UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

NOV 17 2014

The Honorable Barbara A. Mikulski
Chairwoman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Madam Chairwoman:

Enclosed is the final response to Senate Report 112-196, page 229, and House Report 112-493, page 266, both of which accompanied H.R. 5856, the Department of Defense Appropriations Bill, 2013, concerning the Joint Warfighter Medical Research Program (JWMRP). We provided an interim report on September 13, 2013. The enclosed report provides the details of the $50 million directed to the program, including lists of the funded projects, the amount of funding provided to each project, and a thorough description of each project's research. The final science funding allocation total after sequestration reductions and management and execution costs was $43,187,357.

The Fiscal Year 2013 JWMRP funded 35 projects across five research management areas. There were 27 projects funded at a cost of $32,539,356 for technology development efforts, and eight projects with associated funding of $10,648,001 for advanced technology development initiatives. We determined projects for funding based on which on-going projects were close to achieving their objectives and which on-going projects had a clear benefit to military medicine.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being provided to the other congressional defense committees.

Sincerely,

Jessica L. Wright

Enclosure:
As stated

cc:
The Honorable Richard C. Shelby
Vice Chairman

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

NOV 17 2014

The Honorable Richard J. Durbin
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Jessica L. Wright

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As stated

cc:
The Honorable Thad Cochran
Vice Chairman

UNDER SECRETARY OF DEFENSE
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WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

NOV 17 2014

The Honorable Carl Levin
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Jessica L. Wright

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As stated

cc:
The Honorable James M. Inhofe
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

NOV 17 2014

The Honorable Howard P. "Buck" McKeon
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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cc:
The Honorable Adam Smith
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

NOV 17 2014

The Honorable Rodney P. Frelinghuysen
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Jessica L. Wright

Enclosure:
As stated

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The Honorable Peter J. Visclosky
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

NOV 17 2014

The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Sincerely,

Jessica L. Wright

Enclosure:
As stated

cc:
The Honorable Nita M. Lowey
Ranking Member

REPORT TO CONGRESS

Fiscal Year 2013 Joint Warfighter Medical Research Program

October 2014

The estimated cost of report or study for the Department of Defense is approximately $12,300 in Fiscal Years 2013 - 2014. This includes $12,000 in expenses and $300 in DoD labor.

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1. BACKGROUND AND PURPOSE

The Assistant Secretary of Defense for Health Affairs (ASD(HA)) was requested in Senate Report 112-196, page 229, and House Report 112-493, page 266, both accompanying H.R. 5856, the Department of Defense Appropriations Bill for 2013, to provide a report, not later than 180 days after the enactment of the Act, to the congressional defense committees on the status of the Joint Warfighter Medical Research Program (JWMRP). An interim report was provided on September 13, 2013. The Committee reports request a final list of projects that received funding, the amount of funding provided to each project, and a thorough description of each of these research efforts.

The Deputy Assistant Secretary of Defense for Force Health Protection and Readiness (DASD(FHP&R)) is the principal staff assistant and advisor to the ASD (HA) for all force health protection and readiness-related Department of Defense (DoD) policies, programs and activities. In this capacity, the DASD(FHP&R) provides policy and oversight of Defense Health Program (DHP) Research, Development, Test, and Evaluation (DHP RDT&E) activities.

The Defense Health Agency (DHA) manages and executes the DHP appropriation and provides ten shared services to consolidate common services and to further integrate operational missions and capabilities in the Military Health System (MHS). The DHA is comprised of six directorates, one of which is the Research, Development, and Acquisition (RDA) Directorate. The DHA RDA Directorate manages MHS operations in the area of medical research and development. The DHA RDA Directorate manages and executes the DHP RDT&E funds. The DHA RDA Director has dual hat responsibility as the Deputy Commander for the US Army Medical Research and Materiel Command (USAMRMC) to facilitate the coordination of DHP RDT&E and Army RDT&E execution.

