



**Imagenetix, Inc.**  
 10845 Rancho Bernardo Road, Suite 105  
 San Diego, CA 92127  
 Phone: (858) 674-8455  
 Fax: (858) 674-8460  
[www.imagenetix.net](http://www.imagenetix.net)

## Scientifically Tested, Proprietary Bioceutical Products

### Snapshot

July 19, 2010

Imagenetix, Inc. ("Imagenetix" or "the Company") develops and markets **bioceutical**<sup>†</sup> and pharmaceutical products. Bioceuticals, which are estimated to represent a nearly \$124 billion industry worldwide, entail **bioactive** chemicals derived from food that have a beneficial effect on health. Imagenetix's lead bioceutical product, Celadrin<sup>®</sup>, is designed to lubricate and cushion the joints, promoting comfort and flexibility. Marketed as both a **softgel** and a topical cream, Celadrin<sup>®</sup> is widely available in the U.S. at Walgreens, Kroger, Costco, and Walmart, among many other retail outlets. Imagenetix also distributes Celadrin<sup>®</sup> to third parties for use in private-label products and as a branded ingredient for wholesale customers. The Company's bioceutical portfolio further includes a **probiotic**, BioGuard<sup>™</sup>, for supporting a healthy immune system; a proprietary compound, Trisynex<sup>™</sup>, used in products for fat loss and obesity; and a delivery system, CellSorb<sup>™</sup>, being studied for its effect at increasing the body's absorption of **Coenzyme Q<sub>10</sub> (CoQ<sub>10</sub>)**. At present, BioGuard<sup>™</sup> is sold through Costco and other retail outlets, such as Rite Aid. Trisynex<sup>™</sup> is distributed as a bulk raw material. In terms of pharmaceutical development, Imagenetix is conducting preclinical studies of a pilot blend, 1-TDC, and its active compound, MA2009, which may be able to prevent and treat **periodontal disease**.

### Recent Financial Data

Ticker (Exchange)	IAGX (OTC.BB)
Recent Price (07/16/2010)	\$0.42
52-week Range	\$0.25 – \$0.85
Shares Outstanding	~12 million
Market Capitalization	~\$5 million
Average 3-month Volume	3,456
Insider Owners +5%	31%
Institutional Owners	7%
EPS (Year ended 03/31/2010)	(\$0.06)
Employees*	15



\* Includes 6 consultants.

### Key Points

- Imagenetix emphasizes product development backed by clinical studies, believing that bioceuticals supported by scientifically validated claims may realize a competitive advantage in the marketplace as well as create greater consumer confidence in the products.
- In clinical studies, 100% of patients with **osteoarthritis** who were given Celadrin<sup>®</sup> Cream showed an improvement versus patients on placebo. Benefits included improved physical function, reduced pain, and improved postural balance.
- Preclinical studies have demonstrated 1-TDC's ability to inhibit the progression of periodontal disease as well as partially regenerate gum and bone tissue lost due to this disease.
- Imagenetix's leadership is experienced at developing and selling nutritional products globally, including to direct marketers, health food stores, and mass-market merchandisers.
- Imagenetix holds issued patents covering each of its saleable products—Celadrin<sup>®</sup>, BioGuard<sup>™</sup>, and Trisynex<sup>™</sup>—as well as for its preclinical pharmaceutical candidate 1-TDC.
- At March 31, 2010, Imagenetix had cash and cash equivalents of close to \$1 million. Subsequently, in May 2010, Imagenetix raised \$400,000 through an equity financing (800,000 shares of Common Stock at \$0.50 per share) and \$410,000 in a debt financing.

<sup>†</sup>**BOLD WORDS ARE REFERENCED IN THE GLOSSARY ON PAGES 47-49.**

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## Executive Overview

Imagenetix, Inc. ("Imagenetix" or "the Company") is focused on the development of scientifically tested and proprietary bioceutical and pharmaceutical products. The Company's bioceutical activities center around the development of naturally based **nutraceuticals** designed to address specific health issues. These bioceuticals, which provide pharmacological benefits supported by science, include the following: (1) Celadrin® for joint health; (2) BioGuard™ for immune system function; (3) Trisynex™ for fat loss and obesity; and (4) CellSorb™ to enhance absorption of Coenzyme Q<sub>10</sub> (CoQ<sub>10</sub>). The Company's pharmaceutical activities target periodontal disease and other conditions caused by inflammation. The initial pharmaceutical candidate, 1-tetradecanol complex (1-TDC), and its active compound, MA2009, is designed to prevent and treat periodontal disease.

Imagenetix's product development strategy is to maximize revenue potential and competitiveness, with net sales for the year ended March 31, 2010, reported at over \$6.5 million. The Company seeks to develop product candidates that meet the following criteria: (1) novel and proprietary; (2) patentable; (3) targeted toward sizable markets; and (4) supported by scientifically validated claims in reliable, peer-reviewed publications. Imagenetix especially emphasizes this last criterion. The Company believes that the use of clinical data and peer-reviewed journal articles to support its bioceuticals' claims offers a competitive advantage by creating consumer confidence and distinguishing its products from marketed alternatives.

Imagenetix distributes branded nutrition products through mass-market retailers and e-commerce as well as provides finished private-label products to third parties. The Company also offers compounds and formulations (sold as raw ingredients) under license agreements with other bioceutical partners. These third-party offerings, the majority of which contain the proprietary Celadrin® compound, are marketed through various distribution channels, including wholesale, direct sales, and e-commerce.

### Celadrin®

Depicted in Figure 1, the Company's lead product is Celadrin®, a patented compound designed to lubricate and cushion the joints, promoting comfort and flexibility. Imagenetix offers Celadrin® as a branded nutritional supplement, as a private-label product, and as a branded ingredient used by wholesale customers in their product formulations. Celadrin® is available in two formats: (1) as oral softgels designed for long-term relief; and (2) as a topical cream for fast-acting relief.

Natural oils included in Celadrin® work at the cellular level of joints to restore cell membrane fluids and lubrication, which improves cells' health and produces joint mobility. Through 17 studies, Celadrin® was found to provide joint health (softgels) and relief from joint pain and **arthritis** symptoms (topical cream), as well as cumulative and restorative long-term benefits. The anti-inflammatory capabilities of Celadrin® and its ability to increase cell membrane fluidity appear to provide the joints and surrounding tissues with restorative and regenerative opportunities.

In a trial of 64 participants who had chronic knee osteoarthritis, 58% of individuals given Celadrin® Softgels experienced a reduction in pain versus 32% of patients given placebo. As well, 15% of Celadrin® recipients reported reduced swelling versus 0% among those who received placebo. Data also showed that the Celadrin® group had an improvement in knee flexion of +10.1° versus the control group. Imagenetix believes that supplementation with Celadrin® may elicit these favorable effects not only through the stimulation of beneficial responses within the joint cartilage but also through restoration and maintenance of the structural integrity of the joint.

Figure 1  
Imagenetix, Inc.  
CELADRIN®



Source: Imagenetix, Inc.

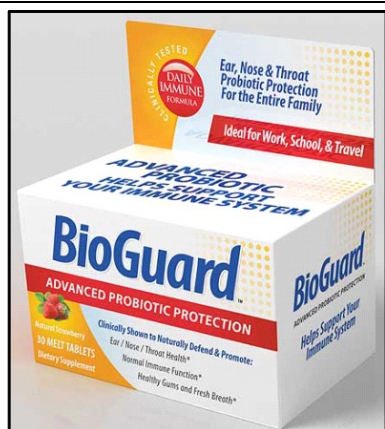
Studies conducted with the topical Celadrin® Cream further suggested that the product could be an effective treatment for improving physical function, reducing pain, and improving postural balance in patients with osteoarthritis. In one study, 100% of patients showed a benefit versus the patients on placebo. Celadrin® patients experienced improvement within 30 minutes and cumulative benefits over the remaining 30 days of the trial (Source: *Journal of Rheumatology* vol. 31[4]:767-774 [2004]).

In 2009, Applied Research-West, Inc. (a full-service market research firm) conducted a survey of 400 rheumatologists and orthopedic surgeons who recommend natural products. As many as 94% of survey respondents stated that they would recommend Celadrin® for supporting joint health.

Celadrin® Softgels and topical Celadrin® Cream can be found in the vitamin aisles of drugstores, supermarket chains, and club warehouse stores. As detailed on pages 6-7, Celadrin® Softgels are available at Walgreen Co. (WAG-NYSE), SUPERVALU Inc. (SVU-NYSE), the Kroger Co. (KR-NYSE), and Rite Aid Corp. (RAD-NYSE), among many other retail outlets. Celadrin® Softgels are also being launched in test markets with Costco Wholesale Corp. (COST-NASDAQ), Wal-Mart Stores, Inc. (WMT-NYSE), and CVS Caremark Corp. (CVS-NYSE). Imagenetix is scheduled to expand from 200 to 400 Costco stores nationwide during 2010. Both the Softgels and Cream are available online, and Imagenetix is working with Costco to launch the Cream in stores by October 2010.

## BioGuard™

Figure 2  
Imagenetix, Inc.  
BIOGUARD™



Source: Imagenetix, Inc.

BioGuard™ (depicted in Figure 2) is a probiotic targeting the ear, nose, and throat in order to benefit the overall immune system. BioGuard™ acts as a natural agent against the growth of harmful bacteria, thereby defending against ear, nose, and throat pathogens and promoting a healthy respiratory system.

The active ingredient in BioGuard™, BLIS K12™, is a naturally occurring but rare strain of ***Streptococcus salivarius* (S. salivarius)** that is found in only approximately 2% of the population. BLIS K12™ is a patented probiotic that produces antibacterial proteins which selectively target bacteria that cause **immune imbalances**, throat irritations, and mouth odor, among other conditions. The *S. salivarius* K12 strain was first identified in a study involving several hundred children in New Zealand who were monitored for bacterial throat infection (e.g., strep throat). The study showed that children who did not have “K12-like” *S. salivarius* bacteria in their mouth were twice as likely to develop bacterial throat infection as those with “K12-like” *S. salivarius*.

In additional studies, BioGuard™ ingredients were shown to improve overall immunity and be proactive against the spread of harmful bacteria in the mouth, ear, nose, and throat.

BioGuard™ is available at Costco.com and is scheduled for distribution to Costco stores as a seasonal and immune system health product. BLIS K12™ was developed by New Zealand-based BLIS Technologies Ltd. (BLT-NZX). Imagenetix holds exclusive rights to BLIS K12™ for mass-market distribution in the U.S., although there exist alternative delivery methods to which the Company does not have exclusive rights.

## Trisynex™

In contrast to many weight loss products, which reduce appetite but do not have a **metabolic** effect, Imagenetix's proprietary Trisynex™ fat-reducing compound is intended to alter body composition, resulting in reduced stored body fat and enhanced lean muscle. To do so, this compound seeks to regulate levels of specific hormones involved in the body fat storage process, resulting in increased fat burning activity and production of lean muscle.

A study designed to evaluate the effectiveness of Trisynex™ demonstrated that combining this compound with exercise and a reduced-calorie diet improved body composition and **adipocytokine** levels versus diet and exercise alone. Altogether, the use of Trisynex™ resulted in improvement in the following areas: (1) weight loss; (2) fat loss; (3) waist circumference; (4) **leptin** reduction; and (5) **adiponectin** increase. Trisynex™ is supplied in bulk as a raw material for private-label products.

### CellSorb™: 100 mg CoQ<sub>10</sub> Softgels

CellSorb™ is one of Imagenetix's newer bioceutical candidates. It is a delivery system that is intended to help increase the body's absorption of CoQ<sub>10</sub>, a natural compound found in every cell of the body. CoQ<sub>10</sub> produces energy to fuel cell growth and maintenance, and works synergistically with vitamin E in the antioxidant cycle to protect the fatty part of the cell from damaging **free radical** attacks. However, CoQ<sub>10</sub> is a lipophilic molecule, indicating that it does not dissolve easily in water. As a result, CoQ<sub>10</sub> is poorly absorbed by the intestines of humans and animals (Source: Clinigene International Ltd., a full-service clinical research organization and subsidiary of Biocon Ltd.). In a comparative study of CellSorb™ and three existing CoQ<sub>10</sub> products, results suggested that CellSorb™ elicited favorable **pharmacokinetics** in terms of **bioavailability**, **bioequivalence**, and absorption relative to the comparator products. Thus, Imagenetix believes that the use of CellSorb™ in conjunction with CoQ<sub>10</sub> could improve the substance's entry into cell membranes and its utilization by the body.

### 1-TDC and MA2009

Imagenetix's pharmaceutical development program is based on preventing and treating chronic inflammatory conditions by leveraging the anti-inflammatory capabilities of the active compound found in 1-tetradecanol complex (1-TDC). The initial therapeutic candidate is 1-TDC, a **monounsaturated** fatty acid complex to prevent and treat periodontal disease, and 1-TDC's active compound, MA2009. Preclinical studies conducted at Boston University have shown that 1-TDC may stop the progression of gum and bone damage as well as partially restore gum and bone lost due to the disease.

Imagenetix is working to complete additional preclinical studies on MA2009, including toxicity and dosage analysis, in preparation for an **Investigational New Drug (IND)** filing, which could require 9 to 12 months. To facilitate further development of MA2009, Imagenetix is evaluating strategic alliances with pharmaceutical companies that could commercialize the candidate.

### Market Opportunities

The global market for bioceuticals was valued at nearly \$124 billion in 2008. It was expected to reach over \$176 billion by 2013, as part of a larger \$236 billion global nutritional product industry. Market drivers include the following: (1) an aging global population; (2) more sophisticated products in response to new research; (3) a trend toward preventive medicine due to rising healthcare costs; (4) greater awareness with regard to the relationship between diet and health; and (5) acceptance of the Internet as a provider of consumer information and as a sales channel. The U.S. leads in sales of nutraceuticals, with over 32% of the global share. Combined, the U.S., Europe, and Japan represent approximately 86% of this market (Source: Global Industry Analysts, Inc.'s *Nutraceuticals: A Global Strategic Business Report* 2008).

Due to medical advances, nearly two billion adults over age 60 may be alive by 2050 (almost triple the 2006 figures). Accordingly, this population contributes to demand for improved treatments targeting conditions that disproportionately affect older individuals, such as arthritis. To this extent, **baby boomers** have ranked joint pain as one of their foremost health concerns, behind heart problems and cholesterol. Imagenetix's research from the *Nutrition Business Journal* values the U.S. market for bone and joint health at roughly \$2.5 billion. Moreover, questions have been raised recently regarding the efficacy of the predominant supplements for joint health—**glucosamine** and **chondroitin**—due to the outcomes of several studies (Source: Decision News Media, April 15, 2010). This, coupled with the harsh side effects of many prescription joint pain products, has led Imagenetix to expect future growth in the bone and joint health segment to be driven by the emergence of alternative ingredients, such as Celadrin®.

### Headquarters and Employees

Imagenetix was founded in 1999 and is headquartered in San Diego, California. The Company currently employs 15 individuals, which includes six consultants.



## Distribution and Sales Strategies

Imagenetix is focused on three key objectives:

- offering proprietary functional products supported by scientific evidence;
- providing quality customer service; and
- attaining brand recognition.

The Company markets its products via several approaches: (1) under its own brand, which is sold primarily through e-commerce and mass-market retailers, such as major club stores; (2) on a private-label basis for wholesale distribution, direct sales, and e-commerce predominantly in international markets; and (3) as patentable compounds and formulations that can be licensed to pharmaceutical partners.

Although Imagenetix capitalizes on the ability of retail and online distributors to supply its products, the Company facilitates product sales by providing distributors with a turnkey marketing strategy. Imagenetix develops specific product formulations; provides scientific studies supporting product efficacy; complies with applicable laws and regulations, including those required for obtaining product approval in foreign markets; and offers full marketing support (e.g., marketing materials).

Going forward, the Company intends to continue its marquee brands in order to increase sales with the expansion of retail placement as well as broaden its consumer focus by developing new products, especially those associated with the direct selling and mass marketing of supplements and other nutraceutical products.

### Product Distribution

For each product, Imagenetix conducts and completes scientific studies necessary for regulatory compliance, arranges for the manufacture of finished products to the Company's specifications, and develops marketing tools and plans to facilitate product sales, including labels and graphic designs, informational brochures, and promotional speakers. These steps facilitate the commercialization process for Imagenetix's distributors and mass-market store sales.

#### *Celadrin<sup>®</sup>*

Imagenetix markets Celadrin<sup>®</sup> as its own proprietary brand; as a private-label formulated product; and as a branded ingredient for wholesale customers to use in their own product formulations and labels.

Celadrin<sup>®</sup> Softgels are available in over 10,000 retail outlets, including major drugstore, supermarket, and club warehouse chains such as Walgreens, SUPERVALU, Kroger, Rite Aid, and Costco, among many others (as illustrated in Figure 3 [page 7]). Imagenetix is working to expand from 200 Costco stores to approximately 400 nationwide during 2010. The Softgels are also available at approximately 800 Walmart stores, 80 Sam's Club stores (a division of Walmart), and 800 CVS locations on a test basis. If test markets are deemed successful, Celadrin<sup>®</sup> Softgels could be sold at all U.S. Walmart, Sam's Club, and CVS stores.

Both the Celadrin<sup>®</sup> Softgels and Celadrin<sup>®</sup> Cream are available online through websites such as Costco.com, Target.com, CVS.com, and Drugstore.com, as well as on Imagenetix's website. Further, Imagenetix is working with Costco to launch the Celadrin<sup>®</sup> Cream in stores by October 2010. The Company intends to position Celadrin<sup>®</sup> as an arthritis and pain relief cream.

As well, both the Softgels and Cream are distributed under private labels at several multi-level marketing (MLM) companies.

