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OSIRIS THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **January 3, 2008**

OSIRIS THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware (State or other jurisdiction of incorporation)	**001-32966** (Commission File Number)	**71-0881115** (IRS Employer Identification No.)

7015 Albert Einstein Drive, Columbia, Maryland (Address of principal executive offices)	**21046** (Zip Code)

Registrant's telephone number, including area code: **(443) 545 - 1800**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 1.01 Entry Into Material Definitive Agreement.

On January 3, 2008, Osiris Therapeutics, Inc. ("Osiris" or the "Registrant") was awarded a contract from the US Army Space & Missile Defense Command, a unit of the United States Department of Defense (DoD), to develop and stockpile Prochymal, an adult stem cell therapy for the repair of gastrointestinal injury resulting from radiation exposure. Under the terms of the contract, DoD will provide approximately $4.2 million in funding to the Registrant for the technology development of Prochymal for the treatment of acute radiation syndrome (ARS). The contract further provides for additional funding for activities leading to United States Food and Drug Administration (FDA) approval of Prochymal for ARS and the scaling up of manufacturing processes, in the aggregate amount of up to $20.5 million, and provides the DoD with successive options for the purchase of a significant number of doses of Prochymal, for stockpiling purposes in the aggregate amount of up to $200 million. The total value of the contract, assuming FDA approval and the exercise by DoD of all of its options to purchase doses of Prochymal at current prices, is up to $224.7 million. The foregoing description of the contract is not complete and is qualified in its entirety by reference to the contract, which is referenced as Exhibit 10.1 to this Current Report on Form 8-K and incorporated into this Item 1.01 by reference.

The contract is the first awarded to the Registrant under the previously announced agreement between the Registrant and Genzyme Corporation for collaboration in the preparation and execution of development and purchase agreements with U.S. and Allied governmental agencies. For the initial product focus, that agreement provides for the contribution by the Registrant of Prochymal and corresponding safety and efficacy databases, and the contribution by Genzyme of product development and large-scale commercialization expertise. The agreement with Genzyme, entered into on July 26, 2007, provides for Genzyme to receive a royalty of 15% of net product sales, limited to those sales made under contract to U.S. or Allied governmental agencies for emergency preparedness.

The performance by the Registrant and the ability of the Registrant to benefit from these agreements is subject to and presents numerous risks and uncertainties, including the risk factors discussed in the Registrant's Annual Report on Form 10-K and other periodic reports. These risks also include risks of adverse changes in U.S. government spending priorities; failure to retain existing U.S. government contracts or to obtain option awards, task orders, or funding under contracts; risks of contract performance; risks of contract termination, either for default or for the convenience of the U.S. government; adverse results of U.S. government audits of our U.S. government contracts; and risks associated with complex U.S. government procurement laws and regulations .

ITEM 7.01 Regulation FD Disclosure.

On January 3, 2008, the Company issued a press release announcing that it had been awarded a contract from the United States Department of Defense to develop and stockpile Prochymal as an adult stem cell therapy for the repair of gastrointestinal injury resulting from radiation exposure. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information included in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into any filing (including any Item of this filing) pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing, except as expressly set forth by specific reference in this or such filing, incorporating by reference such information.

ITEM 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

10.1 Award/Contact issued by the US Army Space & Missile Defense Command to the Registrant, dated January 3, 2008.
99.1 Press Release of the Registrant dated January 3, 2008.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OSIRIS THERAPEUTICS, INC.

Dated: January 4, 2008

By: /s/ PHILIP R. JACOBY, JR.
Philip R. Jacoby, Jr.
Interim Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
10.1	Award/Contract issued by the US Army Space & Missile Defense Command to the Registrant dated January 3, 2008.
99.1	Press Release of the Registrant dated January 3, 2008

Exhibit 10.1

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) ▶ RATING D0-C9

2. CONTRACT (*Proc. Inst. Indent.)* NO.
W9113M-08-C-0028

3. EFFECTIVE DATE
2 Jan 2008

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.

5. ISSUED BY CODE W9113M
US ARMY SPACE & MISSILE DEFENSE COMMAND
SMDC-RDCM
PO BOX 1500
HUNTSVILLE AL 35807-3801

6. ADMINISTERED BY (*If other than Item 5)* CODE

7. NAME AND ADDRESS OF CONTRACTOR (*No, street, city, county, State and Zip Code)*

OSIRIS THERAPEUTICS, INC
7015 ALBERT EINSTEIN DRIVE
COLUMBIA MD 21046-1707

CODE 06JU9 FACILITY CODE

8. DELIVERY

☐ FOB ORIGIN ☒ OTHER *(See below*

9. DISCOUNT FOR PROMPT PAYMENT
Net 30

10. SUBMIT INVOICES (*4 copies unless otherwise specified)* TO THE ADDRESS SHOWN IN: ▶ ITEM G

11. SHIP TO/MARK FOR CODE
See Schedule

12. PAYMENT WILL BE MADE BY CODE HQ0302
DFAS-ROME
DFAS-RO-A, 325 BROOKS ROAD PHONE 800-553-0527
ROME NY 13441-4527

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETION:
☐ 10 U.S.C. 2304(c) ( ) ☐ 41 U.S.C. 253(c) ( )

14. ACCOUNTING AND APPROPRIATION DATA
See Schedule

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				

15G. TOTAL AMOUNT OF CONTRACT ▶ $4,253,390.80

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required in sign this document and return copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth of otherwise identified above and on any continustion sheets for the consideration stated herain. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein)*

18. ☐ AWARD *(Contractor is not required to sign this document)* Your offer on solicitation Number including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award the consummates which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER *(Typs or print)*
C. Randal Mills, President

20A. NAME OF CONTRACTING OFFICER
LYNN M. SELFRIDGE

19B. NAME OF CONTRACTOR 19C. DATE SIGNED
BY /s/ C. Randal Mills 12/31/07
(Signature of person authorized to sign)

20B. UNITED STATES OF AMERICA 20C. DATE SIGNED
BY /s/ Lynn M. Selfridge 1/3/08
(Signature of Contracting Officer

NSN 7540-01-152-8069
PREVIOUS EDITION UNUSABLE

26-107 **STANDARD FORM 26 (REV. 4-85** Presented by GSA
FAR (46 CFR 53.214(a)

USAPPCV 1.00

Section A - Solicitation/Contract Form

CONTINUATION OF FORM 26
Award is hereby made for the Development and Delivery of an FDA Approved Medical Radiation Countermeasure (MRC) product.

The Osiris Therapeutics Inc. proposal dated August 10, 2007 as revised on September 6, 2007, is incorporated into contract No. W9113M-08-C-0028 with the following revisions.

1. Contract Data Requirements List (CDRL) A001, A003, A004 and A008 are requirements associated with SLINs 0001A and 0001AB, not 0001AD. Costs associated with these CDRLs are removed from option SLIN 0001AD and added into SLINs 0001AA and option 0001AB as shown in Section B.

2. SubCLINs (SLINs) 0004AA-0004AB are hereby decreased to a quantity of 5,000 each, and SubCLINs 0004AC, and 0004AD are hereby added with a quantity of 5,000 each. Prior to the first exercise of these optional line items, the Government reserves the right to renegotiate with Osiris the $10,000 unit price for these optional line items at a price not to exceed (i) $10,000 or (ii) the lowest “most favored end user customer” commercial price (including consideration of any discount or rebate arrangement) at the time of negotiation; whichever is lower. If at any time any of these options are exercised the product is commercially available to the public (as defined by FAR part 2.101), the price shall not exceed the (i) the lowest “most favored end user customer” commercial price paid or offered within 6 months of the option exercise or (ii) $10,000; whichever is lower.

3. All costs identified through the revised proposal of September 6, 2007, include any costs that are a result of the Osiris and Genzyme collaborative agreement.

4. Osiris Therapeutics Inc.’s shall implement all recommendations as identified in DCAA Audit Report No. 6311-2007D17740064, within 3 months of contract award to have a fully compliant accounting system audited by the DCAA and approved by the assigned ACO. If at the end of the 3 months, Osiris has failed to fulfill this requirement, the Government shall suspend acceptance of additional vouchers until the requirements are completed.

5. CLIN 0002 is removed.

6. Section E. Inspection/Acceptance terms have been added.

7. Section F. Manpower Reporting requirement is removed.

8. Section H. Unamed clause after 52.234-4 is removed.

9. Section I.

The following clauses are added by reference:
52.211-5, Material Requirements (Aug 2000)
52.232-1, Payments - Fixed Price (Apr 1984)
52.242-15, Stop Work Order (Aug 1989)

The following clauses are incorporated by full text:
52.217-6, Option for Increased Quantity (Mar 1989)
252.211-7003, Item Identification and Valuation (Jun 2005)

The following clauses are revised to include the most current version:
52.203-6 (Sep 2006)
52.204-7 (Jul 2006)

52.209-6 (Sep 2006)
52.222-26 (Mar 2007)
52.222-35 (Sep 2006)
52.244-6 (Mar 2007)
252.209-7004 (Dec 2006)
252.244-7000 (Jan 2007)

The following clauses are deleted:
52.230-2
52.225-5 DEV

10. Section J:
CDRLs A001-A008 are corrected to include the correct Contract Line Item Number.

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	MRC Development and Delivery CPIF (Information CLIN only) FOB: Destination				
				TARGET COST	$0.00
				TARGET FEE	$0.00
				TOTAL TGT COST+ FEE	$0.00
				MINIMUM FEE	$0.00
				MAXIMUM FEE	$0.00
				SHARE RATIO ABOVE TARGET	
				SHARE RATIO BELOW TARGET	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AA					

CPIF
Technology Development phase of the Advanced Development, Demonstration, and Delivery of a FDA-Approved therapeutic Medical Radiation Countermeasure (MRC) product in accordance with the contractor's Statement of Work (SOW) dated August 10, 2007. (As provided in response to the Government's Statement of Objectives (SOO) located as an attachment to Section J generally, and the activities described in paragraph C.3.1 of the SOO specifically) to include delivery to the Government of, at a minimum, one dose of an Investigational New Drug (IND) that has 1) successfully undergone Phase 1 safety testing acceptable for a therapeutic MRC indication and 2) has received FDA authorization to proceed and is not subject to a clinical hold, and 3) has successfully completed two years of International Conference on Harmonisation-compliant stability testing, and 4) has undergone all other work specified in the Contractor's SOW.
FOB: Destination

