### EXECUTIVE SUMMARY

# INTRODUCTION

DiagnosTech, Inc. (“DiagnosTech”, “DTI” or the “Company”) develops, manufactures, and markets rapid medical diagnostics for point-of-care use by health care providers, institutions, and individuals. The Company also markets the complete line of nutraceuticals and personal health care products manufactured by La Jolla Diagnostics and has exclusive sales and marketing rights for these products in certain territories including most of Europe. Nutraceuticals represent a rapidly expanding market worldwide, and are generally defined as food products (including herbals) known to have beneficial health effects. The Company is also presently engaged in the marketing of its anti-sera inventory, acquired from La Jolla Diagnostics, which is currently valued at $2.4 million. After liquidation of this anti-sera inventory through sales, the Company does not envision continuing in the anti-sera business.

The Company was founded in September 1998 as a subsidiary of La Jolla Diagnostics, Inc., with the acquisition of certain diagnostic technology and other assets from ATS, Inc. and La Jolla Diagnostics, Inc., sales and marketing rights from La Jolla Diagnostics, Inc. and anti-sera inventory from La Jolla Diagnostics, Inc.

The Company’s rapid diagnostic product line consists of nine (9) self-contained, rapid, point-of-care diagnostics:

* A rapid test for active M. tuberculosis (TB) disease.
* A rapid serum/plasma test for HIV 1&2 (AIDS) infection.
* A rapid whole blood test for HIV 1&2 (AIDS) infection.
* A rapid test for H. pylori infection (the causative agent in over 90% of ulcers).
* A rapid test for hepatitis B (hepatitis B surface antigen: HBsAg).
* A rapid pregnancy test.
* A rapid test for Trypanasoa cruzi infection (Chagas disease: a common and often fatal parasitic infection endemic to many parts of South and Central America).
* A rapid test for Toxoplasma gondii infection (a common infection among AIDS patients).
* A rapid heart attack predicator (identifies a certain risk factor in a certain subset of mature people).

The Company believes that the TB test in particular has no equivalent in the marketplace. Each test requires only a very small sample of patient blood, serum, urine, or saliva, as the case may be. Each test gives an accurate result in 1-5 minutes. These tests can easily be performed by any health care worker, semi-skilled technician, or by the patients themselves. They are extremely rugged, require no refrigeration, and have a shelf life of 12-18 months. No special equipment is required to perform any test. Each test addresses a large and growing market both domestically and internationally.

The Company’s nutraceutical and personal health care product line consists of four (4) products:

* Feverfew Nasal MistTM
* MigraSprayTM
* Living Water Eye LotionTM
* OptoPet Eye WashTM

Each of the above four products uses proprietary and patented ClusterWaterTM technology. Through a microcluster template induction process, the normally random associations of water molecules are replaced with structured hexamers of water. This new liquid crystalline structure remains chemically identical to untreated water. However, when exposed to active biological molecules, the clusters form new polywater complexes which take on the structural and electronic ‘signature’ of the biomolecules, thus enhancing the solution’s effectiveness. The use of structured water (ClusterWaterTM ) has significant advantages because it increases the bio-availability of the compound in question. This technology can be used with a broad array of compounds. The Company believes that ClusterWaterTM has potential applications as a drug delivery system for the pharmaceutical industry in general and is currently in discussions with pharmaceutical companies along these lines.

Feverfew Nasal MistTM and MigraSprayTM each contain feverfew, an herb recognized for many years as effective in the treatment of migraine, menstrual and other headaches.

# REGULATORY APPROVAL

The Company has no FDA approvals for the marketing or sale of its diagnostic products in the United States. Products are manufactured in several contract facilities under FDA GMP (Good Manufacturing Practices) standards. DTI has completed certain preliminary clinical trials for the rapid HIV tests, the rapid TB test, the rapid H. pylori test, and the rapid hepatitis B test. The Company believes the results of these trials indicate a high likelihood of their ultimately receiving FDA approval, although no assurance to that end can be given.

DiagnosTech plans to file 510K applications for FDA approval of its rapid H. pylori test by November 30, 1998, and for its rapid tuberculosis test and rapid HIV test (serum based; for professional use only) by March 31, 1999. Based on a 510K filing, the Company projects that an FDA approval can be obtained for each product within six (6) months of the initial application. However, there can be no assurance that such approvals will be obtained within this time frame, or at all, or that the FDA will not require additional filings beyond the 510K.