Figure 3  
Imagenetix, Inc.  
DISTRIBUTION



Source: Imagenetix, Inc.

Imagenetix is supporting sales of Celadrin® with national television advertisements. On May 24, 2010, the Company launched a new television campaign called "Stand, Bend, Walk, Climb," which seeks to educate consumers on the benefits of Celadrin® through 15- and 30-second spots on A&E, AMC, CNN, Fox News, Hallmark, Lifetime, TBS, TNT, and USA, among other channels. The commercials are scheduled to air for six weeks with a four-week break, followed by six more weeks on air. These advertisements were designed to run concurrently with Imagenetix's procurement of greater retail shelf space, as the Company continues to add national retailers to its U.S. customer base.

#### BioGuard™

BioGuard™ is currently available on Costco.com, where the Company believes it primarily competes with products such as Airborne®. A trial program with BioGuard™ was completed at 55 Costco stores in the Pacific Northwest, which the Company complemented with television advertising campaigns to promote sales. It is scheduled for distribution to all Costco locations as of September 2010. Imagenetix is now also working to introduce BioGuard™ at additional food, drug, and mass-market stores.

#### Trisynex™

Imagenetix views the U.S. market for weight loss products as one which is highly competitive and characterized by costly marketing campaigns. The Company believes that weight loss products are not always supported by clinical data and claims may be misleading. Thus, Imagenetix is focusing efforts for its weight loss compound, Trisynex™, on international markets. At present, Trisynex™ is only sold as a bulk raw material and to MLM companies. Going forward, Imagenetix may seek further distribution agreements for its patented private-label weight loss compound in international markets. As well, the Company, which holds an exclusive license from the University of Minnesota for Trisynex™, could be receptive to strategic sublicenses of the intellectual property for Trisynex™.

## Intellectual Property

Imagenetix seeks to protect its products via both domestic and international intellectual property, as it is important that the Company have patent-protected products to supply as active compounds in private-label use.

### **Celadrin®**

This product is protected under U.S. patent number 5,569,676, owned by Imagenetix. The Company also received a trademark for Celadrin® in February 2002.

### **BioGuard™**

The ingredients of BioGuard™ are covered by 13 patents worldwide, which include U.S. patent number 6,773,912.

### **Trisynex™**

Trisynex™ is protected under U.S. patent number 6,899,892, owned by the University of Minnesota. Imagenetix retains exclusive commercialization rights to this patent, which comprises 29 claims for fat reduction and enhanced body composition. Trisynex™ is a trademark of Imagenetix.

### **1-TDC**

U.S. patent number 7,612,111 was granted to the Company in November 2009 for 1-TDC's prevention and treatment of periodontal disease.



## Company Leadership

### Management

Imagenetix's management and key personnel are experienced in developing and selling nutritional products to domestic and international marketers, including direct marketers, health food stores, and mass-market merchandisers. Table 1 summarizes the Company's key management, followed by detailed biographies.

Table 1  
Imagenetix, Inc.  
MANAGEMENT

William P. Spencer, MBA	Chief Executive Officer, President, and Director
Lowell W. Giffhorn, MBA	Chief Financial Officer and Principal Accounting Officer
Derek C. Boosey	Vice President—International
Robert L. Hesslink, Jr., Sc.D.	Director of Research and Development
Frank Sajovic	Chief Marketing Officer
Debra L. Spencer	Secretary and Director

*Source: Imagenetix, Inc.*

#### *William P. Spencer, MBA, Chief Executive Officer, President, and Director*

Mr. Spencer has served as a director and the Company's president since January 1999. From January 1986 to December 1996, he served as chief operating officer (COO), chief financial officer (CFO), and executive vice president of Natural Alternatives International, Inc. (NAII-NASDAQ), a company engaged in the formulation and production of encapsulated vitamins and nutrients. He was president of NAII from December 1996 to October 1998 and was a director from January 1986 to October 1998. From 1976 to 1988, he was a regional vice president for San Diego Trust and Savings Bank. Mr. Spencer earned a B.S. in finance and an MBA from San Diego State University.

#### *Lowell W. Giffhorn, MBA, Chief Financial Officer and Principal Accounting Officer*

Mr. Giffhorn has served as the Company's CFO since July 2005. Since October 2005, he has also served as CFO of Brendan Technologies, Inc. (BDTE-OTC), a company that provides computer software to the pharmaceutical and life science industries. He has further served on the Board of Directors of Brendan Technologies since December 2005. From November 1996 to June 2005, Mr. Giffhorn was the CFO of Patriot Scientific Corp. (PTSC-OTC), a semiconductor and intellectual property company. From June 1992 to August 1996 and from September 1987 to June 1990, he was the CFO of Sym-Tek Systems, Inc. and vice president of finance for its successor, Sym-Tek, Inc., a supplier of capital equipment to the semiconductor industry. Mr. Giffhorn obtained an MBA from National University in 1976 and a B.S. in accountancy from the University of Illinois in 1969. Mr. Giffhorn was also a director and chairman of the Audit Committee of DND Technologies, Inc. (DNDT-OTC).

#### *Derek C. Boosey, Vice President—International*

Mr. Boosey has served as Imagenetix's vice president—international since September 1999. From 1994 to September 1999, he was new business manager for NAII and, from 1990 to 1994, was director of marketing for Athletics Canada. From 1984 to 1990, Mr. Boosey was a technical advisor to the Korean Ministry of Sports and a sports and marketing consultant for Nike, Inc. (NKE-NYSE). He earned degrees in physical education from Keele University (England) and Opu University (England) and is the Senior Olympics world record holder in the triple jump within the 55 to 60 age class.

*Robert L. Hesslink, Jr., Sc.D., Director of Research and Development*

Dr. Hesslink has served as the director of research and development (R&D) at Imagenetix since mid-2005 and prior to that consulted for Imagenetix on a variety of research projects since 2000. In his capacity as director of R&D, Dr. Hesslink develops and coordinates preclinical and clinical research projects for all of Imagenetix's compounds. Dr. Hesslink received a Doctorate of Science (Sc.D.) from the Department of Health Sciences at Boston University in 1987. His dissertation investigated limits to human performance under the guidance of Richard P. Adams, Ph.D., M.D. In addition to working with Dr. William Evans and Walter Frontera at the Tufts University/U.S. Department of Agriculture (USDA) Center for Human Nutrition on Aging, Dr. Hesslink worked at the U.S. Army Research Institute of Environmental Medicine under the direction of Dr. Michael Sawka. Dr. Hesslink was stationed at the Naval Health Research Center (NHRC), San Diego, California, in 1990 and remained there until his departure from the U.S. Navy in 1993. During his time at NHRC, Dr. Hesslink directed the Cold Weather Medicine program for the U.S. Marine Corps. In collaboration with Dr. David Systrom at the Massachusetts General Hospital, he co-authored a paper published in *Journal of Applied Physiology*. Dr. Hesslink has continued to publish research in the area of environmental medicine and applied physiology.

*Frank Sajovic, Chief Marketing Officer*

Mr. Sajovic is a senior management executive with over 30 years of experience across multiple industries and expertise in strategic planning, marketing, sales, product development, manufacturing, distribution, and regulatory/legal affairs. His strategic planning and business execution skills focus on branding and building profitable growth and corporate value. He currently functions as the chief marketing officer for Imagenetix, providing go-to-market strategies and plans for Celadrin® and BioGuard™. Mr. Sajovic was CEO and president of Pilot Therapeutics Holdings, Inc., a start-up specialty pharmaceutical company. He positioned this company to develop and capture new category sales by bringing a novel over-the-counter (OTC) medical food, Airozin™, to market. As general manager and vice president for Boehringer Ingelheim GmbH, a global pharmaceutical and consumer healthcare products company, he was responsible for all personnel and business activities related to the U.S. Consumer Healthcare Unit. At Boehringer, Mr. Sajovic managed well-known brands such as Dulcolax® and Ginsana®. At Pharmavite LLC, he served as executive vice president of marketing, international sales and marketing, and research and development, where he was responsible for building corporate sales from \$60 million to \$450 million. Mr. Sajovic helped advance Nature Made® to a leading market position in the vitamin/mineral category and launched the \$60 million dollar SAM-e® business. At Foote, Cone & Belding (now DraftFCB), he was vice president, management supervisor and worldwide account director, where he directed advertising and marketing for pet food brands including Pedigree® Mealtime® and Friskee's® Fancy Feast®, with each resulting in sales exceeding \$100 million. While at Hunt-Wesson Foods (now part of ConAgra Foods, Inc. [CAG-NYSE]), Mr. Sajovic helped reposition Wesson to regain its market position and achieve \$180 million in sales.

*Debra L. Spencer, Secretary and Director*

Ms. Spencer has served as a director and secretary since March 1999 and as treasurer from March 1999 to July 2005. Her responsibilities also include product label copy and graphic design in compliance with U.S. Food and Drug Administration (FDA) regulations as well as developing marketing materials for Imagenetix's private-label products. From 1970 to 1981, she was an executive assistant to the vice president of a local San Diego bank. From 1987 to 1993, she served as vice president, secretary, and treasurer for Vitamin Direct, Inc., a consumer mail-order vitamin company.

## Board of Directors

Imagenetix's Board of Directors oversees the conduct of and supervises the Company's management. Table 2 provides a summary of Board members, followed by detailed biographies.

Table 2  
Imagenetix, Inc.  
BOARD OF DIRECTORS

William P. Spencer, MBA	Chief Executive Officer, President, and Director
Debra L. Spencer	Secretary and Director
Jeffrey G. McGonegal, CPA	Director
Robert Burg	Director
Barry S. King	Director

*Source: Imagenetix, Inc.*

*William P. Spencer, MBA, Chief Executive Officer, President, and Director*

Biography on page 9.

*Debra L. Spencer, Secretary and Director*

Biography on page 10.

*Jeffrey G. McGonegal, CPA, Director*

Mr. McGonegal joined Imagenetix's Board in 2005. He also serves as the CFO of AspenBio Pharma, Inc. (APPY-NASDAQ), a biomedical company, and PepperBall Technologies, Inc. (PBAL-OTC), a security products and services company, and as senior vice president—finance of Cambridge Holdings Ltd (CDGD-OTC), a real estate and business development firm with limited activities. Since 1997, Mr. McGonegal has served as managing director of McGonegal and Co., a company engaged in providing accounting and business consulting services. From 1974 to 1997, he was an accountant with BDO Seidman LLP. While at BDO Seidman, Mr. McGonegal served as managing partner of the Denver, Colorado, office. Until its sale in April 2007, he was also a member of the Board of Directors of Applied Medical Devices, Inc. Mr. McGonegal received a B.A. in accounting from Florida State University and is a certified public accountant (CPA) licensed in Colorado.

*Robert Burg, Director*

Mr. Burg joined the Company's Board in 2005. Since 1998, he has been the owner of The Burg Group, a business development company based in the sports industry. From 1992 to 1998, Mr. Burg held several executive level positions, including as president from 1995 to 1998 of Royal Grip, Inc., which designed and distributed golf club grips and athletic headwear. He received a B.A. in business from Great Western University in 1977.

*Barry S. King, Director*

Mr. King joined Imagenetix's Board in 2003. He was the director of marketing for the U.S. Olympic Committee from 1987 to 2002. Since 2002, Mr. King has been the vice president and general manager of TriActive America, Inc. He graduated with a B.A. from the University of Colorado in 1969.

## Core Story

Imagenetix, Inc. (“Imagenetix” or “the Company”) is focused on the development, formulation, and marketing of scientifically tested, proprietary bioceutical and pharmaceutical products. The Company’s bioceutical activities are targeted toward the development of naturally based nutraceuticals in the form of nutritional supplements and over-the-counter (OTC) topical creams. These bioceutical products provide pharmacological benefits, as supported by scientific research. Imagenetix believes that leveraging clinical data and peer-reviewed journal articles to support product claims may differentiate the Company from other entities in the bioceutical sector, potentially providing a competitive advantage.

At present, Imagenetix’s bioceutical portfolio entails four nutraceutical compositions, each of which is proprietary and targeted toward a sizable market: (1) Celadrin® for joint health; (2) BioGuard™ for immune system function; (3) Trisyne™ for weight management; and (4) CellSorb™, a delivery system to enhance absorption of Coenzyme Q<sub>10</sub> (CoQ<sub>10</sub>). In addition, Imagenetix’s pharmaceutical pipeline is centered on the development of therapies for periodontal disease and other conditions caused by inflammation. An overview of the Company’s products and product candidates is provided in Table 3.

Table 3  
Imagenetix, Inc.  
PRODUCT PORTFOLIO

Bioceuticals		
Product	Indication	Commercial Status
Celadrin®	Joint health	Available for sale
BioGuard™	Probiotic for upper respiratory tract, immune health	Available for sale
Trisyne™	Weight management and fat loss	Available for bulk sales as a raw material
CellSorb™	Absorption enhancer	In development
Pharmaceutical		
Candidate	Indication	Development Stage
1-Tetradecanol Complex (1-TDC) and MA2009	Periodontal disease and inflammation	Preclinical

Sources: Imagenetix, Inc. and Crystal Research Associates, LLC.

Imagenetix markets its branded products through mass-market retailers and e-commerce. In addition, the Company offers finished private-label products that are sold to third parties predominantly in international markets as well as compounds and formulations sold as raw ingredients under licensing agreements with bioceutical partners.

## IMAGENETIX'S BIOCEUTICAL PRODUCTS

Imagenetix's bioceutical activities center on the development of naturally based compounds that are designed to address specific health issues. The Company seeks to maximize revenue potential and competitiveness by developing products that possess the following attributes: (1) novel and proprietary; (2) patentable; (3) targeted toward sizeable markets; and (4) supported by scientifically validated claims in reliable, peer-reviewed publications.

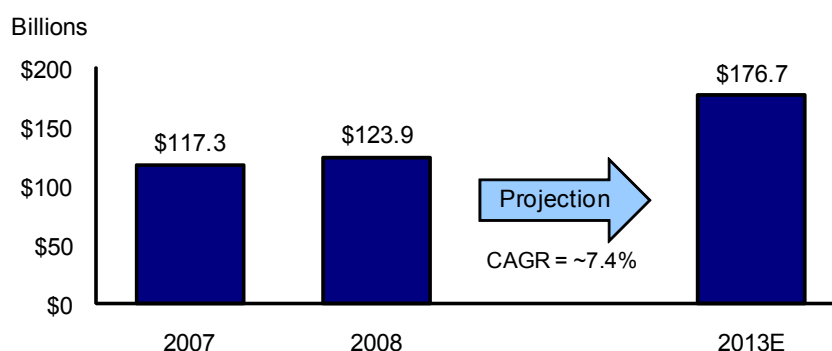
Imagenetix especially emphasizes the use of scientific research to validate its products. Each of the Company's bioceutical offerings is subjected to an array of studies, including tests to characterize the candidate's mechanism of action, toxicity, safety, and efficacy. Imagenetix believes that by presenting these findings at scientific conferences, submitting studies to peer-reviewed journals, and advancing compounds through clinical studies, it can distinguish its product offerings from the competition, increase consumer confidence, and attract other companies that may wish to license the Company's compounds.

### The Bioceutical Market

Bioceuticals (or nutraceuticals) are bioactive compounds derived from foods that are believed to provide a physiological or health benefit, including the prevention and treatment of chronic disease. Nutraceuticals are often concentrated extracts from natural products taken at much higher concentrations than diet alone could provide, and are generally sold in medicinal and nutritional supplement forms.

The global market for bioceuticals was valued at nearly \$124 billion in 2008. It was expected to reach over \$176 billion by 2013, as part of a larger \$236 billion global nutritional product industry. Figure 4 illustrates forecasted growth in the nutraceutical market. Included within the bioceutical/nutraceutical market are nutraceutical supplements (e.g., vitamins, minerals, herbs, botanicals, amino acids, and other compounds), for which demand is anticipated to be more than \$48 billion in 2013 (Sources: The Freedonia Group's *World Nutraceutical Ingredients to 2013* [2009] and BCC Research's *Nutraceuticals: Global Markets and Processing Technologies* [October 2008]). The U.S. leads sales of nutraceuticals, with over 32% of the global share. Combined, the U.S., Europe, and Japan represent approximately 86% of this market (Source: Global Industry Analysts, Inc.'s *Nutraceuticals: A Global Strategic Business Report* 2008).

Figure 4  
ESTIMATED NUTRACEUTICAL MARKET GROWTH



Sources: BCC Research's *Nutraceuticals: Global Markets and Processing Technologies* (October 2008) and Crystal Research Associates, LLC.

Growth drivers contributing to the expansion of nutraceuticals and nutritional supplements include the following: (1) an aging global population; (2) more sophisticated products in response to new research; (3) a trend toward preventive medicine resulting from rising healthcare costs; (4) enhanced awareness with regard to the relationship between diet and health; and (5) acceptance of the Internet as a provider of consumer information and as a distribution channel. In addition, growth in the herbal supplements market has slowed in recent years, due in part to consumer demand for separate products targeting specific ailments (Source: *Nutraceuticals: A Global Strategic Business Report* 2008).

### *Nutraceuticals and Dietary Supplement Regulation*

In the U.S., the Food and Drug Administration (FDA) classifies nutraceuticals as a special class of food, separate from prescription and non-prescription medicines. Thus, these products are regulated differently. The FDA's authority to regulate nutraceuticals is defined in the Dietary Supplement Health and Education Act (DSHEA) of 1994. Under DSHEA, a company is responsible for ensuring that any supplements it manufactures are safe and that any claims made about health effects are supported by "adequate evidence." However, except for those ingredients classified as "**new dietary ingredients**," a manufacturer does not have to provide the FDA with evidence substantiating safety or effectiveness claims and does not need approval from the FDA to begin marketing a dietary supplement (Source: FDA).