The USAMRMC, a major subordinate Command of the U.S. Army Medical Command, manages biomedical research and development programs that are part of the DoD and Army Science and Technology Master Plans. The USAMRMC is responsible for planning, coordinating, integrating, programming, budgeting, executing, reviewing human subject research, and reviewing investigational new drug application regulatory compliance for the applicable research programs aligned to the Command. The Command has a distinguished history in managing and executing congressional special interest research appropriations across a wide range of diseases, as well as specific military-relevant programs focused on the development of products for prevention, treatment, or rehabilitation paradigms in support of our uniformed Services.

The JWMRP is funded and directed by a DHP RDT&E Congressional Special Interest appropriation. The JWMRP is now executed by the USAMRMC in support of the DHA. The Fiscal Year 2013 (FY13) JWMRP is a congressionally directed $50 million (M) appropriation. Congress provided that these funds: "*...shall be used to augment and accelerate high priority Department of Defense and Service medical requirements and to continue prior year initiatives that are close to achieving their objectives and yielding a benefit to military medicine. The funds shall not be used for new projects or for basic research.*"

The funding for the FY13 program was received at USAMRMC on June 13, 2013. After sequestration reductions and all management and execution costs were determined, the initial science funding available was $37,329,000 ($27,835,000 for technology development projects and $9,494,000 for advanced development medical projects).

The JWMRP and the FY13 awards provided the Department great latitude in accelerating prior congressionally funded, high-priority, on-going research efforts which will improve military medicine. The JWMRP provides funding for many valuable and relevant projects that enable the Department to increase the level of effort to that provided in the President's budget DHP RDTE program prioritization processes. This vital research program is the venue to bring to fruition those products that will benefit our Armed Services. As the program moves forward, there is a need to increase the advanced development capability in order to move projects from technology development to manufacturing development, thus enabling the delivery of a finished product. For the FY13 program, 75 percent of the dollars went toward technology development efforts and 25 percent was directed toward advanced development initiatives.

2. FY13 JWMRP DISTRIBUTION ACROSS RESEARCH AREAS

The FY13 JWMRP funded 35 projects across five research management areas. Using the initial science funding of $37,329,000, and adding the scientific reserve and excess management funds, the final science funding allocation total for the JWMRP was $43,187,357. There are 27 projects, funded at a cost of $32,539,356 for technology development efforts, and eight projects with associated funding of $10,648,001 for advanced technology development initiatives. The two prominent parameters in determining projects for funding in this program were on-going projects close to achieving their objectives and on-going projects having a clear benefit to military medicine. All of the projects selected and awarded for continuation have discrete deliverables that will either move the project forward to the next phase of development, result in initiation of a clinical trial, or complete requirements that enable progress towards Food and Drug Administration (FDA) approval.

There are eight projects funded in the Medical Training and Health Information Sciences research area, which focuses on health information technologies and medical simulation. The resultant products include an evaluation of curricula developed in distributed skills, individual healthcare and team training with continuity of care using a regional medical simulation consortium; research that will measure the performance of robotic systems and simulation tool and techniques that improve robotic surgeon performance; a simulation tool for patients with upper extremity prostheses that has the potential to enhance the rehabilitative process; enhancement to an eye and face trauma simulator; a hand-held simulation device that will integrate infrared vein finding capability, and a trauma surgery simulation product. A key initiative will develop a prototype and test a miniaturized, remotely-controlled, image-guided surgical robot, while another project is developing a mobile phone biofeedback game based on heart rate variability analysis, which will allow users to conduct simple self-tests for personal health assessment and special biofeedback training procedures to mitigate the negative effects of stress and increase stress endurance.

There are four projects funded in the Military Infectious Diseases research area. One of the efforts will develop innovative quality assurance process improvement tools in support of FDA-regulated activities, while another key project continues the effort to develop safer drugs for Malaria prevention. A very innovative project is the Malaria clinical trial, with the first live attenuated vaccine developed against a protozoal disease in man. Multi-drug resistant wound healing is an important research need. In this arena, research will explore the use of Blue Light for the prophylaxis and treatment of combat wound infections.

