) for remote applications and, eventually, gridconnected light commercial and residential applications fueled by LPG or natural gas.

GenSite hydrogen generation systems are designed to provide a customer's facility with pure, compressed hydrogen gas at the point of use. The core autothermal reforming technology used in GenSite has been proven in over 380 field installations and over one million hours of field run time.

Plug Power is also developing technology (Home Energy Station) in support of the automotive fuel cell market under an agreement with Honda R&D; and its GenCore platform is expected to provide the basis for the development of the Gen-Drive product, a hydrogen-fueled battery-replacement module for material handling equipment.

At end of FY2004 sales were \$16.14 million and the company has granted underwriters a 30-day option to purchase up to an additional 1,650,000 shares of its common stock. The Company intends to use the net proceeds of the offering for working capital purposes, funds for operations, capital expenditures, research and product development, potential future acquisitions and other general corporate purposes. At end of FY 2004 the company had 330 employees. Source: Compustat and Thomson/FirstCall.

#### **Top 10 Holders:**

Earley (Anthony F Jr) Detroit Edison Co DTE ENERGY CO Stewart (Richard R) GE Asset Management Inc. Mechanical Technology Inc Smith Barney Asset Management Artemis Investment Management, L.L.C.

Security Management Company, LLC

# Barclays Global Investors, N.A. MARKET VIABILITY

Plug Power is highly focused on demonstrating to investors it ability to produce present day power solutions that will contribute to the rapid adoption of fuel cell technology in the future. The company's research platform is based on a proprietary proton exchange membrane (PEM) fuel cell and fuel processing technologies. Nanotechnology is highly relevant to this - in manipulating the atomic building blocks of fundamental matter in a controlled and planned manner PLUG can develop highly programmable fuel cell membrane technologies that significantly increase efficiency and durability. Plug Power is in collaboration with Albany NanoTech, an academic venture to research the use of nanoscience in providing proton exchange membranes that will be competitive with preexisting energy solutions. While these applications are in development, the company is receiving orders for its GenCore® backup fuel cell systems. Tyco recently ordered 35 systems getting the firm ever closer to reaching its sales goal of 300 this year.

#### Key relationships:

GE Fuel Cell Systems since 1999

DTE Energy Technologies since 1997

Honda since 2002

Vaillant since 1999

#### **Product Lines:**

While nano-specific product is under development, back-up and onsite power generation solutions are on the market. This includes backup power products for telecoms, broadband and industrial uninterruptible power supply. Other products include battery replacement modules for material handling equipment; on-site hydrogen generation for industrial gas applications; combined heat and power products for remote residential and small commercial application and home refueling systems.

GenCore®: Plug Power has an established channel to market for GenCore<sup>®</sup> with three major buyers in the U.S. including Tyco Electronics Power Systems, Inc. On the international front the company has six buyers including Tatung in Taiwan. On August 9 the company announced the inclusion of a tax credit with the recently passed energy bill that should have a positive effect on sales. The Energy Bill recently signed by the president allows a 30 percent tax credit up to \$1,000 per kilowatt on the purchase of fuel cells used in residential or commercial applications. The tax credit will be available in January 2006 and specifically includes telecommunications carriers among the eligible end users for the tax credit. The telecom industry is a key market for the GenCore product and accounts for a major portion of the more than 170 GenCore backup systems sold year-to-date. The company's stated yearly sales goal for GenCore is 300.

**GenSiteH**<sub>2<sup>TN</sup></sub>: GenSite makes use of proprietary fuel processor technology combined with commercially available components to form what is essentially an on-site hydrogen gas generator. **The Energy Bill also includes an authorization for \$3.7 billion for hydrogen and fuel cell research and development**, demonstration and market transition over the next 10 years. PLUG expects to install and operate a number of GenSite systems in 2005. The company shipped its first GenSite system and it was fully operational in March 2005.

#### **PRODUCT SAFETY**

PLUG is currently researching ways that nanotechnology will be relevant to the development of highly efficient and durable membrane technologies. The risk associated with the processes involved with membrane production are considered minimal at this stage although we note that several of the fuel cell companies are working with metal oxide powders (see Nanodynamics) which may involve more exposure risk.

## PRODUCT STEWARDSHIP

We note the company's emphasis on Lean Manufacturing which may contribute to the overall reduction of material input and production footprint. However there may be a more general opportunity for the firm to take into consideration the life cycle of its entire product line up.

For example, the Swiss/Swedish electrical equipment producer ABB Ltd. has developed a system for informing customers and investors of the life cycle implications for all of its products from production of raw material to the recycling of material when the products are taken out of service. In each phase of the life cycle there are environmental aspects, e.g. loss of energy and production of waste. The EPDs provide quantitative information on all these aspects in comparable terms, for example use of non-renewable resources, use of renewable resources in each one of the phases.

Given Plug Power's focus it is likely that the firm is aware of the LCA concept.

## SPIRE CORPORATION

	United States
nbol:	SPIR
Sector:	Electrical
	Components &
	Equipment
IVA	N/A
rs:	
bility:	5.0
ety:	4.2
	3.0
<b>):</b>	-
Heathe	r Langsner
646-237	-0212
hlangsn	er@innovestgroup.com
	hbol: Sector: I IVA rs: bility: ety: p: Heather 646-237 hlangsn

## SUB-FACTOR PERFORMANCE



#### **RATING OUTLOOK**

Spire Corporation's strong Clean-Tech focus combined with commercialized products gives them a positive outlook going forward. The company services four business areas: biomedical, solar equipment, solar systems and optoelectronics. While there is some risk involved in the biomedical area of the company, the focus of the other areas on solar equipment and systems will help to offset and mitigate any perception risk. Compared to other companies in our index, Spire's product stewardship score was low due to a lack of transparency. We recommend that Spire look to companies such as ApNano and ALTI for examples on how proactive firms are mitigating perception risk through product stewardship. This is especially

relevant for the company's biomedical business unit which could be impacted by perception risk, regulation, and real risk due to the invasive nature of the nano product.

#### **COMPANY OVERVIEW**

Spire Corporation is a diversified nanotechnology company that specializes in developing, manufacturing and commercializing highlyengineered products with expertise in materials technologies, surface science and thin films. The company serves the solar energy, biomedical, telecommunications and defense industries worldwide with products and services based upon their common technology platform. Revenues for 2004 mark the fifth consecutive year of revenue growth for the Company. The Company's revenues for the past five years have ranged from \$12.8 million to \$17.2 million. The top institutional investors with positions in Spire Corporation are AMH Equity, L.L.C., Dimensional Fund Advisors, Inc., Hauck & Aufhäuser Investment Gesellschaft S.A., Mellon Private Wealth Management, Boston Trust & Investment Management Co. and Northern Trust Investments, N.A.

## MARKET VIABILITY

Spire Corporation stands out among other nanotechnology companies because they have been selling products for many years. Furthermore, the company's focus on CleanTech is seen as a viable and forward thinking market strategy that will create value in the long term. Spire is using nanotechnology across four business platforms: biomedical, solar equipment, solar systems, and optoelectronics. The current status of the market viability for each division is described below.

**Biomedical:** Spire provides surface treatments to manufacturers of

medical devices that enhance the durability, antimicrobial characteristic or other material characteristic of their products. Spire has an exclusive patent license agreement with Bard Access Systems, Inc. for a hemodialysis split-tip catheter. The company also develops and markets devices for the treatment of chronic kidney disease.

Solar Equipment: Spire develops, manufactures and markets specialized equipment for the production of terrestrial photovoltaic modules from solar cells. The company's equipment has been installed in more than 150 factories in 42 countries. . In fact, more than 90% of the photovoltaic modules on the market today were manufactured using Spire equipment. The Company also has an agreement with Hyundai Heavy Industries (HHI) to manufacture photovoltaic (PV) modules for use in the growing Korean and Asian solar PV market and is expected to ship module testers to First Solar, LLC this September.

Solar Systems: Spire also manufactures and markets solar photovoltaic systems suitable both for stand-alone emergency power backup and for interconnection into the electric power grid. The most successful example of the company's solar PV systems in use is in Chicago, IL where Spire has worked with the City of Chicago, the local utility company and the State of Illinois to provide customers in the metropolitan area with gridconnected distributed photovoltaic systems. In fact, Spire's primary business unit is titled Spire Solar Chicago.

**Optoelectronics:** In the optoelectronics area, Spire provides custom compound semiconductor and thin film wafer and device fabrication services to customers in communications, biomedical and aerospace-defense industries.

## PRODUCT SAFETY

Spire Corporation's focus on thin films and surface science as opposed to engineered nanoparticles suggests they have minimal risk. The Company's biomedical business unit represents most of the risk due to the invasive nature of the products. However, the products in this area will be subject to FDA regulations helping to minimize most risk issues. Besides the biomedical area, the Company's primary safety concerns should be with the disposal of their products and the potential for environmental harm. We will continue to monitor the company's progress throughout the year in dealing with these issues.

#### **PRODUCT STEWARDSHIP**

While Spire did provide some information, this remains an area of improvement for the company prior to review next year. The Company should look to other pro-active nano-companies for ways to improve product stewardship as it will help with any product backlash due to consumer misinformation about nanotechnology. We chose Spire for our index because of their Clean-Tech focus and feel improvement in this area would only increase the company's value going forward as public awareness of any risks or benefits should only increase market acceptance.

#### **Disclosure:**

Despite the relatively low risk of the company's nano applications, disclosure should still be of importance to Spire. The company needs to provide more information about their products, especially in the biomedical area, in the future. Even with minimal risk, Spire could be impacted by any consumer rejection of nano products if they are not transparent about the process and potential risks associated with their biomedical products.

#### Life Cycle Analysis (LCA):

This area is of less concern for Spire Corporation as all of their products appear to be of nanoscale but not actually nanoparticles. Spire's primary LCA concern should be end of life, as it is important for them to examine the disposal of their products. The Company may also need to consider their manufacturing process and potential for chemical waste or harm. We will be monitoring their progress in this area.

## **Testing:**

Spire Corporation did not provide information about testing being conducted on their products. It is assumed that the biomedical business unit is relying on some type of FDA approval. We look for this to be an area of improvement for Spire prior to review next year.

