DAVID W. OSBORNE, Ph.D.

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EDUCATION and TRAINING

2005 **Professional Degree in Chemistry (Honorary)**
University of Missouri-Rolla, Rolla, Missouri

1985 **Ph.D.** in **Physical Chemistry**
University of Missouri-Rolla, Rolla, Missouri
Research Advisor: Professor Stig E. Friberg
Dissertation: The interaction of a glyceridacid with lipids of the stratum corneum

1982 **Bachelor of Science** in **Chemistry (ACS Certified), Math Minor**
Southwest Missouri State University, Springfield, Missouri

PROFESSIONAL EXPERIENCE

2017-Present ARCUTIS Inc

2018-present **Chief Technical Officer**

2017-2018 **Senior Vice President, Product Development**
Venture capital (Frazier Healthcare) funded start-up virtual company developing topical dermatological products. Full time employment began April 11, 2017.

2016-Present DAVID W. OSBORNE PHD CONSULTING INC

2016-Present **President**
S-Corporation formed in late August of 2016 providing consulting and educational services in pharmaceutical product development including intellectual property and serving as an expert witness in Paragraph 4 litigations.

2008-2016 TOLMAR Inc. (Retired in June 2016—TOLMAR had about 650 total employees with 105 employees reporting to the CSO)

2014-2016 **Chief Scientific Officer**
Responsible for managing Formulation & Process Development, Analytical Development, Polymer Development, Clinical Development, and Tech Services. In addition to continuing development of generic topical and specialty injectable products,

TOLMAR developed a pipeline of proprietary dermatology products and in-licensed a specialty injectable technology (one active advanced into the clinic prior to 2017). Worked closely with TOLMAR and external patent attorneys concerning intellectual property. Implemented a QbD adoption campaign.

2008-2014 **Vice President, Product Development**

Responsible for managing the Formulations Development, Analytical Development, Clinical Development, and Regulatory groups within TOLMAR. Between October 2008 and March 2010, this team filed five First-to-File topical product ANDAs requiring clinical endpoint bioequivalence studies. All five products successfully navigated litigation, were approved and launched. In addition to generic topical dermatology products (ANDAs filed: 2 in 2009, 3 in 2009, 1 in 2010, 1 in 2011, 1 in 2012, 6 in 2013, 1 in 2014, 2 in 2015, and 2 in 2016), generic specialty injectable product development was added as a second product development focus in 2010.

2003-2008 Dow Pharmaceutical Sciences

Vice President, Product Development

Managed Formulations & Product Development (FPD), Clinical Labeling, Skin Biology Laboratory, and the Internal Development Program (IDP) at Dow. FPD developed dermatological products from pre-formulation through scale-up and commercial manufacturing for Dow clients. Clinical Labeling provided randomization, labeling and product kits for clinical studies. The Skin Biology Lavatory completed in-vitro skin and membrane permeation studies to guide formulation selection. IDP selected development opportunities, established defendable intellectual property, and coordinated initial development of products that were then out-licensed to marketing partners (Valeant acquired DPSI and the IDP pipeline in 2008 for $285 million).

1993-2003 Atrix Laboratories, ViroTex Corporation

(ViroTex was acquired by Atrix on November 30, 1998)

2002 – 2003 **Vice President, Dermatology Division, Atrix**

- Responsible for establishing Atrix as a leading developer of generic and proprietary topical formulations and forward integrating this business unit to become a specialty pharmaceutical company focused on Dermatology.

Operational duties include:

- Selection and Management of generic product development with an ever-increasing number of annual ANDA filings (2 in 2001, 5 in 2002, and 7 in 2003). Marketing partner for this program was Geneva (Sandoz/Novartis).
- Directed all proprietary dermatology product development including being chairman of the Joint Development Management Committee between Atrix and Fujisawa that

directed the development of 5% Aczone Topical Gel. The dapsone development program had a 2003 budget of $18 Million.
- Directed all business development activities related to dermatology products and provide a strategy for the creation of a specialty pharmaceutical company focused on Dermatology.
- Managed both proprietary and generic analytical methods development and validation groups for all Atrix products
- **Responsible for overseeing worldwide patenting of all dermatology related Atrix intellectual property.**

1998 – 2002 **Vice President, Pharmaceutical Development, Atrix**
- Transition of ViroTex technologies into Atrix following the November 30, 1998 acquisition. Managed product and analytical development groups for all products. Managed approximately 20-25% of Atrix Employees for this period of time

Operational duties include:
- Oversight of patent applications;
- Product development from formulation selection to commercial scale-up
- Analytical methods development and validation
- **Project Team Leader for Dapsone Topical Gel**

Laboratory responsibilities included:
- New dermatological and mucosal product development
- Novel delivery system evaluation
- Transfer of Atrigel products from Drug Delivery to Process Development

1993 – 1998 **Vice President, Research & Development, ViroTex**
(3rd Employee, ~ 22 employees in R&D when acquired)
- Designed and equipped a product development laboratory, quality control laboratory, virology/microbiology laboratory and a GMP manufacturing area.

Operational duties included:
- Oversight of patent applications, contract manufacture of both OTC and Rx products, contract toxicology testing, animal pharmacology/efficacy testing, human clinical trials.

Laboratory responsibilities included:
- New product research, topical drug delivery research, analytical methods development, product stability testing, quality control release of raw materials, and antiviral mechanism of action studies.