There are four projects funded in the Military Operational Medicine scientific domain. A key initiative focuses on novel strategies that promote warfighter health and resilience, improve warfighter combat readiness, and sustain warfighter performance. A second effort is a six-year longitudinal study of Ohio National Guard personnel looking at the relationships among resilience, hazardous/risky behaviors, and the development of mitigation of psychopathology. There is a unique project focused on evaluation of a program to optimize veteran's vocational readiness and resilience, and an important effort to develop a virtual reality-based exposure therapy tool focused on patients who have experienced military sexual trauma.

Ten projects were selected for funding under Combat Casualty Care. The key deliverables include: research in biomarkers for monitoring wound healing and to identify mild traumatic brain injury; research on a product which reduces orthopedic surgical infections; research to reduce cell death and improve nerve regeneration for spinal cord injury; a product to improve detection, characterization, and localization of hemorrhage and brain injury; evaluation of a non-invasive treatment for compartment syndrome; development of a transportable pathogen reduction and blood safety system; a non-electric disposable IV infusion pump for final FDA approval; products for treatment of non-compressible bleeding; and completion of the data package to provide an FDA-certifiable life support system that meets the needs of all Services.

There are a total of nine awards in the Clinical and Rehabilitative Medicine research domain. In the regenerative medicine area, efforts are directed toward the development of tissue engineered nerve grafts; developing an integrated therapeutic/diagnostic approach for nerve repair with focus on muscle preservation and development of a novel topical therapeutic that inhibits burn injury progression, accelerates healing, and reduces scarring. In prosthetics, the product development efforts include a lower extremity prosthesis that incorporates neural signals into the control system, which will enhance patient control of the device; a prototype lightweight and ruggedized prosthesis; a prosthetic knee-ankle-foot system with biomechatronic sensing, control and power generation which will enable amputees to walk on level surfaces and inclines with a gait that is biomechanically and energetically equivalent to non-amputees; and a controller that will enable amputees to instinctively transition between terrains. There are two key projects in therapeutics. One is to develop a drug that may prevent the triggering of tinnitus and another effort is investigating the drug (+)-naltrexone which has shown promise as a potential treatment for substance abuse, a stand-alone treatment for acute and chronic pain following traumatic injury, and as an adjunct therapeutic for enhancing the clinical efficacy of opioids for pain control.

Table 1 summarizes of the projects funded by the FY13 JWMRP along with the award recipient, a description of the project, and the funding associated with the research or development effort.

Table 1

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
1	Institute for Simulation and Interprofessional Studies	University of Washington Seattle, WA	This research initiative is a collaboration effort between the University of Washington, Madigan Army Medical Center and the Veterans Administration Medical Center, Boise, Idaho. Utilizing existing facilities and networks this effort will develop a regional medical simulation consortium where experts in simulation curriculum partner to distribute shared, comprehensive and innovative simulation curricula. Building on previously developed curriculum in distributed skills training, individual healthcare provider training and team training with continuity of care, and augmented with other training modules, the research will assess usability, satisfaction and trainee behavior measures.	$1,175,000.00
2	Advanced Development of Stasix – a Platelet Derived Hemostatic Agent	Entegrion, Inc Research Triangle Park, NC	Stasix, a platelet derived hemostatic agent, shows promise in the treatment of non-compressible bleeding. This development effort is to advance the product development beyond preclinical work. The terminal objective for this phase is to develop an advanced manufacturing capacity and additional research to support the filing of an Investigational New Drug application (IND) with the FDA that leads to approval for a clinical study.	$4,254,545.43* *final award determination pending.