TARGET COST	$3,866,719.00
TARGET FEE	$386,671.80
TOTAL TGT COST+ FEE	$4,253,390.80
MINIMUM FEE	$0.00
MAXIMUM FEE	$773,343.78
SHARE RATIO ABOVE TARGET	70/30
SHARE RATIO BELOW TARGET	70/30

ACRN AA $4,253,390.80
CIN: 0000000000000000000000000000000

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AA OPTION					

CPIF
System Development and Demonstration phase of the Advanced Development, Demonstration, and Delivery of a FDA-Approved therapeutic MRC product in accordance with the Contractor's Statement of Work (SOW) dated August 10, 2007. (As provided in response to the Governments Statement of Objectives (SOO) located as an attacment to Section J generally, and the activities described in paragraph C.3.2 of the SOO specifically), to include delivery to the Government of, at a minimum, one dose of the FDA-approved MRC.
FOB: Destination

TARGET COST	$16,815,380.00
TARGET FEE	$1,681,538.00
TOTAL TGT COST+ FEE	$18,496,918.00
MINIMUM FEE	$0.00
MAXIMUM FEE	$3,363,076.00
SHARE RATIO ABOVE TARGET	70/30
SHARE RATIO BELOW TARGET	70/30

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AC OPTION					

CPIF
Implementation of an Earned Value Management (EVM) System in accordance with DFARS 252.242-7002.
FOB: Destination

TARGET COST	$241,229.00
TARGET FEE	$24,123.00
TOTAL TGT COST+ FEE	$265,352.00
MINIMUM FEE	$0.00
MAXIMUM FEE	$48,246.00
SHARE RATIO ABOVE TARGET	70/30
SHARE RATIO BELOW TARGET	70/30

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AD OPTION					

CPIF
Monthly Contract Performance Report in accordance with the relevant DD Form 1423, Contract Data Requirement List (CDRL). See Exhibit A005, attached in Section J.
FOB: Destination

TARGET COST	$801,485.00
TARGET FEE	$80,149.20
TOTAL TGT COST+ FEE	$881,634.20
MINIMUM FEE	$0.00
MAXIMUM FEE	$160,297.00
SHARE RATIO ABOVE TARGET	70/30
SHARE RATIO BELOW TARGET	70/30

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AE OPTION					

CPIF
Quarterly Contract Funding Status Report in accordance with the relevant DD Form 1423, Exhibit A002 attached in Section J.
FOB: Destination

TARGET COST	$407,345.00
TARGET FEE	$40,734.00
TOTAL TGT COST+ FEE	$448,079.00
MINIMUM FEE	$0.00
MAXIMUM FEE	$81,469.00
SHARE RATIO ABOVE TARGET	70/30
SHARE RATIO BELOW TARGET	70/30

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AF OPTION					
	CPIF Technical Data Package to be delivered after FDA approval of MRC FOB: Destination				
				TARGET COST	$190,582.00
				TARGET FEE	$19,058.00
				TOTAL TGT COST+ FEE	$209,640.00
				MINIMUM FEE	$0.00
				MAXIMUM FEE	$38,116.00
				SHARE RATIO ABOVE TARGET	70/30
				SHARE RATIO BELOW TARGET	70/30

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003 OPTION		1	Lot	$116,610.00	$116,610.00
	FFP Drug Master File. Exercised at Milestone B and shall be completed no later than 90 days once the option is exercised. FOB: Destination				
				NET AMT	$116,610.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004 OPTION	Production End Items FFP HOSPITAL-BASED Medical Radiation Countermeasure (MRC): An MRC suitable for delayed administration after diagnosis of the GI syndrome of ARS is made and used at medical treatment facilities in the battle space and the sustaining base, and under the supervision of a Physician. (SubCLINS 0004AA through 0004AD below). (Information CLIN Only) FOB: Destination				
				NET AMT	$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004AA OPTION	HOSPITAL-BASED MRC FFP 5,000 TED FOB: Destination	5,000	Each	$10,000.00	$50,000,000.00
				NET AMT	$50,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004AB OPTION		5,000	Each	$10,000.00	$50,000,000.00
	HOSPITAL-BASED MRC FFP 5,000 TED FOB: Destination				
				NET AMT	$50,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004AC OPTION		5,000	Each	$10,000.00	$50,000,000.00
	HOSPITAL-BASED MRC FFP 5,000 TED FOB: Destination				
				NET AMT	$50,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004AD OPTION		5,000	Each	$10,000.00	$50,000,000.00
	HOSPITAL-BASED MRC FFP 5,000 TED FOB: Destination				
				NET AMT	$50,000,000.00

Section C - Descriptions and Specifications

SECTION C

Contractor's Statement of Work (SOW). See Section J, List of Attachments, in response to Government's Statement of Objectives (SOO).

Section D - Packaging and Marking

SECTION D

Packaging and Marking shall be in accordance with the Contractor's Statement of Work, as provided in response to the Government's Statement of Objectives (SOO).

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

All Supplies/services will be inspected/accepted by the government at Destination.

CLAUSES INCORPORATED BY REFERENCE

52.246-2	Inspection Of Supplies-Fixed Price	AUG 1996
52.246-3	Inspection Of Supplies Cost-Reimbursement	MAY 2001
52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001
52.246-16	Responsibility For Supplies	APR 1984
252.246-7000	Material Inspection And Receiving Report	MAR 2003

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	N/A	N/A	N/A	N/A
0001AA	5 yrs after Award	N/A	JPM-MITS 64 Thomas Johnson Drive Frederick, MD 21702	N/A
0001AB	5 yrs after option is exercised	N/A	Same as above	N/A
0001AC	Implemented 6 mos of option exercised	N/A	Same as above	N/A
0001AD	Monthly after option exercised	N/A	Same as above	N/A
0001AE	Quarterly after option exercised	N/A	Same as above	N/A
0001AF	One yr after option is exercised	N/A	Same as above	N/A
0003	90 days after option is exercised	N/A	Same as above	N/A
0004	N/A	N/A	Same as above	N/A
0004AA	Within 6 mos of exercise of option	5,000	Same as above	N/A
0004AB	Within 6 mos of exercise of option	5,000	Same as above	N/A
0004AC	Within 6 mos of exercise of option	5,000	Same as above	N/A
0004AD	Within 6 mos of exercise of option	5,000	Same as above	N/A

CLASSES INCORPORATED BY REFERENCE

52.242-15	Stop-Work Order	AUG 1989
52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984

52.247-34 F.O.B. Destination NOV 1991

Section G - Contract Administration Data

PAYMENT/INVOICING

In accordance with DFARS Clause 252.232-7003, Electronic Submission of Payment Requests, the contractor shall submit invoices electronically. A copy of the invoice shall be submitted to the Contracting Officer's Representative (COR) listed below to facilitate the process for payment. Payment shall be made by the Defense Finance and Accounting Office, upon acceptance by the COR.

Government Point of Contact:

US Army Space & Missile Defense Command
Attn: SMDC-RDCM-SB/Sandra O'Connell
64 Thomas Johnson Drive
Frederick, MD 21702
(301)619-2895
sandra.oconnell@us.army.mil

Contracting Officer's Representative

MAJ Eric Wagar
64 Thomas Johnson Drive
Frederick, MD 21702
(301)619-8424
eric.wagar@us.army.mil

ACCOUNTING AND APPROPRIATION DATA

AA: 977040026017Y5YCM406038BP000255Y12YMMRW90GXK72270154YMMR12044008
AMOUNT: $4,253,390.80
CIN 00000000000000000000000000000000: $4,253,390.80

Section H - Special Contract Requirements

SPECIAL REQUIREMENT

"The Sponsor shall seek permission from the FDA to re-label and use consistency lot product as FDA-approved product and if allowed by the FDA, the Government reserves the option to apply these doses in the fulfillment of the production quantities to be obtained under the optional production SUBCLIN(s) with the right to obtain a pro rata reduction in price under the exercised production SUBCLIN(s) (taking into account the number of individual doses per TED) using the effective unit price bid under the exercised production SUBCLIN(s) as designated by the Government for the purposes of this special provision."

CLAUSES INCORPORATED BY FULL TEXT

52.234-4 EARNED VALUE MANAGEMENT SYSTEM (JUL 2006)

(a) The Contractor shall use an earned value management system (EVMS) that has been determined by the Cognizant Federal Agency (CFA) to be compliant with the guidelines in ANSI/EIA Standard - 748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been determined compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM System has not been determined by the CFA as complying with EVMS guidelines or the Contractor does not have an existing cost/schedule control system that is compliant with the guidelines in ANSI/EIA Standard - 748 (current version at time of award), the Contractor shall—

(1) Apply the current system to the contract; and

(2) Take necessary actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) The Government will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post award IBR shall be conducted as early as practicable after contract award.

(d) The Contracting Officer may require an IBR at-

(1) Exercise of significant options; or

(2) Incorporation of major modifications.

(e) Unless a waiver is granted by the CFA, Contractor proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the performance criteria referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of this clause: (Insert list of applicable subcontractors.)

(End of clause)

Section 1 - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	JUL 1995
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	SEP 2005
52.204-4	Printed or Copied Double-Sided on Recycled Paper	AUG 2000
52.204-7	Central Contractor Registration	JUL 2006
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	SEP 2006
52.211-5	Material Requirements	AUG 2000
52.215-2	Audit and Records—Negotiation	JUN 1999
52.215-8	Order of Precedence—Uniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Cost or Pricing Data—Modifications	OCT 1997
52.215-15	Pension Adjustments and Asset Reversions	OCT 2004
52.215-19	Notification of Ownership Changes	OCT 1997
52.219-6	Notice Of Total Small Business Set-Aside	JUN 2003
52.219-8	Utilization of Small Business Concerns	MAY 2004
52.219-14	Limitations On Subcontracting	DEC 1996
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity For Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	SEP 2006
52.222-36	Affirmative Action For Workers With Disabilities	JUN 1998
52.223-6	Drug-Free Workplace	MAY 2001
52.223-14	Toxic Chemical Release Reporting	AUG 2003
52.225-13	Restrictions on Certain Foreign Purchases	FEB 2006
52.227-11	Patent Rights—Retention By The Contractor (Short Form)	JUN 1997
52.227-14	Rights in Data—General	JUN 1987
52.227-23	Rights to Proposal Data (Technical)	JUN 1987
52.228-7	Insurance—Liability To Third Persons	MAR 1996
52.232-1	Payments	APR 1984
52.232-17	Interest	JUN 1996
52.232-20	Limitation of Cost	APR 1984
52.232-23 Alt I	Assignment of Claims (Jan 1986) - Alternate I	APR 1984
52.232-25	Prompt Payment	OCT 2003
52.232-33	Payment by Electronic Funds Transfer—Central Contractor Registration	OCT 2003
52.233-1	Disputes	JUL 2002
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001

52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.243-1 Alt V	Changes--Fixed Price (Aug 1987) - Alternate V	APR 1984
52.243-2	Changes--Cost Reimbursement	AUG 1987
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	MAR 2007
52.249-2	Termination For Convenience Of The Government (Fixed-Price)	MAY 2004
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2004
252.204-7004 Alt A	Central Contractor Registration (52.204-7) Alternate A	NOV 2003
252209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.211-7003	Item Identification and Valuation	JUN 2005
252.215-7000	Pricing Adjustments	DEC 1991
252.232-7003	Electronic Submission of Payment Requests	MAR 2007
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.235-7011	Final Scientific or Technical Report	NOV 2004
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	JAN 2007
252.247-7023	Transportation of Supplies by Sea	MAY 2002
252.247-7024	Notification Of Transportation Of Supplies By Sea	MAR 2000

CLAUSES INCORPORATED BY FULL TEXT

52.216-7 ALLOWABlE COST AND PAYMENT (DEC 2002)

(a) Invoicing.

