

## Corporate Profile

### People

Kenneth (Bill) Yates, DVM  
*Founder, President and CEO*

Dr. Yates is highly experienced in all phases of pharmaceutical development and has previously secured registrations for multiple topical and mucosal products. He was formerly president of Delsite Biotechnologies and previously managed both R&D and operations for Carrington Laboratories. He currently serves as chair of the department of pharmaceutical sciences at Harding University College of Pharmacy.

Celia Proctor, PharmD  
*Co-Founder and Technology Specialist*

Dr. Proctor is a graduate of Harding University College of Pharmacy and is obtaining advanced training at Johns Hopkins Hospital and University. She serves as Technology Specialist in support of product formulation, business development and operations.

Daniel Atchley, Ph.D.  
*Co-Founder and Consultant*

Dr. Atchley is a medical microbiologist and immunologist at Harding University and presently serves as a grant reviewer for the Defense Threat Reduction Agency. He is retired from the US Air Force and was formerly an associate professor at the Air Force Academy.

Judith I. Blakemore  
*Business Development Consultant*

Ms. Blakemore provides business and corporate development services to CelaCare. She was formerly COO of Onyx Pharmaceuticals; president of XTL Biopharmaceuticals, and VP of biological therapeutics development at Cetus Corporation.

Robert A. Fildes, Ph.D.  
*Senior Advisor on Strategy & Operations*

Dr. Fildes is president of SB2, Inc., and is a current or former board member of a number of biotechnology companies. He was formerly CEO of Cetus Corporation, Scotgen and Atlantic Pharmaceuticals, president of Biogen Inc., and a senior executive at Bristol Myers Squibb and GlaxoSmithKline.

James Norris, Ph.D.  
*Preclinical Consultant*

Dr. Norris is a Diplomate of the American Board of Toxicology and a Eurotox Registered Toxicologist. He was formerly general manager of Charles River Laboratories Preclinical Services.

### CelaCare's Novel Antimicrobial Silver Formulations

CelaCare is a privately-held specialty pharmaceutical company engaged in the development and manufacture of a series of antimicrobial silver products for topical and mucosal application. The formulations are based on a proprietary form of silver citrate, a potent antimicrobial agent, in combination with acemannan, a high molecular weight carbohydrate isolated from *Aloe vera* with demonstrated immunomodulatory properties. This novel combination is the basis of unique compositions that exhibit highly potent, broad-spectrum antimicrobial activity against a range of pathogens, including fungi and multi-drug resistant strains of bacteria, while providing enhanced functional properties that enable wound healing.

CelaCare has discovered a strong antimicrobial synergism between the silver citrate used in its products and acemannan. This synergism enables substantial reductions in the levels of silver required, which translates into ease of formulation of advanced wound and oral care products. The combination of these two actives together with other components in CelaCare's proprietary formulations creates products for infection control that aid in healing by maintaining the proper degree of moisture at the surface of wounds.

CelaCare's initial product is a clear, spreadable gel that the company plans to register as a professional Class II Medical Device for the management of first and second degree burns, surgical wounds, diabetic foot ulcers, venous leg ulcers and decubitus (pressure) ulcers. The potency of this gel has been evaluated against both methicillin-resistant and non-resistant strains of *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans*, and compared to silver citrate alone (API), silver sulfadiazine (SSD) and miconazole (MZ). In the table below, the mean of the minimal inhibitory concentrations of total silver required for 99.9% kill is compared for the silver-containing preparations; for miconazole, the units reflect the concentration of the drug.

Antimicrobial Wound Product Comparison				
Comparison (MIC <sub>99.9</sub> -µg/mL)	MRSA Mean ± SD	<i>S. aureus</i> (non-MRSA) Mean ± SD	<i>P. aeruginosa</i> Mean ± SD	<i>C. albicans</i> Mean ± SD
CelaCare Product Silver Citrate	0.34 ± 0.15* 10.48 ± 4.20	0.25 ± 0.15* 5.03 ± 1.91	0.41 ± 0.31* 2.07 ± 0.86	0.13 ± 0.05* 2.46 ± 2.51
CelaCare Product Silver Sulfadiazine	0.34 ± 0.15* 8.23 ± 3.59	0.25 ± 0.15* 6.68 ± 3.38	0.41 ± 0.31* 5.21 ± 3.10	N/A
CelaCare Product Miconazole	N/A	N/A	N/A	0.13 ± 0.05* 1.40 ± 0.44
N	34	18	14	9

\* = P value <0.01

### Intellectual Property

CelaCare's technology is protected by pending patent applications that provide a broad hedge of protection for the fundamental technology, extending from composition to use. The pending U.S. and International patents describe the molecular composition of the material and its use as a treatment for multiple types of wounds.

### Product Development Contractors

CelaCare is sourcing the proprietary form of silver citrate used in its products from a supplier who has agreed to enter into an exclusive supply agreement with the company. CelaCare has also engaged the services of contractors to provide formulation and scale-up services, preclinical toxicology and pharmacology studies and primary packaging, and has secured the services of an international CRO that advises the company on regulatory strategy.

### Selected Potential Markets (US)

Indication	Patients
Non-healing open surgeries	514,000
Diabetic or pressure ulcers	785,000
Burn wounds	500,000
Non-healing traumatic wounds	300,000
Oral mucositis and oral candidiasis	~40% of chemotherapy pts

### Competition

A number of companies including Johnson & Johnson, Medline Industries, Smith & Nephew, Gentel, Coloplast, Convatec, Kendall, Hollister, Derma Sciences and others market antimicrobial silver dressings. CelaCare believes that its products offer advantages over these competitive products.

### Contact Information

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CelaCare's antimicrobial wound gel was used in an equine case study to treat a severe non-healing laceration to the right rear hock of an 8-year old gelding. Over the course of two months, the gel was applied two or three times a week and the wound was bandaged. After two months, the use of gel was discontinued and the wound continued to heal to completion.



January 21, 2011    February 14, 2011    February 25, 2011    March 25, 2011

### Development Timeline

CelaCare has completed formulation development, preliminary accelerated stability, small batch production, and batch record preparation for pilot scale production of the prescription antimicrobial wound gel. *In vitro* microbiological studies and cytotoxicity studies have also been completed. The company projects that 9-12 months and further investment will be required to complete the CMC work and limited toxicology studies to support a 510(k) filing.

### Pipeline

The company plans for follow-on products that include an OTC antimicrobial gel and a prescription gel for treatment of third degree burns, an indication in which CelaCare's water-soluble product is expected to offer improved ease in cleaning wounds prior to changing dressings. Formulation development has been completed for both products. In addition, the company is conducting formulation development for an oral rinse to treat and manage cancer-associated oral mucositis and oral candidiasis.

Product	Indications	Regulatory Pathway	Formulation Development	Process Development	Preclinical Studies	Human Studies	FDA Filing
Prescription Antimicrobial Gel I	Burns (first and second degree), surgical wounds, diabetic foot ulcers, venous leg ulcers, decubitus ulcers	510(k)	██████████	██████████		None	
OTC Antimicrobial Gel	Prophylaxis of superficial skin infections in minor abrasions, burns and cuts; treatment of minor bacterial skin infections and dermal ulcers	510(k)	██████████	██████████		Limited	
Prescription Antimicrobial Gel II	Third degree burns	PMA	██████████	██████████			
Prescription Oral Rinse	Oral mucositis and oral candidiasis in cancer patients treated with radiotherapy and chemotherapy	PMA	████				