
Case Study

Beacon Sciences: Commercialisation from biothreat detection to beauty enhancement

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ABSTRACT Beacon Sciences is an excellent example of how technology from an American university can be developed and commercialised resulting in applications across multiple industries and a spin-out company utilising the technology in totally new directions for the global marketplace. The pioneering work of renowned scientist, Dr Eric V. Anslyn, has led to new discoveries in the field of chemiluminescence. Financing from a life sciences venture firm, Emergent Technologies, Inc. (ETI), in an agreement with the University of Texas at Austin where the intellectual property was developed, led to the launch of Beacon Sciences and the commercialisation of the company's proprietary 'glow chemistry' technology and dye synthesis. The technology has wide-ranging applications, including medical diagnostics, biowarfare detection, molecular tools, environmental monitoring, food and beverage testing, chronic disease monitoring and pre-clinical drug safety testing. Funding and strong technology commercialisation management expertise provided by ETI has already led to Beacon Sciences spawning a spin-out company, Reveal Sciences, which is capitalising on Beacon Sciences technology in innovative applications for the cosmetics and personal care products industries.

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SYNTHETIC RECEPTORS AND SUPRAMOLECULAR CHEMISTRY

In its simplest embodiment, supramolecular chemistry involves the 'recognition' of

targeted analytes by molecules designed to recognise them similarly to the way a key fits a lock, hence the term 'lock and key' chemistry. An analyte may be an ion, like sodium, or a small molecule, like aspirin, or larger bio-molecules, such as proteins or polymers. Binding of the analyte into the cavity can occur through ionic pairing, hydrogen bonding, pi bonding and Van der Waals forces. Based on the size of the cavity and on the extent of binding, the receptor discriminates between analytes. The affinity of such an interaction is quantified by the association constant (K_{ass}) of the receptor toward an analyte.

When synthetic receptors incorporate a signalling mechanism for the binding of analytes, they become chemical sensors. A favourite signalling mechanism involves either a colorimetric, fluorescent or luminescent dyes modulating upon binding. To enable such a change, the design integrates a chromophore or luminophore into the receptor, either by covalent or non-covalent attachment. Whether the signalling dye is attached covalently or not, it is the modulation of its optical properties upon analyte binding that provides signal visible to the eye or instrumentation.

Receptors have found many applications in modern science. Non-sensing receptors are involved in separations; for example, chromatography and extractions, catalysis and biological modelling. Sensing receptors have analytical and imaging relevancy. Although biological receptors optimally bind their analytes under physiological conditions, with proper design synthetic receptors have the distinct advantage of performing in relatively harsh conditions, outside of the physiological range of pH or temperature. In addition, synthetic receptors can incorporate molecular moieties or sequences not found in nature, thereby expanding their versatility. A final advantage is that costs of synthesis normally fall short of the costs of producing antibodies or proteins.

SCIENTIFIC FOUNDATIONS

As early as 1873 Johannes Diderik van der Waals first postulated the existence of intermolecular forces. In 1890, Nobel laureate Hermann Emil Fischer suggested that enzyme-substrate interactions take the form of a 'lock and key', pre-empting the concepts of molecular recognition and host-guest chemistry. Non-covalent bonds were gradually understood in more detail, with the hydrogen bond being described in 1920 by Latimer and Rodebush.

The use of these principles led to an increasing understanding of protein structure and other biological processes. For instance, the important breakthrough that allowed the elucidation of the double helical structure of DNA occurred when it was realised that there are two separate strands of nucleotides connected through hydrogen bonds. The use of non-covalent bonds was critical for a clear understanding of DNA's double helical structure. Chemists began to recognise and study synthetic structures based on non-covalent interactions, such as micelles and microemulsions.

Eventually, these concepts began to be applied to synthetic systems. The 1960s saw the breakthrough in the synthesis of crown ethers by Charles J. Pedersen. Following Pedersen's work, other researchers such as Donald J. Cram, Jean-Marie Lehn and Fritz Vogtle became active in synthesising shape- and ion-selective receptors. During the 1980s this research area progressed rapidly with emerging concepts such as mechanically interlocked molecular architectures.