Prior to obtaining any FDA approvals, DiagnosTech will sell and distribute its entire diagnostic product line outside of the United States in compliance with the export laws of the U.S. and the requirements of each importing country.

The health care products listed above, as over-the-counter (OTC) products, generally do not require pre-clearance from the FDA. The Company is currently investigating additional indications for Feverfew Nasal MistTM for which FDA pre-clearance might be necessary.

# MARKET

The following table sets forth the Company’s abbreviated assessment of the indications and total potential market size for several of its products.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Product: | **Tuberculosis Test** | **H. pylori Test** | **HIV (AIDS) Test** | **MigraSpray** | **Eye Lotion** |
| Indication | Third World;  Exposure  High Risk Pts. | Peptic Ulcers;  Gastritis;  Acid Reflux | High Risk Pts;  Screening;  Exposure | Migraine, or recurring headaches | contact lens use, irritated eyes |
| DOMESTIC  Total Patients  Projected Price  Total Market | 3,000,000/year  $10.00/test  $30,000,000 | 3,000,000/year  $5.00/test  $15,000,000 | 1,000,000/year  $3.00/test  $3,000,000 | 15,000,000  $30.00/bottle  $450,000,000 | 60,000,000  $7.00/bottle  $420,000,000 |
| INTERNATIONAL  Total Patients  Projected Price  Total Market | 200,000,000/yr  $5.00/test  $1,000,000,000 | 3,000,000/year  $3.00/test  $9,000,000 | 100,000,000/yr  $2.00/test  $200,000,000 | 100,000,000  $10.00/bottle  $1,000,000,000 | 200,000,000  $5.00/bottle  $1,000,000,000 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| TOTAL | $1,030,000,000 | $24,000,000 | $203,000,000 | $1,450,000,000 | $1,420,000,000 |

# SALES AND MARKETING

DiagnosTech must continually focus on sales and marketing. As the medical and healthcare marketplace is very competitive, obtaining the best representation in each territory is paramount to the Company’s success.

It is therefore the Company’s policy is not to grant exclusivity in any territory until the distributor has shown concrete performance either by obtaining regulatory approval, when required, or by generating sales. Exceptions to this policy are considered only when (i) the distributor in question is judged extremely credible and capable by past performance, and (ii) exclusivity is only maintained by substantial performance within a relatively short time frame.

Regardless of product quality or market size, the ultimate value of any company is determined by its ability to generate sales and net income. DiagnosTech is committed to maximizing shareholder value through financial performance.

# NEW PRODUCT DEVELOPMENT

With a relatively modest investment of time and energy, it should be possible to develop additional diagnostic and healthcare products that utilize the same technology and format as the current products. Leveraging the Company’s proven abilities to expand the product base should be pursued as a means to maximize shareholder value.

Diagnostic products currently under development include:

* A rapid test for Hepatitis C (working prototype now complete).
* A rapid test for bacterial (E. coli) food contamination.
* A rapid test for Malaria.
* A rapid test for Dengue.

Other healthcare products currently under development include:

* Pentapeptide ClusterWaterTM eye drops for relief of allergy symptoms
* Pilocarpine ClusterWaterTM solution for use in glaucoma
* additional ClusterWaterTM nutraceutical products

# DiagnosTech’s goal is to introduce at least one new product every six months through internal development and/or acquisition.

# MANAGEMENT

**Donald Brucker**

Mr. Brucker is a founder of the Company and currently serves as Chief Executive Officer, Chairman and Chief Financial Officer. Mr. Brucker has been in the medical products business for over 30 years. He was a founder and the Chief Executive Officer of Continuous Curve Contact Lenses, Inc., at one time the second largest manufacturer of contact lens products. Continuous Curve was recognized as an innovator in

introducing a new series of FDA-approved contact lenses. As Chief Executive Officer of Continuous Curve, Mr. Brucker administered their initial public offering in 1977 and then its subsequent sale 4 years later to Revlon for more than $100,000,000. Following that acquisition, Mr. Brucker became President of Revlon Vision Care. From 1981 to 1982, Mr. Brucker served as Chief Executive Officer of Immunetech Pharmaceuticals (now known as Dura Pharmaceuticals). From 1982 to 1989, Mr. Brucker served as a consultant for several healthcare and medical device companies.