## **STARPHARMA GROUP**

Country:		Australia
Ticker Symbol:		SPL
Industrial Sector:		Pharmaceuticals
Combined IVA Rating:		N/A
Sub-Factor	rs:	
Market Viability:		4.9
Product Safety:		3.0
Product Stewardship	):	4.1
Analyst:	Heather 646-237 hlangsne	r Langsner -0212 er@innovestgroup.com

#### SUB-FACTOR PERFORMANCE



## **RATING OUTLOOK**

Starpharma's performance on two of our three sub-factors is above our analytical set average and their rating outlook is positive. Although the company is not currently selling product, it has the ability to mitigate perception risk associated with nanotechnology due to its focus on beneficial global health products. The company's product application and product stewardship makes it stand out as a leader in our index. Starpharma's initial product is VivaGel<sup>TM</sup>, a topical microbiocide gel with the potential to inhibit the transmission of HIV, genital herpes, Chlamydia and other sexually transmitted infections (STIs). The target market for this product is global with initial roll-out in the developed world. The company has embarked upon clinical trials with VivaGel<sup>TM</sup> which will support its commercialization in all major markets. The FDA new drug trials follow a fairly standard sequence, to demonstrate safety, tolerability, and efficacy. Results from trials to date are positive. Risk of failure at a later stage is real however, and that may be of concern for investors. The forward thinking actions of the company suggest quality management that will be able to mitigate most perceived and real risks impacting future investors interested in the nanopharma market.

#### **COMPANY OVERVIEW**

Starpharma is an Australian dendrimer-based pharmaceutical nanotechnology company that specializes in drug development and application against major diseases such as HIV. The company also has a large equity interest in Dendritic Nanotechnologies Inc. (DNT), a US based company. Starpharma has a focused commercialization strategy to use dendrimer nanodrugs against a wide range of diseases fulfilling unmet market needs. The strategy incorporates much international collaboration (e.g. DNT, The Dow Chemical Company, ReProtect Inc, Johns Hopkins University and University of Washington), a large patent portfolio, investments in synthesis and applications of dendrimer technology and partnerships and licensing agreements with pharmaceutical companies. The company was just awarded the 2005 Frost & Sullivan Growth Strategy Leadership Award for its development of revolutionary products, specifically its VivaGel<sup>TM</sup> product. Starpharma was given this award based on unrivalled performance over the past year for the following reasons: revolutionary products in a new market sector, the most developed lead product to date, pipeline diversification across a range of indications, and strong market positioning.

American Depositary Receipts (ADRs): Starpharma's ADRs trade under the code SPHRY (CUSIP number 855563102). Each Starpharma ADR is equivalent to 10 ordinary shares of Starpharma as traded on the Australian Stock Exchange (ASX: SPL). The Bank of New York is the US depositary bank.

## MARKET VIABILITY

Starpharma has the ability to minimize perception risk for pharmaceutical nanotechnology products because of their focus on global health applications. The company's main development projects are focused on products for the following areas: sexually transmitted infections, respiratory viruses, systemic viral diseases, and oncology. The current status of the market viability for each division is described below.

**Sexually Transmitted Infections:** The Company's primary product is VivaGel<sup>TM</sup>, a topical vaginal microbiocide that can potentially reduce or prevent the transmission of HIV and other STI's when applied prior to sexual intercourse. The company has an active IND on VivaGel<sup>TM</sup> and is currently conducting human clinical trials. HIV and STI's already affect over 120 million people and cost the US over \$10 billion annually. These products are also of particular use to the rest of the population interested in prevention of sexually transmitted infections.

The following product lines are all in the discovery stage.

**Respiratory Viruses:** The Company has an active dendrimer-based drug discovery program devoted to respiratory pharmaceuticals to address several respiratory diseases including respiratory syncitial virus (RSV).

**Systemic Viral Diseases:** Starpharma is in early development of a novel dendrimer hepatitis B virus (HBV) therapeutic agent. Currently, only a vaccine is available for HBV treatment which infects approximately 350 million people worldwide.

**Oncology:** The Company also has projects with applications to cancer therapy. Fr example, Starpharma is using its drug technology for the reduction of angiogenesis, a process associated with the growth and spread of cancer.

## PRODUCT SAFETY

Starpharma is cognizant of the potential risks and impact of regulation on their business and are taking a proactive approach to mitigating these risks. Having elected to pursue the NDA route for VivaGel<sup>™</sup>, the company is working with government agencies such as the FDA to ensure all necessary data is available for the product. In doing this, the company is working with universities and private service providers to generate the requisite full toxicity and pharmacokinetic assessments. Starpharma has already completed one human clinical trial with their product - which represents the first time a defined nanopharmaceutical has been tested on humans. VivaGel<sup>™</sup> is not believed to be especially invasive, in that it is applied as a topical microbicide. Furthermore, the active ingredient is of relatively large molecular size and has surface properties that should prevent passage into cells thus reducing health concerns related to free nano particles. However, other products in Starpharma's pipeline are engineered to pass into cells and risk associated with this increased invasiveness should be recognized as similar to most mainstream pharmaceutical products. We have classified nanopharmaceuticals as "free" in that they tend not to be bound into solid matrices. VivaGel<sup>TM</sup> is formulated in a gel however, blurring this classification,

and perhaps reducing risk. In general, we are satisfied that the management appears capable of mitigating any real or perceived risks associated with the company's products.

#### PRODUCT STEWARDSHIP

Starpharma is another nano pure play in our index that appears to be a market leader in the area of product stewardship, representing one of the few transparent companies we screened. The company's proactive approach towards product stewardship, especially operational quality, is likely to yield real value in the future as it is better prepared to deal with any global regulatory changes involving nanoparticles. Starpharma also stands to have global acceptance and market reach due to the application of standards and processes such as ICH (International Conference on Harmonization) guidelines, Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) to ensure compliance with all major regulatory agencies. The company provided information about disclosure, testing, operational quality, and small business grants, all issues we examined in this area of our due diligence.

## **Disclosure:**

Starpharma has disclosed the particle and provided it for assessment by the FDA. They were one of the few pharmaceutical companies we interviewed that provided particle information and disclosure about the nanoparticle being used, full information about dendrimers is also included on the company's website. This is in part a consequence of the advanced stage of development of VivaGel<sup>TM</sup>: as all details of this nature must be disclosed prior to testing in humans. A beneficial side effect is that investors get a clearer understanding of the technology, thus reducing risk involving disclosure issues.

#### Life Cycle Analysis:

In line with current FDA requirements, the Company is not yet conducting life cycle analysis on their dendrimer products. Given the partially free nature of the nanoparticles and the ability of any pharmaceutical to potentially accumulate in the environment through waste streams, we will expect continued improvement in this area during our annual reviews and as the company's product lines advance toward commercialization.

## **Testing:**

Starpharma is submitting its products to the requisite regulatory processes such as that of the FDA. Due to the pharmaceutical nature of their products, we can expect that each product candidate will undergo thorough toxicity testing as part of the process of bringing it to market. Furthermore, Dendritic NanoTechnologies (DNT), 33% owned by Starpharma, has worked with both CBEN and the FDA by supplying dendrimers for testing and characterization.

## **Operational Quality:**

Starpharma is a leader in the area of operational quality especially for a pharmaceutical company. The company operates in compliance with FDA regulations and also complies with Good Laboratory Practices and Good Clinical Practices. Furthermore, Starpharma requires its contractors to meet similar quality and regulatory standards. The company is cognizant of the risk related to its product and has implemented quality systems and risk management procedures to reduce risk and increase the likelihood of regulatory approval. Starpharma's approach to operational quality is important for investors as it is a sign of quality management and represents the potential for increased future value.

## Small Business Innovation Research:

Starpharma has not received any SBIR grants. However, the company has received grants from the National Institute of Health (NIH), the US government, and the Australian government (they have received two START grants). Public funding for these areas is known to be available from agencies such as the Bill Gates Foundation, the Rockefeller Foundation, the World Health Organization (WHO), and the NIH. Starpharma is actively engaged in pursuing funding opportunities with some of these bodies. Starpharma has also recently been awarded a grant of AUD \$5.6 million over four years under the Australian Government's Pharmaceutical Partnerships Program.

#### **VEECO INSTRUMENTS, INC.**

Country:		United States	
Ticker Symbol:		VECO	
Industrial Sector:		Industrial	
		Technology	
Combined IVA		N/A	
Rating:			
Sub-Facto	rs:		
Market Viability:		5.0	
Product Safety:		N/A	
Product		N/A	
Stewardship	p:		
Analyst:	Heathe	Heather Langsner	
-	646-237	-0212	
	hlangsn	er@innovestgroup.com	

#### SUB-FACTOR PERFORMANCE



### **RATING OUTLOOK**

At this point it is well understood that the instrumentation companies are critical players in taking nanotech to the next level. Investors are looking at these firms for their contribution to innovation and their potential role in scaling up production to commercial capacity. Moreover, the companies focusing on the development of visualization equipment play an important part in the detection and characterization of nanoparticles. This is important to reducing uncertainty regarding their use. It is not entirely unreasonable to consider the possibility that FEI and VEECO will eventually merge. The technologies of both firms are complimentary. One specializes in the ability to view the interior of the particle while the other specializes in viewing the exterior particle. There is literally no particle related

risk to investors when investing in the instrumentation companies.

### **COMPANY OVERVIEW**

Veeco's slogan is "solutions for a nanoscale world". This includes Process Equipment and Metrology technologies for the data storage, semiconductor, compound semiconductor, wireless and lighting markets. These technologies continually require new techniques for nanoscale fabrication and universities/laboratories involved in nano research represent the primary addressable market for the company's broad line of atomic force microscopes (AFM), optical interferometers and stylus profiles for metrology. During 2004, the company split out its former Process Equipment segment into two separate reportable segments. The first segment, Ion Beam and Mechanical Process Equipment (34.3% of 2004 net sales), combines the etch, deposition, and dicing and slicing products sold mostly to data storage customers. The second segment, Epitaxial Process Equipment (24.0%), includes the Molecular Beam Epitaxy (MBE) and Metal Organic Chemical Vapor Deposition (MOCVD) products primarily sold to HB-LED and wireless telecommunications customers. Veeco's Metrology equipment (41.7%) is used to provide critical surface measurements on semiconductor devices and TFMHs. This equipment allows customers to monitor their products throughout the manufacturing process in order to improve yields, reduce costs and improve product quality.