The 1987 Nobel Prize for Chemistry was awarded to Donald J. Cram, Jean-Marie Lehn and Charles J. Pedersen in recognition of their work in supramolecular chemistry. Specifically, the significance of the development of selective 'host-guest' complexes in particular, in which a host molecule recognises and selectively binds a certain guest, was cited as an important contribution.¹

Supramolecular chemistry evolved to greater sophistication in the 1990s. Researchers developed molecular machinery, complex self-assembled structures, and sensors and methods of electronic and biological interfacing. During the 1990s, electrochemical and photochemical focal points were integrated into supramolecular systems in order to increase functionality, and work on molecular information processing devices as well as synthetic self-replicating system research began. The emerging science of nanotechnology has had an influence on supramolecular chemistry with building blocks such as fullerenes, nanoparticles and dendrimers becoming involved in synthetic systems.

The signalling mechanism depends upon the specifications of the needed detection scheme or assay and can be fluorometric, colorimetric or chemiluminescent. Chemiluminescence, the emission of visible light resulting from a chemical reaction in which multiple chemical compounds are mixed, is acknowledged as one of the fastest emerging applications in the field of molecular biology. The reaction between multiple compounds leads to the electronic excitation of the molecules. For these chemiluminescent molecules to relax to these lower energy state, light is released.

Chemiluminescence immunoassay has been established as one of the best alternatives to conventional radioimmunoassay for the quantitation of low concentrations of analytes in complex samples. Over the past 20 years the technology has evolved into analytical procedures with performance that greatly exceeds immunoassays based on radioactive label use. Without the limitations of radioactivity, this type of analytical procedure has progressed beyond clinical chemistry laboratory into other disciplines such as microbiology, veterinary medicine, agriculture, food and environmental testing.

UNIVERSITY TECHNOLOGY COMMERCIALISATION

Building on the discoveries of the 1990s, Dr Eric Anslyn, Professor of Chemistry at the University of Texas at Austin, focused on academic research in physical and bio-organic chemistry of synthetic and natural receptors and catalysts. By combining synthetic and molecular biology techniques, Dr Anslyn and his research team successfully mimicked the mammalian sense of taste and smell in analysis protocols. This breakthrough new technique had multiple applications in environmental, industrial and medical diagnostics.

Already an internationally recognised expert in thermodynamics, kinetics, organic synthesis, combinatorial library methods and molecular design, Dr Anslyn was named the 2006 Cope Scholar by the American Chemical Society for his pioneering research in the fields of pattern recognition and supramolecular chemistry. He was also elected a Fellow of the American Association for the Advancement of Science in 2007.

In the fall of 2006, Dr Anslyn and the University of Texas licensed technology to ETI, a life sciences venture capital firm, to form Beacon Sciences, LLC based on his new research discoveries. ETI forms and manages companies and funds that commercialise groundbreaking institutional and university-based technologies, with the aim of converting university science into high-return ventures.

The biotechnology start-up, Beacon Sciences, became an ETI Portfolio company. The Emergent Technologies Fund had been established to invest in early-stage companies formed to commercialise technologies created, developed, owned and/or synergistic with The University of Texas System. The University of Texas System consists of nine academic and health institutions and, in fiscal year 2007, spent in excess of \$1.8 billion in research endeavours. This resulted in 117 US patents and 655 invention disclosures.

