PLUROGEN RESULTS SUMMARIZATION
Prepared 10/3/2014 at the request of Mr. Andre Gudger; OSBP

This Briefing will be utilized to reflect the results of PluroGen’s line of patented PluroGel products that have been tested and documented in various phases of lab, clinical trials and patient use to date. This information is to be used for evaluation of the PluroGel Biomaterial that was in part, funded with $4.7M contract with the US Government/JIEDDO from July 2010 to July 2013.

PluroGen is seeking an FDA Indication to be the first topical product to combat mildly infected diabetic ulcers- an indication and treatment that is not currently available to patients today. PluroGel products and PluroGen’s DoD contract are targeted to chronic wound patients and have been reported to provide (1) substantial improvement in patient outcomes and (2) significant cost reduction and (3) significant pain reduction due to the water solubility and ease of rinsing PluroGel off the wound. One major milestone of the preliminary data of the Phase II clinical trials was that approximately 79% of patients with mildly infected diabetic foot ulcers had their wounds healed using PluroGel in combination with Nitrofurantoin, a drug never utilized before in topical use.

Clinical Information: Section 1 of this summarization pertains directly to PluroGen results funded by the DoD contract. Section 2 pertains to multiple studies and results from all PluroGel products and years of use. There is significant and compelling evidence to support superior results for the PluroGel Biomaterial when the collective body of work and data is taken into account.

SECTION 1: RESULTS FROM DOD CONTRACT:

STUDY 1: IN VITRO ANTIMICROBIAL ACTIVITY OF A NEW TOPICAL GEL TECHNOLOGY USED WITH A UNIQUE TRIPLE ANTIMICROBIAL COMBINATION (PLUROGEL® PNN) AGAINST MULTI-DRUG RESISTANT ORGANISMS.

This study was conducted at Walter Reed Army Medical Center (WRAMC). PluroGel PNN (triple antimicrobial) was effective in killing 15 strains of bacteria isolated from the wounds of war-injured patients at WRAMC. Some of these strains were resistant to almost all known antibiotics. Treating wounds infected with these bacteria ordinarily requires prolonged and potentially toxic IV therapy. PluroGel PNN offers unique benefits as a topical agent to fight these infections.

Exhibit 1, Walter Reed Study: Antimicrobial Activity Effective Against 15 Strains

PHASE I CLINICAL TRIALS RESULTS: The Phase I clinical trials design was to determine if the test products, PluroGel PNN and PluroGel, were sensitizing to abraded skin and non-abraded skin. 231 healthy human subjects were evaluated. For abraded skin and non-abraded skin, the test products, PluroGel PNN and PluroGel, were the same as the negative control product, 0.9% saline. PluroGel PNN and PluroGel were non-sensitizing to skin.

Exhibit 2, Phase I Protocol 303 Final Report (198 Patients)
Exhibit 3, Phase I Protocol 304 Final Report (33 Patients)

STUDY 2: EVALUATION OF PLUROGEL PNN COMPARED TO VANCOMYCIN BEADS WHEN USED WITH NPWT ON CONTAMINATED TRAUMATIC WOUNDS. This study was conducted at the US Army Institute for Surgical Research (ISR) at Fort Sam Houston. In this animal study, testing was done to demonstrate bacteria kill in conjunction with negative pressure wound therapy (NPWT). PluroGel PNN with NPWT killed 99.9% of bacteria in 48 hours, compared with the Army’s best candidate, Vancomycin Beads and NPWT, which reported 33.3% of bacteria killed in 48 hours. PluroGel PNN provided a significant improvement to bacterial kill.

Exhibit 4, ISR Study: Evaluation of PluroGel PNN, Vancomycin Beads and NPWT on Contaminated Traumatic Wounds

PHASE II CLINICAL TRIAL PRELIMINARY RESULTS ARE IMPRESSIVE

In the Phase II trial for PluroGel N (single), approximately 79% of patients with mildly infected diabetic foot ulcers experienced a favorable clinical response. Further, no sign of infection was seen in 74% of the wounds when they were cultured. For patients treated with PluroGel Burn and Wound (plain), 63% had wounds that improved enough that they appeared healed, though bacteria were still present in all but 24% of wounds. This finding is consistent with the known
inherent anti-inflammatory and wound healing properties of the PluroGel base product. The Phase II trial results provide an encouraging outlook for new treatment tool not available today for patients in the VA and civilian populations and further research is recommended.