Revenues were \$103.4M, up 4% from Q204 and 10% above Q105; above guidance. Approximately 17% of Veeco's net sales for 2004 constituted revenues from part sales, service and support. In 2004, 29% of Veeco's sales were to scientific research and industrial customers, 32% to data storage customers, 25% to HB-LED/wireless customers and 14% to semiconductor customers. Sales to Seagate Technology, Inc. accounted for 10%, 11% and 13% of total net sales in 2004, 2003 and 2002, respectively. The company had approximately 1,261 employees at end of FY 2004 and 384 of them are involved in manufacturing.

The company is establishing a nanotechnology center in Bangalore, India. The Veeco-India Nanotechnology Laboratory will be jointly operated with the Jawaharlal Nehru Center for Advanced Scientific Research (JNCASR). The JNC promotes scientific research in interdisciplinary areas of science and engineering. Source: Compustat and Thomson/FirstCall

## **Top Ten Institutional Holders:**

Capital Research & Management Co. Longwood Investment Advisors, Inc. Capital Guardian Trust Co. Barclays Global Investors, N.A. Royce & Associates, LLC Lehman Brothers, Inc. TCW Asset Management, Co. The Clark Estates, Inc. P.A.W. Partners MARKET VIABILITY

Veeco predicts that its growth prospects are rooted in fundamental developments at the nanoscale. These market trends include:

- Key developments in data storage: Continued growth of the market for 80 GB hard drives and rapid progress toward 120 and 160 GB programs. Estimated growth in demand for minidrives;
  - Semiconductor Metrology: Veeco has a line of automated, in-line 3-D Atomic Force Microscope technology for metrology at the 90 and 65 nm

scale. Semiconductor metrology sales grew from \$3 billion in 2002 to 4.5\$ billion in 2005 according to VLSI Research;

- Chemical Vapor Deposition: The Company predicts that its metal organic chemical vapor deposition (MOCVD) and molecular beam epitaxy equipment (MBE) will be critical to future development of compound semiconductor devices for use in Wi-Fi, and other consumer electronics applications. (Contact the analyst for further information on the competitive prospects in this market);
- Scientific research: Veeco points to the yearly increases in government funding around the world for nanotechnology and life science research. Veeco's AFM, SPMS, AFP, and line of optical and stylus products serve these markets. (contact the analyst for further analysis on other firms competing in this space).

#### PRODUCT SAFETY

Instrumentation providers are not subject to analysis of particle risk. However, these firms are selected for the index for the very fact that their products will contribute to the reduction of any uncertainty that may be associated with the use of certain types of engineered nanoparticles in the future.

#### **PRODUCT STEWARDSHIP**

Veeco is positioning itself to be at the forefront of moving nanotechnology from laboratory to commercial scale production. In light of this it would be relevant for Veeco to begin providing information to investors about what role its line of processing and metrology equipment may have in minimizing any production safety related issues that may be associated with working at the nanoscale. This may not be immediately relevant (particularly not for semiconductors or thin films) but should be in the future given the company's role in addressing the specific needs of the university and laboratory research markets where work is being done with particles. Over the long-term it is likely that VEECO will be fully integrated into commercial production scenarios at which point this type of disclosure would be an important differentiator for the company.

# 8. Brief Profiles of Research Group

## ENER1, INC.

Ener1 (EBB:ENEI) clearly would have a lot of work to do in order to be investment worthy, however the company's nano subsidiary holds some interest particularly in light of the company's overall focus on providing next generation fuel cell technologies. Note that the fuel cell industry is valued at approximately \$8 billion (source: Frost & Sullivan). The company's nano-related subsidiary, NanoEner, is developing advanced nanomaterials for use in Ener1's lithium batteries and other high-energy storage devices. The company claims that its nanotechnology-based manufacturing process can be used to produce electrodes (anode and cathode) with substantially more power output at higher discharge rates and with faster recharging times. These qualities meet the higher performance requirements for lithium-ion batteries for hybrids and other applications. The company believes that its nanotechnology process for producing electrodes, which is based on its proprietary vapor deposition process and equipment, represents a major innovation in battery technology that could greatly improve performance in many existing and emerging battery-powered applications. Also of note - Ener1 just announced that its joint venture with ITOCHU Corporation will enable subsidiary EnerDel to implement automated mass production processes for high-rate lithium batteries. The company's relationship with Delphi and ITOCHU will be particularly important.

## KONARKA TECHNOLOGIES, INC.

Konarka (private) is definitely relevant to Innovest's analysis. The company set to revolutionize photovoltaic energy conversion. Konarka's chemistry-based PV cells will be lightweight, flexible, inexpensive and hopefully more efficient than solar products on the market today. The product is still in development. Existing technologies get 15 percent efficiency while Konarka' thin film technology is still only getting about 7 percent under best conditions. However, when efficiency has been achieved, the company claims that the manufacturing process will be faster and less expensive. Red Herring named Konarka on its list of the most innovative 100 private firms noting that Konarka PV plastics will likely allow manufacturers to offer structures and devices that will both consume and generate power in a single unit. The company was apparently founded on the dream of Sukant Tripathy, a scientist/engineer intent on bringing affordable, clean energy to his homeland of India. We also like Konarka because it recently named a notable environmental consultant to guide senior management on the issues of health, safety and environmental sustainability strategy development. The long list of high caliber investors makes us think this is a company to watch.

## **MEMS USA**

MEMS USA (OTCBB:MEMS) works in piezo-crystal electromechanical systems for use in various metering and process control applications, and this is the primary reason the company is considered relevant to nanotechnology. The company is a major licenser of MEMS technology for application in sensing and industrial control. The pre-existing capacity for MEMS production is a precursor to the company's ability to produce nano-based detection systems within the next two years according to the Chief Technology Officer and Chief Operating Officer, Daniel Moscharitolo. Founded in 2000, MEMS USA is a developer and manufacturer of advanced engineered products, systems and services mostly for the energy sector. The company recently announced that its joint venture deal with Can-Am Ethanol One and Accelon® Energy System of Canada to establish a system that will convert 800 tons of Canadian wood waste per day into 160,000 gallons of clean burning fuel-grade ethanol. We understand that Merrill Lynch will provide a significant amount of funding upon finalization of the land deal. While the nano application is still in research, the company's current ventures fit well with the environmental strategic profit opportunity requirement. We continue to monitor progress in the development of nano-based systems for use in detection and control for the energy sector.

## NANODYNAMICS

We like Nanodynamics (private) for its focus on solid oxide fuel cells (SOFCs) a potentially better technological approach relative to Plug Power's (PLUG) polymer exchange membrane technology (PEM). According to the company's website, ND Energy is developing portable solid oxide fuel cell systems which may provide long lasting power in less volume and at a lighter weight relative to PEM cells. Another important feature is that SOFCs can operate on hydrocarbon fuels rather than pure hydrogen. Given the problems with generation, storage and delivery of hydrogen this effectively solves a major obstacle to the uptake of fuel cell technology. The result is still just water vapor and carbon dioxide byproducts. The challenge here is that solid oxide nanopowders may represent a certain EHS risk that would warrant caution. Investors may note that ND is a recipient of NASA Nanotech Briefs', Nano 50TM Award which recognizes the top 50 technologies, products, and innovators that have significantly impacted - or are expected to impact - the state of the art in nanotechnology.

## NANOMIX

Detection will be critical to minimizing any risks that could be associated with using free nanoparticles in production, Nanomix is launching a portfolio of devices based on its Sensation<sup>TM</sup> detection technology and is currently pursuing product lines in three categories: Industrial Detection Devices, Medical Breath Analysis Devices, and Bio Detection Devices. This scaleable, nanoelectronic devices use ultra-sensitive carbon nanotube sensing elements combined with proprietary chemistries and can be applied in a variety of applications. The benefits of this nanodetection technology include: low power consumption, small form factor and high sensitivity for access to critical information for health and for safety protection. Note the company's work with carbon nanotubes. Carbon nanotubes are a focal point for toxicity research. However, despite these potential risks, the company appears to be proactive in addressing such issues. This is important as it is the best way for companies to mitigate both real and perceived risks. Some examples of value for our analysis include: management's efforts to form partnerships with several corporate and academic institutions with regard to toxicity research, the award an SBIR grant, and the company's standing with several notable venture capital firms. Furthermore, it is important to note that the Company is currently selling product.

## NANOSIGHT

Bio-detection is an estimated \$500 million segment of the security industry that is growing at more than 10% annually. Mimicking the body's own processes for detecting viruses, Nanosight's Halo<sup>TM</sup> LM10 will be a critical tool in homeland security type applications. The technology can also be applied to the detection of waterborne nanoparticles in real time – an advantage in that current methods for biological agent

detection are slow. Moreover, the company claims that the technology will be a more affordable alternative to the scanning electron microscope (See the FEI profile). The company received 1 million pounds in funding and partnered with Smith Detection to develop bio-terrorism detection in 2004. Now it appears that Halo<sup>™</sup> LM10 is being distributed and is conceivably comparable with GE's line of bio-detection instrumentation.

## NANOSOLAR, INC.

Nanosolar has successfully developed a new generation of solar cells and panels using its proprietary throughput thin-film process technology, roll printing, which uses novel nanostructured components that are non-silicon based to "print" the most expensive layers of a solar cell. This technology allows Nanosolar to produce solar panels in a highly cost and capital efficient way that can match conventional silicon modules in both energy output and long-term durability. Nanosolar also appears to be proactive in the area of product stewardship. The company has secured funding from venture capital firms, the California Energy Commission and the National Science Foundation which recently granted Nanosolar a Phase II SBIR grant of \$750,000. Furthermore, Nanosolar has been awarded a substantial and competitive grant by the Defense Advanced Research Projects Agency (DARPA). Nanosolar also maintains collaborations with several research institutions including Stanford University, UC Berkeley, California Institute of Technology, and Sandia National Laboratories. Finally, Nanosolar has been named one of the Top 10 Clean Energy Companies and Top 100 Private Companies by Red Herring. The key to Nanosolar's future success and IPO potential is in their ability to provide commercial scale production of their products.

## NANOSYS, INC.

Despite backing out of its IPO last year, Nanosys remains a private nanotechnology company to monitor for future value. Nanosys has partnerships with several large corporations including Sharp, DuPont, Intel, Matsushita Electric Works and SAIC and a large patent portfolio capable of producing a disruptive technology. Nanosys' core technology is based on a proprietary class of inorganic nanostructures that are synthesized atom by atom in a controlled chemical environment. The technology allows Nanosys to create functional engineered nanostructures with specific chemical and physical characteristics such as composition, shape, size and surface chemistry for specific product applications. Some current application areas for its technology include flexible electronics, lightweight and conformal solar cells, memory, fuel cells and novel nanostructured surface coatings. We are interested in the ability of Nanosys' technology combined with core competencies of its many partners to develop and commercialize CleanTech products. We will monitor the company's ability to deliver product while maintaining a focus on product stewardship issues.

