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AWARD NUMBER: W81XWH-14-C-0095

TITLE: Development & Commercialization of an Ideal Mechanical Wound Therapy System

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REPORT DATE: December 2015

TYPE OF REPORT: Final Phase I

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
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1. REPORT DATE December 2015		2. REPORT TYPE Final Phase I		3. DATES COVERED 30 Jan 2014 - 29 Sep 2015	
4. TITLE AND SUBTITLE Development & Commercialization of an Ideal Mechanical Wound Therapy System				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-14-C-0095	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Michael Shuler, MD				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) . J&M Shuler Medical, Inc Athens, GA 30606				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This was a 15-month pilot study, the purpose of which was to progress the development and commercialization efforts of a novel advanced wound care device. The SubAtmospheric Woundcare System (SAWS) is a next-generation dressing for Negative Pressure Wound Therapy (NPWT) systems, which answers unmet needs of combat casualty care (and civilian) providers that have been known and unaddressed over the last decade. The innovative features of this dressing are its unified and universally customizable fabrication, integration of active irrigation and overcoming in-growth and other adverse events related to non-ideal COTS wound filler. This project had 2 primary phases. In the initial phase, design work and bench testing led to an optimized prototype for animal testing. The second phase included a 3-tier animal testing protocol (IACUC/ACURO approved), which identified areas for iterative improvement of the prototype and served as a basis for burden of proof data needed to support a FDA 510-K application for this dressing system and future grant applications to address additional critical unmet needs in combat casualty wound care, specifically for wounds about the face, scalp and special areas. The stated tasks of this proposal were all accomplished on-time and on-budget. The outcome of this work is a mature, TRL 8 design frozen prototype that has successfully overcome sealing issues which plague all COTS NPWT dressings and is the first to provide safe and effective care for 6 continuous days. The prolonged use, negates repetitive and painful dressing change procedures, that are required 2-3x more frequently with COTS dressings. While great advance was made, especially given the small budget of this pilot project, work remains to translate the findings of this project into clinically available solutions to unmet military and civilian advanced wound care needs.					
15. SUBJECT TERMS-					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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1. INTRODUCTION:

This was a 15-month pilot study, the purpose of which was to progress the development and commercialization efforts of a novel advanced wound care device. The SubAtmospheric Woundcare System (SAWS) is a next-generation dressing for Negative Pressure Wound Therapy (NPWT) systems, which answers unmet needs of combat casualty care (and civilian) providers that have been known and unaddressed over the last decade. The innovative features of this dressing are its unified and universally customizable fabrication, integration of active irrigation and overcoming in-growth and other adverse events related to non-ideal COTS wound filler. This project had 2 primary phases. In the initial phase, design work and bench testing led to an optimized prototype for animal testing. The second phase included a 3-tier animal testing protocol (IACUC/ACURO approved), which identified areas for iterative improvement of the prototype and served as a basis for burden of proof data needed to support a FDA 510-K application for this dressing system and future grant applications to address additional critical unmet needs in combat casualty wound care, specifically for wounds about the face, scalp and special areas. The stated tasks of this proposal were all accomplished on-time and on-budget. The outcome of this work is a mature, TRL 8 design frozen prototype that has successfully overcome sealing issues which plague all COTS NPWT dressings and is the first to provide safe and effective care for 6 continuous days. The prolonged use, negates repetitive and painful dressing change procedures, that are required 2-3x more frequently with COTS dressings. While great advance was made, especially given the small budget of this pilot project, work remains to translate the findings of this project into clinically available solutions to unmet military and civilian advanced wound care needs.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

Negative Pressure Wound Therapy; Mechanical Wound Therapy; Combat Open Wound; Complex Wound

3. ACCOMPLISHMENTS:

The table below contains a list of the 3 major tasks and their respective sub-tasks which were stated in the original proposal. All tasks have been completed at this point in time. The 3 tasks broadly speak to the development of a mature prototype (TRL 7-8) of the first generation SAWS dressing (Task 1), the iterative bench testing of this prototype (Task 2) and the animal testing of a preferred embodiment of the dressing under real-life circumstances. This pilot project has been the most successful research and development project this team has ever participated in. We have met all stated tasks on-time and on-budget, which is made all the more impressive by the very modest budget and timeline compared to the very ambitious stated goals of this project. The tremendous success to date, leaves this project in a tenuous state, since failure to fund and progress to the final validation and translation work, would negate the successes of the prior work and investment.