Accordingly, the bioceutical/nutraceutical market would benefit from clinical studies and more straightforward marketing practices—thereby creating credibility in a segment that remains constrained by a level of mistrust generated through misleading or unsupported claims (Source: *Nutraceuticals World*, a publication serving manufacturers of dietary supplements, functional foods, and nutritional beverages, 2008). For many bioceutical products, the most compelling evidence for efficacy remains anecdotal or based on small or poorly controlled studies. Claims have been made for nutraceutical efficacy in scenarios from fighting cancer and cardiovascular disease to supporting healthy living; although, few products have been characterized by solid quantitative support, and most nutraceuticals have been subjected to more marketing hype than methodical clinical testing (Source: *Scientific American* 2008). Thus, Imagenetix's emphasis on scientific support and clinical studies documenting its products' health benefits could favorably impact acceptance and demand.

### **Imagenetix's Celadrin® Product**

The Company's lead product, Celadrin®, is a patented compound that lubricates and cushions the joints, promoting comfort and flexibility. Celadrin® has been shown to provide joint health and increase joint mobility. Celadrin® is composed of a matrix of proprietary **esterified, cetylated fatty acids (CFAs)** and other compounds that are intended to improve joint mobility and health. These natural oils work at the cellular level to restore cell membrane fluid and lubrication, with the aim of increasing cell membrane fluidity and elasticity throughout the body. Celadrin® is marketed as a joint health supplement.

Imagenetix markets Celadrin® as a proprietary branded product; as a private-label formulated product; and as a branded ingredient used by wholesale customers in their product formulations and labels. Pages 6-7 in Distribution and Sales Strategies describe the current distribution channels for Celadrin® and list the U.S. retailers where it is presently available for sale.

Based on customer feedback, Imagenetix believes that Celadrin® may be more effective than leading competitive products. In 2009, Applied Research-West, Inc. (a full-service market research firm) conducted a survey of 400 rheumatologists and orthopedic surgeons who recommend natural products. As many as 94% of survey respondents stated that they would recommend Celadrin® for supporting joint health.

Celadrin® is sold in two formulations: (1) as oral softgels designed for long-term relief; and (2) as a topical application targeted for fast-acting, temporary relief. Figure 5 (page 15) overviews the Celadrin® Softgels and the Celadrin® Cream. Imagenetix can also offer Celadrin® as a product in certain veterinary applications, including for joint health in dogs.



Figure 5  
Imagenetix, Inc.  
CELADRIN® PRODUCTS

### Celadrin® Softgels



- Targeted to reduce joint discomfort
- Promotes joint flexibility and mobility
- Cumulative benefits may be achieved through long-term daily use
- Many customers may experience benefits in 30 days or less

### Celadrin® Cream



- Designed to temporarily relieve aches and pains in sore muscles, joints, and tissues
- 100% of osteoarthritis patients studied in a clinical trial showed a benefit with Celadrin® Cream versus placebo, with no reported side effects
- Fast acting (within 30 minutes) with rapid and deep absorption into the affected area

Sources: Imagenetix, Inc. and Crystal Research Associates, LLC.

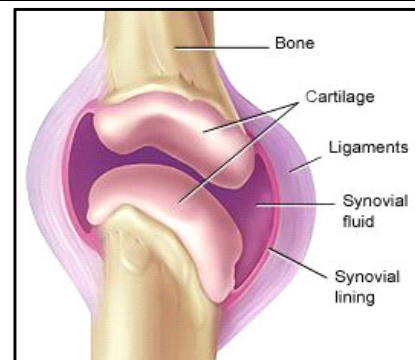
### Joint Pain and Arthritis Background

Note: According to Imagenetix, studies have shown joint pain relief using Celadrin® Cream and joint health and mobility benefits using Celadrin® Softgels.

As depicted in Figure 6, a joint is formed at the ends of two or more bones connected by thick bands of tissue called ligaments. The ends of the bone are covered with a smooth, soft material called cartilage that cushions the bones and allows the joint to move without pain. Normally, cartilage allows nearly frictionless movement of the bones, protects the joint, and absorbs shock. The remainder of the joint is lined by a thin, smooth tissue called the synovium. The synovium produces a slippery fluid that acts as a lubricant to reduce friction and wear in the joint.

Joint pain, called **arthralgia**, can be caused by many factors, including inflammation, injury, or arthritis affecting any of the joint structures. Arthritic pain is considered to be a chronic pain, which differs from an acute pain or injury in that it gradually becomes more painful.

Figure 6  
JOINT STRUCTURE



Source: WebMD, Inc.

The term arthritis describes more than 100 disorders and conditions that involve inflammation of one or more joints, resulting in pain, swelling, stiffness, and limited mobility. The type, severity, and location of symptoms depend on the specific form of the disease. Arthritis is associated with a range of causes from wear and tear of cartilage (such as osteoarthritis) to inflammation resulting from an overactive immune system (such as rheumatoid arthritis). In osteoarthritis, due to the breakdown of protective cartilage, bones rub together. This causes pain, swelling, inflammation, and stiffness. In contrast, rheumatoid

arthritis results when the immune system attacks a joint's synovial membrane. The synovium becomes inflamed and produces excess fluid, and the cartilage becomes rough and pitted.

#### Arthritis Prevalence

Arthritis is one of the most common causes of disability in the U.S. As of 2005, as many as 66 million U.S. adults were afflicted with arthritis or chronic joint conditions. Of these individuals, more than 46 million people (or 21% of adults) specifically had physician-diagnosed arthritis. A subset of approximately 19 million adults is affected by arthritis or arthritis-attributable activity limitation. As the population ages, these numbers are projected to increase. By 2030, 67 million adults, approximately 25% of the total adult population, are expected to have physician-diagnosed arthritis (Sources: *Arthritis & Rheumatism* vol. 58 [1]:15-25 [2008] and the U.S. Centers for Disease Control and Prevention [CDC]).

Due to advances in medicine and medical technology, nearly two billion people over age 60 are expected to be alive by 2050, which is almost triple the 700 million people over 60 who were alive in 2006 (Source: *World Population Ageing 2007* from the United Nations' Department of Economic and Social Affairs, Population Division). Moreover, individuals over 80 years old are a rapidly increasing subset of the adult population. This segment expands at 3.9% annually, far more than the population as a whole, which increases by 1.1% each year (Source: *World Population Ageing 2007*). Accordingly, the global aging population contributes to demand for improved healthcare services and treatments for the conditions that disproportionately affect older individuals, such as arthritis and other forms of joint pain.

Baby boomers have ranked joint pain as one of their foremost health concerns, behind heart problems and cholesterol (Source: Information Resources, Inc.'s *Baby Boomers: One Size Does Not Fit All* [2008]). Additionally, due to the negative side effects of prescription drugs, Imagenetix estimates that 60% of baby boomers are looking for effective alternatives to treat joint pain and bone disease, such as natural supplements.

#### *Existing Bone and Joint Health Therapies*

Boosted by the expanding aging population, concern about prescription drug side effects, and growing consumer awareness, bone and joint health is ranked among the largest U.S. health supplement markets by volume, after multivitamins. Predominant products in this market are glucosamine and chondroitin, which are often used in conjunction as base ingredients in bone and joint health dietary supplements. Glucosamine has been shown to help rebuild and repair human cartilage, and chondroitin gives cartilage elasticity. Greater details of these two ingredients are provided in the Competition section on page 32.

As an indication of the market size for bone and joint health supplements, Euromonitor International Inc., a business intelligence provider, reported that products containing glucosamine and chondroitin had estimated annual sales of \$872 million in the U.S. and \$2 billion worldwide during 2008 (Source: Decision News Media SAS, March 2, 2009). The largest markets for these nutraceuticals remain Asia Pacific, North America, and Europe. From 2004 to 2009, the global annual growth rate for glucosamine and chondroitin was roughly 7%. Imagenetix's research from the *Nutrition Business Journal* values the overall U.S. market for bone and joint health at approximately \$2.5 billion.

Going forward, global growth of glucosamine and chondroitin is forecasted to level off at around 2% over the next four years. Contributing to the slowed growth of these products are recent questions that have been raised by various studies regarding glucosamine and chondroitin's efficacy, which in turn have fueled the development of alternative ingredients (Source: Decision News Media, April 15, 2010). Accordingly, Imagenetix expects future growth in the bone and joint health segment to be driven by the emergence of alternative ingredients, such as Celadrin®.

## The Science Supporting Celadrin®

Wear on a joint can be attributed to a variety of conditions, such as insufficient lubrication or the lack of cell membrane fluidity. The cell membrane is the semipermeable structure that separates and protects the cell from the outside environment. A major component of the cell membrane entails structural **lipids** that regulate the movement of nutrients, minerals, and other substances in and out of the cell—a critical process for the adequate function of an individual cell. Loss of cell membrane integrity from internal and external stressors can cause age-related and chronic conditions, including inflammation and arthritis.

Dietary fatty acids may be beneficial in the treatment and prevention of chronic inflammatory disease. The joint inflammation that accompanies osteoarthritis is regulated in large part by essential fatty acids. Although fatty acids' protective mechanism of action is not fully understood, the ratio of **omega-3** to **omega-6** fatty acids can either promote or hinder production of **prostaglandins**, the messenger molecules that influence pain and inflammation. It has been found that some omega-3 fatty acids decrease the production of pro-inflammatory prostaglandins, and thus are important in providing protective benefits against chronic inflammation and joint pain (Source: *Journal of Rheumatology* 29:1708-1712 [2002]). Other suggested mechanisms contributing to fatty acids' anti-inflammatory response include the following: (1) reduced expression and activity of **proteoglycan**-degrading enzymes; (2) inhibition of 5-lipoxygenase, a potent enzyme that mediates inflammation; and (3) alterations in cell membrane fluidity and permeability (Source: *Journal of Strength and Conditioning Research* vol. 19[2]:475-480 [2005]).

### Studies with Celadrin®

A number of safety and efficacy studies have been conducted on cetylated fatty acids (CFAs), which form the principal ingredients in Celadrin®. To date, 17 clinical studies—for which results have been published in peer-reviewed medical journals and released at scientific conferences—have demonstrated that Celadrin® may provide effective joint health and joint mobility as well as cumulative, long-term benefits. A selection of related publications and presentations is listed in Table 4 (below and continued onto page 18).

Table 4  
Imagenetix, Inc.  
SELECTED STUDIES AND PUBLICATIONS FOR CELADRIN®

Year	Publication	Title/Subject Area
2005	<i>Journal of Strength and Conditioning Research</i> ; Vol. 19(2):475-480	A cetylated fatty acid topical cream with menthol reduces pain and improves functional performance in individuals with arthritis
2005	<i>Journal of Strength and Conditioning Research</i> ; Vol. 19(1):115-121	Effects of treatment with a cetylated fatty acid topical cream on static postural stability and plantar pressure distribution in patients with knee osteoarthritis
2004	<i>Journal of Rheumatology</i> ; Vol. 31(4): 767-774	Effect of a cetylated fatty acid topical cream on functional mobility and quality of life of patients with osteoarthritis
2002	<i>Journal of Rheumatology</i> ; Vol. 29(8): 1708-1712	Cetylated fatty acids improve knee function in patients with osteoarthritis

Source: Imagenetix, Inc.

Table 4 (Continued)

Imagenetix, Inc.

SELECTED STUDIES AND PUBLICATIONS FOR CELADRIN®

Year	Publication	Title/Subject Area
2007	Scientific presentation	The effects of cetylated fatty acid's oral form on pain, range of motion, and quality of life of patients with osteoarthritis
2003	Scientific presentation	The effects of a cetylated fatty acid cream on functional mobility and performance in patients with osteoarthritis
2003	Scientific presentation	Absorption and metabolism of a cetylated fatty acid
2002	Scientific presentation	Digestion and metabolism of cetylated fatty acids in rats
2002	Scientific presentation	The effects of a cetylated fatty acid complex on canine osteoarthritis
2001	Scientific presentation	A fatty acid ester (CMC) improves quality of life outcomes in osteoarthritis patients

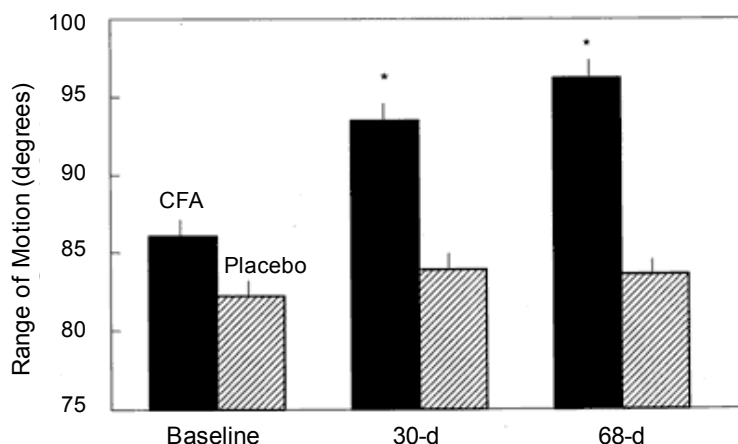
Source: Imagenetix, Inc.

The initial clinical basis for Celadrin® Softgels' effectiveness was provided in a blinded, placebo-controlled trial of 64 participants with chronic knee osteoarthritis. Patients were evaluated at the beginning of the trial, at 30 days, and at the end of the 68-day study. Evaluations included physician assessment, range of motion in the affected joint, and responses to questions on the **Lequesne Algofunctional Index (LAI)**. In the Celadrin® group, 15% of participants experienced reductions in swelling versus 0% in the placebo group. As well, 58% of the people who received Celadrin® reported a reduction in pain versus 32% of patients given placebo. Results also showed that the Celadrin® Softgels were associated with an improvement in knee flexion of +10.1° when compared to the control group, as depicted in Figure 7.

Figure 7

Imagenetix, Inc.

RANGE OF MOTION IN THE KNEE



\* Reaches statistical significance

Source: *Journal of Rheumatology* Vol. 29:1708-1712 (2002).

Study participants also experienced a reduction in pain as measured by knee-specific LAI. Patients using Celadrin® noted a reduction of 5.0 and 5.4 points in overall LAI score after 30 days and 68 days, respectively. **Ordinal logistic regression** showed a positive response on LAI scores with CFA versus placebo. In addition, LAI scores showed that Celadrin® provided relief for individuals who were also receiving traditional medications (Source: *Journal of Rheumatology* vol. 29:1708-1712 [2002]).

Pharmacokinetic properties of Celadrin<sup>®</sup>, specifically its bioavailability and cellular distribution, were documented in a research study at the University of Minnesota in 2003. Results showed that when taken orally, Celadrin<sup>®</sup> achieved greater than 95% bioavailability, which allows required dosages to be kept low. In addition, Celadrin<sup>®</sup> was distributed systematically within cellular membrane structures, which is believed to contribute to an anti-inflammatory response by altering cell membrane fluidity and permeability (Source: *FASEB [The Federation of American Societies for Experimental Biology] Journal Scientific Meeting Summary* vol. 17[4]:A341 [2003]).

A series of additional trials have been performed to assess the benefits of a topical formulation of Celadrin<sup>®</sup>. At the University of Connecticut, 42 patients with knee osteoarthritis received Celadrin<sup>®</sup> Cream or placebo and were evaluated before application of the Cream (T1), 30 minutes after application (T2), and after 30 days (T3). Researchers evaluated the effects of the Cream on physical function, postural movement, and pain by measuring participants' range of motion, ability to rise from chairs, walk, ascend and descend stairs, and postural stability.

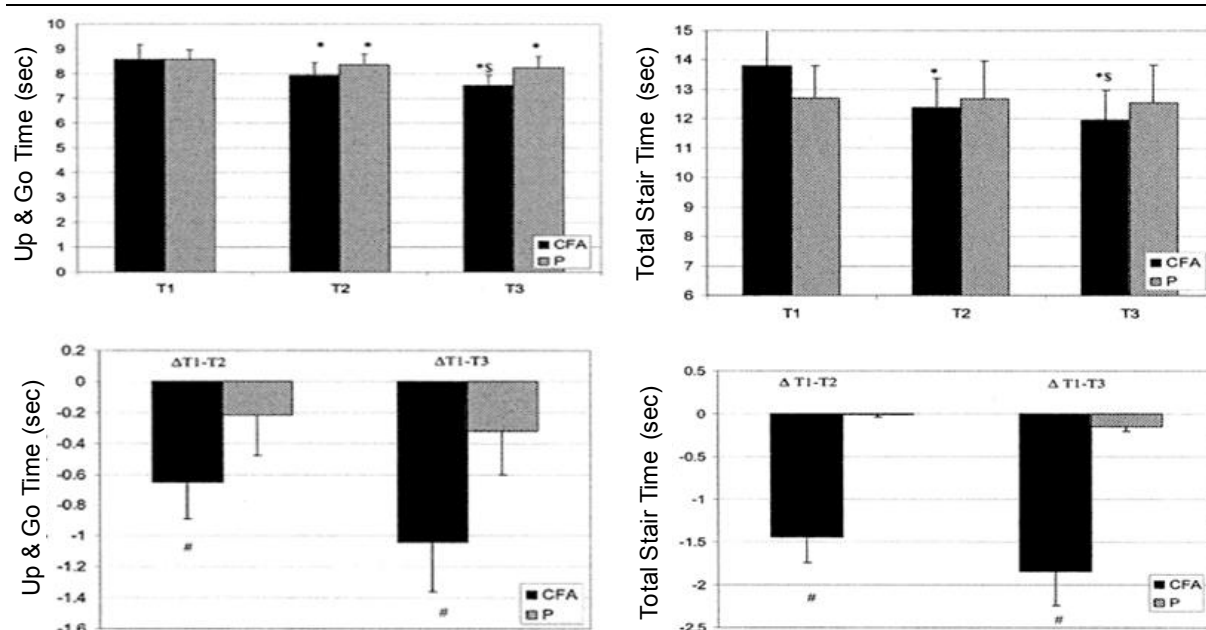
The University of Connecticut study concluded that the use of Celadrin<sup>®</sup> Cream could be an effective treatment for improving physical function, reducing pain, and improving postural balance. In the study, 100% of patients showed a benefit versus placebo. Use of Celadrin<sup>®</sup> Cream improved range of motion, ability to ascend/descend stairs, ability to rise from sitting, walk and sit down, standing balance, and local muscular endurance. Patients experienced improvement for most of these measures in just 30 minutes and reported cumulative benefits throughout the remaining 30 days of the trial (Source: *Journal of Rheumatology* vol. 31[4]:767-774 [2004]).