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
3	Development of a Simulation Tool for Upper Extremity Prostheses	University of South Florida Tampa, FL	This effort continues development of the robotic human upper body model (RHBM) to produce a simulation tool with an expanded RHBM including a kinetic component, pseudo-joint, and Return To Duty tasks database; an improved graphical user interface with an enhanced visualization using solid modeling animation and avatar overlay capability; and a rehabilitation and training module for the CAREN system's virtual reality environment to incorporate the RHBM predictive visualization. This initiative has the potential to enhance the rehabilitative process for patients with upper extremity prostheses.	$355,819.00
4	Clinical Development of the PfSPZ Vaccine to Protect the Warfighter From Malaria	Sanaria, Inc Rockville, MD	Initial clinical trials with this product demonstrate that the irradiated Plasmodium falciparum sporozoite (Malaria parasite) vaccine is safe and effective. Larger studies are required. This is the first live attenuated vaccine ever developed against a protozoal disease in man. High efficacy in initial clinical trials (>90%) may lead to a novel, intravenously administered vaccine protective against Plasmodium falciparum malaria. The clinical trial will evaluate protection from controlled human malaria challenges with different malaria strains and the length of such protection induced by intravenous vaccination with different doses regimens and dose potencies of irradiated malaria sporozoites.	$1,597,439.00 In addition: $2,205,234.00 (sent to the Walter Reed Army Institute of Research in support of this clinical trial) $103,860.00 (sent to Navy Medical Research Center in support of this clinical trial)