<u>Stated Task</u>	Accomplished?	Due Date	Completion Date
Task 1. <u>Product Development</u> – The essential			

task of this overall project is to create a mature (Technology Readiness Level (TRL): 7-8) prototype of the basic MWT dressing with proven functionality demonstrated through bench testing and animal testing to prepare for regulatory approval and human clinical testing/use in the military and civilian setting.			
1a. Develop initial functional prototype (TRL 5-6) basic MWT dressing	Yes	SEP 2014	JUN 2014
1b. Conduct bench-top performance testing of the prototype	Yes	SEP 2014	SEP 2014
1c. Respond to deficiencies noted during bench-top testing	Yes (ongoing throughout grant)	SEP 2014	SEP 2014
1d. Iterative prototyping with interval bench-top testing	Yes (ongoing throughout grant)	DEC 2014	DEC 2014
1e. Identification of ideal prototype to progress to animal testing	Yes	DEC 2014	OCT 2014
1f. Respond to deficiencies noted during Phase I animal testing	Yes	FEB 2015	FEB 2015
1g. Respond to deficiencies noted during Phase II/III animal testing	Yes	SEP 2015	SEP 2015
1h. Finalize embodiment/construction of mature prototype – design frozen device (TRL 7-8)	Yes	SEP 2015	SEP 2015
Task 2. Bench-top Testing (Mechanical Feasibility/Performance Testing)			
2a. Create a bench-top performance testing protocol	Yes	SEP 2014	JUN 2014
2b. Bench-top test all iterative prototypes	Yes	FEB 2015	JUN 2015
2c. Demonstrate feasibility of the mature prototype for Phase II/III testing	Yes	MAR 2015	SEP 2015
Task 3. Animal Testing - Conduct animal testing to validate bench testing results and provide data for clinical and regulatory acceptance of this product. Results from this proof-of-concept testing will identify a design frozen device and provide burden of proof data for FDA submission, subsequent GLP animal testing and human-use clinical studies.			
3a. Submit/Obtain IACUC/ACURO approval for animal testing	Yes	SEP 2014	JUN 2014
3b Conduct Phase I animal studies outlined below	Yes	MAR 2015	JUN 2015
3c. Conduct Phase II/III animal studies outlined below	Yes	SEP 2015	SEP 2015
3d. Real-time response between development team & animal testing team	Yes	SEP 2015	SEP 2015
3e. Analyze data to present/publish & support	Yes and on-going	MAR 2015	SEP 2015+

eventual FDA submission			
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What was accomplished under these goals?

The primary accomplishment of the work completed under this 15-month pilot study, was the design, development and bench and animal testing validation of a novel advanced wound care dressing that incorporates key elements of traditional wound care into a single, unified dressing system. Prior to the initiation of this work the development level of the product was TRL5 or below. There were rudimentary mock-ups of the dressing, which could demonstrate the various functionalities of the concept, but the physical prototype was not ready for validation testing and certainly not ready for regulatory approval and clinical use. The work conducted under this grant has progressed this concept invention to a mature prototype.

The current design-frozen embodiment of this dressing is capable of performing the key tasks required of this device. Specifically, the dressing can be applied in a single step as a unified dressing, as opposed to the piece-meal method for COTS dressing. The construction of this dressing still allows universal customizability to wounds of all dimensions. The dressing has a dedicated irrigation circuit that can deliver positive pressure (gravity-fed or by active pump) irrigation fluid directly to the wound surface, as opposed to COTS dressings with irrigation features, that drip irrigant through the dirty wound filler prior to reaching the actual wound surface. As opposed to instillation techniques of COTS dressing, SAWS provides fluid irrigation directly to the wound, which most closely replicates the traditional surgical method of open irrigation of wounds. However, in a SAWS dressing this modality can be performed at bedside, without the need of surgeon or surgical set-up, under the clean, closed and controlled environment of the dressing, with simultaneous negative pressure evacuation of the irrigant and the wound debris that is mobilized through the process of irrigation. This actual wound cleansing functionality translated into a reduction in bioburden as demonstrated in our first 2 animals in the Phase III study (see below).