Figure 8 illustrates a selection of the results achieved with Celadrin<sup>®</sup> Cream (labeled "CFA" in the Figure). The timed up-and-go assessment (as depicted on the left side of Figure 8) shows that although both groups significantly improved their ability to rise from a chair and walk versus T1 (statistically significant results are denoted by an asterisk), the magnitude of improvement at both at T2 and T3 was greater in the CFA group versus placebo (as depicted in the bottom left of the Figure). In addition, only the CFA group significantly improved between T2 and T3. Results for the timed stair climbing assessment, highlighted on the right side of Figure 8, show a significant improvement at both T2 and T3 in patients receiving Celadrin<sup>®</sup> Cream.

Figure 8

Imagenetix, Inc.

#### TOPICAL CREAM STUDY RESULTS



Source: *Journal of Rheumatology* Vol. 31(4):767-774 (2004).

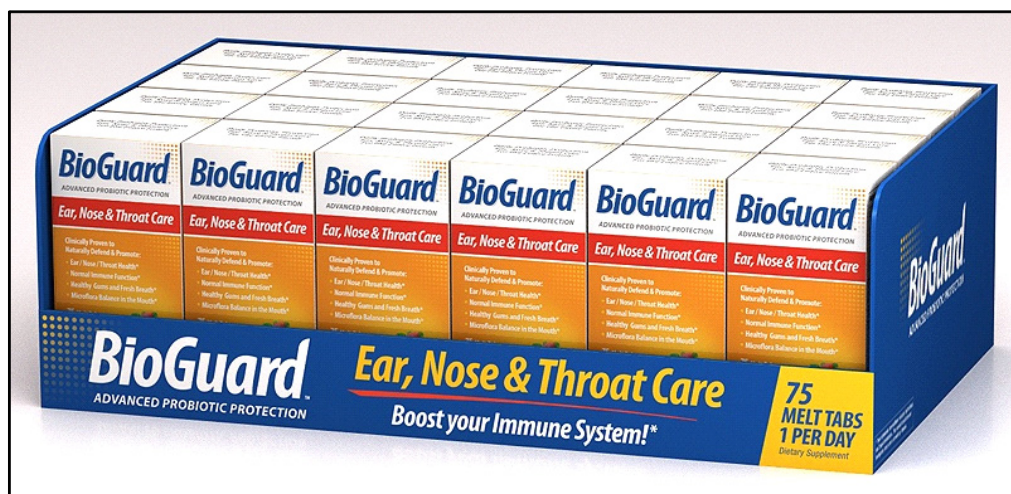


Additional studies have also validated the effect of Celadrin® Cream. The first study, conducted on 40 patients with knee osteoarthritis, indicated that 30 days of treatment with the CFA topical cream improved static postural stability in patients with knee osteoarthritis presumably due to pain relief during quiet standing. Researchers concluded that the pain and stability benefits could translate into enhanced exercise potential for people with osteoarthritis, as less pain and improved stability could result in longer exercise times (Source: *Journal of Strength and Conditioning Research* vol. 19[1]:115–121 [2005]). An additional study evaluated the effects of the Cream on physical function, postural movement, and pain in 28 patients with knee osteoarthritis and severe pain in the wrist or elbow. Results were consistent with prior studies, with the Celadrin® Cream improving stair climbing ability, range of motion, balance, endurance, pain, and physical function (Source: *Journal of Strength and Conditioning Research* vol. 19[2]:475-480 [2005]).

### Imagenetix's BioGuard™ Product

Imagenetix's probiotic, BioGuard™, comprises bacteria that provide a natural defense against immune imbalance. BioGuard™ is designed to target the body's gateways—the ears, nose, and throat—for a healthy respiratory system. Figure 9 depicts a rendering of BioGuard™, as available for distribution and sale. The product is currently carried on Costco.com, as further addressed on page 7.

Figure 9  
Imagenetix, Inc.  
BIOGUARD™: AVAILABLE FOR SALE



Source: Imagenetix, Inc.

The active ingredient in BioGuard™ is BLIS K12™, a naturally occurring but rare strain of the oral bacteria *Streptococcus salivarius* (*S. salivarius*). Certain strains of microorganisms, such as *S. salivarius*, produce **Bacteriocin-Like-Inhibitory-Substances (BLIS)**, which act as natural agents against the growth of disease-causing bacteria. BLIS K12™, developed by New Zealand firm BLIS Technologies Ltd., is a patented probiotic that produces antibacterial proteins which selectively target the bacteria causing immune imbalance, throat irritation, and mouth odor, among other ailments. Imagenetix holds exclusive U.S. rights for mass-market distribution of its method for delivering BLIS K12™.

### Probiotics Background

Probiotics are live microorganisms, in most cases bacteria, that can provide a health benefit when administered in adequate amounts. Probiotics are normally beneficial, native bacteria that are isolated, purified, and packaged into foods or dietary supplements. The effects of probiotics have been studied for both human and animal applications and worldwide research on this topic has accelerated in recent years. More than four times the number of human clinical trials on probiotics were published from 2001 to 2005 than from 1996 to 2000 (Source: Council for Agricultural Science and Technology [CAST] Issue Paper 36: *Probiotics: Their Potential to Impact Human Health* [2007]).



Humans, like all animals, host microbes on the skin, mouth, and gastrointestinal tract, among other places. Most bacteria are not harmful but rather have an important role in overall health. Friendly bacteria are thought to be vital for the proper development of the immune system by maintaining a balance favoring beneficial bacteria over potentially harmful bacteria (Source: usprobiotics.org, a research and education website from the California Dairy Research Foundation and Dairy & Food Culture Technologies).

Possibly due to marketing campaigns for existing probiotic products, such as the Dannon Company, Inc.'s Activia<sup>®</sup> yogurt, U.S. consumers are believed to be accepting of the concept of beneficial bacteria, with only a minority of consumers skeptical about probiotic product claims. In 2008, the Natural Marketing Institute's Health and Wellness Trends Survey reported that U.S. consumer awareness of the term probiotics had increased to 48%, up from 20% in 2006 (Source: Virgo Publishing, LLC's Nutrilearn.com). The Natural Marketing Institute is a strategic consulting, market research, and business development company specializing in the health and wellness marketplace. In 2008, the global probiotic market was valued at approximately \$15.9 billion, expected to reach \$19.6 billion by 2013. In particular, the probiotic supplement sector was estimated at \$1.3 billion in 2008, with the potential to reach \$1.7 billion by 2013 (Source: BCC Research's *The Probiotics Market: Ingredients, Supplements, Foods* [2008]).

While many probiotics currently on the market are directed toward digestive health, researchers have studied other possible areas of benefit as well. An increasing number of studies support the capacity of probiotic bacteria to interact with the immune system, thereby mediating beneficial effects throughout the body. Different probiotics are able to stimulate and regulate multiple aspects of natural and acquired immune responses, boosting the immune system and providing a means to protect against and treat a variety of human and animal disorders, such as allergic disease, autoimmune disorders, and inflammatory diseases (Source: *Journal of Nutrition* vol. 137:781-790 [2007]). Preliminary studies have found that probiotics could halt the effect of unfriendly microorganisms in multiple conditions, as listed in Table 5.

Table 5  
SELECTED PROBIOTIC BENEFIT AREAS

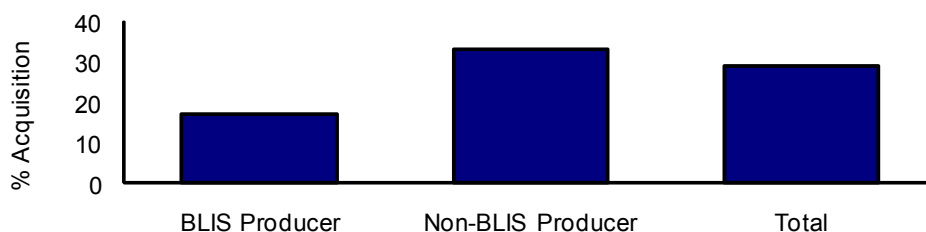
- |   |  |
|---|--|
| ▪ Inflammatory bowel diseases (ulcerative colitis and Crohn's disease)  | ▪ Colds and respiratory infections     |
| ▪ Irritable bowel syndrome  | ▪ Dental decay and periodontal disease |
| ▪ <i>H. pylori</i> infections (ulcers and chronic stomach inflammation) | ▪ Side effects of antibiotic therapy   |
| ▪ Colon tumors (primary evidence in animals)                            | ▪ Allergy development and symptoms     |
| ▪ Infectious diarrhea   | ▪ Blood pressure and high cholesterol  |

Sources: Council for Agricultural Science and Technology and MedicineNet.com.

### Science Supporting BioGuard™

BioGuard™ was developed under the philosophy of bringing scientifically designed and tested products to consumers. Its main ingredient, BLIS K12™, contains the *S. salivarius* K12 strain. *S. salivarius* is a predominantly benign colonizer of oral surfaces in humans. The *S. salivarius* K12 strain, found in approximately 2% of the population, was first discovered in a study of several hundred New Zealand children, who were monitored over eight months for a bacterial throat infection (e.g., strep throat). As shown in Figure 10 (page 22), the study found that children were less likely to develop a bacterial throat infection if they naturally harbored BLIS-producing bacteria in their mouth. Children without "K12-like" *S. salivarius* strains (non-BLIS producers) were twice as likely to acquire an infection as those with "K12-like" *S. salivarius* (BLIS producers).

Figure 10  
Imagenetix, Inc.  
ACQUISITION OF THROAT INFECTION PATHOGENS OVER AN EIGHT-MONTH PERIOD



Source: BLIS Technologies Ltd.

*S. salivarius* BLIS K12™ is an advanced probiotic, as it actively produces targeted antibacterial proteins when it is under threat from potential disease-causing bacteria—which the Company believes is unlike other probiotic organisms. While the majority of probiotic bacteria benefit their hosts by competing with harmful bacteria for space and nutrients, BLIS K12™ probiotics also produce two antibacterial peptides—Salivaricin A and Salivaricin B—that maintain healthy bacteria population levels and target harmful bacteria. Thus, BioGuard™ not only competes with harmful bacteria for living space in the oral cavity but it may also be capable of recognizing and responding to the presence of invading harmful bacteria by ramping up production of these antibacterial proteins. Table 6 summarizes several key properties of BLIS K12™ versus many other probiotics that are currently on the market.

Table 6  
Imagenetix, Inc.  
BLIS K12™ PROBIOTIC VERSUS OTHER PROBIOTICS

	BLIS K12™	General Probiotics
Classic Probiotic Function	Yes	Yes
Known Antimicrobial Activity	Yes	No
Possesses a High Safety Level Designation	Yes	Many
Site of Effect	Oral Cavity	Gut
Dominant Species at the Site	Yes	No

Source: BLIS Technologies Ltd.

### Safety of *S. Salivarius*

To the Company's knowledge, BioGuard™ has been found to be safe with no reported side effects and *S. salivarius* has been the subject of safety studies without significant adverse reports. As *S. salivarius* has been in use since before October 15, 1994, it is deemed to be compliant with DSHEA regulations (overviewed on page 14 under Nutraceuticals and Dietary Supplement Regulation). *S. salivarius* has been found in breast milk and is listed as a **Biosafety Level 1 (BSL-1)** organism in the U.S. The BSL-1 designation is reserved for well-characterized agents not known to consistently cause disease in healthy adult humans and that are believed to be pose minimal potential hazard to laboratory personnel and the environment. *S. salivarius* K12 is believed to have a low pathogenic potential, indicating that it is unlikely to cause disease in healthy humans.

## *Indications Where BioGuard™ Has Been Studied*

BLIS K12™ has been studied in more than 30 tests demonstrating its safety and effectiveness, as summarized in Table 7 (page 24). During these studies, BioGuard™ ingredients were found to be proactive in the following areas:

- oral and upper respiratory tract infections;
- overall immunity;
- **otitis media** (ear) infections; and
- other oral diseases, such as **dental caries** (tooth decay), periodontal disease, and **halitosis**.

### Oral and Upper Respiratory Tract Infections

A feature of *S. salivarius* is its production of a variety of BLIS that act against ***Streptococcus pyogenes* (S. pyogenes)**, an oral pathogen that is one the most significant contributors to bacterial sore throats. Scientific studies have shown that there is a high correlation between a reduction in incidence and acquisition of *S. pyogenes* and the presence of BLIS-producing *S. salivarius*. This type of anti-*S. pyogenes* activity is likely due to the production of the peptides Salivaricin A and Salivaricin B (Source: *Applied Environmental Microbiology* vol. 73[4]:1107-1113 [2007]).

### Overall Immunity

In a study of four adults who took 12 BLIS K12™ Throat Guard lozenges (four lozenges every two hours), the individuals reported that using this probiotic ingredient at the onset of flu-like symptoms appeared to restore health (Source: BLIS Technologies Ltd.). Research has shown that consumption of *S. salivarius* K12 lozenges can lead to an increase in the salivary levels of **interferon gamma**, a **cytokine** that contributes to nonspecific immunity protection against many disease-causing bacteria and viruses. The production of salivary interferon was up to five times higher in subjects exposed to *S. salivarius* K12 cells. An increase in interferon gamma can prevent viral infections, such as the flu, by reducing the virus (Source: *Elevated levels of interferon gamma in human saliva following ingestion of Streptococcus salivarius K12*, presented at a joint meeting of the New Zealand Microbiological Society and the New Zealand Society for Biochemistry and Molecular Biology [2005]).

Studies further indicate that the *S. salivarius* K12 strain contributes to the host's defense by ensuring that it is tolerated by the host and maintained on the **epithelial** surface, while actively protecting against inflammation induced by pathogens (Source: *Infection and Immunity* vol. 76[9]:4163-4175 [2008]).

### Ear Infections

Clinical studies in children susceptible to recurrent ear infections have shown that the administration of specific bacteria with the ability to inhibit the growth of common pathogens can protect against further ear infections. In children with recurrent otitis media, the normal inhibitory activity against common otitis media pathogens is reduced. This can be counteracted by re-colonization of the nasal passages with *S. Streptococci* spray. In 52 children with recurrent ear infections who were given the streptococcal spray, 22 patients (42%) were healthy after three months and had a normal **tympanic** membrane versus 12 (22%) of those given placebo (Source: *British Medical Journal* vol. 322:210-212 [2001]).

### Other

Clinical studies have demonstrated that *S. salivarius* K12 may lessen the likelihood of tooth decay and gum inflammation by fighting pathogens associated with these conditions. *S. salivarius* strains demonstrated inhibitory activity against dental caries and plaque-causing organisms (Source: *Journal of Dental Research* vol. 86[11]:1078-1082 [2007]). In addition, studies on the oral microbiota of people with or without halitosis have confirmed that non-halitosis individuals possessed *S. salivarius* whereas those with halitosis did not (Source: *Journal of Clinical Microbiology* vol. 41[2]:558-563 [2003]).

Table 7  
Imagenetix, Inc.  
SELECTED STUDIES AND PUBLICATIONS SUPPORTING THE USE OF BIOGUARD™

Year	Publication	Title/Subject Area
Oral Infection		
2008	<i>Therapeutic Microbiology: Probiotics and Other Therapies</i> (American Society for Microbiology Press)	Streptococci as effector organisms for probiotic and replacement therapy
2007	<i>Oral Microbiology and Immunology</i> Vol. 22(2):126-130	Distribution and persistence of probiotic <i>Streptococcus salivarius</i> K12 in the human oral cavity as determined by real-time quantitative polymerase chain reaction
2006	<i>International Congress Series</i> Vol. 128:347-350	Oral streptococcal BLIS: Heterogeneity of the effector molecules and potential role in the prevention of streptococcal infections
2004	<i>Indian Journal of Medical Research</i> Vol. 119:13-6	Prevention of streptococcal pharyngitis by anti- <i>Streptococcus pyogenes</i> bacteriocin-like (BLIS) produced by <i>Streptococcus salivarius</i>
2003	<i>Trends in Biotechnology</i> 21(5):217-23	Bacterial replacement therapy: adapting 'germ warfare' to infection prevention
Upper Respiratory Tract Infection		
2008	<i>European Journal of Clinical Microbiology and Infectious Diseases</i> Vol. 27(12):1261-3	Preliminary investigations of the colonization of upper respiratory tract tissues of infants using a pediatric formulation of the oral probiotic <i>Streptococcus salivarius</i> K12
Immunity		
2008	<i>Infection and Immunity</i> Vol. 76(9):4163-4175	The commensal <i>Streptococcus salivarius</i> K12 down-regulates the innate immune responses of human epithelial cells and promotes host-microbe homeostasis
Otitis Media (ear)		
2003	<i>Journal of Medical Microbiology</i> Vol. 52(9):829-33	Bacteriocin-like inhibitory substance (BLIS) production by the normal flora of the nasopharynx: potential to protect against otitis media?
Other		
2007	<i>Applied and Environmental Microbiology</i> Vol. 73(4):1107-13	Salivaricin A2 and the novel antibiotic Salivaricin B are encoded by adjacent loci on a 190 kb transmissible megaplasmid in the oral probiotic strain <i>Streptococcus salivarius</i> K12
2006	<i>Antonie Van Leeuwenhoek Journal of Microbiology</i> Vol. 90 (3):269-80	Megaplasmsids encode differing combinations of lantibiotics in <i>Streptococcus salivarius</i>
2006	<i>Evolution and Ecology of Bacteriocins</i> (Book Chapter)	The diversity of bacteriocins produced by Gram-positive bacteria
2006	<i>Applied and Environmental Microbiology</i> Vol. 72(2):1459-66	Production of the lantibiotic Salivaricin A and its variants by oral streptococci and use of a specific induction assay to detect their presence in human saliva
Safety		
2006	<i>Applied and Environmental Microbiology</i> Vol. 72(4):3050-3	Safety assessment of the oral cavity probiotic <i>Streptococcus salivarius</i> K12

Source: Imagenetix, Inc.

