

STEPHEN M. SIMES

EXECUTIVE SUMMARY

Public company CEO and Board Director with proven success leading emerging biopharmaceutical companies in achievement of drug approvals, financings, and business development transactions. Extensive experience in formulating and implementing corporate strategies, establishing growth metrics, driving performance, and meeting growth objectives through organic expansion, acquisitions, and partnerships.

CORE COMPETENCIES

- Board member of private and public companies
- P&L management, strategic planning, and “hands-on” operations
- Extensive knowledge in clinical drug development (Phase I – Phase III)
- FDA regulatory pathways for clinical development and approval
- Raised \$500M+ in corporate equity financing and M&A
- Business development and product licensing
- Managing large scale clinical studies involving 3,000+ participants
- Oncology, ophthalmology, women’s health, male and female hormone therapy, urology, growth disorders

EXPERIENCE

SMARTHEALTH ACTIVATOR, North Chicago, IL

2017 – Present

SmartHealth Activator discovers and activates extraordinary biotechnology that solves mankind's greatest health problems. SmartHealth accelerates the discovery of drugs, diagnostics and medical devices being developed at Midwest universities that diagnose, prevent and treat life threatening diseases like Alzheimer’s, Parkinson’s and Sudden Cardiac Arrest.

Advisory Board Member

Advisory board member for a new startup called NeuroLucent, a therapeutic drug development company focused on patented breakthrough compounds targeting Alzheimer’s disease.

RESTORGENEX CORPORATION (OTCQX: RESX), Buffalo Grove, IL

2014 – 2016

A public specialty pharmaceutical company focused on developing products for oncology, ophthalmology and dermatology.

Chief Executive Officer and Board Director

Full P&L general management accountability. Responsible for building a successful senior executive leadership team and product development portfolio to deliver significant therapeutic products and stockholder value.

Financial / Strategic Focus

- Raised \$35.6M in equity financing in 2014; Conducted extensive portfolio review and determined company strategic focus.
- Led the initiative and negotiated the merger of RestorGenex with Diffusion Pharmaceuticals, in January 2016, creating a late-stage oncology-focused biotech company.

BIOSANTE PHARMACEUTICALS, INC., Lincolnshire, IL

1998 – 2013

A public specialty pharmaceutical company focused on developing products for women’s and men’s health and oncology. Portfolio included transdermal estrogen / testosterone gels, menopausal treatments, and cancer vaccines. Acquired by ANI Pharmaceuticals (NASDAQ: ANIP) June, 2013.

Financial / Business Development

- As CEO, led strategy development for securing over \$250M in various equity transactions, acquisitions and license agreements.
- Generated \$24M in payments to date, plus \$140M in potential milestone payments and royalties to come by out-licensing first FDA approved product. Second FDA approved product out-licensed generated \$3M+ in cash to date, plus potential milestone and royalty payments.
- Out-licensed three cancer vaccines in exchange for \$50M in potential payments, plus royalties, and \$20M in clinical trial funding commitments. Subsequently, sold cancer vaccines portfolio for potential payments of more than \$150M.
- Sold oncolytic virus anticancer technology in exchange for 19.9 percent of newly formed company, plus potential future milestone payments and royalties.

Product Development

- Directed product development, NDA creation and submission, and negotiated with FDA for BioSante's first FDA (full, non-conditional) approval of key product, and developed second FDA approved product.
- Led strategy and negotiations with FDA for industry's first SPA (special protocol assessment agreement) in the treatment of female sexual dysfunction (FSD), one of the industry's last unmet, unserved medical markets.
- Managed product development strategies, reviewed Phase II and Phase III clinical trials, edited clinical protocols, and served as key spokesperson at every company meeting with FDA; directed application for and receipt of four orphan drug designations.
- Inventor and patent holder of formulations used in company key products. Five patents issued and others pending.

Corporate Development / Mergers

- Negotiated, closed, and integrated \$38M acquisition of another biotechnology company (Cell Genesys) in October 2009, generating \$23M in incremental cash. BioSante's product portfolio expanded with a full pipeline of cancer vaccines in Phase II clinical trials.
- Led the initiative that successfully merged BioSante with ANI Pharmaceuticals in June 2013, creating a fully integrated biotech / pharmaceutical company.