# 9. Explanation of Analytical Set

Our research focused on 200 publicly traded companies and 100 private companies listed on NanoInvestorNews.com.

We identified all the companies in this universe that had corresponding Innovest ratings and made sure that all companies listed on the Lux Nanotech Index<sup>TM</sup> were also included on that set. Lux is an internationally recognized leader in nanotechnology research. The ("Index") is a modified equal dollar weighted index comprised of 26 publicly traded companies which seeks to measure the performance of securities in the nanotechnology field. The Index was created by, and is a trademark of, Lux Research, Inc. The American Stock Exchange serves as the calculation agent for the Index.

To be included in the Lux Index, components must meet the following eligibility requirements:

- Be listed on the New York Stock Exchange or American Stock Exchange, or quoted on the NASDAQ National Markets or Small Cap Market systems.
- Have a minimum \$75 million market valuation.
- Have a minimum average daily trading volume over the preceding three months of 50,000 shares.

We held our universe to different criteria:

- We matched the Innovest coverage universe with the list of the 200 publicly traded companies listed on NanoInvestorNews.com. Of that set, we selected for our AA and AAA firms.
- The list of publicly traded and private companies was also subjected to an intensive search for firms offering strategic profit opportunities in the fields of water technology, renewable energy resources and innovations relevant to large scale medical needs.
- A list of 75 companies were contacted and interviewed. The non-response rate was approximately 2%.

Companies meeting our criteria for product strategy, risk management and product stewardship were eligible for the index.

Ten private development stage companies were also selected for their cleantech applications. Innovest will monitor their progress over time and update coverage in 2006. In the interim, comparative analysis will begin in the Aerospace/Defense, Chemicals, Semiconductors, Pharmaceuticals, Biotechnology, Healthcare and Equipment, Personal Care and Household Products sectors.

## **APPENDIX 1: CHARACTERIZATION OF THE NANOPARTICLE**

Unlike established chemical assessments, nano toxicity is different and more complex. The important characteristics to identify and assess in bulk engineered nanoparticles are **structure**, **surface**, **and size** along with traditional chemical parameters of volume and life cycle analysis. Variation in these three characteristics impacts toxicity requiring toxic assessments to be done on a *case by case basis*. This is not only burdensome but also expensive for companies (impacting their cash burn rate) and governments. Furthermore, the physical or chemical property that is most closely correlated with toxicity and therefore should be measured is unknown. Figure 22 below categorizes the various parameters for nanoparticle characterization.



# Figure 23: A look at the relevant parameters for characterization of nanoparticulate materials.

Source: Future Technologies Division of VDI Technologiezentrum GmbH<sup>45</sup>

<sup>&</sup>lt;sup>45</sup> Luther, Wolfgang. Industrial application of nanomaterials chances and risks: Technological Analysis., August 2004.

Currently, toxicity assessments are being conducted in university laboratories and governmental agencies throughout the world. In examining the existing body of research, it does appear that some nanoparticles are more toxic than others. However, the research has also shown that altering the size, the surface or the structure can significantly impact the toxicity<sup>46</sup>. Moreover, particles can be coated with other substances to reduce reactivity. Based on this current information, proper characterization of nanoparticles is likely to be a long and expensive process.

Globally accepted nomenclature and characterization standards are currently being addressed by a consortium of scientists, regulators, and governmental agencies from around the world to assist in toxicological identifications and regulatory frame working. Acceptable identification and characterization standards are also under construction and should be set within 1 year. Some companies, such as ApNano, are anticipating the risk associated with particle characterization and are mitigating it by having independent laboratories complete EHS screenings and particle identification on their products.

The figure below is an outline of the characterization needs to thoroughly assess nanoparticle toxicity going forward.

#### **Characterization Needs:**

A group of science experts that discussed characterization of nanoscale materials at the University of Florida suggest the following characteristics are needed to assess toxicity:

#### Ex vivo

- <u>Physical</u>: size, shape, surface area, surface porosity, roughness, morphology (agglomerate vs. primary particles, stability of agglomerates), crystallinity, magnetic properties
- <u>Chemical</u>: stability (dissolution), chemical composition, surface chemistry [zeta potential, acidity/basicity, redox potential, functional groups, reactivity (catalysis, redox, and photosensitivity)]

#### In vivo

• Images, dispersibility, dosage (number density for materials with narrow size distribution; mass dosage for materials with wide size distribution)

Figure 24: The future characterization needs of nanoparticles. Source: NanoTox Workshop 47

<sup>&</sup>lt;sup>46</sup> Warheit, David. "Nanoparticles: health impacts?" Materials Today. February 2004.

<sup>&</sup>lt;sup>47</sup> Final Report: Developing Experimental Approaches for the Evaluation of Toxicological Materials. NanoTox Workshop. November 2004.

## **APPENDIX 2: DETECTION METHODS AVAILABLE**

The nanoparticle detection and quantification methods needed to determine workplace exposure levels and risks are not available because current detection, quantification, and characterization equipment is not applicable to large scale production or manufacturing systems. Detection methods for gases and solids are needed to address workplace exposure issues while detection methods for liquids are needed to assess biological tissue and living organism exposures.

Companies, such as NanoSight and Nanomix, which are beginning to enter the detection and nano instrumentation businesses show promise in expediting exposure information. NanoSight, Ltd. has recently launched a nanoparticle detection instrument that should enable rapid and cost effective detection and analysis of nanoparticles. This appears to be a high growth area for nano companies due to the need for workplace exposure reduction as economies of scale improve and more companies begin manufacturing nanoparticles and commercializing nano-products.

Parameter	Measurement Techniques
Number concentration	Condensation Particle Counter (CPC)
Particle number and number-weighted particles size distribution	<ul> <li>Scanning Mobility Particle Sizer (SMPS)</li> <li>Electrical Low Pressure Impactor (ELPI)</li> </ul>
Submicron particle surface area	<ul><li>Epiphaniometer</li><li>Diffusion Charger</li></ul>
Size, morphology and surface properties	<ul> <li>Scanning Transmission Electron Microscopy (STEM)</li> <li>High Resolution Transmission Electron Microscopy (HRTEM)</li> <li>Scanning Near-field Optical Microscope (SNOM)</li> <li>Atomic Force Microscopy (AFM)</li> </ul>

Figure 25: Nanoparticle measurement parameters and techniques.

Source: Future Technologies Division of VDI Technologiezentrum GmbH48

The following is a list of companies commercializing the equipment that may be relevant for future detection needs: FEI Co, Veeco Instruments Inc., Symyx Technologies Inc., JMAR, Accelrys Inc, MTS Systems Corp.

<sup>&</sup>lt;sup>48</sup> Luther, Wolfgang. Industrial application of nanomaterials chances and risks: Technological Analysis., August 2004.

## **APPENDIX 3: POTENTIAL EXPOSURE ROUTES OF NANOPARTICLES**

The possible routes of human exposure to engineered nanoparticles include inhalation, surface contact, and ingestion. The lungs, nasal passages and intestinal tract would act as transporters of foreign objects whereas; the skin would attempt to provide a barrier to a foreign object. Environmental exposure routes include the air, land, and water. An interaction linking environmental exposure with human exposure may be possible through bioaccumulation in the food change.

**Inhalation Exposure:** Any product associated with sprays that may emit nanoparticles either in the finished product or manufacturing phase is susceptible to liability dealing with inhalation. Many of these products are already in the market place and include disinfectant and air-freshener sprays, paints and dyes, coatings, textiles treatments, and sprays for porous materials such as woods and clays.<sup>49</sup>

#### Nanometer particles caused an increased inflammatory response, pathological response, and a difference in the distribution of particles in the lungs.

- The respiratory tract and the lung are the major targets for nanoparticleinduced effects following inhalation exposure but particles can also be inhaled through the nose.
- The lungs consist of airways and alveoli, with the alveoli being more susceptible to environmental damage due to their large surface area and intense air-blood contact. The alveoli would also be the location of nanoparticle transportation into the blood stream. There is also some indication that exposure via the nasal passage may allow for particle transportation to the blood stream and the nervous system, eventually leading to the brain.<sup>50</sup>

Size Matters: The smaller the particle, the deeper it can penetrate into the lung.

- At a size less than 2.5 microns, particles can reach the alveoli.
- Fibers, length to diameter ratio of 3:1, with small diameters can also penetrate the deep lung.
- Published studies on the inhalation of ultrafine particles suggest that *particle size can exacerbate toxicity* equally, if not more so, than chemical composition. <sup>51</sup>
- A large body of evidence, in rats, indicates that nanometer particles are more potent (in mass terms) than micrometer particles in inducing pulmonary toxicity.<sup>52</sup> Potency was equalized when surface area instead of mass was the metric of measurement.

particle size can exacerbate toxicity equally, if not more so, than chemical composition

<sup>&</sup>lt;sup>49</sup> Hett, Annabelle. Nanotechnology: Small matter, many unknowns. Swiss Reinsurance Company. 2004.

<sup>&</sup>lt;sup>50</sup> Oberdörster, Günter. "Extrapulmonary translocation of ultrafine carbon particles following whole-body inhalation exposure of rats." Journal of Toxicology and Environmental Health. 2002.

<sup>&</sup>lt;sup>51</sup> National Toxicology Program Headquartered at the National Institute of Environmental Health Sciences. "Fact Sheet." 2005.

<sup>&</sup>lt;sup>52</sup> Nanoscience and nanotechnologies. Chapter 5. The Royal Society & The Royal Academy of Engineering. July 2004.

Surface Area and Chemical Reactivity Matters: The large surface area of nanoparticles can overwhelm phagocytes, the cells responsible for eliminating foreign objects from the lungs, and trigger a stress reaction which increases inflammation in the surrounding tissue.