## Imagenetix's Fat-reducing Compound, Trisynex™

Trisynex™ is a proprietary fat-reducing compound composed of a patented plant-based blend of modified cellulose and CFAs that have been shown to reduce stored body fat, improve body composition, and enhance weight loss. Trisynex™ is designed to regulate the levels of specific hormones involved in the body fat storage process, resulting in increased fat burning activity and production of lean muscle. Imagenetix supplies this compound as a raw material for use in products.

### *Obesity Background*

Obesity is a chronic condition defined by abnormal or excessive amounts of body fat. The normal amount of body fat is between 25% to 30% in women and 18% to 23% in men. Women with over 30% body fat and men with over 25% body fat are considered obese (Source: MedicineNet.com).

The calculation of **body mass index (BMI)** is also used in the definition of obesity. BMI is a person's weight in kilograms divided by the square of the height in meters. Since BMI describes body weight relative to height, it correlates with total body fat content in adults. The World Health Organization (WHO) defines "overweight" as having a BMI equal to or greater than 25. WHO standards define "obese" as having a BMI equal to or greater than 30, and "morbid" or "severe" obesity as having a BMI equal to or greater than 40 (Source: WHO).

Obesity is a global problem. In 2005, approximately 1.6 billion adults (people older than 15 years of age) were considered to be overweight. More than 400 million adults were obese and at least 20 million children under the age of five were overweight. The WHO projects that, by 2015, approximately 2.3 billion adults worldwide could be overweight, with more than 700 million classified as obese. Obesity has reached epidemic proportions in the U.S. as well. In 2007/2008, the prevalence of obesity in the U.S. was estimated at 33.8%, with the prevalence of both overweight and obese individuals totaling 68% (Source: *Journal of the American Medical Association [JAMA]* vol. 303[3]:235-241 [2010]).

Obesity is not just a cosmetic or quality of life concern; it can lead to serious health consequences. In the U.S., roughly 300,000 deaths per year are directly related to obesity, and more than 80% of these deaths are in individuals with a BMI over 30. Life expectancy for people with a BMI over 40 is reduced significantly—by as many as 20 fewer years for men and five for women (Source: MedicineNet.com).

Concerns regarding the risks associated with obesity are the prime factor driving sales of weight management nutritional supplements. During 2010, weight control products and services are anticipated to total more than \$35 billion with the potential to reach over \$52 billion by 2015 (Source: Global Industry Analysts, Inc.'s *Weight Control Products* 2008). One of the most rapidly growing markets for weight management products is Asia (Source: Decision News Media 2010).

### **Science Supporting Trisynex™**

In contrast to many weight loss products, which work on appetite but do not have a metabolic effect, Trisynex™ was created to alter body composition, reduce stored body fat, and enhance lean muscle.

An eight-week study conducted at the University of Connecticut evaluated the effect of Trisynex™ on patients' response to a weight loss program. Body composition, consisting of body weight, body fat, and waist circumference measurements, as well as **serum** levels of leptin and adiponectin were assessed for 22 women over an eight-week period.

Leptin and adiponectin are key biomarkers for healthy body fat storage and utilization. The mechanism by which exercise and diet modulate weight loss is believed to be regulated by circulating adipocytokines, including leptin and adiponectin, which act on the brain to control appetite and feeding signals. Leptin regulates body fat storage by modulating **satiety** and the appetite regulatory pathways. Leptin has been shown to regulate the storage of excess calories, with an increase of the hormone signaling the need to store fat while a decrease is correlated with weight and body fat reduction. Research from the University of Minnesota shows that reduced serum leptin is correlated with lower regional and total body fat. Additionally, adiponectin regulates **glucose** balance and insulin sensitivity as well as increases fat

oxidation within skeletal muscle, which may serve to increase daily caloric expenditure (Source: *European Journal of Applied Physiology* vol. 105:665-672 [2009]).

The study results, as published in the *European Journal of Applied Physiology*, demonstrated that Trisynex™ usage, combined with exercise and a reduced-calorie diet, elicited improved effects on body composition and adipocytokines' serum levels versus diet and exercise alone. In addition, Trisynex™ enhanced cell membrane stability for improved cellular communication between the liver and **adipose** tissues for enhanced fatty acid utilization leading to targeted and regional fat loss. Key findings of the study are listed in Table 8, followed by data in Table 9 documenting the degree of effect elicited by Trisynex™ versus placebo (which entailed diet and exercise alone) in five categories: (1) body mass; (2) body fat percentage; (3) waist circumference; (4) leptin reduction; and (5) adiponectin increase.

Table 8  
Imagenetix, Inc.  
CLINICAL FINDINGS WITH TRISYNEX™

- Reduction in stored fat and enhanced lean muscle
- Improvement in body composition (e.g., body fat ratio)
  - May promote weight loss by as much as 10% in 8 weeks
  - May reduce stored body fat by more than 16% in 8 weeks
- Reduction in waistline
  - May promote targeted fat loss in waist area
  - May reduce waistline circumference measurements by approximately 10% in 8 weeks
- Reduction in serum leptin and increase in serum adiponectin

Sources: Imagenetix, Inc. and the *European Journal of Applied Physiology*.

Table 9  
Imagenetix, Inc.  
CLINICAL DATA WITH TRISYNEX™ VERSUS PLACEBO IN FIVE CATEGORIES

		0 weeks	8 weeks
<b>Body Mass (Kg)</b>	Trisynex™	87.1 ± 6.2	77.9 ± 5.1
	Placebo	86.9 ± 4.7	82.7 ± 3.8
<b>Body Fat (%)</b>	Trisynex™	43.4 ± 4.1	36.1 ± 3.6
	Placebo	44.3 ± 2.0	40.6 ± 1.2
<b>Waist Circumference</b>	Trisynex™	101.9 ± 4.4	92.1 ± 3.9
	Placebo	102.5 ± 3.6	97.4 ± 4.0
<b>Leptin (ng/ml)</b>	Trisynex™	28.3 ± 3.5	16.2 ± 2.6
	Placebo	29.4 ± 3.2	19.9 ± 1.1
<b>Adiponectin (ng/ml)</b>	Trisynex™	12.2 ± 2.4	26.3 ± 3.0
	Placebo	12.6 ± 2.0	21.8 ± 3.1

Source: *European Journal of Applied Physiology* vol. 105:665–672 [2009].



### **CellSorb™: 100 mg CoQ<sub>10</sub> Softgels**

CellSorb™ is one of Imagenetix's newer bioceutical candidates. It is a delivery system that is intended to help increase the body's absorption of Coenzyme Q<sub>10</sub> (CoQ<sub>10</sub>), a protein that speeds up the rate of chemical reactions occurring in the body. CoQ<sub>10</sub> produces energy to fuel cell growth and maintenance, and works synergistically with vitamin E in the antioxidant cycle to protect the fatty part of the cell from damaging free radical attacks. However, CoQ<sub>10</sub> is a lipophilic molecule, indicating that it does not dissolve easily in water. As a result, CoQ<sub>10</sub> is poorly absorbed by the intestines of humans and animals (Source: Clinigene International Ltd., a full-service clinical research organization and subsidiary of Biocon Ltd.).

Imagenetix believes that the use of CellSorb™ in conjunction with CoQ<sub>10</sub> could improve CoQ<sub>10</sub>'s entry into and utilization by the body. There are existing products marketed in the U.S. targeted toward a similar objective. These are known as ubiquinone products. In an open-label, randomized, crossover bioequivalence study, CellSorb™ 100 mg CoQ<sub>10</sub> Softgels ("CellSorb™-Q10") were evaluated in comparison to three leading U.S. ubiquinone products. In a crossover study, patients are first treated with one substance (a test or reference product) and then later treated with the other substance. This provides intra-individual comparisons. Approximately 30 healthy adult males completed the study, each of whom was administered either one of the reference ubiquinone products or CellSorb™-Q10 over three days followed by a 96-hour monitoring period. After a seven-day washout period, participants returned for the second crossover treatment round.

Results of the study suggested that CellSorb™-Q10 has favorable pharmacokinetics in terms of bioavailability, bioequivalence, and absorption relative to the comparative products. Researchers found higher levels of CoQ<sub>10</sub> in the body compared to the three reference products. CellSorb™-Q10 was bioequivalent to two of the ubiquinone products and was found to have improved bioavailability versus a third ubiquinone product. In addition, CellSorb™-Q10 was associated with a greater area under the curve (AUC) and Cmax averages than the second ubiquinone product. AUC is a measure that can be used to estimate the bioavailability and total clearance of substances. Cmax is the maximum concentration of a substance observed in the plasma after administration of a dose, which occurred approximately six minutes after administration in this study. Over 24 hours, the average AUC for CellSorb™-Q10 was greater than either the second ubiquinone product (by 10%) or the third ubiquinone product (by 3.39 fold). As well, CellSorb™-Q10 elicited an average Cmax response that was 15% greater than the second ubiquinone product. Table 10 (page 28) summarizes selected relative pharmacokinetic relationships and responses, as identified through this crossover study.

Table 10  
Imagenetix, Inc.  
CELLSORB™: RELATIVE PHARMACOKINETIC RELATIONSHIPS AND RESPONSES

Relative Degree of Absorption (RDA)
Reflects the uptake of CoQ <sub>10</sub> from the administered dose
<ul style="list-style-type: none"> <li>CellSorb™-Q10 and the first ubiquinone product were equivalent in the degree of CoQ<sub>10</sub> absorption.</li> <li>CellSorb™-Q10's average RDA was greater than the second and third ubiquinone products by 1.2 times and 2.8 times (P-value=.001), respectively.</li> </ul>
Relative Rate of Absorption (RRA)
A relationship between absorption and the time to achieve absorption
<ul style="list-style-type: none"> <li>RRAs for CellSorb™-Q10 versus the second and third ubiquinone products showed a similar absorption rate.</li> <li>CellSorb™-Q10 absorption had a rate equivalent to 1.8 times that of the first ubiquinone product.</li> </ul>
Relative Bioavailability (RB)
A comparison of the effects of a single dose for all products evaluated
<ul style="list-style-type: none"> <li>CellSorb™-Q10's RB was found to be bioequivalent to that of the first and second ubiquinone products.</li> <li>CellSorb™-Q10's average RB was greater than that of the third ubiquinone product (P-value=0.002).</li> <li>Average responses for CellSorb™-Q10 were 1.4 times that of the second ubiquinone product and 4.4 times that of the third ubiquinone product.</li> </ul>
Repetitive Dosing
Measures of the additive effects on systemic CoQ <sub>10</sub> concentrations created by additional 200 mg/day doses administered at 24 and 48 hours
<ul style="list-style-type: none"> <li>CellSorb™-Q10 provided higher levels of CoQ<sub>10</sub> that increased with each day of repetitive dosing versus the three reference products.</li> </ul>

Source: Clinigene International Ltd.'s Study Report for Study Number BA/BE:101/09.

## IMAGENETIX'S PHARMACEUTICAL DRUG DEVELOPMENT

Imagenetix's drug development program is based on the prevention and treatment of chronic inflammatory conditions. The Company leverages the anti-inflammatory capabilities of the active compound found in its first therapeutic pharmaceutical candidate, 1-tetradecanol complex (1-TDC), a monounsaturated fatty acid complex to prevent and treat periodontal disease. Studies conducted at Boston University have shown 1-TDC stops the progression of gum and bone damage, and recent data suggests that the compound may restore gum and bone lost due to periodontal disease.

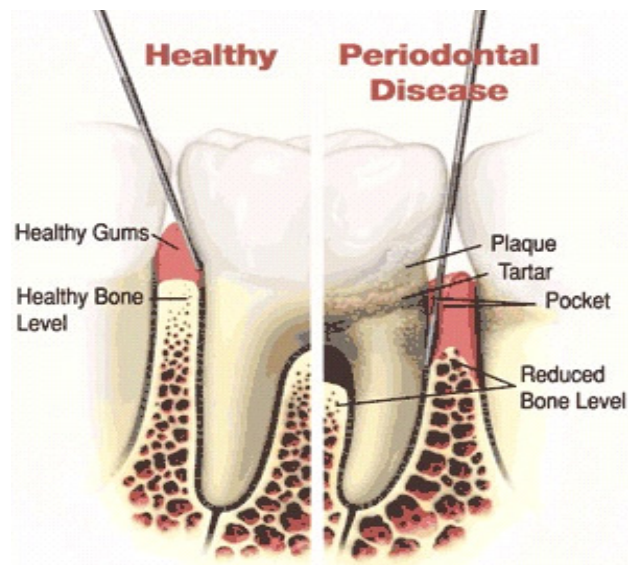
Imagenetix is preparing a timeline for MA2009's (the active compound of 1-TDC) Investigational New Drug (IND) filing, which could require 9 to 12 months. An IND submission will likely require additional preclinical animal studies, including toxicity and dosage analysis, before the Company can be approved for proceeding to human clinical trials. To facilitate further development of MA2009, Imagenetix is evaluating strategic alliances.

## Periodontitis Background

Periodontal (or gum) diseases are bacterial infections of the tissue and bone surrounding the teeth. Periodontal disease is caused by plaque, a film of bacteria on the teeth that can create toxins and damage the gums. Bacterial toxins, as well as the body's enzymes fighting the infection, can cause inflammation that breaks down the bone and connective tissue holding teeth in place.

Periodontal diseases are classified according to the severity of the disease. The two major stages are **gingivitis** and **periodontitis**. Gingivitis is a milder and reversible form of periodontal disease consisting of inflammation or infection of the tissue around the teeth. Gingivitis leads to swollen and bleeding gums. If gingivitis is not treated, it can spread to the ligaments and bone that support the teeth, resulting in the more serious form of periodontal disease called periodontitis (as illustrated in Figure 11). Chronic periodontitis results in continued inflammation within the soft tissues surrounding the teeth, eventually causing the destruction of the gum, bone, and teeth.

Figure 11  
PERIODONTITIS



Source: American Academy of Periodontology.

An estimated 80% of U.S. adults have some form of gum disease (Source: National Institute of Dental and Craniofacial Research [NIDCR]). Periodontal disease is the leading cause of tooth loss and, according to U.S. dentists, a more pressing oral health concern than tooth decay by a 2-to-1 margin (Source: the American Academy of Periodontology). Emerging research links periodontal disease to other health problems as well, including cardiovascular disease, respiratory disease, preterm and underweight births, stroke, osteoporosis, and diabetes (Source: *Journal of Periodontology* vol. 80[2]:190-201 [2009]).

Periodontitis treatments are based on the stage and severity of disease but often consist of a combination of cleaning and scaling, surgery, and medication (as overviewed in the Competition section on page 35). If diagnosed and treated in the early stages, non-surgical therapy may be sufficient. If the condition has advanced to the point where the periodontal pockets are deep and significant amounts of bone are lost, surgical therapy may be necessary. Medications may also be used, but they cannot always take the place of surgery. Some of the medicines used to treat periodontitis include prescription antimicrobial mouth rinses, low-dose oral or topical antibiotics, and enzyme suppressants (Source: NIDCR).

## Science Supporting Imagenetix's 1-TDC Product Candidate

Two preclinical safety and efficacy studies have been conducted to test 1-TDC's effect on the treatment of gum disease, including periodontitis.

The first study investigated the impacts of a topical application of 1-TDC at preventing and improving periodontitis in rabbit models. In chronic periodontitis, pathogens such as *Porphyromonas gingivalis* (*P. gingivalis*) are necessary for inflammation to occur. However, disease progression depends on the host response to bacterial infection and the pro-inflammatory proteins, such as cytokines. The application of monounsaturated fatty acids have been shown to reduce tissue responsiveness to cytokines. This anti-inflammatory activity, together with the epithelial penetration ability of fatty acids, leads Imagenetix to believe that topical application of a monounsaturated fatty acid complex, such as 1-TDC, can have a positive effect on the treatment of oral inflammation diseases.

For these preclinical studies of 1-TDC, experimental periodontitis was induced in rabbits with silk sutures tied around the mandibular premolars, followed by the topical application of *P. gingivalis*. Animals were randomized into four groups: (1) treatment with 1-TDC topically applied in an olive oil vehicle (1 mg/ml); (2) treatment with 1-TDC topically applied in an olive oil vehicle (10 mg/ml); (3) treatment with the olive oil vehicle alone; and (4) no treatment (control group).