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
5	Pre-, Peri-, and Post-deployment Trajectories and Mechanisms of Psychopathology, Psychological Health and Resilience over Six Years of Follow-up in a Reserve Population	University Hospitals of Cleveland Cleveland, OH	The Ohio Army National Guard Mental Health Initiative has evaluated relationships between resilience and risk factors before, during, and after deployment over the past five years. This specific research will complete five waves of data collection over a period of six years, an unparalleled longitudinal study of National Guard Soldiers. The research will examine the roles of pre-, peri-, and post-deployment experiences, both military and civilian, in jointly contributing to trajectories of psychopathology (behaviors or experiences which are indicative of mental illness); it will identify the polygenic drivers of the trajectories of psychopathology over long-term follow-up of a reserve population; it will examine the role of hazardous alcohol use and alcohol use disorders in the multi-morbidity of post-traumatic stress disorder (PTSD), depression, traumatic brain injury (TBI) and other psychopathologies, and their chronicity; and will examine the longitudinal relationships among resilience, hazardous/risky behaviors, and the development and mitigation of psychopathology over six years of follow-up.	$956,289.00
6	IND-Enabling Studies for (+)-Naltrexone, A Novel and Potent Therapy for Substance Abuse and Pain Management	Xalud Therapeutics, Inc. San Francisco, CA	The goal of this research is to complete the pre-clinical studies of (+)-naltrexone to support the filing of an IND with the FDA and eventually conduct a clinical trial. (+)-Naltrexone could become a novel, front-line, and highly efficacious treatment for drug abuse, a stand-alone treatment for acute and chronic pain, and an adjunct therapeutic for enhancing the clinical efficacy of opioids for pain control.	$2,740,675.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
7	Development of Safer Drugs for Malaria in U.S Troops, Civilian Personnel and Travelers	University of Mississippi University, MS	This second year effort is aimed at identification of safe and effective drugs for prophylaxis and treatment of Malaria. The 8-aminoquinoline, which includes primaquine and tafenoquine, is the only drug class effective against all life-cycle stages of the malaria parasite. This effort will seek to reduce the toxicity of the currently available 8-aminoquinoline products which will result in safer drug candidates with broader clinical utility. The effort will complete testing in animals to identify products with an improved therapeutic index which will then progress to clinical trials.	$1,383,151.90 In addition: $1,634,459.00 (sent to the Walter Reed Army Institute of Research in support of this collaborative effort)
8	Collaborative Research to Optimize Warrior Nutrition II	Pennington Biomedical Research Center Baton Rouge, LA	The CROWN 2 project is an extension of the FY12 JWMRP funded project which seeks to discover novel strategies that promote warfighter health and resilience, improve warfighter combat readiness, and sustain warfighter performance. Specifically, this project provides for the most efficient and cost-effective execution of the DoD objectives to ensure a healthy fit military, ready for deployment, and resilient to the stressors of duty. CROWN 2 proposes research in nutrition and metabolism to develop better models to assess resilience or performance capacity. The work is categorized in four thematic areas: 1) Metabolism and Physical Performance, 2) Stress and Inflammation, 3) Nutrition and Resilience, and 4) Healthy Eating and Behavior.	$2,377,899.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
9	Robotic Telesurgery Research	University of Nebraska Medical Center Omaha, NE	The objective of this proposal is to develop a remotely controlled, image-guided, minirobot and to demonstrate its capabilities *in vivo*. The long-term goal is to enable insertable, image-guided minirobots to make surgeries in the peritoneal cavity less invasive than is possible with existing technology and to enable wide utilization of surgical expertise through telesurgical technology. The specific aims of this proposal are to complete the design, produce a prototype, and test a miniaturized, remotely controlled, image-guided, surgical robot and lay the groundwork for FDA device approval.	$1,433,567.00
10	Enhancements and Extension to Eye and Face Trauma Simulator	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	This effort as it moves towards an Ocular and CranioFacial Trauma Training System will develop trauma modules and associated training content for surgical enucleation and for severe mid-face fracture requiring stabilization.	$126,000.00
11	Massachusetts General Hospital Trauma Surgery Simulation	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	This project focuses on further validation studies and the next phase of commercial development for the MGH Trauma Surgery Simulation product. The first stage will focus on the initial validation. During the second stage of the program, further refinements to the prototype will be made with a concentration on ensuring marketability and commercialization of the unit. In addition, the refined trainer will be further validated using the development metrics and assessment tools.	$126,000.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
12	Handheld Simulation Procedure Training Device	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	This project builds on the previously developed prototype which includes an engineered haptic block with an Android phone/tablet to integrate a tactile user interface with visual and auditory representations of IV catheterization. This follow-on effort will enhance the fidelity by using 3D printing to create more realistic anatomic blocks, integrate IR vein finding capability, add instruction on IR and US guided catheterization, expand to iOS platforms, and improve testing and document competency.	$389,000.00
13	Repair of Segmental Nerve Defects-Tissue Engineered Nerve Grafts	Rutgers University / Cleveland Clinic Consortium The Armed Forces Institute of Regenerative Medicine New Brunswick, NJ / Cleveland, OH	TENGs are three-dimensional nervous tissue constructs made by embedding living axons in an extracellular matrix with subsequent placement in a nerve guidance tube. These studies will investigate the ability of TENGs to "jumpstart" nerve regeneration when there is a time delay between injury and surgical repair and to enable ultra-long distance axon regeneration which may produce full functional recovery.	$1,539,000.00
14	A Theragnostic System Solution for Optimal Nerve Repair	Rutgers University / Cleveland Clinic Consortium The Armed Forces Institute of Regenerative Medicine New Brunswick, NJ / Cleveland, OH	The previous funded research developed techniques for fabrication of stretchable polymeric microelectrode array (SPMEA) system. The goal of this project is to develop an integrated therapeutic /diagnostic approach for improved nerve repair with a special focus on muscle preservation during the course of nerve regeneration. The SPMEA technology will be used as an epimysial interface, implanted during the nerve repair surgery, and removed after reinnervation. The effort will develop in vivo electrophysiologic diagnostic and therapeutic techniques to monitor / evaluate and promote nerve repair.	$1,314,000.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
15	Topical Therapies to Inhibit Burn Injury Progression	Rutgers University / Cleveland Clinic Consortium The Armed Forces Institute of Regenerative Medicine New Brunswick, NJ / Cleveland, OH	The overall objective of this project is to demonstrate the *in vivo* safety and efficacy of a novel topical therapeutic that inhibits burn injury progression, accelerates healing, and/or reduces scarring. These studies, if successfully completed, will lead to a pre-IND meeting with the FDA on the topical use of peptide P12 for the treatment of localized burns.	$1,018,000.00
16	Multi-Modal Management of Non-Compressible Hemorrhage	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	This project will investigate the ability to seal abdominal vascular structures by Radio Frequency-mediated heat coagulation of human albumin into a multi-modal treatment for non-compressible hemorrhage. Two approaches to coagulation will be investigated, one based on heating by an external energy source, and a second approach by internal exothermic reaction by mixing of the sealing formula with blood. This treatment is expected to reduce the internal hemorrhage.	$595,000.00
17	Electrical Impedance Spectroscopy as an EKG for the Brain: Portable Point of Care Detection of Acute	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	The project will enhance the sensitivity and depth penetration of Electrical Impedance Spectroscopy (EIS) for the detection, characterization, and localization of hemorrhage and brain injury. The research will develop signal processing algorithms for automated detection and interpretation of EIS data, model the potential added value of a novel EIS pulse delivery system, construct and pre-clinically test an updated, optimized EIS device.	$546,000.00
18	Integrated Blood/Imaging Biomarkers for Mild TBI (mTBI)	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	The proposed study will validate and extend the utility of the previously identified biomarker for white matter injury across different extents of injury, and link these diffusion tensor imaging (DTI) results to blood or CSF-based soluble biomarkers that may have clinical utility for rapid diagnosis of mTBI.	$544,000.00