- Increased inflammation, particle accumulation in the blood, DNA damage, and oxidative damage may lead to arteriosclerosis (blood clotting) and eventually heart disease in humans.
  - Research has shown that both nanospheres and carbon nanotubes may increase blood clotting after exposure.<sup>53</sup>
- Surfaces of some nanoparticles may be able to generate oxidative stress on cells or organs.<sup>54</sup>
- Some nanoparticles will generate free radicals that can damage DNA.
- Variations in surface treatments can cause differences in pulmonary inflammation.<sup>55</sup>
  - Lung diseases attributed to poorly soluble particle exposure, which may apply to nanoparticles, include: *pneumoconiosis, bronchitis, emphysema and asthma*.
  - Another systemic toxicity, not seen in micrometer particle exposure that is related to inhalation exposure at the nanometer scale is 'fume fever'. This acute condition is associated with exposure to freshly formed metal fumes. The systemic response typically resembles influenza-like symptoms that develop a few hours after exposure

**Surface Contact:** Products that will come in direct contact with the skin either during use or manufacturing may be involved in litigation dealing with dermal exposure. Once again, many of these products are already in the marketplace, including: cosmetics, suntan lotions and silver coated wound dressings.

- The strength of the point of contact to the skin (especially important for contact during manufacturing), the susceptibility of the skin (i.e. skin already damaged), and the size and surface area of the particles will all impact the ability of nanoparticles to penetrate the skin.
- Water-soluble fullerenes have shown to be toxic in small levels to both human skin and liver carcinoma cells, whereas, *surface modification creating a fullerene derivative had substantially less toxicity*.
- Again some particles may be able to penetrate the skin and generate free radicals that can cause damage to DNA.
- Based on limited toxicology studies, titanium dioxide has been approved in Europe for use in sunscreens whereas, zinc oxide which showed phototoxic results on cells and DNA, has not.<sup>56</sup>
- NIOSH is currently conducting research on the permeability of engineered nanoparticles with skin. The study should be finished by April 2007.

**Ingestion Exposure:** The products to likely be involved in liability surrounding ingestion exposure include most of the drug applications, drug delivery systems, imag-

...surface modification creating a fullerene derivative had substantially less toxicity.

<sup>&</sup>lt;sup>53</sup> http://www.nature.com/cgi-taf/DynaPage.taf?file=/nbt/journal/v21/n10/full/nbt875.html.

<sup>&</sup>lt;sup>54</sup> Nanoscience and nanotechnologies. Chapter 5. The Royal Society & The Royal Academy of Engineering. July 2004.

<sup>&</sup>lt;sup>55</sup> Warheit, David. "Nanoparticles: health impacts?" Materials Today. February 2004.

 $<sup>^{56}</sup>$  Nanoscience and nanotechnologies. Chapter 5. The Royal Society & The Royal Academy of Engineering. July 2004.

ing applications, and food enhancements. Unlike dermal and inhalation exposures, most of the products that involve ingestion exposure are not yet commercialized.

- There are indications in the literature that manufactured nanoscale materials may distribute in the body in unpredictable ways, and certain nanoscale materials have been observed to preferentially accumulate in particular organs.<sup>57</sup>
  - The spleen, the liver, and the kidney seem the most likely targets for nanoparticle accumulation.
  - Once in these organs, the nanoparticles may not be cleared by normal mechanisms.

## **Environmental Hazards**

Nanoparticle properties such as size, reactivity and mobility will likely create environmental exposure and risk related to nanoparticle transfer (which given their size, the transfer will be invisible) and potential environmental persistence. The environment may be exposed to free or fixed nanoparticles via the air, land, or water (including ground water).

**Air:** Release to atmosphere is one of the most likely scenarios. Nanoparticles have the potential to escape through filters during manufacturing and also have the potential for release at the end of the lifecycle when the products containing engineered nanoparticles are decomposing.

- The best scientific parallel to the hazards associated with air exposure is ultra-fine particles which are nanoparticles currently in the air.
- Ongoing research suggests that ultra-fine particles increase air pollution, thus impacting climate change, and pose a danger to humans.<sup>58</sup>
- Scientific research is associating increases in lung diseases and deaths to ultrafine particle exposure.<sup>59</sup>
- Currently, there does not appear to be any research into the impact or the potential for bioaccumulation of ultra-fine particles to living organisms besides humans.

Land: Environmental exposure via the land is likely to be associated with disposal of products containing engineered nanoparticles or the intentional use of engineered nanoparticles for land contamination treatment. There is a less likely chance that land exposure could come during disposal in the manufacturing phase.

- Some engineered nanoparticles are mobile creating the potential for widespread soil and land contamination.
- Environmental risk is increased if the nanoparticles are not broken down by the ground or if the particles impair the vital role of bacteria.
- It has been suggested by scientists that a few particles may be able to combine with pre-existing toxins and thereby increase the bioaccumulation of the toxin.

<sup>&</sup>lt;sup>57</sup> Colvin, Vicki.

http://www.environmentalfutures.org

<sup>&</sup>lt;sup>58</sup> Nanoscience and nanotechnologies. Chapter 5. The Royal Society & The Royal Academy of Engineering. July 2004.

<sup>&</sup>lt;sup>59</sup>*Ibid*.

- The limited amount of research conducted on bioaccumulation of engineered nanoparticles has shown the ability for certain nanoparticles such as carbon nano-tubes, to penetrate the skin of worms and enter several other invertebrates.<sup>60</sup>
  - These observations suggest the real likelihood of bioaccumulation of engineered nanoparticles.
  - Nanoparticles of titanium dioxide are highly reactive and have been shown to kill bacteria in the soil.<sup>61</sup>

**Water Exposure:** All water sources including ground water have the potential for widespread nanoparticle exposure during every life cycle stage. Free nanoparticles used in applications such as drug delivery systems or food additives have the greatest potential of impacting water (Note: Many conventional pharmaceutical drugs are found in municipal water systems.)

- Several types of engineered nanoparticles appear to be non-biodegradable.
  - For example, carbon nanotubes are completely insoluble in water and are biologically non-degradable.
  - Studies also suggest buckey balls or fullerenes can cause harm to aqueous environments.
- Nanoparticle properties are of significant importance to their environmental risk to aquatic ecosystems.
  - They are highly mobile in aqueous environments.
  - Their properties contribute to their ability to be absorbed, to form aggregates and to be accumulated in aquatic organisms.
  - In aqueous environments, many nanoparticles undergo agglomeration. If the particle aggregates with a toxin, the entire conglomerate could be toxic.

<sup>60</sup> Ibid.

<sup>61</sup> http://www.terressentials.com/nanotech.html

# APPENDIX 4: NANOPARTICLE POTENTIAL FOR ENVIRONMENTAL INTERACTION

Nanoparticles may interact with the environment in three ways: absorption, aggregation, and biotic uptake. <sup>62</sup>

#### Absorption:

- Many molecules will absorb to nanoparticles in various environments.
- Biological interactions and bio-uptake may be influenced by these absorbed molecules.
- Nanoparticles that penetrate cells will allow entrance of absorbed molecules.
  - Toxins and other molecules unable to enter cells under normal conditions may be able to enter, thus causing the potential for toxicity and bioaccumulation.

#### **Aggregation:**

- Nanoparticles may undergo aggregation in certain aqueous environments.
  - Biological interaction with aggregated nanoparticles will be similar to bulk materials.
- Aggregated nanoparticles that can enter the cell may cause extensive damage and induce cell death.

## **Biotic Uptake:**

- The surface of nanoparticles needs to be bound to cell-interacting or targeted molecules in order to interact with cells.
- Nanoparticles may bioaccumulate if they are unable to be degraded or excreted.
  - Most nanoparticles are not biodegradable.
  - Studies have shown the ability of nanoparticles to enter lower level organisms, a threat for bioaccumulation.



Figure 26: Nanoparticles interactions with the environment. Source: Dr. Vicki Colvin, Associate Professor, Rice University<sup>63</sup>

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This raises concern about the ability of nanoparticles to combine with toxic chemicals already present in the environment and make thereby increasing bioaccumulative properties of the in situ toxic chemical.

<sup>&</sup>lt;sup>62</sup> Colvin, Vicki. "Nanotechnology: Environmental Impact." Presentation.

## APPENDIX 5: OVERVIEW OF REGULATORY LANDSCAPE

### **United States**

## Toxic substances control act

Enacted nearly 30 years ago, TSCA is the central law governing industrial chemicals.

TSCA authorizes EPA to screen and regulate "new" and "existing" chemicals

Legal experts have identified several aspects of TSCA that can be interpreted as being relevant to the regulation of nanoparticles. These experts have also identified several reasons why attempting to do so might be problematic under current law. The following is a rough summary provided by Lynn Bergeson of Bergeson and Campbell P.C. of the issues and possibilities for company confusion related to these statutes<sup>64</sup>.

#### **TSCA Section 4 Testing**

- Triggered in amounts exceeding 500 kg per year. This would obviously exclude many nanoparticle manufacturers.
- Processors do not have to submit unless risks are related to processing. Since there is no data on the process related risks for nanomaterials. Many manufacturers might be confused about whether to submit.
- Experts indicate that there has been a significant amount of litigation concerning Section 4. Moreover, promulgating section 4 is known to take years.

#### **TSCA Section 5 Existing Chemicals and New Chemicals**

- Section 5's distinction between existing and new chemical is based on size is unclear
- A particle at the nanoscale may not necessarily be identical to its macro scale analog. Does this make the material in question a new chemical?
- Rules associated with this would govern whether a company has to submit to regulators before commercializing. Confusing for companies and confusing for regulators.

#### **TSCA Section 6 Unreasonable Risk**

TSCA Section 6 authorizes EPA to prohibit/limit the TSCA Section 6 authorizes EPA to prohibit/limit the manufacture, import, processing, distribution in commerce, use, manufacture, import, processing, distribution in commerce, use, or disposal of a chemical if there is a reasonable basis to or disposal of a chemical if there is a reasonable basis to conclude the chemical presents or will present an conclude the chemical

<sup>63</sup> Ibid.