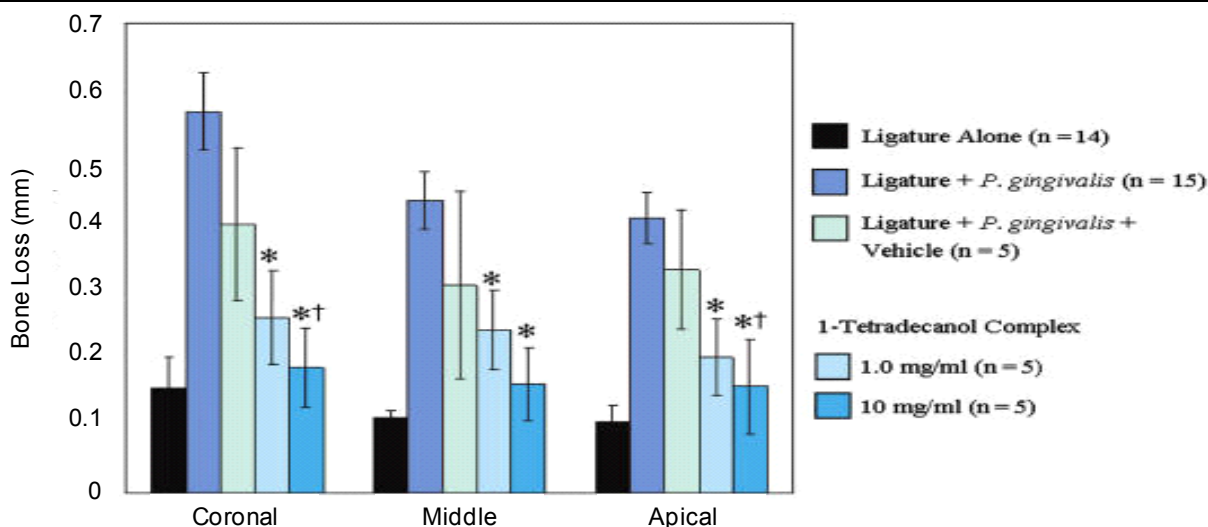
Topical application of 1-TDC demonstrated cessation of the progression of the disease, as it prevented bone loss, inflammatory cell infiltration, and connective tissue destruction in the rabbit periodontitis model. Treatment with both concentrations of 1-TDC prevented macroscopic periodontal inflammation and bone loss versus the control group, where significant periodontal tissue destruction characterized by attachment and bone loss was detected. However, no significant differences resulted between the 1-TDC treatment groups and the vehicle group.

Although the vehicle group had preventive activity similar to the groups treated with 1-TDC, it failed to replicate those results in **histopathologic** changes of periodontitis. In measurements conducted to test for bone loss, application of 1-TDC at the higher concentration showed less bone loss than the control group and the vehicle group. In addition, testing on bone resorption and inflammation showed 1-TDC application inhibited inflammatory cell infiltration and prevented **osteoclastogenesis**. The application of 1-TDC in the higher dose also showed greater bone loss prevention versus the lower dose, control group, and the vehicle group, as illustrated in Figure 12.

Figure 12

Imagenetix, Inc.

### BONE LOSS IN PERIODONTITIS MODELS



\*P < 0.05 compared to ligature + *P. gingivalis*; †P < 0.05 compared to ligature + *P. gingivalis* + vehicle.

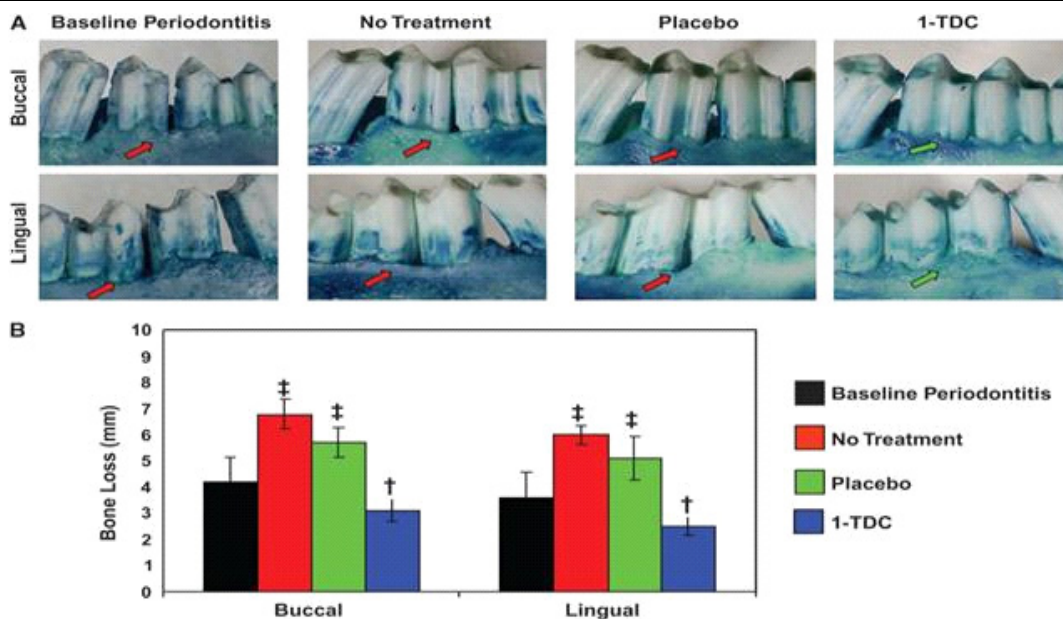
Source: *Journal of Periodontology* Vol. 78(5):924-932 (2007).

Subsequently, a follow-up study was designed to investigate the therapeutic effect of 1-TDC in periodontitis at higher dose levels. The design was similar to the original study, using the same periodontitis model with rabbits assigned to three groups: (1) treatment with 1-TDC at 100 mg/ml; (2) treatment with mineral oil (placebo); and (3) no treatment (control group).

Data illustrated that 1-TDC not only stopped the progression of periodontal disease but also demonstrated regeneration capabilities with improvement and partial restoration of both the gum and bone tissue lost to periodontal disease versus placebo (Source: *Journal of Periodontology* vol. 80:1103-1113 [2009]).

Macroscopic evaluation demonstrated that treatment with 1-TDC resulted in a significant reduction in soft tissue inflammation and bone loss. 1-TDC treatment was associated with reduced bone loss versus the control and placebo groups and even resulted in bone gain compared to the control group, as pictured in Figure 13. **Osteoblast cell** activity was assessed to measure the potential for new bone formation. 1-TDC had increased osteoblast density at all levels versus the other groups. These findings and the normal characteristics of newly formed bone in the 1-TDC sections suggested that 1-TDC was able to stop the progression of the disease and initiate healing, leading to bone reformation.

Figure 13  
Imagenetix, Inc.  
1-TDC BONE GAIN



Source: *Journal of Periodontology* Vol. 80:1103-1113 (2009).

Furthermore, the cytokine inflammatory pathway examined in the periodontal disease model is similar to that proposed for joint inflammation in rheumatoid arthritis and other inflammatory conditions (Source: *New England Journal of Medicine* vol. 344[12]:907 [2001]). Thus, 1-TDC and MA2009's anti-inflammatory capabilities may be applicable to other chronic inflammatory conditions in which cytokines have an important role, such as rheumatoid arthritis. Further research is planned to investigate this relationship.



## Competition

The nutritional supplement market is sizable and highly competitive. Competitive factors include price, safety, efficacy, scientific validation, quality, packaging, brand loyalty, proprietary formulations, reliability of product delivery, and marketing. Imagenetix believes that its business strategy addresses each of these elements. Additionally, while Imagenetix may compete with companies that have longer operating histories or greater product offerings, name recognition, or financial resources, the Company believes that its turnkey approach of providing distributors with significant regulatory and marketing support as well as novel, scientifically validated products improves its overall competitive position.

Imagenetix generally competes with companies that manufacture and market related nutritional products, including Twinlab Corp., Weider Global Nutrition, and Perrigo Company (PRGO-NASDAQ), as well as with organizations that supply nutritional products to direct distribution companies, such as Leiner Health Products, Inc., Natural Alternatives International, Inc., and Vita-Tech International, Inc. Beyond these entities, Imagenetix may also compete with companies developing products to address the same conditions that the Company aims to treat. While not intended to be an exhaustive collection of Imagenetix's potential sources of competition, the accompanying pages provide an overview of some competitive products that the Company may encounter as it continues to market its products. Imagenetix believes that its bioceuticals are differentiated from other supplements on the market, as they are supported by peer-reviewed research and clinical trials.

### **Celadrin®** ([www.celadrin.com](http://www.celadrin.com))

Imagenetix's joint health product, Celadrin®, is available in both oral softgel pills for long-term therapy and as a topical cream for short-term relief. The Company believes that its competition for Celadrin® comes primarily in the form of glucosamine- and chondroitin-based supplements and methylsulfonylmethane (MSM).

#### *Glucosamine and Chondroitin*

Glucosamine and chondroitin are two joint supplements used—often in combination—to treat arthritis. Glucosamine is a major component of joint cartilage. Derived from the shells of shellfish, glucosamine supplements claim to slow cartilage deterioration, relieve pain, and improve joint mobility in patients with osteoarthritis. A 2005 **Cochrane Review** of glucosamine analyzed data from 2,570 patients in 20 studies, finding that while glucosamine was safe, it was not superior to placebo at reducing pain and stiffness or improving function (Source: *Arthritis Today*, a national consumer health magazine published by the Arthritis Foundation).

Chondroitin is a component of human connective tissues found in cartilage and bone. Often produced from bovine trachea or pork byproducts, chondroitin supplements have been found to reduce pain and inflammation and improve joint function. In a trial of glucosamine and chondroitin therapy conducted by researchers at the U.S. National Institutes of Health (NIH), the supplements were more effective for decreasing pain when combined.

#### *Methylsulfonylmethane (MSM)*

Naturally found in plants, animals, and humans, MSM is available in the U.S. as a dietary supplement. It can be administered orally or topically. MSM has been used to treat chronic pain, arthritis, joint inflammation, rheumatoid arthritis, osteoporosis, tendonitis, musculoskeletal pain, muscle cramps, scar tissue, stretch marks, wrinkles, eye inflammation, periodontal disease, and wounds, among many other ailments; however, there is not much published scientific research to support the use of MSM (Source: WebMD, LLC).

As such, based on the available therapies, Imagenetix believes that there is a need for alternative products that can benefit osteoarthritis patients without causing harmful side effects.



**Osteo Bi-Flex®**  
NBTY, Inc. (NTY-NYSE)  
[www.osteobiflex.com](http://www.osteobiflex.com)

Osteo Bi-Flex® tablets contain glucosamine and chondroitin and are marketed as a supplement to help renew cartilage, lubricate joints, and improve range of motion over time. In addition, Osteo Bi-Flex® contains Joint Shield™, which includes 5-Loxin®—a highly concentrated extract of gum resin from the *Boswellia serrata* tree. 5-Loxin® may induce anti-inflammatory and analgesic effects. While the combination of glucosamine and chondroitin is intended to rebuild and repair joints, the ingredients in Joint Shield™ (e.g., 5-Loxin®) are believed to work to protect against the actions of enzymes that impact joint health. A 90-day, double-blind, randomized, placebo-controlled study of 75 patients with osteoarthritis of the knee showed that 5-Loxin® was safe and could reduce pain and improve physical functioning in as few as seven days (Source: *Arthritis Research & Therapy* 10[5]:116 [2008]). Osteo Bi-Flex® is available in Regular Strength, Advanced, Advanced Double Strength, Advanced Triple Strength, Advanced Triple Strength with Vitamin D3, Advanced Energy, and Advanced MSM formulations.

**Move Free® Advanced**  
Schiff Nutrition Group, Inc.  
[www.movefreeadvanced.com](http://www.movefreeadvanced.com)

Move Free® Advanced is an oral formula that combines Uniflex®—an antioxidant system designed to protect cartilage and joint tissue—with glucosamine and chondroitin. The formulation also contains Joint Fluid, a form of hyaluronic acid (a lubricating fluid that exists naturally in the joints), which is believed to rejuvenate, rehydrate, and lubricate joints. Uniflex® is composed of two herbal extracts: (1) Chinese skullcap root, which has been used in traditional Chinese medicine to treat allergies, infections, inflammation, cancer, and headaches; and (2) Black Catechu bark, an antiseptic/astringent that can be used for chronic diarrhea, dysentery, mucous colitis, and as a mouthwash in gingivitis, stomatitis, and pharyngitis. Both extracts have been used for hundreds of years to promote health. Schiff Nutrition Group reported results from a preliminary, randomized, prospective, double-blind, placebo-controlled, eight-week study where Move Free® Advanced tablets were found to be twice as effective as glucosamine and chondroitin therapy for overall joint health, with 100% of patients experiencing discomfort relief after eight weeks. As well, patients taking Move Free® Advanced felt improvements in one to two weeks versus four to eight weeks for glucosamine/chondroitin treatment. Move Free® Advanced is available in three formulations: (1) Triple Strength; (2) Triple Strength Plus MSM and Vitamin D; and (3) Plus MSM.

**Cosamin® DS**  
Nutramax Laboratories, Inc.  
[www.nutramaxlabs.com](http://www.nutramaxlabs.com)

Cosamin® DS is an oral glucosamine/chondroitin sulfate product available in both tablet and capsule form that is designed to reduce joint pain and stiffness, stimulate cartilage production, and prevent cartilage breakdown. Nutramax reports that Cosamin® DS reduced joint pain in controlled, published U.S. clinical studies. Additionally, published experimental trials showed that ingredients in Cosamin® DS protected against cartilage breakdown. Nutramax also offers Avoca® ASU (Avocado/Soybean Unsaponifiables)—a vegetarian formula using non-shellfish glucosamine—and Cosamin® ASU, a formula for joint discomfort that has been shown in laboratory research to inhibit compounds associated with cartilage breakdown. Nutramax believes that ASU complements glucosamine and chondroitin to deliver comprehensive joint health support. In cell studies, this combination of ingredients was shown to inhibit expression of several agents involved in cartilage breakdown better than glucosamine/chondroitin sulfate therapy.

**TripleFlex®**  
Pharmavite LLC  
[www.tripleflex.com](http://www.tripleflex.com)

TripleFlex® triple strength liquid softgel and tablet formulations contain a combination of glucosamine, hyaluronic acid, and chondroitin complex designed to improve joint comfort, mobility, and flexibility. Chondroitin complex is a chondroitin and white willow bark mixture that helps promote joint comfort in as few as seven days. A formulation called TripleFlex® 50+ is also available for individuals over age 50. TripleFlex® 50+ contains the same ingredients as the traditional TripleFlex® formulation with added calcium and vitamin D for improved bone and muscle strength.

**BioGuard™** ([www.bioguardhealth.com](http://www.bioguardhealth.com))

BioGuard™ is Imagenetix's immune-boosting probiotic that promotes immune health by protecting the ears, nose, and throat. The active ingredient in BioGuard™ is BLIS K12™, an advanced probiotic designed to prevent upper airway infection (including bacterial sore throats) and tooth and gum disease as well as to treat chronic bad breath.

Imagenetix believes that there are several factors which could limit market adoption of BioGuard™: (1) credible competition from existing over-the-counter (OTC) products (e.g., Tylenol® Cold and Flu, Advil® Cold and Sinus); (2) consumers' belief that an effective natural product could enhance the immune system; (3) consumers' education on the ability of BioGuard™ to help prevent immune and illness issues with daily use; and (4) consumers' belief that probiotics are for digestive health only.

Imagenetix's BioGuard™ faces competition from other products containing the BLIS K12™ probiotic, including Nature's Plus Ear, Nose, and Throat Lozenges with K12 Probiotics ([www.naturesplus.com](http://www.naturesplus.com)), CulturedCare™ ProbioticGum with BLIS K12 (<http://culturedcare.com>), Aktiv-K12 Probiotics (<http://aktiv-k12.com>), and Swanson Health Products' Oral Probiotic BLIS K12 for Immune System Support ([www.swansonvitamins.com](http://www.swansonvitamins.com)), among others.

Additionally, BioGuard™ may compete with products that use different active ingredients but address the same indications. For example, EvoraPlus™ ([www.evoraplus.com](http://www.evoraplus.com))—a mint that supports gum and tooth health, fresh breath, and white teeth—uses Probiora3™ probiotics. Both the product and the probiotics are produced by Oragenics, Inc., a Florida-based biopharmaceutical company. The Airborne® health products (<http://airbornehealth.com>), which contain blends of vitamins, minerals, and herbs to support the immune system, may also pose significant competition for BioGuard™.

**Trisynex™**

Products in the weight loss market are classified as dietary supplements; thus, they do not require marketing preapproval by the FDA. A lack of regulation in the industry had led to misleading, false, or unsubstantiated marketing claims. The U.S. Federal Trade Commission (FTC) is responsible for monitoring the accuracy and validity of marketing claims made by food and dietary supplement manufacturers. In January 2007, the FTC settled allegations of deceptive advertising with marketers of four weight-control pills for at least \$25 million. Further, in April 2009, the FTC charged marketers of Hoodia weight loss supplements with deceptive advertising for claiming that using the product would lead to weight loss and appetite suppression.

Thus, Imagenetix views the weight loss industry as being litigious, with a regulatory climate that is difficult to navigate. Additionally, the cost to be noticed in the market is high. Given the short life cycle of many weight loss products, companies seek to make an impact quickly via intensive advertising campaigns. As a result, Imagenetix has opted to focus its patented fat-reducing compound on international markets. At present, Trisynex™ is sold as a bulk raw material and to multi-level marketing (MLM) companies.

Table 11 (page 35) overviews a number of common weight loss products on the market, including claims made by the respective marketers/manufacturers and a summary of each product's efficacy and safety based on 2010 data. Imagenetix believes that its ability to substantiate products based on science is a key competitive advantage.