(I) The Government will make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) subpart 31.2 in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(2) Contract financing payments are not subject to the interest penalty provisions of the Prompt Payment Act. Interim payments made prior to the final payment under the contract are contract financing payments, except interim payments if this contract contains Alternate I to the clause at 52.232-25.

(3) The designated payment office will make interim payments for contract financing on the 30th (Contracting Officer insert day as prescribed by agency head; if not prescribed, insert “30th”) day after the designated billing office receives a proper payment request.

In the event that the Government requires an audit or other review of a specific payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date.

(b) Reimbursing costs. (1) For the purpose of reimbursing allowable costs (except as provided in subparagraph (b)(2) of the clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term “costs” includes only—

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for—

(A) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made—

(1) In accordance with the terms and conditions of a subcontract or invoice; and

(2) Ordinarily within 30 days of the submission of the Contractor’s payment request to the Government;

(B) Materials issued from the Contractor’s inventory and placed in the production process for use on the contract;

(C) Direct labor;

(D) Direct travel;

(E) Other direct in-house costs; and

(F) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of financing payments that have been paid by cash, check, or other forms of payment to subcontractors.

(2) Accrued costs of Contractor contributions under employee pension plans shall be excluded until actually paid unless—

(i) The Contractor’s practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor’s indirect costs for payment purposes).

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (g) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (d) of this clause.

(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor’s expense or at no cost to the Government shall be disregarded for purposes of cost-reimbursement under this clause.

(c) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(d) Final indirect cost rates. (1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (FAR) in effect for the period covered by the indirect cost rate proposal.

(2)(i) The Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor within the 6-month period following the expiration of each of its fiscal years. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer. The Contractor shall support its proposal with adequate supporting data.

(ii) The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause.

(5) Within 120 days (or longer period if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract, the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates.

(6)(i) If the Contractor fails to submit a completion invoice or voucher within the time specified in paragraph (d)(5) of this clause, the Contracting Officer may—

(A) Determine the amounts due to the Contractor under the contract; and

(B) Record this determination in a unilateral modification to the contract.

(ii) This determination constitutes the final decision of the Contracting Officer in accordance with the Disputes clause.

(e) Billing rates. Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates—

(1) Shall be the anticipated final rates; and

(2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(f) Quick-closeout procedures. Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(g) Audit. At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be (1) Reduced by amounts found by the Contracting Officer not to constitute allowable costs or (2) Adjusted for prior overpayments or underpayments.

(h) Final payment. (1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (d)(4) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver—

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except—

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

52.216-10 INCENTIVE FEE (MAR 1997)

(a) General. The Government shall pay the Contractor for performing this contract a fee determined as provided in this contract.

(b) Target cost and target fee. The target cost and target fee specified in the Schedule are subject to adjustment if the contract is modified in accordance with paragraph (d) below.

(1) "Target cost," as used in this contract, means the estimated cost of this contract as initially negotiated, adjusted in accordance with paragraph (d) below.

(2) "Target fee," as used in this contract, means the fee initially negotiated on the assumption that this contract would be performed for a cost equal to the estimated cost initially negotiated, adjusted in accordance with paragraph (d) below.

(c) Withholding of payment. Normally, the Government shall pay the fee to the Contractor as specified in the Schedule. However, when the Contracting Officer considers that performance or cost indicates that the Contractor will not achieve target, the Government shall pay on the basis of an appropriate lesser fee. When the Contractor demonstrates that performance or cost clearly indicates that the Contractor will earn a fee significantly above the target fee, the Government may, at the sole discretion of the Contracting Officer, pay on the basis of an appropriate higher fee. After payment of 85 percent of the applicable fee, the Contracting Officer may withhold further payment of fee until a reserve is set aside in an amount that the Contracting Officer considers necessary to protect the Government's interest. This reserve shall not exceed 15 percent of the applicable fee or $100,000, whichever is less. The Contracting Officer shall release 75 percent of all fee withholds under this contract after receipt of the certified

final indirect cost rate proposal covering the year of physical completion of this contract, provided the Contractor has satisfied all other contract terms and conditions, including the submission of the final patent and royalty reports, and is not delinquent in submitting final vouchers on prior years' settlements. The Contracting Officer may release up to 90 percent of the fee withholds under this contract based on the Contractor's past performance related to the submission and settlement of final indirect cost rate proposals.

(d) Equitable adjustments. When the work under this contract is increased or decreased by a modification to this contract or when any equitable adjustment in the target cost is authorized under any other clause, equitable adjustments in the target cost, target fee, minimum fee, and maximum fee, as appropriate, shall be stated in a supplemental agreement to this contract.

(e) Fee payable. (1) The fee payable under this contract shall be the target fee increased by 30 . [Contracting Officer insert Contractor's participation] cents for every dollar that the total allowable cost is less than the target cost or decreased by 30 [Contracting Officer insert Contractor's participation] cents for every dollar that the total allowable cost exceeds the target cost. In no event shall the fee be greater than 20 [Contracting Officer insert percentage] percent or less than . . . . . 0 . . . . .[Contracting Officer insert percentage] percent of the target cost.

(2) The fee shall be subject to adjustment, to the extent provided in paragraph (d) above, and within the minimum and maximum fee limitations in subparagraph (1) above, when the total allowable cost is increased or decreased as a consequence of (i) payments made under assignments or (ii) claims excepted from the release as required by paragraph (h)(2) of the Allowable Cost and Payment clause.

(3) If this contract is terminated in its entirety, the portion of the target fee payable shall not be subject to an increase or decrease as provided in this paragraph. The termination shall be accomplished in accordance with other applicable clauses of this contract.

(4) For the purpose of fee adjustment, "total allowable cost" shall not include allowable costs arising out of—

(i) Any of the causes covered by the Excusable Delays clause to the extent that they are beyond the control and without the fault or negligence of the Contractor or any subcontractor;

(ii) The taking effect, after negotiating the target cost, of a statute, court decision, written ruling, or regulation that results in the Contractor's being required to pay or bear the burden of any tax or duty or rate increase in a tax or duty;

(iii) Any direct cost attributed to the Contractor's involvement in litigation as required by the Contracting Officer pursuant to a clause of this contract, including furnishing evidence and information requested pursuant to the Notice and Assistance Regarding Patent and Copyright Infringement clause;

(iv) The purchase and maintenance of additional insurance not in the target cost and required by the Contracting Officer, or claims for reimbursement for liabilities to third persons pursuant to the Insurance Liability to Third Persons clause;

(v) Any claim, loss, or damage resulting from a risk for which the Contractor has been relieved of liability by the Government Property clause; or

(vi) Any claim, loss, or damage resulting from a risk defined in the contract as unusually hazardous or as a nuclear risk and against which the Government has expressly agreed to indemnify the Contractor.

(5) All other allowable costs are included in "total allowable cost" for fee adjustment in accordance with this paragraph (e), unless otherwise specifically provided in this contract.

(f) Contract modification. The total allowable cost and the adjusted fee determined as provided in this clause shall be evidenced by a modification to this contract signed by the Contractor and Contracting Officer.

(g) Inconsistencies. In the event of any language inconsistencies between this clause and provisioning documents or Government options under this contract, compensation for spare parts or other supplies and services ordered under such documents shall be determined in accordance with this clause.

(End of clause)

52.217-6 OPTION FOR INCREASED QUANTITY (MAR 1989)

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within 60 days . Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

(End of clause)

52.233-4 APPLICABLE LAW FOR BREACH OF CONTRACT CLAIM (OCT 2004)

United States law will apply to resolve any claim of breach of this contract.

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

LIST OF ATTACHMENTS

No.	Description	Date	No Pages
I	Contractor's Statement of Work	Apr 23, 2007 (with revisions dated August 10, 2007)	15

Exhibits — Contract Data Requirements List (CDRL) DD 1423

A001	Contractor's Progress, Status, and Management Report
A002	Contracts Funds Status Report (CFSR)
A003	Contract Work Breakdown Structure (CWBS)
A004	Integrated Master Schedule (IMS)
A005	Contract Performance Report (CPR)
A006	Regulatory Submission File
A007	Technical Data Package (TDP)
A008	Interim Program Review MS Powerpoint Presentation

CONTRACT DATA REQUIREMENTS LIST *(1 Data Item)*	*Form Approved* *OMB No. 0704-0188*

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY:
0001AA, 0001AB	A001	TDP _____TM _____OTHER _X_____

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
Reports	W9113M-08-C-0028	

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A001	Contractor's Progress, Status and Management Report		18. ESTIMATED TOTAL PRICE

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-MGMT-80227	C SOW paragraph C.4.4	MITS JPMO

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
Yes	No	Monthly	TBD
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
		Award Date	TBD

16. REMARKS

This report shall be submitted monthly. The Contractor's Progress, Status, and Management Report indicates the progress of the work, status of the program and of the assigned tasks. The report shall include cost updates, and information relating to existing or potential problem areas and proposed action to resolve the problems. (A draft report is due on the first Tuesday of the month. Issues and questions from the draft report will be discussed at a teleconference to be conducted on the second Tuesday of the month. A final report, with incorporated changes, corrections, and minutes of the teleconference, are due within a week following the teleconference.)