<sup>&</sup>lt;sup>64</sup> "Applicability of U.S. Environmental Laws to Assess, Applicability of U.S. Environmental Laws to Assess, Prevent, and Control Risks of Nanotechnology: TSCA." Lynn Bergeson. Bergeson & Campbell P.C. present on May 25 in Washington DC for the Environmental Law Institute and the Woodrow Wilson Center For Scholars Dialogue on Nanotechnology. On the Internet: http://www2.eli.org/research/events/nanotech5.25.05.cfm

presents or will present an unreasonable risk of injury to health or the environment risk of injury to health or the environment

- Section 6 states that unreasonable risk has to be based on "substantial evidence". Only a handful of studies have been done to date. This makes us wonder about products already in commercial use.
- The burden of proof is heavy on the EPA in relation to a court ruling in 1991. (Proof Fittings v. Fittings vela, 947 F.2d 1201 (5th Cir. 1991)), 947 F.2d 1201 (5th Cir. 1991))

#### **TSCA Section 9 Other Federal Agencies**

This statute lays the ground work for harmonization with other agencies. In essence, if another agency's ruling limits or reduces an "unreasonable risk" ruling by EPA then that agency must inform the EPA. Specifically EPA has a memorandum of understanding (MOU) with the Occupational Safety and Health Administration and Consumer Product Safety Commission regarding the "working relationship" process under which formal referrals will be made.

http://www.osha.gov/pls/oshaweb/owadisp.show\_document

## **TSCA Section 12B Authority**

The EPA will notify foreign governments if chemical substances are subject to the following TSCA rules or orders:

- TSCA Section 4 test rules and Enforceable Consent Agreement Final TSCA Section 4 test rules and Enforceable Consent Agreements;
- Data required under Section 5(b); Data required under Section 5(b);
- Order issued under Section 5; Order issued under Section 5;
- Proposed or final rules issued under Sections 5 or 6; or Proposed or final rules issued under Sections 5 or 6; or
- Actions pending or relief granted under Sections 5 or 7 Actions pending or relief granted under Sections 5 or 7

The problem is that there must be a rule under 5, 6 or 7. In the case of nanomaterials there is nothing applicable.

In essence, this means that there would be not export notification and nanomaterials could be exported for use, distribution, processing, or disposal to anywhere in the world with no way of tracking its movement

## **European Union**

The European Union is in the process of overhauling its chemicals policy. The new policy currently under development known as REACH (Registration Evaluation and Authorization of Chemicals)

Triggered by volume. As with TSCA, this is not relevant for nanomaterials

Starts with a determination of existing vs new chemicals. Also a difficulty under TSCA

Massive Backlog

Shifts the Burden of Proof



Figure 27: REACH Registration Process Source: BASF AG

## **Registration**

Approximately 30,000 existing substances and all future new substances that are manufactured or imported in a volume of more than 1 ton per year in the EU must be registered with a central Agency. It is industry's task to obtain and assess the necessary data about the substances and exposure. The volume thresholds apply to each individual manufacturer or importer.

#### **Evaluation**

In the evaluation, the relevant national authorities can check the dossiers that are submitted for the registration of each substance. This is compulsory in the case of annual volumes of > 100 tons. The authorities are also allowed to carry out a more detailed check of specific substances, if they believe that a risk is to be expected due to the structure of the substance or the total European tonnage.

## **Authorization**

**CMR**<sup>65</sup>, **PBT**<sup>66</sup> and **vPvB**<sup>67</sup> substances as well as **endocrine disruptors**<sup>68</sup> are subject to an authorization procedure. This means that such substances may only be used for authorized applications. The registrant must provide evidence for each use that the risk emanating from the substance is controlled by technical or organizational measures.

#### Chemical Safety Report

A Chemical Safety Report must be compiled for substances of > 10 t/a. This contains physicochemical, toxicological and eco-toxicological data, risk assessments for all uses and measures for risk management.

<sup>&</sup>lt;sup>65</sup> carcinogenic, mutagenic, causing harm to reproductive systems in animal studies or humans

<sup>&</sup>lt;sup>66</sup> persistent, bioaccumulative and toxic

<sup>67</sup> very persistent, very bioaccumulative

<sup>&</sup>lt;sup>68</sup> substances that affect the hormone system

## **APPENDIX 6 – ABOUT INNOVEST**

Innovest Strategic Value Advisors is an internationally recognized investment research and advisory firm specializing in analyzing companies' performance on environmental, social, and strategic governance issues, with a particular focus on their impact on competitiveness, profitability, and share price performance.

Innovest provides its clients with three basic types of products and services:

- Industry, company and specialized reports
- Asset management sub-advisory services
- Custom research, consulting and portfolio analysis

Founded in 1995 with the mission of identifying non-traditional sources of risk and value potential for investors, the firm currently has over US \$1 billion under direct sub-advisory mandates with partners including ABN-AMRO, Mellon Capital, Brown Brothers Harriman, T. Rowe Price, and Credit Lyonnais. Innovest also provides custom portfolio analysis and research to leading fund managers including Schroders, State Street Global Advisors, and Rockefeller & Co., and has a number of pension fund clients including ABP (Netherlands), the largest pension fund in Europe. In addition, the firm provides research and strategic advice to senior executives of Global Fortune 500 industrial companies.

Innovest's chairman emeritus Jim Martin was chief investment officer for North America's largest pension fund for over fifteen years. The firm's founder, Dr. Matthew Kiernan, is a former partner with KPMG and director of the World Business Council for Sustainable Development and its co-founder, Hewson Baltzell, is a former banker and investor from Lehman Brothers and JP Morgan Chase. Innovest's other principals and advisory include former senior executives from several of the world's leading financial companies, as a former G7 finance minister, and the former chairman of Royal Dutch/Shell. Innovest has offices in New York, London, Paris and Toronto.

## **Innovest's Directors and Senior Advisors**

## **Advisory Directors**

- Mr. Jim Martin: Chairman, Innovest Strategic Value Advisors; formerly Chief Investment Officer, TIAA-CREF.
- Mr. David Van Pelt: Vice Chairman, Former Executive Vice President, Citicorp.
- Mr. Alan Silberstein: CEO, Western Union
- Mr. Arthur Lipper III: Founder, The Arthur Lipper Corporation.
- Mr. Ken McCready: Former CEO, Transalta Corporation.
- Sir Mark Moody-Stuart (Emeritus): Chairman, Anglo-American Mining, former Chairman, Royal Dutch Shell Group
- The Rt. Hon. Lord Nigel Lawson (Emeritus): Chairman, Central Europe Trust, former Chancellor of the Exchequer, United Kingdom.

## **Technical Advisory Committee**

- Derek Osborn, Chair, former Director of the U.K. and European Environment Agencies
- Dr. Stuart Hart, Professor, Johnson School of Business, Cornell
- William Russell, former Director, U.S. Environmental Practice, Pricewaterhouse Coopers
- Dr. Andrew King, Professor, Tuck School of Business, Dartmouth
- Alan Willis, Advisor, Global Reporting Initiative
- Stephen Viederman, former President, Jessie Smith Noyes Foundation

Innovest's Directors, Advisors, and Technical Advisors are among the leading thinkers in their fields.

## APPENDIX 7 - LEADING-EDGE INVESTMENT RESEARCH: "NON-TRADITIONAL" RISK FACTORS

"Financial performance tells me what a company has already done. <u>Non</u>-financial performance tells me what it is likely to do."

Ernst & Young, Measures that Matter, 2000

# Investment Risk and the "Iceberg Balance Sheet"

The recent accounting scandals at Enron, WorldCom, Tyco and elsewhere have exposed some, but by no means all, of the limitations of accounting-based investment analysis. Accounting numbers provide at best a static, "rear-view mirror" indication of *past* performance. Differing accounting conventions and assumptions can distort the true financial picture even further. But perhaps the most serious limitation of all is the fact that they can assess only a small and shrinking proportion of companies' true competitive dynamics, risk profiles, and potential for sustainable earnings growth.

As recently as the mid-1980's, financial statements were able to capture at least 75% on average of the true market value of major corporations. As we move deeper and deeper into the era of "knowledge-value" and intangibles, however, conventional balance sheets and profit and loss statements are reflecting less and less of a company's true risk profile and competitive potential.<sup>69</sup>

Today, some of the most powerful risk factors and value drivers for companies are hidden "below the waterline", and cannot be fully assessed by traditional investment analytics. What is needed now, therefore, is a new, more dynamic and forward-looking "iceberg balance sheet" approach to investment analysis, focused on the 60-70% of companies' real competitive and financial prospects which *cannot* be explained by traditional, accounting-based securities analysis.

Innovest Strategic Value Advisors was formed in 1998 specifically to research and analyze these non-traditional risk factors for investors. Innovest's largest external shareholder is ABP, a major Dutch pension fund which is one of the largest and most highly-regarded in the world. Innovest clients include some of the world's leading financial institutions, as well as a number of Fortune Global 500 industrial companies.

Innovest focuses primarily on four key sets of non-traditional risk and value drivers:

- Strategic Governance
- Environment
- Human Capital and Labor Relations
- Stakeholder Capital

<sup>&</sup>lt;sup>69</sup> See, for example, Baruch Lev (2001), Intangibles: Management, Measurement and Reporting. Washington, D.C., Brookings Institutions.


# **Tomorrow's Alpha Potential**

In addition to the out-performance which has already been demonstrated, at least five powerful "mega-trends" are currently converging to make non-traditional risk factors even *more* important for investors in future:

- Post-Enron, WorldCom skepticism about the accuracy, objectivity, and value of traditional, accounting-based Wall Street research.
- Tougher legal requirements for the disclosure of "non-financial" risks by both companies and institutional investors. Eg. Sarbanes-Oxley, recent SEC rules, European pension reform.
- A substantial broadening of the scope of fiduciary responsibility to include companies' ability to manage "non-traditional" business risks including environmental, social, and governance issues.
- Record levels of institutional shareholder activism on environmental and social issues, e.g. climate change.
- The expansion of both industry competition and investment into emerging markets, exponentially increasing the level of exposure to non-traditional business risks.

# **Benefits for Investors and Fiduciaries**

Supplementing their traditional research processes with Innovest's analytical overlay can create significant benefits for investors:

- Risk Control: Identifies hidden sources of risk to portfolio companies eg. Asbestos, climate change, human rights, labor, business costs of HIV/AIDS.
- Alpha Diversification: Consistent demonstrated source of non-correlated alpha.
- **Reputational Capital:** Enhances institutions' reputational capital with both internal and external stakeholders.
- Fiduciary Responsibility: Meets or exceeds emerging global fiduciary requirements eg. New U.K., Swedish, German, French, Swiss, Australian pension regulations.
- Strategic Reinforcement: Aligns investment strategy with clients' social, environmental, and governance concerns.
- **Management Proxy:** Helps investors identify companies with superior management and agility to deal with *other* emerging issues in the future.