Further, this project demonstrated that the SAWS concept is capable of providing 6 consecutive days of sustained NPWT without compromised effect or complication. The Phase II animal study (see below) demonstrated that the dressings can be maintained for 6-days and still produce healthy appearing (at the gross and histological level) granulation tissue that would be able to support immediate skin grafting or delayed primary wound closure. The impact on resource utilization of this extended wear cannot be understated. Essentially all resources (human and supply) related to NPWT are consumed at dressing changes, which are reduced to the smallest number possible (one initial application) using a SAWS dressing. The vast majority of combat related war wounds are capable of undergoing definitive closure or coverage by 6 days from initial NPWT application. The cost savings of this extension in wear time, which cannot be replicated by current COTS dressings due to granulation ingrowth into the wound fillers used, would be substantial.

Lastly, this pilot project showcased the ingenuity, adaptability and dedication of the research team. The initial proposal called for a series of animal studies to be conducted on domestic pigs. In Phase I, it was readily apparent that the artificial hardships the pig's behavior induced would have fatally compromised the objectives of this study. As a result, the team re-engineered a

animal testing protocol that provided the same scientific merit, on-time and on-budget. The transition to the bovine model allowed for testing of 4 wounds per animal and for larger wound sizes. The cow is more sedentary and can be stanchioned. Thus, the animal model did not require model-specific modifications to the dressing, but still provided a high-fidelity in vivo testing environment. This resulted in accomplishment of all stated goals in Task 3.

Unfortunately, delays inherent to regulatory and contracting approval of major changes in the proposed testing plan, as well as delays in identifying an ideal means for sealing the dressing for up to 6 days in vivo, resulted in a shift to the right of some of our animal testing timeline. But through hard work and commitment to the project, we were ultimately able to complete the work within the originally stated study period. Below is a summary of the results from our Phase II and Phase III animal studies. These were the key scientific achievements of this project:

Summary Phase II Animal Study:

Four bovine were used for the evaluations of a negative pressure wound dressing. Each animal was anesthetized and four wound sites were created on the prepared dorsal surface. The wounds were measured and digital images were taken. Dressings were then applied to each of the wound sites using either a test or a control design for wound treatment. The dressings were managed for 6 days at which time the animals were euthanized, digital images of the wound sites captured, the wound sites measured and evaluated in situ, and then harvested for histological evaluation.

Histopathological evaluation showed the following results:

Control Group

The tissue sections contained a full thickness defect of the skin. The defect was filled with irregular layers of granulation tissue. Granulation tissue was comprised of neovascularization, fibroblasts, and collagen fibers. There were eosinophilic proteinaceous material present. Inflammation was predominantly comprised of neutrophils.

Test Circular Group

The tissue sections contained a full thickness defect of the skin. The defect was filled with layers of granulation tissue. Granulation tissue was predominantly comprised of neovascularization, fibroblasts, and collagen fibers. There were eosinophilic proteinaceous material present. Inflammation was predominantly comprised of neutrophils. In one of eight samples examined, there were eosinophils present in granulation tissue.

Morphometric analysis showed that a thickness of granulation tissue in the Test Circular Group (Average = 1.89 mm) and in the Test Elliptical Group (Average = 1.90 mm) was very similar when compared to the Control Group (Average = 1.79 mm).

In conclusion, there was a slightly greater amount of inflammation and fibrin/proteinaceous material covered granulation tissue in both test groups when compared to the control group. The thickness of granulation tissue was similar between the control and test groups. There were no gross infections. There was no marginal maceration.

Examples of the granulation beds after 6-day wear of a Test Dressing and 3-day wear of a COTS dressing (notice in-growth into the sponge):



Green tinted irrigant shows coverage of entire wound with irrigation. No seal breaches or marginal maceration was noted.