UNIMED PHARMACEUTICALS, INC. (NASDAQ: ABBV), Buffalo Grove, IL**1994 – 1997**

A specialty pharmaceutical company focused on developing and marketing drugs in infectious diseases, AIDS, endocrinology, male hormone therapy, and growth disorders markets. (Now an AbbVie Inc. Subsidiary)

President and Chief Executive Officer, Board Director

Full P&L general management accountability. Built, developed, and successfully led R&D, finance, sales, and commercial activities that significantly expanded product portfolio and tripled stockholder value.

Financial / Business Development

- Increased net earnings nine times in 1994, realizing an additional gain of 89% in 1996. Negotiated and closed \$8.4M private placement and increased cash 250% in three years; Improved Marinol® sales by 27% in 1996, including first introductions outside U.S.
- Negotiated and closed 9 marketed product licenses and development product licenses from / to biotech companies in Europe, Australia, Israel, and Scandinavia.

Product Development

- Directed and monitored R&D activities resulting in three orphan drug designations, one compassionate use trial, four Phase II and three Phase III human clinical trials.
- Key product developed by UNIMED reached more than \$1B in annual sales.

BIO-TECHNOLOGY GENERAL, Iselin, NJ **1993 – 1995**
 A publicly traded specialty pharmaceutical company focused on developing products for AIDS, endocrinology, contraception, hormone therapy, urology, and growth disorders.

Board Director 1993 – 1995

Senior Vice President 1993 – 1994

- Successful integration of \$54M Gynex Pharmaceuticals into Bio-Technology General Corp (BTG).

GYNEX PHARMACEUTICALS, INC., Vernon Hills, IL **1989 – 1993**
 Gynex Pharmaceuticals was a publicly traded specialty pharmaceutical company focused on developing products for AIDS, endocrinology, contraception, hormone therapy, urology, and growth disorders.

President, Chief Executive Officer 1989 – 1993

Board Director / Chairman of the Board (1992-1993) 1989 – 1993

Vice President 1984 – 1988

- Negotiated and closed \$54M merger with Bio-Technology General Corp.; Negotiated and signed licenses valued at more than \$150M.
- Directed and monitored R&D activities resulting in five orphan drug designations, two treatment INDs, four Phase II human clinical trials, and four Phase III human clinical trials.

BOARD POSITIONS

THERAPIX BIOSCIENCES, Board of Directors **Present**
 A public specialty pharmaceutical company developing proprietary cannabinoid technologies in the treatment of central nervous system disorders.

RESTORGENEX CORPORATION, Board of Directors **2014 – 2016**
 A public specialty pharmaceutical company focused on developing products for oncology, ophthalmology, and dermatology.

CEREGENE, INC., Board of Directors **2009 – 2013**
 A privately held biotechnology company exploring factors for treating neurodegenerative and retinal disorders. Acquired by Sangamo Biosciences Inc. (NASDAQ: SGMO), October 1, 2013.

BIOSANTE PHARMACEUTICALS, INC., Vice Chairman **1998 – 2013**
 A publicly held company focused on developing products for women’s and men’s health and oncology.

BIO-TECHNOLOGY GENERAL, Board of Directors **1993 – 1995**
 A publicly traded specialty pharmaceutical company focused on developing products for AIDS, endocrinology, contraception, hormone therapy, urology, and growth disorders.

UNIMED PHARMACEUTICALS, INC., Board of Directors **1994 – 1997**
 (AbbVie Inc. Subsidiary) A specialty pharmaceutical company focused on developing and marketing drugs in infectious diseases, AIDS, endocrinology, male hormone therapy, and growth disorders markets.

GYNEX PHARMACEUTICALS, INC., Board of Directors; Board Chairman (1992-1993) **1989 – 1993**
 A former publicly traded specialty pharmaceutical company focused on developing products for AIDS, endocrinology, contraception, hormone therapy, urology, and growth disorders.

EDUCATION

NEW YORK UNIVERSITY, New York, NY **1980**
 MBA – Marketing / Finance

BROOKLYN COLLEGE of THE CITY UNIVERSITY OF NEW YORK **1973**
 BSc – Chemistry