Beacon Sciences obtained an exclusive licence from the University of Texas at Austin

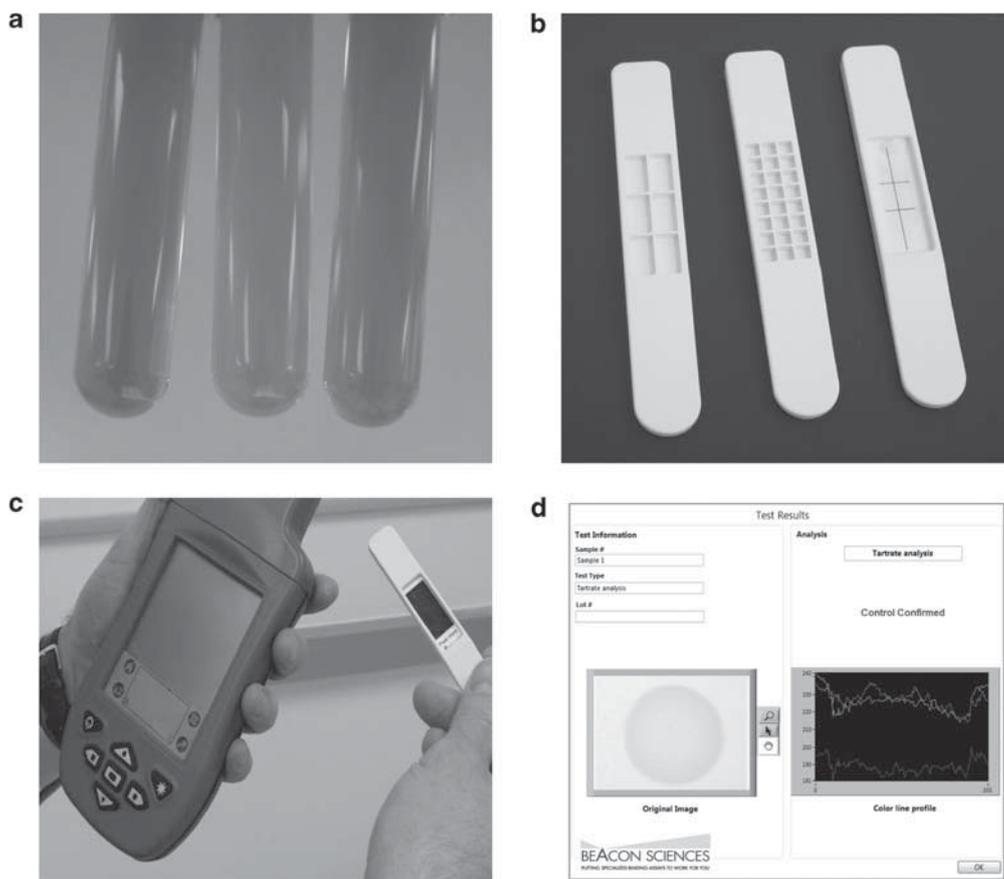


Figure 1: Beacon Sciences colorimetric creatinine detection achieved – A new receptor demonstrates indicator displacement assay for creatinine and indicator displacement assay for tartrate adapted to lateral flow with hand-held reader.

for a ‘lock and key’ chemistry platform for the detection of a wide variety of chemical and biological agents for medical and industrial diagnostic applications. A key aspect of the chemiluminescence cascade and synthetic receptor-based assay development platform is its ability to generate a chemiluminescent signal – or ‘glow’ – when an agent is detected.

Synthetic receptors are now commonly used in academic and industrial settings and Beacon Sciences’ technology has the unique ability to create such receptors for many different kinds of analytes. Using new chemical principles, these receptors can be used to signal the presence of their target analyte by producing a naked-eye visible glow. Although many chemiluminescent assays use enzymes or

antibodies, Beacon Sciences’ assays do not require either of these biological molecules and are compatible with a wide variety of compounds, even non-immunogenic metals, cations and anions (Figure 1).

The technology licensed from the University was based upon a chemiluminescent glow assay for biothreat detection. Other technology licences in Beacon’s portfolio based upon Dr Anslyn’s research have brought the company’s platform and expertise broadly into the category of custom assay developments and sensing platforms utilising synthetic receptors and dye chemistry.

On behalf of Beacon Sciences, ETI began actively screening collaborative partners who

need specialised binding assays for novel biomarkers and other important analytes.