Exhibit 5, Phase II Clinical Human Trials Preliminary Report

SECTION 2: SUPPORTING EVIDENCE FOR THE PLUROGEL BIOMATERIAL AND PLUROGEL PSSD (SINGLE)

- SUPERIOR RESULTS AGAINST BIOFILM: The University of Calgary derived Innovotech MBEC Assay found PluroGel® was effective in preventing and dispersing biofilm. The presence of biofilm in a wound has been reported to be a contributing factor in prevention of wound healing. The prevention and elimination of biofilm by PluroGel is a significant advance and advantage in wound care.

Exhibit 6, Innovotech MBEC Assay Technical Data Sheet on BIOFILM

- EFFICACY OF AN ADVANCED SURFACTANT-BASED BIOMATERIAL USED WITH A UNIQUE TRIPLE ANTIBIOTIC COMBINATION: A REVIEW OF CLINICAL USE FOR BURNS AND CHRONIC WOUNDS: A RETROSPECT FROM 1970 TO PRESENT AT UNIVERSITY OF VIRGINIA.

The University of Virginia (UVA) has been using PluroGel® PNN on approximately 120 burn patients and 600 non-healing chronic wound patients per year with use on over 12,000 patients since the mid-90’s. In the UVA Burn Unit, the incidence of burn wound infection was reduced to less than 1% as compared to published reports as high as 14% for other US hospitals. All complications (including infection) were 21% below the US national average and length of stay was 2% shorter than the US national average. In the chronic Wound Clinic, 86% of wounds treated experienced a 55% decrease in wound size within 4 weeks and 90% of wounds treated within 4 weeks resulted in a reduction in bacterial levels, with 42% of these wounds having no detectable bacteria. Additional findings of the study included identification of a number of clinical and practical advantages for the PluroGel biomaterial.

Exhibit 7, Efficacy of an Advanced Surfactant-Based Biomaterial Used with a Unique Triple Antibiotic Combination

- MULTI-CENTER STUDY REPORTS PLUROGEL PSSD IMPROVES PATIENT RESULTS;
EUROPEAN WOUND MANAGEMENT CONGRESS 2013

In a study of 58 ulcers over a period of 180 days, 3 centers in Europe reported the following results: 30 ulcers were healed within 75 days, at 180 days only 4 ulcers out of the total 58 ulcers were not healed. In almost all patients treated, exudate, inflammation and pain were reduced, and quality of life index was increased.

Exhibit 8, Multi-Center Study Reports PluroGel PSSD Improves Patient Results
• DIABETIC ULCER CLINIC RESULTS FOR PLUROGEL PSSD - EUROPEAN WOUND MANAGEMENT CONGRESS 2013
55 Patients (mostly diabetic foot ulcers) were evaluated with the following results: 65% were healed, 20% remain in treatment, and 2 patients changed therapy. Findings include no allergies, no side effects, no pain, and treatment was well accepted by the patients, no pseudo-eschar and cost savings.
Exhibit 9, Diabetic Ulcer Clinic Results for PluroGel PSSD

BEFORE

AFTER (108 days)

• CARDIFF UNIVERSITY PLUROGEL PSSD FIRST EXPERIENCE CLINICAL RESULTS; SYMPOSIUM FOR ADVANCEMENT IN WOUND CARE 2013 (SAWC)
9 chronic leg ulcer patients with average ulcer duration of 6 years were initially evaluated for 30 days and showed the following results: 2 patients were healed, 7 patients experienced a decrease in wound size, infection was treated effectively for all patients, the product was effective on low to highly exuding wounds, no residue was left on the wound bed and there was no pain on application or during treatment.
Exhibit 10, Cardiff University PluroGel PSSD First Experience Clinical Results

BEFORE

AFTER (30 days)
Eflicacy of a New Multifunctional Surfactant-Based Biomaterial Dressing with 1% Silver Sulphadiazine in Chronic Wounds on 226 Patients; International Wound Journal Publication