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19	Non-Invasive Fasciotomy to Treat Extremity Compartment Syndrome	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	Acute Extremity Compartment Syndrome (AECS) usually requires a fasciotomy but a non-invasive procedure using focused ultrasound may be a viable alternative. This study will characterize the range of applicable technical parameters with animal models, integrate a monitoring component into the prototype device, and perform tests with animal models that have fascia comparable to humans.	$397,000.00
20	Development of a Mobile Phone Measurement Sensor and Mini-Biofeedback Game based on Heart Rate Variability	East Carolina University Greenville, NC	This research further develops a Mobile TeleHealth System (MTS) based upon physiological measurement for remote assessment and intervention in military populations. The MTS is in the final stages of field testing and currently employs a Bluetooth ear clip photoplethesmography (PPG) sensor (used to optically obtain a volumetric measurement of an organ) and heart rate variability (HRV) software analyses to monitor and feedback biometric data for assessment and biofeedback training. This effort will further develop the MTS by creating a more readily available and inexpensive sensor and will develop and test the new sensor and software applications and will provide HRV biofeedback training in the form of a simple arcade game.	$111,037.00
21	Blue Light for Prophylaxis and Treatment of Multidrug-Resistant Combat Related Wound Infections	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	Blue Light is a longer wave length range and much less detrimental to host cells and tissue than UV light. This project evaluate the efficacy of using blue light to treat burns, open fractures, or surgical wounds in rodents infected with multidrug-resistant pathogens most frequently identified in combat-related wounds. Bioluminescence imaging will be used to monitor in real time the extent of infection *in vivo*.	$542,000.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
22	Execution of a Quality Systems Program for FDA Regulated Activities	Amethyst Technologies, LLC Baltimore, MD	This research support effort includes validation for the building automation system (BAS), and the qualification for the training platform (RIID-TRAIN). Amethyst will provide validation for critical equipment and software, developing innovative quality assurance process improvement tools, and implementing quality assured programs for USAMRIID laboratory and clinical practices. This initiative will: promote FDA compliance in research for potential biological threats; develop efficient tools to increase program efficiency while ensuring quality assurance to DoD and FDA standards; and increase functionality and applicability of current USAMRIID systems to support FDA regulated studies. These programs will assist the scientists at USAMRIID to achieve their technical milestones and result in reduction of some manual tasks.	$539,000.00
23	Re-entry With Resilience: Optimizing Veterans Vocational Readiness and Resilience	East Carolina University Greenville, NC	The objective of this research project is to conduct an initial structure and process evaluation of a web-based vocational screening and intervention tool with Marines and Sailors who have physical injuries and/or psychological distress prior to their entry into a transition program. Vocational Vital Signs will: screen, via a web-based service facilitated by an avatar, the individuals' vocational readiness; and provide a vocational readiness report that includes recommendations for vocational-based services to increase the individuals' understanding of and motivation for addressing their vocational readiness.	$187,768.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
24	Development of Therapeutic Drugs that Prevent the Triggering of Tinnitus	University of Pittsburgh Pittsburgh, PA	The previously funded study revealed that a reduction in Kv7.2/3 potassium channel activity is essential for the induction of tinnitus. A pharmacological enhancement of Kv7 channel activity with retigabine, a Kv7 channel activator, prevents the development of tinnitus. This significant role of Kv7 channels makes them promising targets for the development of therapeutic approaches for preventing the induction of tinnitus. This study will determine the critical period within which enhancement of Kv7.2/3 channel activity is capable to prevent tinnitus and will develop selective Kv7.2/3 activators that prevent the induction of tinnitus.	$399,079.00
25	Advanced Restoration Therapies in Spinal Cord Injury	Hugo Moser Research at Kennedy Krieger, Inc. Baltimore, MD	This effort will determine if functional electrical stimulation (FES) in a mouse model with chronic spinal cord injury (SCI) induces proliferation and differentiation of genetically labeled oligodendrocyte progenitor cells. The study will also determine if FES induces remyelination by mature oligodendrocytes in mouse model with chronic SCI. Finally, this effort will determine if FES in a mouse model with chronic SCI induces cortical plasticity as measured by resting state functional magnetic resonance imaging.	$1,032,569.11