OPPORTUNITY IN MULTIPLE INDUSTRIES

Beacon Sciences has a combined market opportunity in multiple billion-dollar markets. The rapid development time, high sensitivity, ease-of-use and low costs of the company's tests meet the needs of many markets, including environmental, life science research, in vitro diagnostics, biodefence testing, and food and beverage testing.

Key opportunities exist in molecular reagent kits production and rapid biodefence tests for nerve agents and other biothreat agents. Beacon Sciences' antibody- and enzyme-free tests are well suited to point-of-care and field-based testing applications. The immunoassays market is estimated at \$7 billion annually, and the clinical diagnostics market at \$25 billion.²

Target markets include:

- (a) Environmental and industrial QA/QC
 1. Water purity
 2. Chemical analysis
 3. Trace element and compound toxicity
- (b) Life science research
 1. Profile-oriented screening
 2. Novel molecular tools and reagents
 3. Compound manufacturing validation
 4. Cellular and molecular imaging agents
- (c) Clinical diagnostics
 1. Infectious disease
 2. Immunodiagnostics
 3. Oncogenic markers/drugs of abuse
 4. Cardiac markers
- (d) Biodefence
 1. Chemical agent detection in gas and liquid phase
 2. Biothreat agent detection in gas and liquid phase

Beacon Sciences seeks partnerships with leading assay development and novel biomarker discovery companies in the environmental, life sciences, clinical

diagnostics, molecular tools and biodefence fields for collaborative development of key applications.

MARKET DIFFERENTIATION

Strategic co-development partnerships with leading assay providers and biomarker discovery companies usually involve synthetic receptors designed to improve upon conventional technologies through enhancing sensitivity and performance. Beacon Sciences' approach is modular, such that customers can request a customised platform, a signalling modality and finally an end platform. Through this process, Beacon Sciences significantly shortens the development time, thereby accelerating sophisticated technologies into the marketplace; and, at the same time, increasing its intellectual portfolio and providing assets that increase the value of the company for its investors.

The company's motto is 'Simple, single-step detection of chemicals'. One of the core technologies through which this importance is self-evident is the detection of chemical nerve agents by chemiluminescence. The technology's signalling method is similar to common glow sticks and novelty devices that begin to glow when the internal membrane is ruptured by the user. Beacon Sciences' technology was designed to rapidly detect a nerve agent by the generation of an intense glow only in the presence of the nerve agent. Although this applies to a specialised market, the simplicity of the approach quickly generated commercial interest in the product by several customers.

For more practical applications with a more general and broader appeal, lock and key technology has been applied to food and beverage quality ranging from the peak time to pick grapes, as well as bacterial detection of spoiled food. In the medical arena, the company's technology has been applied to complex biological matrices such as urine and blood to detect drug metabolites and markers of health.

To enhance existing products, Beacon Sciences core dye signalling technology is being used to enhance difficult-to-detect analytes by signal amplification. This may be thought of as a single event that triggers a cascade to provide an enhanced signal. The process significantly enhances detection at levels great enough to result in disruptive technologies in each of the application areas. The lock and key detection with custom dye signalling may then be married to Beacon Sciences' reader system for a complete system.

CHALLENGES AND OPPORTUNITIES

Two major challenges faced Beacon Sciences early on.

First, the relative novelty and not widely understood synthetic receptor technology does require some orientation to the technology. Beacon Sciences is approached by companies, executives and researchers who want the receptors adapted to a specific platform. It is a challenge to demonstrate technology at the stage of 'chemistry in a bottle' to potential customers who contact the company and quickly convince them that it is going to work on their platform. This is actually a major advantage of Beacon Sciences' synthetic receptor technology – the relative ease and versatility with which it can be adapted to a given platform, especially as compared to traditional antibody- or enzyme-based assays. To this end the company is currently adapting its receptors to various platforms in house.

To further this objective, Beacon Sciences has licensed and developed its own reader platform, and recently presented the adaptation onto lateral flow technology of one of its synthetic receptors for tartrate, a component of grape-based beverages including wine, at the International Symposium on Macrocyclic & Supramolecular Chemistry. Beacon Sciences is also specialising in adapting the chemistry to microfluidic devices ranging from simple test strips to the integrated computer-based reader. As such, Beacon Sciences can package the technology into

custom chemical reagents, combine them into a dye-buffer package, apply them to a dry chemistry strip or combine them into a mobile system for remote chemical detection.