Address to: Joint Product Manager-Medical Identification Treatment Systems
(JPM-MITS)
64 Thomas Johnson Dr.
Frederick, MD 21702

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES Draft	Final Reg	Final Repro
MITS/COR	2	3	
See address in block 16			
15. TOTAL →	2	3	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
E. J. Wagar MAJ, U.S. Army	27 NOV 2007		NOV 27 2007

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CONTRACT DATA REQUIREMENTS LIST *(1 Data Item)*	*Form Approved* *OMB No. 0704-0188*

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY:
0001AD	A002	TDP _____TM _____OTHER _X_____

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
Reports	W9113M-08-C-0028	

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A002	Contract Funds Status Report (CFSR)		

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
DI-MGMT-81468	C SOW paragraph C.4.5	MITS JPMO	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
Yes		Quarterly	TBD

8. APP CODE	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION
	Award Date	TBD

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a. ADDRESSEE	b. COPIES Draft	Final Reg	Final Repro
MITS/COR	2	3	
See address in block 16			
15. TOTAL →	2	3	0

16. REMARKS

A draft CFSR (DD Form 1568) is due on the first Tuesday of the first month of a fiscal year quarter (federal fiscal year begins Oct 1). Issues and questions from the draft report shall be discussed at a teleconference on the second Tuesday of the month. This teleconference may be the same as for the Contractor's Progress, Status and Management Report, A001. A final report, with incorporated changes, corrections, and minutes of the teleconference, are due five working days following the teleconference.

Address to: Joint Product Manager-Medical Identification Treatment Systems
(JPM-MITS)
64 Thomas Johnson Dr.
Frederick, MD 21702

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
E. J. Wagar MAJ, U.S. Army	27 NOV 2007	EJWagar	NOV 27 2007

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A. CONTRACT LINE ITEM NO. 0001AA, 0001AB	**B. EXHIBIT** A003	**C. CATEGORY:** TDP _____TM _____OTHER X
D. SYSTEM/ITEM Reports	**E. CONTRACT/PR NO.** W9113M-08-C-0028	**F. CONTRACTOR**
1. DATA ITEM NO. A003	**2. TITLE OF DATA ITEM** Contract Work Breakdown Structure (CWBS)	**3. SUBTITLE**
4. AUTHORITY ***(Data Acquisition Document No.)*** DI-MGMT-81334B	**5. CONTRACT REFERENCE** C SOW paragraph C.3.3	**6. REQUIRING OFFICE** MITS JPMO
7. DD 250 REQ Yes	**9. DIST STATEMENT REQUIRED** No	**10. FREQUENCY** Monthly
8. APP CODE		**11. AS OF DATE** Award Date
12. DATE OF FIRST SUBMISSION TBD	**13. DATE OF SUBSEQUENT SUBMISSION** TBD	

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

16. REMARKS

The CWBS and the CWBS dictionary shall be updated quarterly. The revised CWBS and CWBS dictionary are due on the first Tuesday of the first month. Issues and questions from the CWBS will be discussed at a teleconference to be conducted on the second Tuesday of the month. This teleconference may be the same as for the Contractor's Progress, Status and Management Report, A001. A final report, with incorporated changes, corrections, and minutes of the teleconference, are due within a week following the teleconference. The Offeror shall extend the selected CWBS elements to define the complete contract scope. The CWBS will be to a depth and breadth necessary to accurately describe the Offeror's proposed effort, to a minimum of Level 4. The CWBS shall be structured to correlate with the Government's Statement of Objectives.

Address to: Joint Product Manager-Medical Identification Treatment Systems
(JPM-MITS)
64 Thomas Johnson Dr.
Frederick, MD 21702.

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a. ADDRESSEE	b. COPIES Draft	Final Reg	Final Repro
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See address in block 16			
15. TOTAL	2	3	0

G. PREPARED BY E. J. Wagar MAJ, U.S. Army	**H. DATE** 27 NOV 2007	**I. APPROVED BY** EJWagar	**J. DATE** NOV 27 2007

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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

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A. CONTRACT LINE ITEM NO. 0001AA, 0001AB	**B. EXHIBIT** A004	**C. CATEGORY:** TDP _____TM _____OTHER X
D. SYSTEM/ITEM Reports	**E. CONTRACT/PR NO.** W9113M-08-C-0028	**F. CONTRACTOR**
1. DATA ITEM NO. A004	**2. TITLE OF DATA ITEM** Integrated Master Schedule (IMS)	**3. SUBTITLE**
4. AUTHORITY ***(Data Acquisition Document No.)*** DI-MGMT-81650	**5. CONTRACT REFERENCE** C SOW paragraph C.3.3	**6. REQUIRING OFFICE** MITS JPMO

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

7. DD 250 REQ	**9. DIST STATEMENT REQUIRED**	**10. FREQUENCY**	**12. DATE OF FIRST SUBMISSION**
YES		Monthly	TBD
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
	NO	Award Date	TBD

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES Draft	Final Reg	Final Repro
MITS/COR	2	3	
See address in block 16			
15. TOTAL	2	3	0

16. REMARKS

The IMS shall be updated monthly. The revised IMS is due on the first Tuesday of the month. Issues and questions from the IMS draft report shall be discussed at a teleconference on the second Tuesday of the month. This teleconference may be the same as for the Contractor's progress, Status and Management Report, A001. The IMS shall be structured to correlate with the Statement of Objectives (SOO). A final report, with incorporated changes, corrections, and minutes of the teleconference, are due within a week following the teleconference.

Address to: Joint Product Manager-Medical Identification Treatment Systems
(JPM-MITS)
64 Thomas Johnson Dr.
Frederick, MD 21702

G. PREPARED BY	**H. DATE**	**I. APPROVED BY**	**J. DATE**
E. J. Wagar MAJ, U.S. Army	27 NOV 2007	EJWagar	NOV 27 2007

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CONTRACT DATA REQUIREMENTS LIST *(1 Data Item)*	*Form Approved* *OMB No. 0704-0188*

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing date sources, gathering and maintaining the date needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate {0704-0188}. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it do not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO.	**B. EXHIBIT**	**C. CATEGORY:**
0001AD	A005	TDP _____TM _____OTHER _X_____

D. SYSTEM/ITEM	**E. CONTRACT/PR NO.**	**F. CONTRACTOR**
Reports	W9113M-08-C-0028	

1. DATA ITEM NO.	**2. TITLE OF DATA ITEM**	**3. SUBTITLE**
A005	Contract Performance Report (CPR)	

4. AUTHORITY ***(Data Acquisition Document No.)***	**5. CONTRACT REFERENCE**	**6. REQUIRING OFFICE**
DI-MGMT-81466A	C SOW paragraph C.4.4	MITS JPMO

7. DD 250 REQ	**9. DIST STATEMENT REQUIRED**	**10. FREQUENCY**	**12. DATE OF FIRST SUBMISSION**
YES		Monthly	TBD
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
	NO	Award Date	TBD

16. REMARKS

The CPR shall be submitted monthly. The CPR shall contain Formats 1-5 containing data for measuring Contractors' cost and schedule performance. These reports shall be integrated with the CWBS (A003) and IMS (A004). A draft report is due on the first Tuesday of the month. Issues and questions from the draft report will be discussed at a teleconference to be conducted on the second Tuesday of the month. This teleconference may be the same as for the Contractor's Progress, Status and management Report (A001). A final report, with incorporated changes, corrections, and minutes of the teleconference, are due within a week following the teleconference.

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64 Thomas Johnson Dr.
Frederick, MD 21702

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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY	**H. DATE**	**I. APPROVED BY**	**J. DATE**
E. J. Wagar MAJ, U.S. Army	27 NOV 2007	EJWagar	NOV 27 2007

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A. CONTRACT LINE ITEM NO.	**B. EXHIBIT**	**C. CATEGORY:**
0001AA, 0001AB	A006	TDP _____ TM _____ OTHER _X_____

D. SYSTEM/ITEM	**E. CONTRACT/PR NO.**	**F. CONTRACTOR**
Reports	W9113M-08-C-0028	

1. DATA ITEM NO.	**2. TITLE OF DATA ITEM**	**3. SUBTITLE**	**17. PRICE GROUP**
A006	Regulatory Submission File		

4. AUTHORITY ***(Data Acquinition Document No.)***	**5. CONTRACT REFERENCE**	**6. REQUIRING OFFICE**	**18. ESTIMATED TOTAL PRICE**
DI-MGMT-81466A	C SOW paragraph C.3.1	MITS JPMO	

7. DD 250 REQ	**9. DIST STATEMENT REQUIRED**	**10. FREQUENCY**	**12. DATE OF FIRST SUBMISSION**
YES		As Required	TBD
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
	No	Award Date	TBD

16. REMARKS

This data package shall contain copies of Investigational New Drug (IND) submissions, annual reports, New Drug Application (NDA) submissions, and other communications with the U.S. Food and drug Administration (FDA). The data package shall also contain all FDA-initiated correspondence, to include meeting minutes, requests for additional information, etc. The preferred format for these regulatory documents is electronic. The Contractor shall send copies of regulatory documents to the Government at the same time they are sent to the FDA. Copies of regulatory communications received from the FDA shall be sent within three to five working days of receipt.

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A. CONTRACT LINE ITEM NO. 0001AF	**B. EXHIBIT** A007	**C. CATEGORY:** TDP _____TM _____OTHER X_____
D. SYSTEM/ITEM Reports	**E. CONTRACT/PR NO.** W9113M-08-C-0028	**F. CONTRACTOR**

1. DATA ITEM NO. A007	**2. TITLE OF DATA ITEM** Technical Data Package (TDP)	**3. SUBTITLE**	**17. PRICE GROUP**
4. AUTHORITY ***(Data Acquisition Document No.)***	**5. CONTRACT REFERENCE** C SOW paragraph C.3.4	**6. REQUIRING OFFICE** MITS JPMO	**18. ESTIMATED TOTAL PRICE**

7. DD 250 REQ	**9. DIST STATEMENT REQUIRED**	**10. FREQUENCY**	**12. DATE OF FIRST SUBMISSION**
Yes		One Time	TBD
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
	No	Award Date	TBD

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16. REMARKS

The Government shall direct preparation of a Technical Data Package that includes all necessary documentation and data for the Government, or its designee, to continue the development or production of the product. At any time the product ceases to be marketed and is retired or in the event the Contractor defaults and fails to remedy said default before or after approval, the Contractor shall transfer the TDP to the Government or its designee. The Contractor shall also assist in the technical transfer as determined by the Government. The draft TDP shall be grammatically and typographically correct. The corrected TDP with recommended changes made, is due within ten working days after receipt of the Government's comments.