In September 2014, a 226 patient paper was published in the prestigious International Wound Journal reporting use of a new topical PluroGen Antimicrobial Product, PluroGen PSSD, that is approved outside the US. This paper reports a chronic wound healing rate for these long standing, difficult to heal wounds of 73% compared to the expected standard-of-care combined reported rate of 43.8%. PluroGen PSSD was well accepted by patients. Patients reported a range of significant reduction in pain to no pain at dressing change, less pain overall during the entire treatment and less odor in the wound. Patient compliance with the clinical instructions on care of the wound was improved. The costs for products used in treatment were calculated for one (1) patient and this calculation lead to the assumption that using PluroGen PSSD, a significant economic savings may be realized. The treatment cost for each chronic wound patient has been estimated by the Cleveland Clinic to be on an inflation-adjusted $14,000+ per patient depending on severity of the wound.

Exhibit 11, Efficacy of a New Multifunctional Surfactant-Based Biomaterial Dressing with 1% Silver Sulphadiazine in Chronic Wounds on 226 Patients, International Wound Journal ISSN 1742-4801; September, 2014

A Prospective Trial Comparing Cream Silver Sulfadiazine to a Surfactant-Based Topical Antimicrobial Gel in Partial Thickness Burns; Southern Medical Association

8 adult inpatients with partial thickness burn wounds were enrolled to begin with either (1) cream silver sulfadiazine (SSD) or (2) UVA PluroGen therapy and then (3) alternate therapies daily. 4 of 8 patients (50%) refused to continue receiving cream SSD due to pain. UVA burn nursing staff refused to continue enrolling patients with the cream SSD due to the negative effect of the cream SSD causing significant pain during application and removal. The amount of time to perform dressing changes using cream SSD was an average of 79 minutes longer than PluroGen.

Conclusion: PluroGen therapy was vastly superior to cream SSD to patients in both pain reduction and dressing management.

Exhibit 12, A Prospective Trial Comparing Cream Silver Sulfadiazine to a Surfactant-based Topical Antimicrobial Gel in Partial Thickness Burns

New Surfactant-Based Dressing Product to Improve Healing Rates of Non-Healing Wounds: A European Multicenter Study Including 1,036 Patients

Draft submission to Advances in Skin and Wound Care, October, 2014

A landmark, multi-center clinical study (ten centers from seven countries) has recently been completed with 1,036 patients successfully treated reporting superior results using the PluroGen PSSD (Single antibiotic). In total, for all 1,036 patients PluroGen PSSD resulted in 70.0% healed compared to the expected Standard of Care reported at 43.8% healed. The reported averaged results for other leading edge products were reported at 58.9% healed. In addition, PluroGen products are less expensive and easier to use. This paper is expected to be published late 2014.

Exhibit 13, New Surfactant-Based Dressing Product to Improve Healing Rates of Non-Healing Wounds: A European Multicenter Study Including 1,036 Patients

The Diabetic Epidemic: According to Diabetes.org, in the US alone there are almost 19 million people with diabetes, over 2.8 million complications of ulcers and 58% of those ulcers will become infected. The World Health Organization estimates there are 34.7 billion people with diabetes globally. Diabetes has become an increasingly significant public health concern in both the developed and the developing world, and is a major cause of hospitalizations, as well as the leading cause of lower-extremity amputations. Diabetic Foot Ulcers (DFUs) are a major complication of diabetes and the most common foot injury in diabetics. Diabetic Foot Infections (DFIs) are the most common problems in persons with diabetic ulcers. These individuals are predisposed to foot infections because of a compromised vascular supply secondary to diabetes. Local trauma, pressure, in addition to microvascular disease, may result in various diabetic foot infections that run the spectrum from simple to severe.

Conclusion: If PluroGen can continue the Phase II and Phase III human clinical trials and receive FDA approval for the first topical indication for diabetic ulcers, this will be a paradigm shifting treatment for all sufferers.

For access to all documents, please visit our secure webpage: http://plurogen.com/plurogen-collective-results-exhibits