The second major adjustment along the development path has been the challenge of the broad and diverse range of markets for which the company's chemistry can offer valuable and innovative solutions. In order to compartmentalise and focus its research and business development the company created a subsidiary, Reveal Sciences, focused exclusively on the application of Beacon Sciences synthetic receptor technology to the personal care industry.

SPIN-OUT COMPANY LAUNCH

Before spinning out a subsidiary, both scientific and senior management looked at the mistakes of other start-ups in the field and determined to avoid the common pitfalls of launching a new company. Chief among these were:

- (a) *Due diligence*: Beacon Sciences determined that early commercialisation of products could best be developed through establishing a subsidiary. Opportunity versus risk assessment as well as market research were undertaken to ascertain the real marketability of the unique intellectual property. There was no 'rush to expand' without due diligence, which has been a common problem with many start-ups.
- (b) *Adequate funding*: Beacon Sciences had adequate funding to launch a subsidiary. Management knew that the Reveal Sciences' development programme could not succeed if it was underfunded. Many biotechnology start-ups, and their spin-out companies, are fearful of dilution, of giving away too much of their companies. As a consequence, they turn down funding that could contribute greatly to their growth and success.

- (c) *Right investors*: A lot of start-ups do not attract the right kind of investors. If their investors panic at the first difficulty, commercialisation progress can quickly grind to a halt. 'Smart' investors understand not only the ups and down of the biotechnology industry, but the growing pains of any early-stage company's development, particularly an early-stage biotechnology company's efforts to launch a subsidiary.
- (d) *Experienced management team*: Building a successful biotechnology company requires experienced management. Many life sciences companies fail because of inexperienced management. Many, perhaps most, entrepreneurs believe they can do it all, but successful biotechnology start-ups quickly move from 'just us founders' to multidisciplinary experts in various disciplines. As Beacon Sciences already had a multidiscipline management team in place, this made for a smoother and smarter launch of the spin-off.
- (e) *Milestone-focused operating plan*: Both Beacon Sciences and Reveal Sciences have benefited greatly from putting in place practical, milestone-oriented operating plans tied to future funding strategy. This ties back to having an experienced management team running the company. An experienced management team develops a business plan based on the realities of the marketplace – a plan that will satisfy the expectations of investors, the goals of the founders and the demands of partners and industry. Many start-ups have failed due to having a poor, ultimately unrealistic plan not based on marketplace dynamics and practical considerations.

Reveal Sciences was formed in November 2007 as a subsidiary of Beacon Sciences. Through the launch of Beacon Sciences into the clinical, industrial processing and biodefence markets, it became clear to company management that market demand

for personal care applications would warrant a specialised focus of the team and Reveal Sciences was spun-out to meet this demand. Multiple interactions with leading consumer health companies indicated a strong need for consumer-focused innovation in personal care products and testing. With advances in manufacturing, formulation technologies, distribution and Internet-based sales of consumer products it had become evident to leading personal care companies that product differentiation needed to go well beyond traditional advertising, packaging and glorified non-scientific claims. With Beacon Sciences' chemical and biomedical advances adapted to personal care, Reveal Sciences is uniquely positioned to leverage its innovative detection and formulation platform into substantial product differentiation in these burgeoning personal care markets.

The global cosmetics and personal care markets are estimated at more than \$300 billion in business per year.³ Personal care describes a market composed of products purchased by, monitored by, applied by and applied to an individual person as a single customer. Although this industry has succeeded in branding or messaging to the individual consumer, manufacturers and suppliers have fallen short of empowering an individual with truly personalised products. Research has shown that there are a wide variety of underlying biological elements and causative agents leading to such skin symptoms, including poor skin barrier function, irritants, surfactants, allergies, bacteria, oxidation/sun damage, inflammation and others. Typical questionnaires and even three-dimensional imaging devices cannot discern the underlying cause, so the consumer must undergo a trial-and-error approach.