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64 Thomas Johnson Dr.
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G. PREPARED BY	**H. DATE**	**I. APPROVED BY**	**J. DATE**
E. J. Wagar MAJ, U.S. Army	27 NOV 2007	EJWagar	NOV 27 2007

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A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY:
0001AA, 0001AB	A008	TDP _____TM _____OTHER X

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
Reports	W9113M-08-C-0028	

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE	17. PRICE GROUP
A008	Interim Program Review MS PowerPoint Presentation		

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE	18. ESTIMATED TOTAL PRICE
	C SOW paragraph C.4.5	MITS JPMO	

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
Yes		Quarterly	TBD

8. APP CODE	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION
	Award Date	TBD

16. REMARKS

A draft Microsoft PowerPoint presentation shall be submitted to the Government by the Contractor or Subcontractor ten days prior to the quarterly Interim Program Review. This gives the Government the opportunity to review the slides and present any changes to be made prior to the review with JPM-MITS.

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Solicitation Number: W9113M-07-R-0002

2.1 Statement of Work (SOW)

Osiris Therapeutics, Inc. is a stem cell company manufacturing adult-derived human mesenchymal stem cells (hMSCs) intended for "off-the-shelf" therapeutic use to repair tissue damage and reduce tissue inflammation. The lead stem cell product, Prochymal ™, is currently being tested in two Phase III clinical trials to treat Gastrointestinal (GI) Diseases (Graft versus Host Disease (GvHD) and Crohn's Disease). Both preclinical and clinical evidence suggest that Prochymal ™ could be used to repair GI damage from Acute Radiation Syndrome (ARS) to restore the anatomic integrity and normal physiological functioning of the GI tract. Data suggest that Prochymal ™ may impact overall survival because it is a cellular product that can repair tissue damage resulting from cell death, which is the hallmark of radiation exposure.

Osiris plans to develop a post-exposure Medical Radiation Countermeasure (MRC) that will increase survival and decrease incapacity of military forces so that these forces can maintain operational effectiveness within a contaminated area following radiation exposure, irrespective of radiation source. Osiris plans to develop the hMSCs product for treatment of GI-ARS through product approval/licensure with FDA and sell quantities of the MRC to the government sufficient to achieve the Initial Operating Capability (IOC).

Osiris has already met several of the work items listed in the Statement of Objectives. The work that has been completed has been included in this SOW for completeness; this completed work is indicated by italicized text.

INSERTED TEXT

A summary of Osiris' progress in completing sections C.3.1 (CLIN 0001AA) and C.3.2 (CLIN 0001AB) of the Statement of Work is provided in the table below.

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INSERTED TABLE

	SOO Paragraph	SOO Element	Completion Date
Solicitation Number W9113M-07-R-0002 CLIN 0001AA	C.3.1	IND Submission	**4Q 2007**
	C.3.1.1	Development & Qualification of Small Scale GMP Manufacturing Process	**COMPLETE**
	C.3.1.2	Manufacture GMP MRC for Toxicology Studies & Clinical Trial	**COMPLETE**
	C.3.1.3	Develop Product Formulations Suitable for Humans	**COMPLETE**
	C.3.1.4	Develop & Validate Product Characterization & Lot Release Assays for Large-Scale Manufacturing Process	**COMPLETE**
	C.3.1.5	Conduct GLP Acute Toxicology Studies	**COMPLETE**
	C.3.1.6	Carry Out Efforts to Ensure Successful Submission of IND Application	**4Q 2007**
	C.3.1.7	Support Submission of EUA	**2Q 2008**
	C.3.1.8	Conduct Phase I Clinical Trial	**COMPLETE**
	C.3.1.9	Store Phase I Product for Two Years	**COMPLETE**
	C.3.1.10	Carry Out Stability Testing for Phase I Product	**COMPLETE**
	SOO Paragraph	***SOO Element***	***Completion Date***
CLIN 0001AB	C.3.2	Conduct Activities Leading to FDA Approval	**3Q 2010**
	C.3.2.1	Qualification and Validation of Large-Scale GMP Manufacturing Process	**COMPLETE**
	C.3.2.2	Demonstrate Lot Consistency for Large-Scale GMP Manufacturing Process	**COMPLETE**
	C.3.2.3	Refine Product Formulation and Develop Delivery System Suitable for Human Use	**COMPLETE**
	C.3.2.4	Develop & Validate Product Characterization & Lot Release Assays for Large-Scale Manufacturing Process	**COMPLETE**
	C.3.2.5	Active Pharmaceutical Ingredient Stability Testing (2yr Interim Report)	**3Q 2009**
	C.3.2.6	GMP Formulated Product Stability Testing for Shelf Life (2yr Interim Report)	**3Q 2009**
	C.3.2.7	Operational Storage / Military Scenario Stability Studies	**4Q 2009**
	C.3.2.8	Nonclinical Studies to Support BLA Submission	**COMPLETE**
	C.3.2.9	GLP Animal Efficacy Studies	**2Q 2009**
	C.3.2.10	GCP Phase II Safety Clinical Study	**COMPLETE**
	C.3.2.11	BLA Submission	**1Q 2010**
	C.3.2.12	Delivery of 1 TED of FDA-Approved MRC	**4Q 2010**

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Osiris shall be the sponsor and remain the sponsor for so long as the product is marketed for the gastrointestinal component of ARS (GI-ARS). If the product ceases to be marketed for GI-ARS and in the event that Osiris defaults and fails to remedy said default, the sponsorship shall be transferred to the government to include all data related to GI-ARS product development and manufacture, as follows: upon written request from the Contracting Officer, Osiris agrees to immediately request approval, in writing, from FDA to effectuate transfer of the Investigational New Drug (IND) application and/or New Drug Application (NDA) Biological License Application (BLA) to the Government or its designee, and Osiris agrees to use its best efforts in obtaining such approval, including but not limited to, the execution of any and all documents which are reasonably necessary to effectuate such a transfer. In the case of where Osiris would be required to transfer sponsorship to the government, the government shall only use the technology for GI-ARS and shall not use the technology for other indications. All such transfers of technical data that may be required under this paragraph will be in accordance with relevant Federal Acquisition Regulations and terms of the final contract.

Human Mesenchymal Stem Cell Manufacturing Process Description

Osiris is providing a description of the manufacturing process flow to provide a reference point for statements made about manufacturing, stability testing, and product release testing in this SOW.

Figure 2.1-1 is an overview of the *ex vivo* cultured hMSC manufacturing process. The flow starts with the BMA, continues with the production of the Drug Substance (Donor cell bank, DCB, in-process intermediate), and ends with the generation of the Medicinal Product (Product dose, PD) shipped for use in clinical trials. The DCB is an in-process intermediate and a major in-process control for the overall manufacturing

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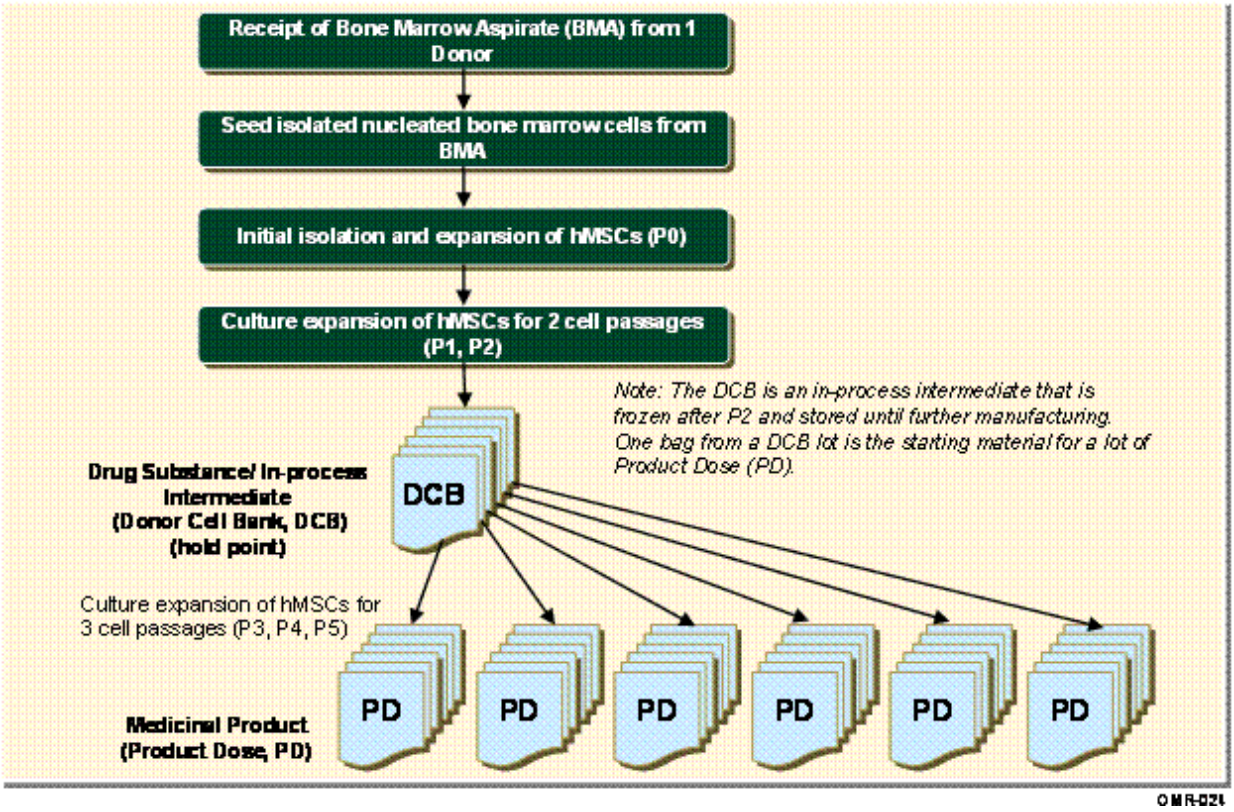

Figure 2.1-1. Overall Schematic of the Ex Vivo Cultured hMSC Manufacturing Process

process for making the PD. One single BMA can generate numerous PD lots. Please note that this is a representative diagram that does not reflect the actual number of DCBs and PDs generated during the manufacturing process.