1991 – 1993 **Calgon Vestal Laboratories, Subsidiary of MERCK & CO. (Product Development ~45 employees)**

Group Leader, Skin Care

Development of:
- Routine and high-risk handwashing products for preventing the spread of infection;

- Development of skin conditioning products for maintaining healthy, normal and aging skin in hospitals and nursing homes;
- Development of topically applied products to treat diseased skin or relieve skin discomfort.
- Development efforts included evaluation of potential actives/products for licensing, formulation design including stability and efficacy testing, manufacture of GLP and GMP supplies for use in toxicological evaluations, and support of clinical studies.

1985-1991 THE UPJOHN COMPANY (~7,000 employees)

1988 – 1991 **Research Scientist, Drug Delivery R&D-Specialty Products**

- Areas of specialization included: topicals, transdermal delivery systems (patches), and suppositories.
- Typical activities were: pre-formulation characterization, bulk drug stability, formulation design, final formulation stability, Phase I, II and III clinical supply manufacture, GLP pathology/toxicology supply manufacture and preparation of the corresponding sections of the IND and NDA.

1985 – 1988 **Research Scientist, Pharmaceutical Manufacturing Technical Services**--Group was reorganized into Drug Development R&D in January 1988

- Areas of specialization included: topicals
- Responsible for scale-up, manufacturing phase-in and marketed product support including validation of packaging and raw material changes.

COMMERCIALIZED PRODUCTS

Inventor/Developer
PrimaHex Foam (Approved "NDA" marketed by CV Ltd)
Orajel Ultra (OTC marketed by Del Laboratories)
Eucalyptamint 2000 (OTC marketed by Heratige)
Aczone (Approved NDA marketed by Allergan)
Onsolis (BEMA-Fentanyl NDA marketed by Meda Pharmaceuticals)

Named Inventor on Orange Book listed patent
Bunavail (BEMA-Buprenorphine and Naloxone) US 6,159,498 and 7,579,019
Belbuca (BEMA-Buprenorphine) US 6,159,498 and 7,579,019

Developer
Viractin Cream (OTC marketed by Combe Inc)
Viractin Gel (OTC marketed by Combe Inc)
Aloe Vestal Antifungal Ointment (OTC marketed by ConvaTec)
Cleocin Vaginal Ovules (Approved NDA marketed by Pfizer)
Eligard 1 month (Approved NDA marketed by TPI, Astellas, and others)
Eligard 3 month (Approved NDA marketed by TPI, Astellas, and others)
Eligard 4 month (Approved NDA marketed by TPI, Astellas, and others)
Eligard 6 month (Approved NDA marketed by TPI, Astellas, and others)
MetroGel 1% (Approved NDA marketed by Galderma)

Clobex Spray (Approved NDA marketed by Galderma)
Desonate Gel (Approved NDA marketed by Bayer AG)
Ziana Gel (Approved NDA marketed by Medicis)
Acanya Gel (NDA marketed by Arcutis/Valeant)
Erythromycin Benzoyl Peroxide Gel (Approved ANDA marketed by Sandoz)
Fluticasone Cream (Approved ANDA marketed by Sandoz)
Lidocaine/Prilocaine Cream (Approved ANDA marketed by Impax)
Mometasone Ointment (Approved ANDA marketed by Impax)
Betamethasone Dipropionate Cream (Approved ANDA marketed by Impax)
Ketoconazole Shampoo (Approved ANDA marketed by Sandoz)
Metronidazole Topical Gel (Approved ANDA marketed by Impax)
Metronidazole Vaginal Gel (Approved ANDA marketed by Sandoz)
Mometasone Cream (Approved ANDA marketed by Impax)
Mometasone Lotion (Approved ANDA marketed by Impax)
Orajel Protective Mouth Sore Discs (OTC marketed by Del Laoratories)
Clindamycin Benzoyl Peroxide Gel (Approved ANDA-BenzaClin marketed by Mylan)
5% Imiquimod Cream (Approved ANDA marketed by Impax)
Calcipotriene Cream (Approved ANDA marketed by Sandoz)
Diclofenac Gel, 3% (Approved ANDA marketed by Impax)
Calcipotriene 0.005% and Betamethasone Dipropionate Ointment
(Approved ANDA marketed by Sandoz)
Adapalene Gel, 0.03% (Approved ANDA marketed by Sandoz)
Jublia (efinaconazole) Topical Solution 10% (Approved NDA marketed by Valeant)
Clindamycin Benzoyl Peroxide Gel (Approved ANDA-Duac marketed by Impax)
Naftifine Cream 2% (Approved ANDA marketed by Impax)
Clindamycin Benzoyl Peroxide Gel (Approved ANDA-BenzaClin marketed by Impax)
Acyclovir Ointment 5% (Approved ANDA marketed by Impax)
Azeleic Acid 15% (Approved ANDA marketed by Impax)

Combined annual sales of developed products exceeded $1.2 billion in 2015

PROFESSIONAL SOCIETIES

American Chemical Society
American Academy of Dermatology
American Association of Pharmaceutical Scientists (inactive)
The Society for Investigative Dermatology (inactive)
Skin Pharmacology Society (inactive)

PROFESSIONAL ACTIVITIES AND HONORS

2016-2019	Chair, Q3 Working Group
2015-2016	CSU Advisory Board Member for developing a Professional Science Master's degree in Biodata Analytics in the Department of Biochemistry and Molecular Biology
2011-present	Member of the UMKC School of Pharmacy Research Advisory Council
2005	Chair AAPS Dermatopharmaceutics Focus Group

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