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26	Anti-Biofilm Trauma Device Phase Two	Teleflex, Inc Cambridge, MA	Protecting the surface of trauma implants from biofilm formation is critical to reduce orthopedic infection. The initial project developed a product for orthopedic surface to reduce infections. This project will evaluate the product on titanium Kirschner wires to full-size intramedullary nail to evaluate protection from both initial bacterial challenges and long-term biofilm formation. The efficacy and biocompatibility of the product will be tested in small animal models to optimize performance and demonstrate efficacy. Once the performance formulation is identified, the full-size tibial nails will be modified and tested in large animal model. Pending success of these proposed preclinical studies, preparations will be made to develop a process to prepare devices that could be used to support future clinical studies.	$2,109,584.00
27	Medical Robotic and Telesurgical Simulation and Education Research	Adventist Health System/Sunbelt, Inc., dba Florida Hospital Orlando, FL	This research effort is focused on Telesurgery and Surgical Rehearsal. The Telesurgery component will measure the performance of robotic systems being used across a metropolitan, state and national area. The Surgical Rehearsal will explore new simulation-based tools and techniques that will be useful for improving robotic surgeon performance.	$806,380.55
28	Configuration and Adaptive Recalibration of Lower Extremity Neural Control Systems	Rehabilitation Institute of Chicago Chicago, IL	The Rehabilitation Institute of Chicago demonstrated that the incorporation of neural signals into a control system for powered prosthetic legs has the potential to significantly improve an amputee's ability to control these devices. By enabling a dramatic improvement in mobility, this type of control system would make the use of a prosthetic leg "seamless". The project is further developing the prosthesis to make the prosthetic leg more robust and simplify the configuration for new users. Upon completion of the currently funded effort, the system will be ready for home-trials with injured service members.	$2,929,441.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
29	Prosthetic Knee-Ankle-Foot System With Biomechatronic Sensing, Control, and Power Generation	Massachusetts Institute of Technology Boston, MA	The purpose of this effort is to develop a transfemoral bionic limb that will enable amputees to walk on level surfaces and inclines with a walking gait that is biomechanically and energetically equivalent to non-amputees. There are two primary development components to this effort: 1) inverse and forward modeling of the reflex-based neuromuscular simulation and 2) implementation of the forward model in a control system developed for the powered transfemoral prosthesis. The prototype prosthesis and control scheme will be tested in a full biomechanical study with ten transfemoral amputees.	$460,978.18
30	Development of a Lightweight, Ruggedized Prosthesis	Rehabilitation Institute of Chicago Chicago, Ill	Through previous DoD funding, amyoelectric upper extremity prosthesis was developed. It balances improved function with design constraints such as strength and low weight. This follow-on effort will implement design refinements based on user feedback from a field trial, initiate a design ruggedization process and identify areas for improvement. This effort will initiate development of the manufacturing system and fabricate two pre-production prototype iterations based on the design refinements and manufacturing plan. The documentation required for regulatory approval will be prepared as part of this product development effort.	$1,998,735.00