1. **Donor Cell Bank, DCB** - The DCB is a process intermediate of cryopreserved, partially expanded hMSCs, representing the first two cell passages (P0→P1, P1→P2). The DCB is used as the starting material for Product Dose.

2. **Product Dose, PD** — The PD is the final packaged product, representing the three cell passages (P2→P3, P3→P4, P4→P5). The PD is ultimately released for distribution and use in clinical trials.

C.3. Contract Objectives

C.3.1. Investigational New Drug (IND)

Osiris shall provide all labor and materials to prepare and submit an IND for ARS. Osiris shall submit copies of regulatory documents to the government in accordance with CDRL A006.

Osiris has completed several INDs demonstrating a strong safety profile. These INDs will be used to support the IND for ARS. The IND designation and current clinical status for each investigational agent that supports the IND for ARS is given in Figure 2.1-2.

Prochymal™ is the product that is intended for use in treating ARS. The Prochymal™ formulation is identical to that of the development-stage Osiris product Provacel™. Both are intended for IV delivery. The current cryopreserved Chondrogen™ formulation is also identical to Prochymal™. However, further processing steps are required prior to Chondrogen™ use, and the agent is injected directly into the knee joint.

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Product Name	*IND Number*	*Disease Category*	*Indication*	*Clinical Status*
Prochymal™	BB-IND-7939	Immune	grade II-IV acute GvHD	Phase II completed
Prochymal™	BB-IND-7939	Immune	treatment refractory acute GvHD	Phase II completed
Prochymal™	BB-IND-7939	Immune	steroid refractory acute GvHD	Phase III initiated
Prochymal™	BB-IND-12770	Immune	Crohn's Disease	Phase II completed
Provacel™	BB-IND-10419	Cardiovascular	myocardial infarction	Phase I completed
Chondrogen™	BB-IND-10441	Orthopedics	meniscal repair (knee)	Phase I/II completed

OMR-025

Figure 2.1-2. Prochymal TM 's advanced regulatory approval status reduce the risk fo approval for its us in ARS

Osiris is far along in the clinical development of Prochymal TM with the completion of three Phase II human trials. Pivotal ARS animal trials following the animal rule are all that remain before product approval, as shown in Figure 2.1-3.

C.3.1.1. Conduct Small Scale Manufacturing for cGMP MRC

Osiris has completed small-scale process development and qualification for Prochymal™ and currently manufactures Prochymal™ for clinical trials in three cGMP compliant manufacturing facilities. This is the same product that would be used for treating radiation exposure.

The manufacturing process for ex vivo cultured hMSCs has been designed and implemented in a manner consistent with International Conference on Harmonization (ICH) and Food and Drug Administration (FDA)'s regulatory guidelines. Specific considerations are given to cGMP regulations (21 CFR Part 210 and 211) and practicing aseptic techniques as defined in Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - cGMPs. For the manipulation of human-derived tissue material, consideration is given to FDA policies on human-derived products: 21 CFR 1271 Human Cells, Tissues, and Cellular and Tissue Based Products and Guidance for the Submission of Chemistry, Manufacturing and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products (US Federal Register Docket No. 95N-0200).

CHANGE

"Rats" to "Small Animal"

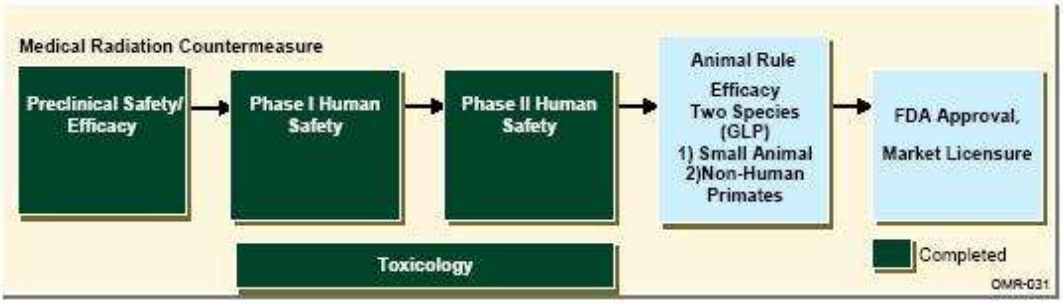

Figure 2.1-3. Osiris has completed the clinical development objectives for this contract through Phase II human trials. Pivotal minimal efficacy studies are all that remain for FDA approval

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C.3.1.2. Manufacture cGMP for Nonclinical Toxicology and Phase I

Osiris has completed the Phase I clinical trial that shall be used to support the ARS IND (see section C.3.1.8) Osiris has completed non-clinical toxicology studies that shall be used to support the ARS IND (see section C.3.1.5).

C.3.1.3. Develop Product Formulations Suitable for Administration in Humans

Osiris has completed development of a product formulation that is suitable for administration in humans and a delivery system that is suitable for military use. The final product formulation contains 100 x 10(6) viable hMSCs plus the following excipients: HSA, DMSO and PlasmaLyte-A ®. These excipients are required to maintain stable, viable cells through the freezing and thawing process. DMSO is a cryopreservative to assist in freezing. HSA is protein that acts a cellular stabilizer and provides protection from shearing forces in agitated cell culture systems. PlasmaLyte-A ® is an electrolyte solution that acts as the diluent. All of the excipients are compatible with the hMSCs. There are no novel excipients in the formulation.

At the final stage of production, the product is filled into bags and cryopreserved at the manufacturing facility. The product is then shipped to the clinical site where it is stored, thawed, diluted and administered intravenously.

Osiris shall continue product development efforts towards achieving ease of administration in an operational military environment (see section C.3.2.3).

C.3.1.4. Develop and Validate Analytical Assays For Small-Scale Lot Release

Osiris has completed development and validation of analytical assays for cGMP compliant product characterization and lot release. The lot release specifications were established in cooperation with FDA. The lot release specs are currently being used to release product for a Phase III clinical trial to treat GvHD. Lot release is performed on the in-process intermediate (Donor Cell Bank, DCB) and on the final product (Product Dose, PD). The lot release specs for DCB include tests for cell phenotype, potency, appearance, viruses, cell line species identity, karotyping, sterility, endotoxin and mycoplasma. The lot release specs for PD include tests for viability, cell phenotype, potency, appearance, sterility, endotoxin, and mycoplasma.

INSERTED TEXT

Osiris believes that the current potency assay used for product release of Prochymal™ for the treatment of GvHD is also relevant for use as a release assay for Prochymal™ for the treatment of ARS. Osiris will discuss the the utility of the TNFR release assay for product release for the ARS indication with FDA. In the event that FDA requires an alternate assay, Osiris will proceed with development of an ARS- specific release assay accordingly. For product release of animal MSCs for use in preclinical studies, Osiris will develop a corresponding assay targeting the analog molecular marker.

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C.3.1.5. Conduct Appropriate Nonclinical GLP Acute Toxicology Studies

Osiris has completed a GLP acute toxicology study to support Prochymal TM . This study was reviewed and verbally approved by FDA and shall support the BLA filing for Prochymal TM for ARS.

C.3.1.6. Perform Efforts to Ensure the Successful Submission of an IND

Osiris shall perform the necessary and appropriate efforts to assure the successful submission of an IND for ARS.

C.3.1.7. Support the Submission of an EUA with of Letters of Cross-Reference

Osiris shall support the submission of an EUA by preparation of letters that cross-reference the IND file and/or other regulatory documentation.

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C.3.1.8. Conduct Phase I Clinical Study in Accordance with FDA GCP

Osiris has completed a Phase I dose escalation clinical safety study in a relevant human subject population in accordance with FDA Good Clinical Practices (GCP). This was Osiris Protocol 401. Osiris Protocol 401 was a safety study testing hMSC treatment for people who had suffered an acute myocardial infarction (AMI). This Phase I study shall be used to support pivotal animal trials for Prochymal ™ -ARS. To date, Osiris has completed several clinical trials for IV administration of hMSCs and is currently conducting a Phase III clinical trial for treating GvHD (see Figure 2.1-2). IRB approval was necessary at all institutions that participated in the clinical trials.

INSERTED TEXT

Osiris believes the current safety profile for Prochymal™ will support a BLA filing for the use of Prochymal™ as an ARS therapy. However, Osiris will arrange a Type B meeting with FDA to confirm the sufficiency of current human safety data for an ARS BLA.

C.3.1.9. Store Phase 1 Product for Two Years Following Clinical Trial

INSERTED TEXT

Osiris shall store Phase I product under cGMP-controlled conditions for two years following the clinical trial. Osiris has stored Phase I product under cGMP-controlled conditions from a Phase I safety study completed in October 2001(Protocol 201).

Osiris' most recent Phase I safety study (Protocol 401) was completed in May 2006. Osiris shall store this product until May 2008.

C.3.1.10. Perform an ICH-Compliant Stability Testing Program

Osiris shall perform an ICH-compliant stability program on Prochymal ™ . The stability program is currently being reviewed by FDA and is planned to capture stability data for 30 months.

C.3.2. Conduct Activities Leading to FDA Approval of the Product

INSERTED TEXT

Osiris shall conduct activities to lead to FDA approval of Prochymal ™ for ARS. Osiris plans to file for approval under the animal rule. However, data collected in GLP animal studies will be supplemented with human data obtained in a Phase II clinical trial to evaluate the safety and efficacy of Prochymal™ therapy for the treatment of radiation-induced enteropathy.

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C.3.2.1. Scale-up Manufacturing Processes

Osiris shall scale-up the manufacturing process to achieve a cGMP compliant large-scale manufacturing process. *Osiris is currently scaling-up Prochymal ™ production to meet clinical trial demands. In order to meet clinical trial demands, and in preparation for eventual product marketing, Osiris has contracted outside manufacturing facilities to manufacture Prochymal ™*. More manufacturing facilities shall be contracted if necessary to produce product for this contract. Osiris shall conduct product comparability studies to demonstrate cGMP-compliant product comparability between contract manufacturers.

Presently, MSC manufacturing takes place at the following three GMP compliant manufacturing facilities.

1. ***Osiris Therapeutics, Inc.***
2001 Aliceanna Street,
Baltimore, MD 21231

2. ***Lonza Bioscience***
8830 Biggs Ford Road
Walkersville, MD 21793

3. ***AppTec***
4751 League Island Blvd.
Philadelphia, PA 19112

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FDA granted Osiris comparability approval for product manufactured at Osiris and at Lonza Bioscience.