# How Can Innovest Add Value?

### An "Early Warning System" for Investors

Innovest's proprietary research on non-traditional risk factors has provided clients with early warning signals months and in some cases years before the general market picked up its own negative signals and punished companies' share price and/or credit rating. Some of the "problem companies" identified by Innovest's research before Wall Street and the City of London are:

- HealthSouth strategic governance and transparency
- GE asbestos and other environmental liabilities
- Monsanto genetically modified foods
- Anglo-American costs of HIV/AIDS in the workforce
- Tyco strategic governance and transparency
- American Electric Power climate change
- Federal Mogul (now bankrupt) asbestos liability

# Adding Value on the Upside

It is also increasingly well-established by leading-edge investors and financial analysts that there is a strong and growing link between companies' ability to manage non-traditional business risks and their financial performance.<sup>70</sup> Simply put, a com-

<sup>&</sup>lt;sup>70</sup> See, for example, West LB Panmure (2002) More Gain than Pain: Sustainability Pays Off, and (2002) From Economics to Sustainomics: SRI – Investment Style with a Future; UBS Warburg (2001) Sustainability Investment: The Merits of Socially Responsible Investment; Bank Sarasin (1999) Sustainable Investments: an Analysis of Returns in Relation to Environmental and Social Criteria; and (1998) Environmental Shareholder Value.

pany's ability to manage these complex risks better than its competitors has proven to be a robust – but largely neglected – proxy for superior management quality overall, the most significant single driver of excess returns.

Innovest has systematically analyzed the non-traditional risk profiles of over 1,500 large and mid-cap firms around the world in nearly 50 industry sectors. Companies with a demonstrably superior capacity to manage those risks have generated a wide range of financial and strategic benefits:

- Enhanced market access in difficult countries and regions (e.g. Royal/Dutch/Shell)
- Reduced regulatory risk exposure (e.g. BHP Billiton)
- Reduced energy and materials costs (e.g. BASF)
- Improved relations with regulators and other stakeholders (e.g. Intel)
- Greater ability to attract and retain a high-quality workforce (e.g. 3M)
- Lower cost of capital and insurance (e.g. Real Estate Investment Trusts)

### **Empirical Tests of Innovest Ratings**

### 1. Ongoing work by Innovest

A major U.S. public pension fund wanted to investigate whether or not environmental and social (SRI) analysis can be used as part of decision-making in its investment process without adverse impacts on its portfolios' risk-adjusted return, and to pursue this, the client engaged Innovest. We applied Innovest ratings as an overlay to the investment portfolios of four third-party money managers that the client currently uses. Innovest created a number of live simulations, or "shadow portfolios", to investigate possible uses and impacts of the ratings. The goal of this initiative was to have a live simulation of the effects of Innovest ratings (rather than a back test), to use actual portfolios, to apply actual current Innovest ratings, to track performance, and to repeat the procedure during the course of one full year. The client wanted to answer two questions in particular: 1.What effect, if any, does adding SRI considerations to an existing investment? 2. Which investment styles, capitalization levels, and regional focus lend themselves to an SRI overlay?

To perform the simulations, Innovest obtained from the client's managers the actual holdings of each of the four portfolios as of 12/31/01, and at the end of each quarter thereafter through 12/31/04. For each quarter, we applied the Innovest ratings to the portfolios and created three simulations per portfolio (i.e. 12 simulations in total per quarter). This is analogous to "turning up the volume" of the Innovest signal to three different levels. This was accomplished using a portfolio optimization model such as is commonly used in the investment management business, and setting the "tracking error" to three different levels – 50 basis points, 100 basis points and 200 basis points. In these simulations, we maximized the Innovest ratings subject to these tracking errors.

After three years of simulations, the results generally indicate that the application of Innovest ratings to the investment process has a positive effect on investment performance. In all four investment portfolios at the 200 basis point tracking error level, use of Innovest ratings significantly improved investment return relative to the performance of the underlying portfolio. In most cases, this improvement increases as the "volume" of the Innovest signal increases (see **Figure A1**), that is, as the weight for the Innovest information is increased. Note, however, that the addition of Innovest information to US Large Cap Core portfolio did not help its overall performance at the lower tracking error levels, as is clear from Figure A1.

These results would seem to be significant, inasmuch as the portfolios to which the Innovest overlay was applied represent a considerable range of investment styles (growth, value, active), capitalization levels (large cap, mid and small cap), and geographic exposures (U.S., EAFE, global). Due to the use of the portfolio optimization model, the outperformance realized in these simulations is achieved without industry sector biases.

The study confirms that portfolio managers can indeed add value by incorporating a comprehensive assessment of companies' environmental and social performance into their investment analyses.

While the results are entirely consistent with other academic findings, it must be acknowledged here that the study results *are* specific to the Innovest methodology. In other words, a different rating system, especially one less heavily weighted towards financial performance considerations, could yield different results. What *can* be said with certainty is that the Innovest methodology did indeed generate out-performance in five out of the six portfolios, and that the greater emphasis given to the Innovest rankings, the greater the out-performance.

Note: This simulation work is ongoing, and Innovest will continue to update performance figures as they become available.



# Figure A1 - Relative Performance of Innovest Enhanced Portfolios vs. Underlying Portfolios

Source: Innovest's EcoValue21® Rating Model and databases

### 2. Potash, 4/05

Study by Daniel A. Potash of Power Project Financing LLC, used Innovest time series.<sup>71</sup>

Construction:

- Investigated Price/Earnings ratios as a measure of company value
- Tested Innovest's Global 100 (as presented at World Economic Forum) against comparable companies not on this list

#### **Results:**

Companies in the Global 100 had P/E ratios 15% higher than their peers; this
would translate into "billions of dollars of stock market increased value for most
large companies traded on major exchanges".

#### **Conclusion:**

 "The stock market may give better share price valuation in terms of P/E to companies that are perceived of as sustainable versus comparison companies not so designated."

### 3. Guenster et al, 4/05

Study by Erasmus University and Maastricht University, The Netherlands, used Innovest time series.<sup>72</sup>

Construction:

- Investigated relationship of eco-efficiency as determined by Innovest and firm value as measured by Tobin's Q
- Ran tests quarterly from 1997 to 2002, and many statistical analyses

#### **Results:**

- Cumulative differential over the test period was about 30%. The least ecoefficient companies had values that were significantly lower compared to those of the remainder of the sample.
- Environmental winner companies initially did not trade at a premium relative to losers, but that the premium increased strongly over time
- "...the least eco-efficient firms display significant operational underperformance. Our findings, thus, strongly reject the notion expressed by CSR skeptics that the benefits of adopting a strong environmental policy are unlikely to outweigh the costs."

 <sup>&</sup>lt;sup>71</sup> Daniel A. Potash, The Stock Market Value of Sustainability, April 2005 (see Appendix 3 for the full report).
 <sup>72</sup> Nadja Guenster et.al, The Economic Value of Corporate Eco-Efficiency, April 2005 (see Appendix 3 for

<sup>&</sup>lt;sup>22</sup> Nadja Guenster et.al, The Economic Value of Corporate Eco-Efficiency, April 2005 (see Appendix 3 for the full report).

#### **Conclusion:**

"Investors may interpret our results as evidence that corporate environmental performance is a potential source of information that facilitates them in generating superior excess returns."

### 4. Columbia University 6/04

Columbia's Center for Environmental Research & Conservation investigated, among other subjects, financial market reactions to sustainability performance, including fixed income markets (for which Innovest ratings were used).<sup>73</sup>

#### **Construction:**

Simulation conducted using SSgA Active Quantitative strategy in combination with Innovest Environmental Research

- Match Innovest ratings to corporate bonds
- Select comparable bonds based on term to maturity, liquidity and other factors
- Testing period: snapshot of one point in time (at time of study)

#### **Results:**

- Companies in industries rated by Innovest as having as least environmental impact had on average a 50 basis points lower spread over Treasuries than companies in the industries with the highest environmental impact.
- Companies rated in the top half in their industry had on average a 34 basis points lower spread over Treasuries than companies rated in the bottom half of that industry (of those companies and industries for which data was available and gathered).
- A portfolio of corporate bonds of companies rated highest by Innovest in each of the industries analyzed has a spread over Treasuries of 40 basis points lower than a similar portfolio of corporate bonds of companies rated lowest in each of the industries analyzed.
- There was no correlation between the Innovest company score and the bond rating (pearson correlation coefficient = 0.093).

# 5. State Street Global Advisors 2/04

SSgA analyzed the effect of Innovest ratings on an actively managed US portfolio.  $^{74}$ 

#### **Construction:**

Simulation conducted using SSgA Active Quantitative strategy in combination with Innovest Environmental Research

<sup>&</sup>lt;sup>73</sup> Charles Kimball et.al, Economic Benefits of Certification Programs

Producers, Resellers and End Consumers, June 2004 (see Appendix 3 for the full report).

<sup>&</sup>lt;sup>74</sup> Kimberly Gluck et.al, The Impact of Eco-Efficiency Alphas on an Actively Managed U.S. Equity Portfolio Performance, February 2004 (see Appendix 3 for the full report).

- Selected stocks within each industry with the highest return potential while satisfying all the investment constraints
- No companies were excluded from the eligible universe
- Stringent risk controls
  - o Neutral to market, value/growth, and large/small biases
  - Maximum active security weight +/- 2.0%
  - Maximum tracking error 5.0%
  - Active Industry weights +/- 3.0%
- Investable universe: Russell 1000
- Benchmark: S&P 500 Index
- Turnover of less than 100% per annual (one-way)
- Transaction cost assumed to be 2% per year
- Testing period: January 1998 to February 2004

#### **Results:**

- Environmental alpha has power as a stand-alone factor to determine future stock returns over the testing period (December 1998 to February 2004)
- Over the simulation period:
  - Average Innovest rating of S&P 500 Index was BB while average rating of US Core Environmental Strategy was AA
  - US Core Environmental portfolio produced an annual excess return of 6.82% (IR=1.35%), over the benchmark (S&P 500 Index), net of transaction costs
  - Environmental inputs added 1.88% annually and 12.4% cumulatively over the study period relative to the "baseline" portfolio without Innovest data

#### **Conclusion:**

- Combining environmental analysis and traditional financial analysis makes sense given the shifting competitive landscape
- Sophisticated analysis of environmental risks can help generate portfolio outperformance relative to the benchmark

### 6. Derwall et al, 10/03

A study completed in late 2003 by Jeroen Derwall et al. that used Innovest time series data is worth noting.<sup>75</sup>

Construction:

• Constructed 2 portfolios, one consisting of high-ranked companies and the other of low-ranked companies (U.S. companies only)

<sup>&</sup>lt;sup>75</sup> Jeroen Derwall et.al, The Eco-Efficiency Premium in the U.S. Equity Market, October 2003 (see Appendix 3 for the full report).