Summary Phase III Animal Study:

Four cows were used for the evaluations of a negative pressure wound dressing in comparison to standard-of-care wound dressing in the presence of a bacterial infection. Each animal was anesthetized and four wound sites were created on the dorsal surface of the animal. The wounds were measured and digital images were taken. The wounds were then inoculated with *Staphylococcus aureus* (ATCC #6538) at a concentration of 10^7 CFU/mL. Dressings were then applied to each of the wound sites using either a test (i.e. mature SAWS prototype – 3/animal) or a control dressing (KCI Wound V.A.C. – 1/animal) for wound treatment. The test dressings was left in place for 6 days at which time the animals were euthanized, digital images of the wound sites captured, the wound sites measured and evaluated in situ, and then harvested for

microbiological and histological evaluation. The control dressings were managed for 3 days, removed, swabbed for microbiological assessment, replaced, and managed for the remaining 3 days; at which time the animals were euthanized, digital images of the wound sites captured, the wound sites measured and evaluated in situ, and then harvested for microbiological and histological evaluation.

Unfortunately, the last 2 animals in this phase of testing had medical problems and wound seal issues for all 4 wounds (3 test and 1 control) on both animals. Since this lab occurred at the end of our grant period, there was no time or budget to perform testing on an additional pair of animals. This compromised the quality of the data obtained, as the poor seal allowed for secondary bacterial contamination (*pseudomonas*) and actual gross infection developed in the control wound on one animal. This was the only gross infection in all wounds tested in Phase III. No wound treated with a SAWS dressing in Phase III manifested evidence of gross infection and all wounds developed pink, healthy appearing granulation tissue. While the issues with the final 2 animals were disappointing, the data from this animal testing phase still met the stated goal in providing pilot information regarding the ability to contain or reduce bacterial bioburden. The SAWS dressing performed as well or better than the KCI dressing in regards to controlling bioburden following an inoculated load over a 6-day study period, but required only 1 application, as opposed to the KCI dressing which had to be changed at the 3-day mark in accordance with the manufacturers recommendation for maximal dressing life. The results of this phase support further confirmatory testing of the ability of the SAWS dressing to reduce bioburden in contaminated wounds over an extended period of wear. Confirmation of this finding with additional animal testing would mark a leap forward in combat wound care.

Histopathological evaluation showed the following results:

Control Group

The tissue sections contained a full thickness defect of the skin. The defect was partially filled with granulation tissue. Granulation tissue was comprised of neovascularization, fibroblasts, and collagen fibers. There was multifocal fibrous tissue extended to subjacent muscle fibers.

Test Group

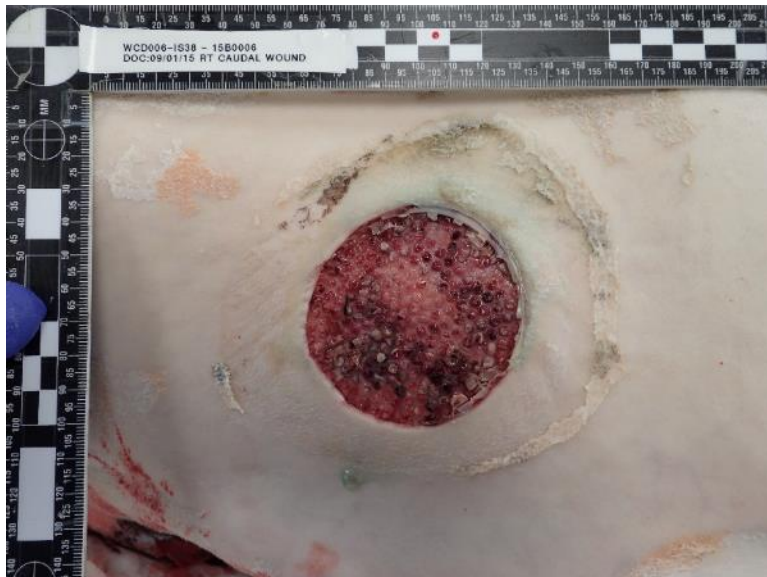
The tissue sections contained a full thickness defect of the skin. The defect was partially filled with granulation tissue. Granulation tissue was comprised of neovascularization, fibroblasts, and collagen fibers. There were inflammatory cells present and they were predominantly comprised of neutrophils. This layer was covered by a mild to moderate serocellular crust comprised of a fibrin/proteinaceous material admixed with numerous neutrophils, cellular and karyorrhectic debris. There was multifocal fibrous tissue extended to subjacent muscle fibers.

Morphometric analysis showed that a thickness of granulation tissue in the Test Group (Average =1.38mm) was slightly greater when compared to the Control Group (Average =1.27 mm).