**Stephen C. Roberts, M.D.**

Dr. Roberts is a founder of the Company and currently serves as President and director. Prior to founding the Company, from 1995 through 1997, he was a Principal of Maven Securities, Inc., and one-third owner of Maven Holdings, its parent company, both in Minneapolis, Minnesota. Prior to this, from 1993 to 1995, he was self-employed and primarily managed his own investments in real estate. Prior to this, in 1991, he was self-employed doing business as Talon and Associates, a consulting firm specializing in market evaluation and planning for medical device companies. Dr. Roberts received his Bachelor of Arts degree in 1985 from St. Olaf College in Northfield, Minnesota where he majored in chemistry and biology. He graduated from the University of Minnesota Medical School in 1991 and completed his medical internship at Bergen Pines County Hospital, an affiliate of the University of Medicine and Dentistry of New Jersey at Paramus, New Jersey. Dr. Roberts currently serves on the board of Sojourn Adult Day Care Centers and Maven Holdings, Inc.

**Bruce Whitfield, J.D.**

Mr. Whitfield is a founder of the Company and currently serves as Executive Vice President and director. Prior to joining the Company, from 1990 to 1997, Mr. Whitfield was a founder and partner of the law firm of Whitfield & Assoc. He specializes in the practice of business transactional law and litigation. Mr. Whitfield has previously participated in the formation and development of several successful ventures including United Staffing Solutions and Bixel Financial, where in each case he continues presently as a board member. Mr. Whitfield is also currently serves on the board of the Los Angeles Free Clinic and the Bresee Foundation.

**Robert N. Hamburger, M.D.**

Dr. Hamburger serves as a director and as the Company's medical laboratory director with responsibility for reviewing the quality and accuracy of all clinical assays. Since July 1, 1990, Dr. Hamburger has been a Professor Emeritus at USCD School of Medicine, where from 1970 to 1990 he was Chairman of the Pediatric Allergy and Immunology Division. Dr. Hamburger has published over 200 articles, is the

holder of three patents, and has achieved national and international recognition for his research in immunology.

# Gregory S. Campbell

Mr. Campbell serves as a director. Mr. Campbell was previously Executive Vice President of Coldwell Banker Corporation, where he directed operations for Coldwell Banker Residential Affiliates, Coldwell Banker Residential Brokerage, Guardian Tile & Escrow, Corporate Marketing, Education and Real Estate, and The Home Mortgage Network Joint Venture. Coldwell Banker is a national residential real estate company with more than 2,500 offices and 56,000 sales associates. Prior to joining Coldwell Banker, Mr. Campbell served as Senior Vice President of asset management for Homart Development, Co., a Sears-owned national regional shopping center and office building developer. He has also held senior positions at a number of leading nationwide real estate consulting, management and brokerage firms. Mr. Campbell is a Wheaton College graduate with a degree in business and economics.

# Robert A. Rist

Mr. Rist serves as director. Before joining the Company he has held a variety of positions in marketing and management, and previously headed the entire marketing effort for menswear for Sears Roebuck (a $1.5 billion annual revenue business), where he subsequently became a corporate officer and General Manager of its subsidiary, Sears Roebuck de Mexico. Mr. Rist later joined Coldwell Banker Corporation where he assisted in the organization of their overall marketing effort, eventually rising to the position of President and CEO, Coldwell Banker Residential Affiliates in 1996. He remained with Coldwell Banker until its acquisition. Mr. Rist has served on the Board of Directors of the National Association of Realtors, The International Franchise Association, and has served as Chairman of the Real Estate National Networks. For the past five years, Mr. Rist has been a Trustee for the Burnham Institute (formerly the La Jolla Cancer Research Institute), which is one of the ten Basic Science Cancer Centers in the nation, as designated by the National Cancer Institute.

# Thomas V. Cajka

Thomas V. Cajka serves as a director. He graduated from San Diego State University in 1978 with a B.A. in Business Administration/Accounting and became a Certified Public Accountant. He began his career in the entertainment industry at the well-known firm of Gelfand, Rennert & Feldman, and later with Breslauer, Jacobson & Rutman. Mr. Cajka worked in business management where he advised top-rated entertainers in their financial and business affairs. In 1986, Mr. Cajka joined The Michael Mann Company, known best for such award-winning television shows as Miami Vice, Crime Story and Drug Wars. As producer and executive in charge of production, Mr. Cajka supervised the business affairs of the company and coordinated all activities of the film and television projects from budget preparation to negotiation of contracts to hiring.

# SUMMARY FINANCIAL PROJECTIONS\*

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|  | **1999 (projected)** | **2000 (projected)** | **2001 (projected)** |
| Sales | $3,480,000 | $7,800,000 | 12,450,000 |
| **Earnings** | $828,000 | $2,306,907 | $3,670,000 |