- Used a best-in-class approach on a sector by sector basis and remained sectorneutral overall
- Ran portfolios from May 1997 to December 2002

#### **Results:**

- Best-in-class portfolio had annual return of 5.76%
- Worst-in-class portfolio had annual return of 0.84%
- Cumulative differential over the test period was about 30%

#### **Conclusion:**

We find that the average excess return on a zero-investment strategy that buys the eco-efficient portfolio and sells short the eco-inefficient portfolio is most pronounced after adjusting for multiple factor sensitivities. The factoradjusted return increases sharply and becomes statistically significant once industry effects are controlled for as well. Since the observed differential is neutral with respect to risk, investment style and industry exposures, we interpret this result as evidence of an "eco-efficiency premium" in the U.S. equity market. To address the practical value of our findings, we demonstrated how a best-in-class investment strategy yields significant excess returns under different transactions costs scenarios.

# 7. QED International Analysis

In tests performed by QED International Associates, a quantitative financial analysis firm, the returns of equally weighted portfolios composed of the highest-rated companies (ratings equal to AAA or AA) were compared to the returns of the equally weighted total universe of all rated companies. The portfolios were rebalanced at each year-end, over the period from December 31, 1996 through year-end 2000. The highly rated portfolio outperformed the universe by over 700 basis points (7.21%) over the four-year period.

The following chart demonstrates the ability of Innovest ratings to generate investment out-performance.



Characteristics	1997	1998	1999	2000
Rating Date	Dec-96	Dec-97	Dec-98	Dec-99
No. of Stocks in Top-Rated Portfolio	49	61	89	130
No. of Stocks in Innovest Universe	184	190	342	490
Ann. Weekly Std. Dev. Of Top-Rated (%)	9.51	10.59	12.59	13.82
Ann. Weekly Std. Dev. Of Universe (%)	10.00	10.89	14.02	15.11
Average Rating of Top-Rated Stocks (%)	5.33	5.38	5.48	5.55
Average Rating of the Universe (%)	3.11	3.25	2.89	2.94
Return of Top-Rated Stocks (%)	14.45	6.91	19.00	9.52
Return of Innovest Universe (%)	13.97	4.93	14.74	2.31
Difference in Basis Points	48	198	426	721

Figure A3: Innovest Test Portfolio – 4 Year Performance. Source: QED International Associates

Given the sophisticated normalization techniques used in the study, none of this outperformance can be explained by traditional securities analysis; it appears to be purely a function of companies' management quality, as evidenced by their performance in managing these non-traditional risk factors.

### **APPENDIX 8 - INNOVEST RATING METHODOLOGIES**

The EcoValue'21<sup>®</sup> and Intangible Value Assessment <sup>TM</sup> analytical models have been developed to enable investors and industry analysts to assess companies' relative environmental and social performance, risk, and strategic positioning as well as the financial consequences of these factors. The following section describes the models.

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At the heart of EcoValue'21® analytical model and risk algorithms is the attempt to balance the level of environmental risk with the companies' capacity to manage that risk strategically and profitably into the future. It is the product of these two variables, not the absolute level of risk alone, which determines the ultimate financial consequences of environmental risk for industrial companies and their investors.

The Intangible Value Assessment <sup>TM</sup> (IVA<sup>TM</sup>) analytical model makes use of a similar approach: balancing the level of social sustainability risk with management's capacity to manage that risk. Further, the IVA<sup>TM</sup> model is specifically designed to draw out variances in corporate strategies on a range of intangible factors. These factors – including corporate governance, management of human capital, and quality of strategic partnerships - are widely perceived to be highly relevant to corporate profitability and investor returns.

From a broad perspective, the two methodologies can be outlined as follows:

#### EcoValue'21®

The EcoValue'21® model addresses three fundamental types and sources of environmental risk factors:

- Historical Liabilities Ongoing risk exposure arising from past actions.
- **Operating Risk** Risk exposure arising from current operations.
- Sustainability and Eco-Efficiency Risk Future risk exposure caused by potential undermining of the company's material sources of long-term profitability and competitiveness. For example, electric utility companies emitting more pollutants per megawatthours (MWH) generated than their competitors would have greater financial and competitive exposure to the likely imposition of more stringent emission restrictions.

In addition, the model evaluates:

- The company's capacity to manage environmental risk effectively; and
- The company's ability to position itself to profit from environmentally-driven business opportunities.

Advanced sustainability analysis means that risks, management, and profit opportunities are all considered.

Rating a company

means examining not

ability to manage that

only environmental

and social risk, but also a company's

risk.

### Intangible Value Assessment<sup>TM</sup>

The IVA<sup>TM</sup> model uses over 80 different performance metrics to assess relative corporate positioning in each of the five major categories addressed by the model. The following list provides a broad outline of the analytical approach taken within each of these five categories:

- Sustainable Governance Does the firm's overall strategy and demonstrable strategic capacity/adaptability map well against its risk profile? Is the firm's traditional corporate governance closely aligned with shareholder interests and industry best practice?
- **Human Capital:** How well does the company manage its human capital from a variety of financially-relevant perspectives: recruitment/retention strategies, training and development programs, employee motivation initiatives, labor relations and health and safety performance.
- **Stakeholder Capital:** Relative to industry peers, how does the firm compare in building value through strategic relationships/partnerships with key stakeholder groups (e.g. customers, regulators, local communities, supply chain)?
- **Products/Services:** Does the firm hold any proprietary knowledge related to sustainability/social issues? Are there any product safety programs and policies and are there any outstanding controversies for any of the firm's product lines?
- Emerging Markets: What amount of risk does the firm carry through its presence in emerging markets, and how well has management responded with strategies to mitigate these risks? How sophisticated are the firm's policies and programs to detect and manage unique emerging market risks such as human rights challenges, working conditions and operating in oppressive regimes?

# **Performance Data**

Broadly speaking, the EcoValue'21® and IVA<sup>TM</sup> models use two kinds of inputs and data:

- Quantitative data on the sources and levels of corporate environmental and social risk and performance relative to industry competitors; and
- Qualitative judgments about future, financially-relevant environmental and social performance and risk, based on an expert assessment of the companies' environmental and sustainability risk management capabilities.

Examples of the types of data used in the model include:

### **Quantitative Sustainability Risk Indicators**

- Historical environmental/social risk profile of the company's industrial sector;
- Number of Superfund sites relative to industry average;
- Officially estimated capital cost of remediation and clean-up liability exposures, relative to industry averages;
- Ratio of environment-related fines (RCRA, CAA, CWA, etc.) to revenues, relative to industry averages;

If properly performed, environmental and intangible value analysis takes a comprehensive and detailed look at both quantitative and gualitative indicators.

- Corporate governance statistics (percentage of independent board members, board/management diversity);
- Concentration of high-risk products in company product portfolio;
- Site-specific emissions data on individual plant sites;
- Employee and customer turnover rates;
- Employee and contractor injury rates;
- Adequacy of environmental insurance cover.

# **Qualitative Risk Mitigation Factors**

- Adequacy of board-level mechanisms for environmental/social reporting and management;
- Company-wide environmental/social management capability;
- Staff resource commitment to sustainability management;
- Environmental/social audit capacity, frequency and transparency;
- Sustainability cost accounting and measurement systems;
- Adequacy and universality of staff training on environmental/social risk management;
- Capacity to manage supplier relations for environmental/social performance;
- Sustainability innovation capacity;
- Mechanisms for corporate reporting of sustainability performance;
- Integration of environmental/social performance with staff compensation; and
- Potential for successful commercialization of sustainability research and development.

A significant factor to examine is the future capability of a company to handle controversial sustainability issues. While companies' current performance levels are obviously important to the analysis, the EcoValue'21® and IVA<sup>TM</sup> models are designed to move beyond simply providing a static snapshot of the present situation. Instead, they attempt to provide dynamic, predictive indication of companies' relative ability to manage sustainability issues profitably into the future. Accordingly, the models place considerable emphasis on the trajectory and rate of performance improvement (if any), and on the robustness of the company's strategic management capability.

The EcoValue'21® rating model can be expressed schematically as shown below:



Figure C1: Schematic of EcoValue'21® Analysis Factors. Source: Innovest The following schematic outlines the focus areas for the Intangible Value Assessment  $^{\text{TM}}$ .



Figure C2: Schematic of Intangible Value Assessment TM Analysis Factors. Source: Innovest

### **Data Sources**

Information needed to complete EcoValue'21® and IVA<sup>TM</sup> ratings is gathered from several sources, including company literature (sustainability reports, annual reports, 10Ks, 10Qs, websites, etc.), environmental/social groups and other NGOs, trade groups and other industry associations, government data bases, periodical searches, and financial analysts' reports. Following a review of the literature, Innovest analysts usually interview senior executives at the companies responsible for environmental, human resources and other intangibles management. When comparing companies, data is normalized by the most relevant, available factor, such as domestic sales or production levels.

Eco-efficiency and intangibles analysis demands thorough data acquisition and disciplined examination.

# The Scoring System

The end result is the translation of complex sustainability issues into financially relevant measures. For most categories, the data is then converted to a relative score, by allocating the company with the best performance within its industry sector in a given category a ten, the top score, giving the company with the worst performance a zero, the lowest, and scoring the remainder pro-rata between ten and zero. This system is designed to clarify and highlight performance differentials that would otherwise be more difficult to discern.

All of this data is then input into the scoring matrix, where it is adjusted by weightings for each category. We originally developed the weightings through extensive back-testing with over 350 Fortune 500 companies. The weightings were then further refined through beta-testing with our strategic partners such as PriceWaterhouse-Coopers, with financial institutions such as Union Bank of Switzerland and the Zurich Insurance Group, and with specialist environmental engineers and other colleagues. Further, our Director of Quantitative Research conducts continuous testing on the analytical platform. The weightings reflect our view of the relative importance of each category in determining companies' medium-term profitability and share price performance.

The final EcoValue'21<sup>®</sup> and IVA<sup>TM</sup> relative score is intended for comparison within industry sectors. The scores have been converted into the familiar letter categories used by bond rating agencies.