In conclusion, although variability was high within and between the samples in both groups, the test dressings, which were not changed for the entire 6-day study period, had a similar overall

histopathologic appearance when compared to the control samples. The thickness of granulation tissue was slightly greater in the test group when compared to the control group. The test dressing is capable of providing equivalent or superior histological outcomes as compared to a COTS dressing, but requires ½ the number of dressing changes to achieve this outcome. The only gross infection in Phase III occurred in a control dressing site.

Examples of Test Dressing In Place and After Removal:



What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

It is premature to disseminate the results gathered to date. When data analysis is completed, the expectation is that the results of the Phase II and III animal studies with descriptions of the bench work and Phase I animal study included will be publicized as a single or two separate medical journal articles. The work for this is underway. An abstract for the work completed will be submitted to military and non-military relevant medical research meetings (i.e. 2016 SOMOS, 2016 MHSRS...).

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

The impact of this project is exceedingly high. The following is a brief list of major clinical science accomplishments:

1. Perfected NPWT seal – the mixed thin film adhesive and hydrocolloid sealing layer, which is was designed, tested and fabricated specifically for this project as part of the real-time response to issues identified in bench and Phase I testing resulted in the first NPWT dressing ever that truly produces a complete seal in clinical use. All COTS dressings accept a significant air-leak, which is overcome by the frequent or continuous activation of the noisy vacuum motor, which disturbs sleep and requires tether to the pump.
2. 6-day duration of wear – no dressing to date has been tested to a 6-day duration of wear. This is the average period of time between injury and definitive wound closure for most uncomplicated combat open wounds. This means, a single dressing can be applied and monitored through the evacuation process and until the wound is ready for skin grafting or delayed primary closure.
3. Active irrigation – no NPWT dressing actually delivers irrigant directly to the wound surface. All COTS dressings with an irrigation modality drip the irrigation fluid on the dorsal side of the dirty wound filler and rely on saturating the wound filler to provide a cleansing effect. SAWS replicates the traditional method of direct fluid irrigation of wounds. The collapsable irrigation tubing that was developed in this project allows for direct wound irrigation in the smallest footprint possible. In addition, the fact that there are 2 dedicated flow paths, one for irrigation and one for suction, means that the fluid can be lavaged across the wound, with active suction applied to remove debris that is solubilized/mobilized by the irrigation.
4. No tissue ingrowth – the construction of the SAWS dressing in the mature embodiment developed and tested under this grant is a solid medical grade pliable plastic. Human tissue cannot grow into the wound filling portions of this dressing, like it can into the reticulated sponge and cotton gauzed used in COTS systems. This was demonstrated consistently over the course of the 3 phases of animal testing.

What was the impact on other disciplines?

This pilot study was singular in focus. The aims were to directly address unmet needs in a specific discipline (wound care).

What was the impact on technology transfer?

The excellent performance of the mature dressing prototype in Phase II and III animal testing provides unquestionable substantiation of the clinical utility of this concept. There remains no further development risk for this product. The information obtained over the course of this project will support the remaining validation testing needed to achieve FDA approval. Given continued funding and support, this product will be commercialized in the next 12-24 months.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

This ambitious project saw many unanticipated issues, which challenged our ability to successfully complete all stated tasks on time and on budget. That said we were able to overcome these challenges, each of which made the overall prototype that was developed and validated all the more superior than COTS dressings. Our monthly reports fully detailed each of these unanticipated challenges, the following is a summary:

1. Inadequate seal. The initial adhesive film sealing layer that was trialed was inadequate for obtaining and holding an air tight seal for up to 6-days continuous. We used small, quiet vacuum pumps. The air leak that is a design flaw of all current COTS dressing sealing layer, was a fatal flaw for our extended wear work on animals. This problem was amplified by the disruptive behavior of the pigs. The solution of this issue was the addition of a hydrocolloid portion to the sealing layer. This along with the thin adhesive film produces a stable and durable air tight seal.
2. Poor animal model to test 6-day wear of a NPWT dressing. All NPWT dressings require continuous tethering to the vacuum pump. Despite several attempts, we were not able to develop a solution for the pigs behavior that did not compromise the fidelity of the model. We therefore switched to the calf, which turned out to be an excellent choice. The calf allowed for less wounds, and larger wounds (in area). There was significant time lost to the transition, but we were able to make it up at the end.
3. The high coagulability of calf transudate, made clogging of the evacuation tubing a real challenge. We increased the diameter of the evacuation tube and we placed a screen layer between the inlet of the evacuation tube and the central portion of the dressing. Lastly we designed a wound-interface chamber, which further improved the distribution of the vacuum and the preservation of outward flowpaths.