Table 11  
AN OVERVIEW OF COMMON WEIGHT LOSS PILLS

Product	Claim	Effectiveness	Safety
<b>Alli® (OTC version of prescription drug Xenical® [orlistat])</b>	Decreases absorption of dietary fat	Effective; weight loss often less for OTC versus prescription	FDA investigating reports of liver injury
<b>Bitter orange</b>	Increases calories burned	Insufficient reliable evidence	Possibly unsafe
<b>Chitosan</b>	Blocks absorption of dietary fat	Insufficient reliable evidence	Possibly safe
<b>Chromium</b>	Increases calories burned, decreases appetite, and builds muscle	Insufficient reliable evidence	Likely safe
<b>Conjugated linoleic acid (CLA)</b>	Reduces body fat and builds muscle	Possibly effective	Possibly safe
<b>Country mallow (heartleaf)</b>	Decreases appetite and increases calories burned	Insufficient reliable evidence	Likely unsafe and banned by FDA
<b>Ephedra</b>	Decreases appetite	Possibly effective	Likely unsafe and banned by FDA
<b>Green tea extract</b>	Increases calorie and fat metabolism and decreases appetite	Insufficient reliable evidence	Possibly safe
<b>Guar gum</b>	Blocks absorption of dietary fat and increases feeling of fullness	Possibly ineffective	Likely safe
<b>Hoodia</b>	Decreases appetite	Insufficient reliable evidence	Insufficient data

Sources: the Mayo Foundation for Medical Education and Research (Mayo Clinic), the FDA, and the Natural Medicines Comprehensive Database.

## 1-TDC and MA2009

Periodontitis is an inflammation of the gum and bone around the tooth that may lead to tooth loosening or loss. In the early stages of periodontitis, patients may be treated using several minimally invasive, non-surgical therapies: (1) “scaling,” which is the removal of tartar and bacteria from teeth and gums; (2) root planning, which smoothes the root surfaces to discourage further tartar buildup; and (3) administering oral or topical antibiotics, which may help control bacterial infection. These therapies are designed to thoroughly clean the pockets of bacteria to prevent further damage. However, when periodontitis reaches the more advanced stages, the patient may require dental surgery, including the grafting or guided regeneration of bone or soft tissue to improve the mouth’s appearance, cover exposed roots, and prevent tooth loss. Additionally, patients may require flap surgery, a procedure in which a section of gum tissue can be lifted back.

To address the symptoms of periodontal disease, Imagenetix has developed a proprietary blend, 1-TDC and its active compound, MA2009. Imagenetix is not aware of any directly competitive products currently on the market. Available products, such as OraPharma, Inc.’s Arestin® (minocycline HCL), combat the growth of bacteria after periodontal gum procedures (e.g., scaling or root planning) but do not directly address the disease. As such, the Company believes that MA2009 could represent a new therapeutic class in the marketplace.

## Milestones

### Recent Milestones

Imagenetix has achieved several key development milestones during the past 12 months, as highlighted below.

- The Company continued to build a distribution base and marketing campaign for Celadrin<sup>®</sup>, adding further retailers to its network and launching 15- and 30-second advertisements on multiple television channels in May 2010. Celadrin<sup>®</sup> is now available for sale at a number of major retailers, including national warehouse clubs and drug stores, and through several online venues. Pages 6-7 detail the distribution of Celadrin<sup>®</sup>.
- Imagenetix completed a trial program with BioGuard<sup>™</sup> at Costco stores throughout the Pacific Northwest.
- The Company was granted U.S. patent number 7,612,111, which relates to 1-TDC for the prevention and treatment of periodontal disease.
- Imagenetix conducted a second study on 1-TDC for the treatment of periodontal disease, for which findings were published in the July 2009 issue of the *Journal of Periodontology*.

### Anticipated Future Milestones

Going forward, Imagenetix aims to accomplish the following:

- Introduce Celadrin<sup>®</sup> to additional food, drug, and mass-market stores;
- Complete an IND for MA2009 and commence clinical trials;
- Continue advancing the distribution of BioGuard<sup>™</sup> as a year-round immune system booster at additional food, drug, and mass-market stores;
- Advise the market of potential strategic alliances involving the weight loss product; and
- Enter into a strategic alliance for the periodontal drug candidate.

## Key Points to Consider

- Imagenetix develops proprietary bioceutical and pharmaceutical products. The Company emphasizes the use of scientific research to validate its products, believing that clinical data and peer-reviewed publications may provide a distinctive competitive advantage and enable consumer confidence.
- Imagenetix's lead product is Celadrin<sup>®</sup>, which the Company offers as a branded nutritional supplement, as a private-label formulation, and as a branded ingredient for wholesale customers. In a 2009 survey of 400 rheumatologists and orthopedic surgeons who recommend natural products, 94% stated that they would recommend Celadrin<sup>®</sup> for joint health.
  - Through 17 safety and efficacy studies, Celadrin<sup>®</sup> was found to provide joint health and relief of joint pain and arthritis symptoms as well as restorative benefits. In clinical studies of topical Celadrin<sup>®</sup> Cream, 100% of osteoarthritis patients showed benefits versus placebo, which included improved physical function and postural balance and reduced pain.
- The global market for nutraceuticals was estimated at over \$123 billion in 2008, forecast to reach \$176 billion in 2013 as part of a larger \$236 billion global nutritional product industry. Moreover, future growth of bone and joint health products is expected to be driven by alternative ingredients and not solely glucosamine and chondroitin.
- BioGuard<sup>™</sup> is a probiotic designed to protect the ear, nose, and throat in order to benefit the overall immune system. BioGuard<sup>™</sup> acts against the growth of harmful bacteria. The active ingredient in BioGuard<sup>™</sup>, called BLIS K12<sup>™</sup>, produces antibacterial proteins to selectively target the bacteria causing immune imbalance, throat irritations, and mouth odor, among other ailments.
  - In clinical studies, BioGuard<sup>™</sup> ingredients were shown to improve overall immunity and to be proactive against oral and upper respiratory tract infections, otitis media (ear) infections, and other oral diseases (e.g., dental caries, periodontal disease, and halitosis).
  - In 2008, the global probiotic market was approximated at \$15.9 billion and was expected to exceed \$19 billion by 2013.
- A study of the Company's Trisynex<sup>™</sup> compound demonstrated that Trisynex<sup>™</sup>, exercise, and diet improved body mass, body fat percentage, and waist circumference (among other criteria) more than diet and exercise alone. Imagenetix supplies this compound as a raw material. Approximately 2.3 billion adults could be overweight by 2015 with more than 700 million considered obese; thus, products facilitating weight loss management are becoming increasingly important.
- Imagenetix's initial pharmaceutical candidate is 1-tetradecanol complex (1-TDC) and its active compound, MA2009, to treat and prevent periodontal disease. Studies conducted at Boston University have shown that 1-TDC may inhibit the progression of gum and bone damage and produce partial restoration of gum and bone lost due to the disease.
  - An estimated 80% of U.S. adults have some form of gum disease, and periodontal disease is a leading cause of tooth loss. Periodontal disease is also linked to other health problems, including cardiovascular disease, respiratory disease, stroke, osteoporosis, and diabetes.
- Imagenetix's management and key personnel are experienced in developing and selling nutritional products to domestic and international marketers, including direct marketers, health food stores, and mass-market merchandisers.
- At March 31, 2010, Imagenetix had cash and cash equivalents of close to \$1 million. Subsequently, in May 2010, Imagenetix raised \$400,000 through an equity financing (800,000 shares of Common Stock at \$0.50 per share) and \$410,000 in a debt financing.



## Historical Financial Results

Tables 12, 13, and 14 provide a summary of Imagenetix's key historical financial statements—its Consolidated Statements of Operations, Balance Sheets, and Statements of Cash Flows.

Table 12  
Imagenetix, Inc.  
CONSOLIDATED STATEMENTS OF OPERATIONS

<i>Years Ended March 31,</i>	<b>2010</b>	<b>2009</b>
Net sales	\$ 6,596,071	\$ 7,460,872
Cost of sales	<u>3,732,252</u>	<u>4,003,303</u>
Gross profit	2,863,819	3,457,569
Operating expenses:		
General and administrative	2,571,080	2,240,988
Payroll expense	1,089,597	1,076,473
Consulting expense	1,481,331	1,059,309
Operating expenses	<u>5,142,008</u>	<u>4,376,770</u>
Operating (loss)	<u>(2,278,189)</u>	<u>(919,201)</u>
Other income (expense):		
Other income	7,790	25,012
Settlement income	1,168,000	1,785,000
Interest expense	(2,405)	(1,741)
Other income	<u>1,173,385</u>	<u>1,808,271</u>
Income (loss) before income taxes	<u>(1,104,804)</u>	<u>889,070</u>
Provision for (benefits from) income taxes	<u>(407,700)</u>	<u>459,114</u>
Net income (loss)	<u>\$ (697,104)</u>	<u>\$ 429,956</u>
Basic and diluted income (loss) per share	<u>\$ (0.06)</u>	<u>\$ 0.04</u>

*Source: Imagenetix, Inc.*

Table 13  
Imagenetix, Inc.  
CONSOLIDATED BALANCE SHEETS

March 31,	2010	2009
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 981,510	\$ 1,225,723
Accounts receivable, net	1,049,047	1,095,946
Inventories, net	1,350,041	1,337,241
Prepaid expenses and other current assets	150,690	109,028
Deferred tax asset	932,800	535,200
Total current assets	4,464,088	4,303,138
Property and equipment, net	89,137	115,918
Long-term prepaid expenses	18,000	30,000
Other assets	124,598	134,356
<b>Total Assets</b>	<b>\$ 4,695,823</b>	<b>\$ 4,583,412</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 996,827	\$ 274,311
Accrued liabilities	82,392	80,696
Income tax payable	—	69,803
Customer deposits	25,374	58,850
Contract payable	85,972	43,645
Short-term license payable	—	2,980
<b>Total current liabilities</b>	<b>1,190,565</b>	<b>530,285</b>
<b>Stockholders' equity</b>		
Preferred Stock, \$.001 par value; 5,000,000 shares authorized: none outstanding	—	—
Common Stock, \$.001 par value; 50,000,000 shares authorized: 11,010,788 issued and outstanding at March 31, 2010 and 2009	11,010	11,010
Capital in excess of par value	12,801,171	12,651,936
Accumulated deficit	(9,306,923)	(8,609,819)
Total stockholders' equity	3,505,258	4,053,127
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 4,695,823</b>	<b>\$ 4,583,412</b>

Source: Imagenetix, Inc.

Table 14  
Imagenetix, Inc.  
CONSOLIDATED STATEMENTS OF CASH FLOWS

<i>Years Ended March 31,</i>	<b>2010</b>	<b>2009</b>
<b>Operating activities:</b>		
Net income (loss)	\$ (697,104)	\$ 429,956
Adjustments to reconcile net income (loss) to cash provided (used) by operating activities:		
Amortization and depreciation	53,140	45,067
Provision for doubtful accounts, returns, and discounts	75,000	(44,000)
Provision for inventory obsolescence	1,423	(1,960)
Non cash expense related to issuance of Warrants and Stock Options	149,235	145,579
Stock issued for services	—	25,000
Loss on sale of property and equipment	—	3,643
Change in deferred taxes	(407,700)	400,497
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	(28,101)	(286,454)
(Increase) decrease in employee receivable	—	2,409
(Increase) decrease in inventory	(14,223)	(225,436)
(Increase) decrease in other assets	(29,662)	152,701
Increase (decrease) in accounts payable	722,516	(446,287)
Increase (decrease) in accrued liabilities	1,696	8,395
Increase (decrease) in income taxes payable	(69,803)	69,803
Increase (decrease) in customer deposits	(33,476)	(4,366)
Net cash provided by (used in) operating activities	(277,059)	274,547
<b>Investing activities:</b>		
Purchases of property and equipment	(6,501)	(43,464)
Proceeds from disposal of property and equipment	—	1,625
Net cash used in investing activities	(6,501)	(41,839)
<b>Financing activities:</b>		
Proceeds from contracts payable	141,849	92,219
Payments on contracts payable	(99,522)	(87,500)
Payments on patent license financed	(2,980)	(34,259)
Net cash provided by (used in) financing activities	39,347	(29,540)
<b>Net increase (decrease) in cash</b>	<b>(244,213)</b>	<b>203,168</b>
<b>Cash and cash equivalents, beginning of year</b>	<b>1,225,723</b>	<b>1,022,555</b>
<b>Cash and cash equivalents, end of year</b>	<b>\$ 981,510</b>	<b>\$ 1,225,723</b>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Cash paid during the period for:		
Interest	\$ 2,405	\$ 1,741
Income taxes	\$ 69,803	\$ —
<b>Non Cash Investing and Financing Activities:</b>		
Common Stock issued for services	\$ —	\$ 25,000

*Source: Imagenetix, Inc.*

## Risks

Some of the information in this Executive Informational Overview<sup>®</sup> (EIO<sup>®</sup>) relates to future events or future business and financial performance. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in the Company's statements on Forms 10-K, 10-Q, and 8-K, as well as other forms filed from time to time. The content of this EIO<sup>®</sup> with respect to Imagenetix has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings. Imagenetix is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Imagenetix. Certain summaries of activities have been condensed to aid the reader in gaining a general understanding. For more complete information about Imagenetix, please refer to the Company's website at [www.imagenetix.net](http://www.imagenetix.net).

Investors should carefully consider the risks and information about Imagenetix's business described below. Investors should not interpret the order in which these considerations are presented as an indication of their relative importance. The risks and uncertainties described below are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Imagenetix or that the Company currently believes to be immaterial may also adversely affect its business. If any of the following risks and uncertainties develops into actual events, the business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company's shares could decline.

**There is only one supplier for Celadrin<sup>®</sup>. If Imagenetix is unable to purchase Celadrin<sup>®</sup> from this supplier, the Company's business would be harmed.**

There is only one supplier for Celadrin<sup>®</sup>, which Imagenetix uses in approximately 61% of its products and which represented approximately 72% of the Company's sales for the year ended March 31, 2010. Imagenetix expects to rely upon Celadrin<sup>®</sup> to expand its product lines and revenue in the future. If the Company's Celadrin<sup>®</sup> supplier goes out of business or elects for any reason not to supply Imagenetix with Celadrin<sup>®</sup>, the Company would have to find another Celadrin<sup>®</sup> supplier or suffer a significant reduction in its revenue.

**Imagenetix relies upon a limited number of customers, the loss of which would reduce its revenue and any earnings.**

Imagenetix's largest customers accounted for 42% and 15% of net sales for the year ended March 31, 2010, and 23%, 19%, and 17% for the year ended March 31, 2009. During the year ended March 31, 2010, the Company entered into a buyout agreement with its largest customer, which was expected to result in no significant revenue from that customer in future periods. Imagenetix has several other customers with increased revenue during the year ended March 31, 2010, which will likely at least partially offset the loss of this significant customer. If not replaced by other large customers, the loss of any significantly large customer could reduce the Company's revenue and adversely affect its cash flow and earnings, if any.

**Imagenetix relies upon other outside suppliers to produce its products, which could delay product deliveries.**

All of the Company's products are produced by outside manufacturers that process ingredients provided to them by Imagenetix's suppliers and with which the Company has contracts. Imagenetix's profit margins and its ability to deliver products on a timely basis are dependent upon these manufacturers and suppliers. Should any of these manufacturers or suppliers fail to provide the Company with product, Imagenetix would be required to obtain new manufacturers and suppliers, which would be costly and time consuming and could delay its product deliveries.

**Product liability claims against Imagenetix could be costly.**

Some of the Company's nutritional supplements contain newly introduced ingredients or combinations of ingredients, and Imagenetix has little long-term health information about individuals consuming those ingredients. If any of these products were thought or proved to be harmful, Imagenetix could be subject to litigation. Although the Company carries product liability insurance in the amount of \$1,000,000 per occurrence and \$2,000,000 in the aggregate and requires its suppliers and manufacturers to include Imagenetix as insured parties on their product liability insurance policies, the Company's coverage may not be adequate to protect it from potential product liability claims and costs of defense.

**Imagenetix is subject to intense competition from other nutritional supplement marketers, which could reduce its revenue and profit margins.**

Competition in the nutritional supplement market is intense. Imagenetix competes with numerous companies that have longer operating histories, more products, and greater name recognition and financial resources than the Company. In order to compete, Imagenetix could be forced to lower its product prices, which would reduce revenue and profit margins.

**Imagenetix is highly regulated, which increases its costs of doing business.**

The Company is subject to laws and regulations which cover the following:

- the formulation, manufacturing, packaging, labeling, distribution, importation, sale, and storage of its products;
- the health and safety of food and drugs;
- trade practice and direct selling laws; and
- product claims and advertising by the Company or for which Imagenetix may be held responsible.

Compliance with these laws and regulations is time consuming and costly. Moreover, new regulations could be adopted that would severely restrict the products Imagenetix sells or its ability to continue its business. The Company is unable to predict the nature of any future laws, regulations, interpretations, or applications, nor can it predict what effect additional governmental regulations or administrative orders, when and if promulgated, would have on its business in the future. These future changes could, however, require the reformulation or elimination of certain products; imposition of additional record keeping and documentation requirements; imposition of new federal reporting and application requirements; modified methods of importing, manufacturing, storing, or distributing certain products; and expanded or different labeling and substantiation requirements for certain products and ingredients. Any or all of these requirements could harm the Company's business.

**There are limitations on the liability of the Company's officers and directors, which may restrict stockholders from bringing claims.**

Imagenetix's bylaws substantially limit the liability of its officers and directors to the Company and its stockholders for negligence and breach of fiduciary or other duties. This limitation may prevent stockholders from bringing claims against the Company's officers and directors in the future.