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31	Powered Leg Prosthesis for the Restoration of Amputee Balance, Locomotory Metabolism and Speed	Massachusetts Institute of Technology Boston, MA	This development effort will design and implement a controller that will predict terrain transitions and allow for volitional adjustment of a powered ankle-foot prosthesis. The intrinsically-predictive controller will enable amputees to instinctively transition between terrains, such as ramps or stairs, by classifying data from intrinsic sensors and adjusting ankle position in real-time. A second component of the effort will pair this controller with volitionally-adjusted, myoelectric control. This will further enable transtibial amputees to fine-tune the position of their prosthesis around the biomimetic intrinsic default by activating their residual limb muscles.	$521,224.14
32	MOVES – Life Support System for the Continuum of Care	Thornhill Research, Inc. Toronto, Canada	Mobile, Oxygen, Ventilation, and External Suction (MOVES) – Life Support System for the Continuum of Care. This JWMRP effort will complete enhancements to an integrated transport life support system, which monitors patient ventilation, oxygen, and suction through a wireless display and control. This work will provide data to support FDA pre-market approval. Once approved by the FDA, this device will provide a portable life support system that supports all Services on all transportation platforms across the continuum of care.	$1,420,000.00
33	BRAVEMIND: Advancing the Virtual Iraq/Afghanistan PTSD Exposure Therapy for MST	University of Southern California Los Angeles, CA	Bravemind is a clinical, interactive, virtual reality (VR) based exposure therapy tool being used to assess and treat PTSD. Military Sexual Trauma (MST) has been recognized as a significant risk factor for the development of PTSD. This effort will develop content for inclusion in the BRAVEMIND virtual reality exposure therapy (VRET) system that will provide new customizable options for persons who have experienced MST and to run a pilot randomized clinical trial with a sample of 34 persons diagnosed with PTSD due to MST.	$1,442,306.99

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34	Non-Electric Disposable IV Infusion Pump	BioQuiddity Inc. San Francisco, CA	BioQuiddity completed assembly validations for the fixed rate dispenser under GMP conditions for the combination product. Performance testing was successfully completed concurrent with product validation through human factors testing by an independent clinical site. The human factors evaluation was successful. Clinical lot production of the pain management dispenser was completed, including sterilization validation of the dispensing system. Extensive design test build cycles for various iterations of the propofol dispenser were also conducted. Extensive biocompatibilities testing of the pain management dispensers were also successfully conducted. Despite minor delays in the commencement of the bioavailability study, the Company remains on target to complete the contract deliverables on budget. The tasks for the next year are: 1) Perform clinical lot manufacture for Propofol Dispensers; 2) Perform final verification & performance testing for Propofol Dispensers; 3) Conduct pre-clinical testing on Propofol Dispensers; 4) Conduct clinical evaluations on Ropivacaine and Propofol Dispensers; 5) Complete FDA submission and obtain approval for Ropivacaine Dispenser; and 6) Provide samples of Propofol Dispensers for military testing.	$1,069,000.00

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35	Transportable Pathogen Reduction & Blood Safety System	Terumo BCT Biotechnologies, LLC Lakewood, CO	The Whole Blood Pathogen Reduction Device (WBPRD) will reduce the risk of pathogen transmission and graft versus host disease in wounded Warfighters receiving emergency whole blood transfusions. The WBPRD uses ultraviolet light illumination combined with riboflavin administration to reduce and/or eliminate pathogens (viruses, bacteria, parasites) and white blood cells in donor whole blood. The program utilized FY12 JWMRP funding to prepare and implement a Project Management Plan and a Quality Plan, optimize the treatment process, and convene a panel of external toxicology experts to identify the necessary pre-requisite safety studies for the planned pivotal clinical trial. These identified safety studies will be executed over the next 12 months. FY13 funding will be applied toward the execution of the pivotal clinical trial, a critical component of the Premarket Approval submission to the FDA planned for FY17. The Phase II Clinical Trial was completed in 3QFY14. In discussion with FDA, patient population and crossover design of Phase III Pivotal Study the Clinical Strategy will be decided in 4QFY14.	$806,315.40