As the global consumer becomes savvier through exposure to electronic media and advertising, the burden of proof is raised for new products and subsequent performance claims. Unsubstantiated product claims are influencing consumer buying decisions and driving the need for interactive product

to otherwise cause a colour change to indicate the presence of such elements or related conditions. The technology will enable 'companion' testing products that match a person's skin or hair condition to a specific product, or to ensure product compliance such as a facial mask changing colours after the appropriate amount of time on the skin.

Reveal Sciences was officially launched at the international In-Cosmetics conference in Amsterdam, April 2008 (Figure 2).

VERTICAL INTEGRATED SOLUTIONS FOR NEW MARKETS

The first manifestation of Reveal Sciences' technology is the CareType™ Analysis System for skin and hair care testing. The new CareType™ System enables detection of biological elements that correlate to certain skin and hair conditions. By reporting accurate information about a skin or hair type, a customer can be better matched to a specific product, such as an anti-ageing cream or a dry skin lotion. This informative product experience promises not only to facilitate better product matching, but also to build brand confidence.

The CareType™ System consists of a user-friendly software-driven analysis platform, with disposable cartridges for reading samples. Reveal Sciences is also developing a prototype for a hand-held device that would perform the same analysis but with on-board analysis avoiding the need for a computer. Advantages of this innovative system are its manageable size, ease of use, quantitative data and reliability (Figure 3).

The CareType™ System is based upon simple non-invasive, painless tissue sample acquisition that can be performed in seconds by the consumer to evaluate a variety of skin and hair conditions. This is accomplished by a unique process that samples a superficial layer of skin or hair strands and images the sample under proprietary optical interrogation conditions to produce an image. The image is then processed using defined algorithms

that can decipher and quantitatively report a variety of conditions that drive appropriate product selection. Measurable conditions range from standard skin moisture levels, dryness, scaling, irritation and sensitivity to more specific assays that define aging parameters, damage, contaminants, specific toxins and, most importantly, skin and hair product regimen performance and improvement.

The CareType™ System is a vertically integrated solution that provides real-time feedback for the following market segments:

- *Industrial/clinical research market:* There is a strong need for clinical tools that cosmetic and personal care product research and development groups can use to express and define relevant product benefits. Reveal Sciences plans to use this research market to launch the initial CareType™ device in an environment that will have the additional benefit of creating/expanding awareness of the system in the larger marketplace. This market consists of internal research and development groups at major cosmetic, personal care and cosmeceutical companies as well as independent research labs, contract manufacturing QA/QC departments and consumer testing/product validation groups.
- *Professional spa and salon market:* Following its introduction and refinement in the research market, Reveal Sciences will seek appropriate cosmetic retail partners for the CareType™ Systems. Company management envisions these partners will either license the system on an exclusive basis or simply purchase systems on a non-exclusive basis to use as a point-of-sale consulting tool for product regimen evaluation. This market consists of high-end vertically integrated stand-alone cosmetic stores (such as MAC, Sephora), multi-product line cosmetic stores and beauty salons, spas and/or department stores. Whether exclusive or not, Reveal Sciences



Figure 3: The Reveal Sciences CareType™ System.

anticipates significant revenues in this market from consumables, such as test strips, and software modification/customisation for individual product lines (Figure 4).

- *Retail cosmetics sales and home self-testing market:* The company will also seek direct partnerships with cosmetic companies to provide customised tests and assays based on existing or new product lines. In this model, Reveal would benefit from licensing the CareType™ Systems to individual companies to brand and place in key opinion leader markets or as use as a companion diagnostic and monitoring device.

NEW PRODUCT EXPANSION

Creatinine is a urine metabolite commonly used to gauge an individual's kidney function and ability to metabolise drugs. Recently, the Beacon Sciences team created a new product, an assay that changes colour for creatinine.