**Shares of the Company's Common Stock that are eligible for sale by Imagenetix's stockholders may decrease the price of the Company's Common Stock.**

Imagenetix has 11,810,788 Common Shares outstanding, which are freely tradable or saleable under Rule 144. The Company also has outstanding Common Stock Warrants and Stock Options exercisable into up to 5,549,707 Shares of Common Stock, which could become free trading if exercised. If the Company's stockholders sell substantial amounts of Imagenetix's Common Stock, the market price of its Common Stock could decrease.



**There is a limited but potentially volatile trading market in the Company's Common Stock, which may adversely affect its stock price.**

The Company's Common Stock trades on the Electronic Bulletin Board. The Bulletin Board tends to be highly illiquid, in part because there is no national quotation system by which potential investors can track the market price of shares except through information received or generated by a limited number of broker-dealers that make a market in particular stocks. There is a greater chance of market volatility for securities that trade on the Bulletin Board as opposed to a national exchange or quotation system. This volatility may be caused by a variety of factors, including the following:

- the lack of readily available price quotations;
- the absence of consistent administrative supervision of "bid" and "ask" quotations;
- lower trading volume; and
- market conditions.

There could be wide fluctuations in the market price of the Company's Common Stock. These fluctuations may have a negative effect on the market price of Imagenetix's securities and may prevent investors from obtaining a market price equal to their purchase prices when they attempt to sell the Company's securities in the open market. In these situations, the investor may be required to either sell Imagenetix's securities at a market price lower than the purchase price or to hold the Company's securities for a longer period of time than planned.

**Because the Company's Common Stock may be classified as "penny stock," trading in it could be limited, and Imagenetix's stock price could decline.**

The Company's Common Stock may fall under the definition of penny stock if Imagenetix's net tangible assets decline below \$2,500,000. In such event, trading in the Company's Common Stock would be limited because broker-dealers will be required to provide their customers with disclosure documents prior to allowing them to participate in transactions involving Imagenetix's Common Stock. These disclosure requirements are burdensome to broker-dealers and may discourage them from allowing their customers to participate in transactions involving the Company's Common Stock.

Penny stocks are equity securities with a market price below \$5.00 per share, other than a security that is registered on a national exchange or included for quotation on the NASDAQ system, unless, as in the Company's case, the issuer has net tangible assets of more than \$2,000,000 and has been in continuous operation for greater than three years. Issuers who have been in operation for less than three years must have net tangible assets of at least \$5,000,000.

Rules promulgated by the SEC under Section 15(g) of the Exchange Act require broker-dealers engaging in transactions in penny stocks to first provide to their customers a series of disclosures and documents, including the following:

- a standardized risk disclosure document identifying the risks inherent to investing in penny stocks;
- all compensation received by the broker-dealer in connection with the transaction;
- current quotation prices and other relevant market data; and
- monthly account statements reflecting the fair market value of the securities.

In addition, these rules require that a broker-dealer obtain financial and other information from a customer, determine that transactions in penny stocks are suitable for such customers and deliver a written statement to such customers, setting forth the basis for this determination.

## **Legal Proceedings**

Imagenetix is involved in litigation from time to time in the normal course of business. The Company believes that there are no such claims which would have a material effect on its financial position.

### *Sun Research Arbitration*

On November 23, 2009, Sun Research, Inc., a sales distributor for Imagenetix, submitted a demand for arbitration with the American Arbitration Association related to a Regional Distributor Agreement entered into on March 31, 2008. Sun Research asserted that under the terms of the Agreement, it was entitled to compensation from an acceleration agreement Imagenetix entered into with a customer. Sun Research has demanded damages of approximately \$265,625 (excluding claims for costs, interests, and attorneys' fees). The Company denied the allegations and believed the claims to be frivolous and totally devoid of merit. In April 2010, the Company and Sun Research agreed to settle the dispute by the Company paying \$82,000 to Sun Research over a six-month period. The \$82,000 was recorded as a charge against settlement income during the fiscal year ended March 31, 2010.

### *TriPharma Suit*

On April 30, 2010, TriPharma, Inc., a customer of Imagenetix, filed a legal action in the U.S. Southern District Court of California, case number 10CV0933IEG, related to an Exclusive Marketing and Supply Agreement, as amended on June 19, 2008. TriPharma asserts that Imagenetix breached the terms of the Agreement and seeks injunctive relief and unspecified damages. The Company denies the allegations and believes the claims to be frivolous and totally devoid of merit. The Company has retained litigation counsel and intends to vigorously defend the claims. The amount, if any, of ultimate liability with respect to the foregoing cannot be determined. Despite the inherent uncertainties of litigation, the Company at this time does not believe that TriPharma's claim will have a material adverse impact on its financial condition, results of operations, or cash flows.

## Recent Events

**06/21/2010**—Imagenetix, Inc. announced results for its fiscal year ended March 31, 2010. Net sales decreased 12% for the year to \$6,596,000 from the \$7,461,000 reported for the same period in fiscal 2009. Gross profit as a percentage of sales decreased to 43% from 46% for the prior fiscal year. This decrease was primarily due to the sales mix, which included increased percentages for advertising allowances for the Company's branded retail products. Net loss for the year was \$697,000, or (\$0.06) per share, versus a net profit of \$430,000, or \$0.04 per share, in the prior fiscal year.

**04/26/2010**—Announced that it continued to build a distribution base for Celadrin<sup>®</sup>, adding a leading national retailer to its network. Celadrin<sup>®</sup> is now available for sale at national warehouse clubs, drug stores, and retailers. Imagenetix also announced its intention to support the availability of Celadrin<sup>®</sup> at these retailers with national television advertising and promotion campaigns.

**02/09/2010**—Reported financial results for the three and nine months ended December 31, 2009. Net sales decreased 15% for the third quarter of fiscal year (FY) 2010 to \$1,765,000 from \$2,084,000 for the same period of FY 2009. The primary reasons for the sales decrease were a reduction of approximately \$726,000 in distributor sales as a result of entering into an acceleration agreement with one of Imagenetix's customers during the previous fiscal quarter and a reduction of approximately \$300,000 in sales of the weight loss product offset by increases in sales of Celadrin<sup>®</sup> to the mass-market segment of approximately \$733,000.

For the nine months ended December 31, 2009, net sales decreased 12% to \$5,368,000 from \$6,134,000 for the comparable year-ago term. Net loss for the third quarter FY 2010 was \$294,000, or (\$0.03) per share, versus break-even for the same period of FY 2009. Net loss for the nine months ended December 31, 2009, was \$156,000, or (\$0.01) per share, versus a net profit of \$786,000, or \$0.07 per share, for the same year-ago period.

**11/10/2009**—Reported financial results for the three and six months ended September 30, 2009. Net sales decreased 28% for the second quarter FY 2010 to \$1,901,000 from \$2,656,000 for the same period of FY 2009. For the six months ended September 30, 2009, net sales decreased 11% to \$3,603,000 from \$4,051,000 for the same period of FY 2009. Net income for the second quarter FY 2010 was \$553,000, or \$0.05 per share, versus a net profit of \$199,000, or \$0.02 per share, for the second quarter FY 2009. The current fiscal year period was positively impacted by a one-time buyout agreement of \$1,250,000. Net income for the six months ended September 30, 2009, was \$138,000, or \$0.01 per share, versus \$786,000, or \$0.07 per share, for the same year-ago term.

**11/04/2009**—Announced the issuance of a new U.S. patent (Number 7,612,111). The patent provides intellectual property protection for the Company's 1-TDC early stage pharmaceutical candidate, which seeks to prevent and treat periodontal disease.

**08/19/2009**—Announced the expanded distribution of Celadrin<sup>®</sup> in retail markets. Celadrin<sup>®</sup> Extra Strength Softgels became available at a drug chain, two supermarket stores, and a club warehouse store.

**08/19/2009**—Announced that the introduction of BioGuard<sup>™</sup> to the Pacific Northwest region via a national club warehouse chain was scheduled for October 2009.

**08/17/2009**—Announced that Dr. Robert L. Hesslink, Jr., Imagenetix's director of research and development (biography on page 10), discussed 1-TDC and periodontal disease on Bloomberg Radio.

**08/12/2009**—Announced the publication of a second study conducted on 1-TDC for the treatment of periodontal disease in the July issue of the *Journal of Periodontology*. In the study, 1-TDC was applied to the gum line using the rabbit periodontitis model developed by Boston University investigators. The study results showed that 1-TDC stopped the progression of periodontal disease with an improvement and restoration of tissue and bone health versus placebo.

**08/10/2009**—Reported financial results for the first fiscal quarter ended June 30, 2009. Net sales increased 22% for the quarter to \$1,702,000 from the \$1,394,000 reported for the year-ago period. Net loss for the quarter was \$415,000, or (\$0.04) per share, versus a net profit for the same period of the prior fiscal year of \$587,000, or \$0.05 per share. The prior fiscal year period was positively impacted by a one-time settlement of \$1,785,000.

## Glossary

**Adipocytokine**—A class of cytokines secreted by adipose tissue.

**Adiponectin**—A protein hormone that modulates a number of metabolic processes, including glucose regulation and fatty acid metabolism. High blood levels of adiponectin are associated with a reduced risk of heart attack. Low levels of adiponectin are found in people who are obese.

**Adipose**—Usually refers to tissue composed mainly of fat cells, such as the yellow layer of fat beneath the skin.

**Arthralgia**—Severe pain in a joint.

**Arthritis**—An inflammatory condition characterized by pain, swelling, and stiffness in the joints.

**Baby Boomers**—People born in the post-war years (generally considered as the decade between 1945 and 1955), when there was an increase in the birth rate following the return of servicemen at the end of World War II.

**Bacteriocin-Like-Inhibitory-Substances (BLIS)**—Any of a group of substances released by certain bacteria that kill other strains of bacteria.

**Bioactive**—Biologically active, thus having an effect upon a living organism, tissue, or cell. Antibiotics, enzymes, and vitamins are all bioactive substances.

**Bioavailability**—The amount of an administered dose that reaches systemic circulation throughout the body; the rate and extent that a substance becomes available in the body's circulatory system.

**Bioceutical**—Bioactive chemicals derived from foods but taken as supplements at much higher concentrations than diet alone could provide; a food or naturally occurring food supplement that has a beneficial effect on health.

**Bioequivalence**—Two treatments are said to be bioequivalent if there is no significant difference in bioavailability.

**Biosafety Level 1**—The lowest level of biosafety, which applies to agents that do not ordinarily cause human disease.

**Body Mass Index (BMI)**—An index that relates an individual's weight to his or her height. BMI is determined by dividing weight (in kilograms) by height (in meters) squared.

**Chondroitin**—A naturally occurring nutrient found in the connective tissue of all mammals, chondroitin draws fluid into the cartilage tissues that lubricate, cushion, and support joints; part of a large protein molecule (a proteoglycan) that gives cartilage elasticity.

**Cochrane Review**—A review of the effects of interventions for prevention, treatment, and rehabilitation in a healthcare setting. These also assess the accuracy of a diagnostic test for a given condition in a specific patient group and setting. The research is reviewed using stringent guidelines to establish whether or not there is conclusive evidence about a specific treatment.

**Coenzyme Q<sub>10</sub> (CoQ<sub>10</sub>)**—A protein that speeds up the rate of chemical reactions occurring in the body. CoQ<sub>10</sub> produces energy to fuel cell growth and maintenance, and works synergistically with Vitamin E in the antioxidant cycle to protect the fatty part of the cell from damaging free radical attacks.

**Cytokine**—Any of several regulatory proteins that are released by cells of the immune system and that act as intercellular mediators in the generation of an immune response.

**Dental Caries**—Also known as tooth decay, dental caries entail the formation of cavities in the teeth caused by bacteria.



**Epithelial**—Relating to the epithelium, the outside layer of cells that covers all the free, open surfaces of the body, including the skin, and mucous membranes that communicate with the outside of the body.

**Esterified, Cetylated Fatty Acid (CFA)**—A fatty acid is an organic acid occurring naturally as fats and oils in plant and animal materials. An esterified fatty acid is a naturally occurring anti-inflammatory compound derived from animals.

**Free Radical**—An atom or group of atoms with at least one unpaired electron. In the body, it is usually an oxygen molecule that has lost an electron and that stabilizes itself by stealing an electron from a nearby molecule. Free radicals are high-energy particles that ricochet wildly and can damage cells.

**Gingivitis**—An inflammation of the gums surrounding the teeth caused by a build-up of plaque or food particles.

**Glucosamine**—A molecule derived from the sugar glucose by the addition of an amino (NH<sub>2</sub>) group, glucosamine is a compound of a number of structures, including cartilage. Glucosamine is a nutritional supplement that may improve symptoms of pain and stiffness.

**Glucose**—A form of sugar that is the body's primary fuel. Glucose broken down from food can be converted into energy or stored by the body.

**Halitosis**—The condition of having stale or foul-smelling breath.

**Histopathologic**—Relating to histopathology, which is the study of microscopic changes in diseased tissue.

**Immune Imbalance**—An imbalance of the ratio of beneficial and harmful bacteria that can lead to a bacterial infection.

**Interferon Gamma**—A naturally occurring substance possessing the capability to interfere with viruses' ability to reproduce. This property allows interferon to serve as an immune stimulator.

**Investigational New Drug (IND)**—Refers to the FDA's program for pharmaceutical companies to obtain permission to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved.

**Leptin**—A hormone that has a central role in fat metabolism. Leptin was originally thought to be a signal to lose weight but it may, instead, be a signal to the brain that there is fat on the body.

**Lequesne Algofunctional Index (LAI)**—A 10-question survey given to patients with osteoarthritis of the knee. It has five questions pertaining to pain or discomfort, one question for maximum distance walked, and four questions about activities of daily living. The total questionnaire is scored on a 0 to 24 scale. Lower scores indicate there is less functional impairment.

**Lipids**—Biological molecules that are essential structural components of living cells. Lipids are insoluble in water but soluble in organic solvents.

**Metabolic**—Pertaining to, or affected by, metabolism.

**Monounsaturated**—Of or noting a class of fats that lack a hydrogen bond at one point on the carbon chain and that are associated with a low cholesterol content of the blood.

**New Dietary Ingredients**—Vitamins, minerals, herbs or other botanicals, amino acids, dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or concentrates, metabolites, constituents, or extract that were not sold in the U.S. in a dietary supplement before October 15, 1994. Dietary supplements containing ingredients in use before this date do not need FDA approval before marketing and may be used without providing the FDA with evidence to substantiate safety or effectiveness claims.

**Nutraceuticals**—See *Bioceutical*.

**Omega-3**—A class of essential fatty acids found in fish oils, especially from salmon and other cold-water fish, that act to lower the levels of cholesterol and low-density lipoproteins (LDL) in the blood. The difference between the omega oils (Omega-3, Omega-6, and Omega-9) lies in a small shift in their chemical structure, as each fatty acid has a different position for its first double hydrogen bond.

**Omega-6**—See *Omega-3*.

**Ordinal Logistic Regression**—A statistical technique that is used to predict behavior of dependent variables with a set of independent variables, e.g., the probability that a person has a heart attack within a specified time period might be predicted from knowledge of the person's age, sex, and BMI.

**Osteoarthritis**—Chronic breakdown of cartilage in the joints; the most common form of arthritis usually occurring after middle age.

**Osteoblast Cell**—Belonging to a class of cells that aid in the formation of bones.

**Osteoclastogenesis**—Creation of osteoclasts, which are cells that break down old bone in order to form new bone.

**Otitis Media**—An inflammation of the middle ear occurring commonly in children as a result of infection and often causing pain and temporary hearing loss.

**Periodontal Disease**—Disease affecting the bone, connective tissue, and gum surrounding and supporting a tooth.

**Periodontitis**—Inflammation of the gums caused by bacteria that infect the roots of teeth and the surrounding gum crevices, producing bleeding, pus formation, and gradual loss of bone and the tissues that support the teeth.

**Pharmacokinetics**—The actions of drugs in the body over a period of time, including the processes of absorption, distribution, localization in tissues, biotransformation, and excretion.

***Porphyromonas gingivalis* (*P. gingivalis*)**—Oral bacteria associated with periodontal lesions, infections, and adult periodontal disease.

**Probiotic**—A preparation (as a dietary supplement) containing live microorganisms, in most cases bacteria, that when administered in adequate amounts provide a health benefit on the host.

**Prostaglandins**—Any of a group of potent hormone-like substances that are produced in various mammalian tissues, are derived from arachidonic acid, and mediate a wide range of physiological functions, such as control of blood pressure, contraction of smooth muscle, and modulation of inflammation.

**Proteoglycan**—A macromolecule that forms the ground substance of connective tissue.

**Satiation**—The state produced by having had a specific need, such as hunger or thirst, fulfilled.

**Serum**—The clear liquid that can be separated from clotted blood. Serum differs from plasma, the liquid portion of normal un-clotted blood containing the red and white cells and platelets.

**Softgel**—A pliable, soft, gelatin capsule containing a liquid preparation (as a medicine).

***Streptococcus pyogenes* (*S. pyogenes*)**—A common bacteria of the skin that causes different maladies, including strep throat, impetigo, other skin infections, and rheumatic fever.

***Streptococcus salivarius* (*S. salivarius*)**—The principal bacterium of the oral cavity in humans. *S. salivarius* is a normal inhabitant of the upper respiratory tract.

**Tympanic**—Pertaining to the tympanum (the eardrum), or pertaining to the tympanic cavity, which is the major portion of the middle ear, consisting of a narrow air-filled cavity in the temporal bone that contains the bones of the middle ear.

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# Crystal Research

a s s o c i a t e s

**Jeffrey J. Kraws and Karen B. Goldfarb**

**Phone: (609) 306-2274**

**Fax: (609) 395-9339**

**Email: [eio@crystalra.com](mailto:eio@crystalra.com)**

**Web: [www.crystalra.com](http://www.crystalra.com)**

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