Osiris shall conduct qualification and validation studies of the manufacturing process. These studies are currently underway to support licensure of Prochymal ™ - GvHD. The same manufacturing process shall be used for Prochymal ™ -ARS.

C.3.2.2. Manufacture cGMP Product Suitable for Expanded Nonclinical Safety Studies, Definitive Animal Efficacy Studies, and Phase II Clinical Trials

Osiris has completed non-clinical safety and toxicology studies. FDA has reviewed these studies and has deemed them acceptable for supporting a BLA filing for Prochymal ™ -GvHD.

Osiris shall contract out cell production for definitive animal efficacy studies.

Osiris has completed Phase II clinical trials that support the safety profile for Prochymal ™ .

Osiris has completed an FDA approved comparability study on consistency lots, which demonstrated comparability between Osiris and Lonza Bioscience cGMP manufactured product.

Osiris shall cooperate with the FDA Pre-Approval Inspection as required for product approval.

C.3.2.3. Refine and Select a Final Product Formulation Suitable for Military Use

Osiris has completed development of a product formulation that is suitable for administration in humans and a delivery system that is suitable for military use (see section C.3.1.3).

For the military setting, we foresee a scenario where the product would be stored in liquid nitrogen freezers at a secure location anywhere in the world. If a radiological situation were to occur, the product could be shipped to the treatment location. At the treatment location, the product could be thawed, diluted with an electrolyte solution using a syringe, and administered intravenously. There is no need for working in a sterile environment and there is no necessity for hospital beds. The bags of cells would just have to be thawed, spiked, diluted, and hung for intravenous delivery.

INSERTED TEXT

Osiris shall continue development efforts for improving product storage and delivery techniques. These activities will include studies to support alternate packaging and storage conditions appropriate for the military setting.

Study Cell Delivery Technique

Osiris shall test new techniques for transferring the product from the thawed product bag into the IV bag with minimal manipulation.

C.3.2.4. Develop and Validate Analytical Assays for Large-Scale Lot Release

Osiris has completed development and validation of analytical assays for cGMP compliant product characterization and lot release. The lot release specifications were established in cooperation with FDA. The lot release specs are currently being used to release product for a Phase III clinical trial to treat GvHD (see section C.3.1.4).

Lot release specifications shall be updated if required by FDA for the scale-up manufacturing process.

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C.3.2.5. Perform an ICH-Compliant Stability Testing Program on Bulk API

Osiris shall perform an ICH-compliant stability testing program on bulk API. The active pharmaceutical ingredient (API) for Prochymal ™ manufacturing is termed the Donor Cell Bank (DCB). An ICH-compliant stability protocol for DCB is currently under review with FDA.

Preliminary data from a development study suggest that DCB is stable for a minimum of 35 months under the storage conditions of ≤ -135° C.

C.3.2.6. Perform an ICH-Compliant Testing Program on Formulated Product

Osiris shall perform an ICH-compliant stability testing program on the cGMP formulated product from consistency lots produced from initial large-scale manufacturing to establish a shelf life for the product. The formulated medicinal product is termed Product Dose (PD). An ICH-compliant stability protocol for PD consistency lots is currently under review with FDA

Preliminary data from a development study suggest that the PD is stable for at least 18 months under the storage conditions of ≤ -135°C.

C.3.2.7. Stability Testing to Establish Operational Storage and Distribution Temperature Ranges and Extremes

Osiris shall conduct stability testing to establish operational storage and distribution ranges as well as temperature extremes. One major benefit of Prochymal ™ is that it can be administered several days after radiation exposure, and therefore does not need to be carried on the warfighter. The product can be shipped anywhere in the world within this dosing window. The product cannot be carried on the warfighter because it needs to be stored at ultra-low temperatures. Osiris suggests storing the product in remote liquid nitrogen freezers until a radiological incident occurs. When a radiation exposure occurs, the product would just need to be removed from remote liquid nitrogen freezers and shipped to arrive on site as soon as possible. Osiris requests assistance from the military in determining the optimal logistical plan for shipping the product following a radiological incident.

With the current envisioned logistical scenario in mind, Osiris shall perform studies to establish operational storage and distribution temperature ranges, as well as temperature extremes expected for use in the field.

Study 1. Shipping Stability

Osiris shall test product stability in shipping containers at temperature extremes.

Study 2. Product Stability After Thaw

Osiris shall test post thaw product stability at temperature extremes that are possible in a military setting.

C.3.2.8. Conduct Appropriate Nonclinical Studies in Accordance with GLP Regulations and Guidelines to Support Submission of a BLA/NDA

Osiris has completed appropriate nonclinical studies in accordance with GLP regulations and guidelines to support submission of a BLA for Prochymal ™ - GvHD. This nonclinical package shall be used for Prochymal ™ -ARS.

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On February 21 st 2007, FDA agreed that the package of preclinical studies submitted and underway was appropriate to support BLA for Prochymal ™-GvHD. The package of studies included acute infusional toxicity, cardiovascular safety, pulmonary safety, immunological study, ectopic foci formation, and biodistribution.

A technical hurdle exists for PK and absorption, distribution, metabolism, and excretion (ADME) studies for cell therapies. There is currently no good cell tracking technique. This topic has been addressed with FDA. Osiris' clinical and non-clinical studies shall support the submission of a BLA.

C.3.2.9. Conduct Necessary Definitive Efficacy Studies in Relevant Animal Models in Accordance with GLP Regulations and Guidelines

Osiris shall perform efficacy studies in relevant animal models in accordance with GLP regulations and guidelines. Osiris shall discuss these studies with FDA for product approval under the animal rule.

REPLACED TEXT
"Rats" to "small animal", studies include tissue repair.

Osiris shall perform the following studies:

1. Small animal studies using total body irradiation to evaluate survival and tissue repair in Prochymal™-treated and control subjects. GI data shall be analyzed.

2. Non-human primate survival study using total body irradiation. GI data shall be analyzed.

3. Non-human primate GI-efficacy study using targeted abdominal irradiation. This study shall only be conducted if targeted abdominal irradiation is needed for FDA approval.

C.3.2.10. Conduct a Phase II Expanded Safety Clinical Study in a Relevant Human Subject Population in Accordance with GCP

Osiris has completed two Phase II studies in relevant human subject populations in accordance with cGCP. The human subjects in these trials were people with GI damage resulting from GvHD. The damage to the intestinal mucosa from GvHD and irradiation is the same. IRB approval was obtained at all clinical sites involved in these clinical trials.

INSERTED TEXT

To further supplement data collected under the Animal Rule, Osiris will conduct a Phase II clinical study to explore the safety and efficacy of Prochymal™ therapy for treating normal tissue damage in the GI tract in patients that have received radiotherapy. This development strategy will mitigate risks associated with product approval under the Animal Rule. FDA representatives have recently commented publicly that, for products evaluated under the Animal Rule, supplementation of animal data with human data collected in clinical trials would be considered "highly valued".

C.3.2.11. Submit a NDA/BLA for FDA Review

Osiris shall prepare and submit a BLA for FDA review for treating ARS. Osiris has completed a Pre-IND meeting with FDA on February 26 th to discuss an ARS IND.

Osiris shall prepare and submit responses to requests for additional information from FDA during the review process.

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C.3.2.12. Deliver One Dose of the FDA-Approved MRC to the Government

Osiris shall deliver a minimum of one dose of the FDA approved countermeasure as part of CLIN 00001.

C.3.3. Prepare a SOW, IMS, CWBS, CWBS Dictionary, and Integrated Risk Management Plan

Osiris shall submit a SOW, IMS (CDRL A004), CWBS (CDRL A003), CWBS dictionary and Integrated Risk Management Plan for the proposal that encompasses the entire scope of the project. The IMS and CWBS shall be updated monthly. The CWBS elements shall define the complete scope of the contract to a breadth and depth necessary to describe the proposed effort to a minimum of Level 4.

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C.3.4. Prepare a Technical Data Package (TDP)

Osiris shall prepare a TDP (CDRL A007) solely for the use of Prochymal ™ to treat Acute Radiation Syndrome. This TDP shall include technical information pertaining to the manufacture, safety, and known efficacy of Prochymal ™ for the sole purpose of treating complications from Acute Radiation Syndrome.

C.3.5. Option: Prepare and Deliver a DMF

Osiris has completed a Master File with FDA for the ex vivo manufacture of human mesenchymal stem cells (MF-13146).

C.3.6. Option: Produce 50,000 — 500,000 Troop Equivalent Doses (TED) of the MRC

If the option is exercised by the government, Osiris shall produce no fewer that 50,000 and not to exceed 500,000 Troop Equivalent Doses (TED) of the MRC and shall deliver product to the government as directed.

C.4. General

C.4.1. Provide the Necessary Qualified Personnel, Facilities, Equipment, Supplies, Services, Subcontractors and Related Administrative and Information Technology Support

Osiris shall provide the necessary qualified personnel, facilities, equipment, supplies, services, subcontractors, and related administrative information technology support to accomplish the objectives.

C.4.2. Allow Access to Records Files and Other Data for FDA and/or MITS JPMO Audit

Osiris shall allow access to records, files, and other data derived from this work for the purposes of audit by the FDA and/or by MITS JPMO or its designees.

C.4.3. Allow the Government or its Designee to Audit the Contractor and/or its Subcontractor for Regulatory Compliance and Quality Assurance Purposes

Osiris shall allow the Government or its designee to audit Osiris and/or its subcontractors for regulatory compliance and quality assurance purposes.

C.4.4. Provide Monthly Contractor's Progress, Status and Management Reports

Osiris shall provide monthly Progress, Status, and Management Reports (CDRL A001) that describe progress made within the period, summarize projected vs. actual progress, report costs, and inform the government of existing or potential problem areas. Invoices shall be submitted during the report month. Osiris shall submit a monthly Contract Performance Report (CPR) in accordance with CDRL A005.

C.4.5. Provide Quarterly Contract Funds Status Reports Using DD Form 1568

Osiris shall provide quarterly Contract Funds Status Reports using DD form 1568. Osiris shall participate in a periodic teleconference in accordance with CDRL A002. Osiris shall submit a MS PowerPoint presentation for quarterly Interim Program Reviews in accordance with CDRL A008.