4. Sick animals in Phase III. Unfortunately our final 2 animals in the Phase III testing contracted “lumpy jaw” disease. This resulted in a need to change animals. Given quarantine and acclimation times, we were pushed to our limit in funds and time. Unfortunately, for reasons that are not entirely clear to us, the seals for all dressings on all 4 wounds (3 –SAWS, 1 KCI VAC) were poor in both animals. They required frequent supplementation and still had frank leaks and failures. This allowed for exogenous bacteria to enter the wounds and complicate the inoculated wounds, especially in the KCI treated wounds, where 1 of 2 developed gross clinical infection with Staph A and Pseudomonas. Thus, while there were lessons learned in all animal labs, the learning from the last 2 animals in Phase III was compromised. The first 2 animals in Phase III went very well with perfect seals and no issues. These animals showed predicted results with respect to bioburden control.

Changes that had a significant impact on expenditures

Nothing to report. Despite the very modest budget, we completed all tasks within the funding allocated.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals.

The primary change over this grant was that we switched from a 3-wound swine model with 6 animals per group to a 4-wound bovine model with 4 animals per group. This was necessitated by the destructive behavior of the awake pigs over the attempted 6-day use. We confirmed this in Phase I. This was the primary goal of Phase I, specifically to develop a mature testing protocol and dressing prototype to be used in the Phase II and III labs. This change was submitted to and approved by IACUC and ACURO. There was no substantial change in the risks or pain to the animals or the outcomes being measured, from that originally proposed.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**
A peer-reviewed manuscript reporting the results of Phase II and III studies is under work. Abstracts will be submitted to 2016 meetings.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name: *Michael S. Shuler, MD*
Project Role: *PI*
Nearest person month worked: *15*

Contribution to Project: *Overall supervision. Contributed to the design and conception of solutions to overcome problems identified in the progress of this grant. Managed research budget and reporting.*

Funding Support: *USAMRMC – Subcontracted: J&M Shuler Medical*

Name: *Michael Conforti, DVM, MS, MBA*
Project Role: *Lead Veterinarian*
Nearest person month worked: *12*

Contribution to Project: *Overall supervision of animal testing. Contributed to the design, approval and conduct of animal testing across 3 phases of animal experiments.*

Funding Support: *USAMRMC – Subcontracted: American Preclinical Services*

Name: *Carlus S. Dingfelder, BS*
Project Role: *Clinical Scientist*
Nearest person month worked: *12*

Contribution to Project: *Direct daily animal care and animal outcomes data collection and reporting.*

Funding Support: *USAMRMC – Subcontracted: American Preclinical Services*

Name: *Lars Runquist, BS*
Project Role: *Principal, Lead Design Engineer*
Nearest person month worked: *15*

Contribution to Project: *Overall supervision of prototype development and bench testing. Contributed to the design,*

Funding Support: *development and bench testing of all iterative prototypes.*
USAMRMC – Subcontracted: Red Group

Name: *Alex Win, BS*
Project Role: *Design Engineer*
Nearest person month worked: *10*

Contribution to Project: *Contributed to the design, development and bench testing of all iterative prototypes.*
Funding Support: *USAMRMC – Subcontracted: Red Group*

Name: *Evan Leingang, BS*
Project Role: *Design Engineer*
Nearest person month worked: *15*

Contribution to Project: *Contributed to the design, development and bench testing of all iterative prototypes.*
Funding Support: *USAMRMC – Subcontracted: Red Group*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

No

What other organizations were involved as partners?

None

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

- 9. APPENDICES:** Proposal for Supplemental Funding - A PDF, which outlines successes to date and a plan and budget for subsequent work required to complete the translation of this concept invention to a clinically available product. This was submitted through our COR to the PM on 10 Aug 2015, in keeping with our stated task 4c. (Write, submit, receive subsequent grant funding.)