Creatinine was detected using an indicator displacement assay with a synthetic receptor. The colour change assay technology was also shown to work in a lateral flow format, similar to a pregnancy strip test. The assay can be analysed using a hand-held reader.

The novelty in the product stems from the ability to see visual colour change as a result of the test and that it is combined with the hand-held reader. The new assay offers the potential of simplicity and speed over existing methods.

The total immunoassays market is at \$7 billion.² Beacon Sciences' current projections calculate that this synthetic receptor technology could be worth \$50 million within the next 5 years. Although Beacon Sciences provides the core technology for the chemistry, the first applications for the new assay may actually be seen in Reveal Sciences. In addition to bioassay companies, cosmeceutical companies typically pursue this



Figure 4: A Reveal Sciences CareType™ System test strip.

type of technology. Reveal Sciences has already established a number of ongoing discussions with companies in the cosmeceutical industry, as well as in bioassay development, interested in applications of the new technology.

SUMMARY

In summary, Beacon Sciences is an emerging success story along with its subsidiary, Reveal Sciences, that stands as an example of how much rapid progress start-up biotechnology companies can make in a short period of time with the combination of scientific innovation and creativity coupled with strong commercialisation management expertise from an experienced venture capital firm that understands the biotechnology marketplace. Led by a prominent scientist in the field and funded and managed by a business-savvy life sciences venture firm, Beacon Sciences has been able to establish itself in less than 2 years as strongly differentiated both scientifically

and commercially from its competitors.

In addition, the company launched a spin-out company, Reveal Sciences, last year and it is already experiencing early business success.

Beacon Sciences started from the traditional pathway of university technology transfer and licensing, leading scientist turned entrepreneur and venture capital funding. Now, both Beacon Sciences and Reveal Sciences occupy approximately 10 000 square feet of wet-chemistry laboratory space provided by the life sciences venture firm, ETI, for research and development. Both companies remain biotechnology companies focused on technology innovation, leaving the product development and marketing to commercial partners. Reveal Sciences expects to have multiple products on the market within the near future, whether launched directly by the company or by one of its commercial partners (Figure 5).

Lessons learned to pass on to fellow scientist-entrepreneurs include the following:



Figure 5: Beacon Sciences and Reveal Sciences research and development laboratories located in the Emergent Technologies, Inc. facilities.

1. Choose the right venture capital firm that is an excellent fit with the start-up company and business goals. Beacon Sciences benefits from ETI, primarily for three reasons.
 - (a) Venture firm focused exclusively on life sciences.
 - (b) Firm with a unique business model and non-traditional approach to the management of intellectual property.
 - (c) Experienced management team of PhDs, MDs and fellow scientists with considerable business development expertise and resources.
2. Establish and build the company in a macro environment that supports biotechnology and business growth.

Both Beacon Sciences and Reveal Sciences are located in Austin, Texas and so is their venture capital firm. Last year Texas was named as one of the five top biotechnology economic

development centres in the world.⁴ Texas also ranks high in the top 10 states in America in the categories of overall biotechnology strength, biotechnology venture capital investments, funding for bioscience research, state bioenergy investments, business climate and overall tax climate.⁵

3. Streamline the start-up's commercialisation approach.

Beacon Sciences and Reveal Sciences were able to do this through their relationship with their venture capital firm. Of course, not all biotechnology start-ups are funded through a venture firm. However, whether funding is through a university, other institution or various private sources, it is critical to conservatively and effectively manage time, money and resources while still moving forward at a good pace to the commercialisation phase.

4. Build or put the company in the hands of a strong management team and follow their guidance and direction. Scientists are experts in their chosen fields and although often business-savvy, they are not always business development experts. An experienced management team knows how to accelerate a start-up's growth in a controlled manner. Interdisciplinary and specialised management teams also can have established contacts with market leaders and other potential strategic partners that start-ups can greatly benefit from without having to business network from scratch as it were.

Beacon Sciences and Reveal Sciences have benefited immeasurably through these factors

and are poised to make a significant and profitable contribution across several industries, both in the United States and internationally.

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