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C.4.6. Utilize an Earned Value Management (EVM) System Complying With The Criteria Provided in the American National Standards Institute/Electronic Industries Alliance (ANSI/EIA) Standard 748

Osiris shall use an Earned Value Management System (EVMS) recognized by the Administrative Contracting Officer (ACO) as complying with the criteria provided in American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) EVMS standard (ANSI/EIA-748), DoD 5000.2-R, Mandatory Procedures for Major Defense Acquisition Program (MDAPs) and Major Automated Information System (MAIS) Acquisition programs (DFARS 252.242-7001 and DFARS 252.242-7002) as well as the policy letter, "Revision to DoD Earned Value Management Policy" dated March 7, 2005.

Osiris shall hold an Integrated Baseline Review (IBR) to assess the realism and accuracy of the integrated performance measurement baseline. The IBR shall be initiated no later than 6 months from the contract award, the exercise of significant contract options, and the incorporation of major modifications or as otherwise agreed upon. Osiris shall provide monthly EVM reports.

C.4.7. Provide a Summary Report of Events That Will Cause More Than a Two Week Delay in Schedule or an Increase in Cost Estimate At Completion

Osiris shall provide a Summary Report within three working days of events that will cause more than a two-week delay in schedule, or an increase in cost Estimate at Completion.

C.4.8. Participate in Teleconference as Needed

Osiris shall participate in teleconference with the government when needed. Osiris shall provide minutes of the teleconferences within one week.

C.4.9. Employ an Automate Information System (AIS)

Osiris shall employ an automated information system (AIS) in accordance with electronic common technical document (eCTD) and ICH guidance for electronic data submissions to FDA.

Osiris currently submits all documents to FDA electronically through the secure electronic submission gateway.

Osiris shall allow MITS JPMO read only remote access via Osiris' AIS to clinical and non-clinical data pertaining to ARS following quality assurance review and acceptance.

C.4.10. Report All Contractor Manpower (Including Subcontractor Manpower) Required for Performance of this Contract

Osiris shall report all contract manpower (including subcontractor manpower) required for performance of this contract. Osiris shall completely fill in information using the Army data collection site at (URL: https://contractormanpower.army.pentagon.mil).

Osiris shall provide estimated total cost (if any) incurred to comply within this reporting requirement. The reporting period will be the period of performance not to exceed twelve months ending September 30 of the Government's Fiscal Year and must be reported by October 31 of each subsequent Fiscal Year.

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Exhibit 99.1

Osiris Therapeutics Awarded Department of Defense Contract for Prochymal™ Fully Valued at $224.7 Million

First award granted under Osiris - Genzyme partnership is aimed at protecting U.S. military from the lethal effects of acute radiation syndrome

COLUMBIA, MD – January 3, 2008 - Osiris Therapeutics (Nasdaq:OSIR) announced today that it has been awarded a $224.7 million contract, including purchase options, from the United States Department of Defense (DoD) to develop and stockpile Prochymal, an adult stem cell therapy, for the repair of gastrointestinal injury resulting from radiation exposure.

Under the terms of the contract, the DoD will provide funding to Osiris for the development of Prochymal for acute radiation syndrome (ARS) in two stages, with an initial amount of $4.2 million in 2008. Upon Food and Drug Administration approval for ARS, the contract provides for the purchase of up to 20,000 doses, at $10,000 per dose, of Prochymal in four 5,000 dose increments. Prochymal was selected by the DoD as part of an open and competitive solicitation with pre-specified criteria that included safety and efficacy data, manufacturing capacity, soundness of the development plan, and time to final product delivery.

"We are honored that the Department of Defense has selected Prochymal in this critical effort to better safeguard our armed forces against the potentially horrendous effects of battlefield exposure to a radiological weapon," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "The contract also brings into focus a substantial new market opportunity for Prochymal. We are working diligently towards licensure of Prochymal for ARS and stand ready to assist other sectors of the United States government and allied nations in their emergency preparedness efforts."

"Prochymal's unique mechanism of action and strong clinical profile make it very well suited to address the complicated injuries associated with ARS," said Major General John Parker, MD, (Ret.), former Commanding General responsible for countermeasure development and acquisition, and member of Osiris' Medical Countermeasure Advisory Board. "Currently, every scenario contemplating a radiological emergency, both civilian and military, involves people suffering from the life-threatening effects of ARS without effective treatments. Today's decision by DoD sets in motion a sound plan to change that, by expeditiously completing development of the first effective therapy for ARS."

Osiris and Genzyme Corporation (Nasdaq:GENZ) recently announced an agreement to jointly develop Prochymal for use by U.S. and allied nations for emergency preparedness. The Department of Defense decision to fund Prochymal marks the first award under this new partnership.

"We are pleased to partner with Osiris in developing this innovative cell therapy to treat the potentially lethal complications of ARS for the U.S. military," said Henri A. Termeer, Chairman and Chief Executive Officer of Genzyme Corporation. "With our combined first-in-class technology and development expertise, Osiris and Genzyme have the necessary resources to complete this assignment for the Department of Defense and to work with other governmental organizations committed to safeguarding our nation and its allies."

Prochymal is currently in Phase III clinical trials for the treatment of Graft vs. Host Disease and Crohn's Disease and a Phase II trial for type 1 diabetes. Prochymal has also demonstrated preliminary efficacy in the treatment of patients experiencing heart attacks. Prochymal has demonstrated a strong safety profile in 7 previous Phase I and II trials and has shown the potential to reverse cellular damage and improve survival in disease states similar to ARS.

"Prochymal represents a breakthrough in countermeasure development for ARS," said Thomas J. MacVittie, Ph.D., Professor of Radiation Oncology and Pathology at the University of Maryland and member of the NIAID Medical Countermeasures and CDC Strategic National Stockpile Radiation Working Groups. "Prochymal has demonstrated therapeutic utility in humans repairing many of the major organ systems affected by radiation injury. Where most approaches only target a single component of ARS, Prochymal has the potential to address the entire syndrome including both acute and delayed effects in multiple organ systems." Dr. MacVittie also serves as a member of Osiris' Medical Countermeasure Advisory Board.

About Acute Radiation Syndrome

Acute Radiation Syndrome (ARS) involves damage to DNA predominately affecting the rapidly dividing cells of the gastrointestinal (GI) tract, skin and the bone marrow. The clinical manifestation of ARS can be divided into four distinct stages: prodrome, latency, manifest illness, and recovery or death. Typically, the prodromal phase consists of GI symptoms that include abdominal pain, nausea, vomiting and diarrhea lasting 2 to 6 days. Depending on exposure, during the latent phase there is a brief abatement of symptoms as the patient appears to recover from the initial illness. However, within days to weeks, a hematopoietic (blood-forming) crisis ensues as a consequence of the depletion of both white blood cell and red blood cell progenitors within the bone marrow. The manifest illness is characterized by immunosuppression, fever and diarrhea. Victims can die within days to several months following initial exposure.

About Prochymal

Prochymal is a highly purified formulation of mesenchymal stem cells (MSCs) that are grown in culture, permitting large-scale production. The MSCs utilized in Prochymal are isolated from the bone marrow of healthy adult donors. Because the cells can be expanded, thousands of doses can be produced from a single donation. Numerous studies have demonstrated that the stem cells in Prochymal are able to facilitate tissue repair through a number of mechanisms. Specifically, MSCs are able to down-regulate severe inflammation, which is responsible for much of the tissue destruction that occurs as a result of radiation exposure. MSCs also work at the cellular level to rebuild damaged tissue through the coordinated release of tissue specific growth factors. Preliminary studies suggest that these characteristics are able to abate many of the complications of ARS.

Prochymal offers several unique advantages as a countermeasure for the treatment of ARS both for civilian and military populations. These include:

- **Flexible Treatment Paradigm** – Prochymal is intended for the treatment of patients post-exposure, even in those who are already exhibiting symptoms, eliminating the need for immediate administration in a predefined treatment window. This approach has the added benefit of not requiring biodosimetry.

- **Advanced Development Stage** – Prochymal has demonstrated safety and efficacy in 7 clinical trials, and has advanced into Phase III for three indications, each of which has been granted FDA Fast Track status. The product also has an established stability profile that permits long-term storage.

- **Large scale manufacturing** – Osiris has existing capacity at multiple manufacturing sites to mass produce large quantities of Prochymal under GMP conditions.

- **Multiple Applications** – Exposure to a radiological weapon can affect multiple organ systems, referred to as combined injury. Because MSCs are normally responsible for the repair of tissue injury in adults, Prochymal has the potential to address multiple aspects of ARS, including combined injury.

About Genzyme

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with more than 9,500 employees in locations spanning the globe and 2006 revenues of $3.2 billion. In 2007, Genzyme was chosen to receive the National Medal of Technology, the highest honor awarded by the President of the United States for technological innovation. In 2006 and 2007, Genzyme was selected by FORTUNE as one of the “100 Best Companies to Work for” in the United States.

With many established products and services helping patients in nearly 90 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopedics, cancer, transplant, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as immune disease, infectious disease, and other areas of unmet medical need.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is a leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Osiris currently markets and sells Osteocel® for regenerating bone in orthopedic indications. Prochymal™ is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease and also Crohn's disease, and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. Osiris has also partnered with Genzyme Corporation to develop Prochymal™ as a medical countermeasure to nuclear terrorism and other radiological emergencies. Prochymal is also being developed for the repair of heart tissue following a heart attack and for the protection of pancreatic islet cells in patients with type 1 diabetes. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for arthritis in the knee. Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. Osiris has developed an extensive intellectual property portfolio to protect the company's technology in the United States and a number of foreign countries including 47 U.S. and 215 foreign patents owned or licensed. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "ongoing," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project" or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Examples of forward-looking statements include, but are not limited to, statements regarding the following: our product development efforts; our clinical trials and anticipated regulatory requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for mesenchymal stem cells and biologic drug candidates; our cash needs; patents and proprietary rights; ability of our potential products to treat disease; our plans for sales and marketing; our plans regarding our facilities; types of regulatory frameworks we expect will be applicable to our potential products; and results of our scientific research. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section entitled "Risk Factors" in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission. Risk factors relative to the matters discussed in this press release also include risks of adverse changes in U.S. government spending priorities; failure to retain existing U.S. government contracts or to obtain option awards, task orders, or funding under contracts; risks of contract performance; risks of contract termination, either for default or for the convenience of the U.S. government; adverse results of U.S. government audits of our U.S. government contracts; and risks associated with complex U.S. government procurement laws and regulations. Accordingly, you should not unduly rely on these forward-looking statements. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this press release or to reflect the occurrence of unanticipated events.

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