Small Business Sources Sought Notice

This is a Small Business Sources Sought notice. This is **NOT** a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether there are small businesses; HUBZone small businesses; service-disabled sources; veteran-owned small businesses; 8(a) small businesses; veteran owned small businesses; woman-owned small businesses; or small disadvantaged business; and (3) their size classification relative to North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. **An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice.**
A determination by the Government not to compete this requirement as a set-aside based upon responses to this notice is solely within the discretion of the Government.
Interested parties are expected to review this notice and the draft Statement of Work to familiarize themselves with the requirement of this project; failure to do so will be at your firm's own risk.

Background:
The Pharmaceutical Resources Branch, Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) is seeking Offerors for the purpose of procurement and/or synthesis of bulk chemicals and drugs that are needed by the Developmental Therapeutics Program(DTP) for preclinical and clinical use. Assigned compounds are not readily available in the quality or quantity required from the original source, other suppliers or the open market. The compound could be known or new chemicals with a wide variety of chemical structures. Multi-step preparation sequences will generally be involved and process development for scale-up preparation will be expected using provided investigator's procedures. The quantity of a given material synthesized may range from multi-grams to multi-kilograms. All materials prepared will be fully characterized for high purity and the preparation cost will also be calculated. Most of the assigned projects should be performed under good manufacturing practices (cGMP) complied with the Food and Drug Administration (FDA) rules and regulations. The following MANDATORY QUALIFICATION CRITERIA must be met at the time of receipt of initial proposals by the Contacting Officer in order to be considered: (A) All Offerors shall be registered with the U.S. FDA as a manufacturer of bulk drugs; and (B) the facilities shall conform to the applicable regulations of the U.S. Environmental Protection Agency, Occupational Safety and Health Administration, U.S. Department of Transportation and those of state and local regulatory agencies.
All chemicals handled during the project should be considered to be potentially hazardous and/or toxic and, thus, should be handled accordingly. Offerors will be instructed to describe their safety program and their proposed approach for handling of hazardous and toxic agents. Submission of safety manuals will be required. In addition, Offerors must have facilities to handle cytotoxic agents because most projects involve preparation of potentially carcinogenic compounds (e.g. adequate air-handling systems).
It is expected that eight to twelve deliveries per year are expected to be completed excluding reports. Monthly progress reports describing work performed and annual project reports will be submitted, but additional reports may be required. Laboratory notebooks containing raw data should be maintained at the Contractor site for reviewing at the discretion of the Government. Prepared compounds are shipped to the NCI or the NCI repositories along with data sheets. Synthetic procedures and cost information should be submitted for each compound when available.

Purpose and Objectives:
The purpose of this Small Business Sources Sought Notice is to identify qualified small business concerns including HUBZone small businesses; service disabled, veteran-owned small businesses; 8(a) small

businesses; women-owned small businesses; or small disadvantaged businesses that are interested in and capable of performing the work described herein. The NCI does not intend to award a contract on the basis of responses received nor otherwise pay for the preparation of any information received.
As a result of this SBSS notice, the NCI may issue a Request for Proposal (RFP). THERE IS NO SOLICITATION AVAILABLE AT THIS TIME. However, should such a requirement materialize, no basis for claim against the NCI shall arise as a result of a response to this Small Business Sources Sought Notice or the NCI's use of such information as either part of our evaluation process or in developing specification for any subsequent requirement.
If a RFP is issued, the NCI anticipates multiple awards may result from the issuance of the RFP.

Project Requirements:

- Assigned compounds are not readily available in the quality or quantity required from the original source, other suppliers or the open market. The compound could be known or new chemicals with a wide variety of chemical structures.

- Multi-step preparation sequences will generally be involved and process development for scale-up preparation will be expected using provided investigator's procedures.

- The quantity of a given material synthesized may range from multi-grams to multi-kilograms.

- All materials prepared will be fully characterized for high purity and the preparation cost will also be calculated.

- Most of the assigned projects should be performed under good manufacturing practices (cGMP) complied with the Food and Drug Administration (FDA) rules and regulations.

Anticipated Period of Performance:
The period of performance for this requirement is five (5) years, consisting of a one year base period, and four one-year options. The anticipated state date is on or about March 31, 2012.

Other Important Considerations:
A copy of the draft Statement of Work (SOW), which is subject to revisions, may be accessed on the NCI Officer of Acquisitions Website at http://rcb.nci.nih.gov/ . Once there, click on Current Requests for Proposals.

NAICS Code and Size Standard:
In event an RFP is issued, the NAICS code is 54171 and a size standard of 500 employees.

Capability Statement/Information Sought:
Sources are expected to have the personnel, facilities, equipment, and experience to outline a strategy and propose the specifications for the purchase or synthesis of compounds not readily available in the quality or quantity required.
Tailored capability statements shall demonstrate a clear understanding of all tasks specified in the draft SOW, to include document understanding of the multi-step preparation sequences as outlined in the draft SOW. Tailored Capability Statements for this requirements shall also address the following areas:

1. Documented understanding of laboratory workflows;

2. Approach and documented history of multi-step preparation sequences;

3. Demonstrated knowledge of and ability to handle cytotoxic agents;

4. Ability to deliver 8 to 12 compounds per year;

5. Documented track record of senior personnel with experience to implement an effective synthesis;

6. Documented current facilities and equipment, capability and past experience in managing potentially hazardous and/or toxic materials;

7. Documented experience in the development and management of a project of this magnitude.

Information Submission Instructions:

1. **Page Limitations**: Interest qualified small business organizations should submit a tailored capability statement for this requirement not to exceed twenty-four (24) single-sided pages including all attachments, resumes, charts, etc. (single spaced, 12 point font minimum) that clearly details the firm's ability to perform the aspects of the notice described above and in the draft SOW. Tailored capability statements should also include an indication of current certified small business status. This indication should be clearly marked on the first page of your capability statement (preferably placed under the eligible small business concern's name and address) as well as the eligible small business concern's name, point of contact, address and DUNS number.

2. **Deliver Point**:

   All capability statements sent in response to this Small Business Sources Sought notice must be submitted electronically (via email) to Marrita Murphy, Contract Specialist, at murphymar@mail.nih.gov with a cc to MaryAnne Golling, Contracting Officer, at gollingm@mail.nih.gov in MS Word or Adobe Portable Document Format (PDF). The subject line must specify HHS-NIH-NCI-SBSS-TSB-17029-73. Facsimile responses will not be accepted.

3. **Common Cut-Off Date**:

   Electronically submitted tailor capability statements are due no later than 2:00 PM (Easter Prevailing Time) on Wednesday, August 17, 2011. CAPABILITY STATEMENTS RECEIVED AFTER THIS DATE AND TIME WILL NOT BE CONSIDERED.

DISCLAIMER AND IMPORTANT NOTES: This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organizations qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation notice may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation. Confidentiality: No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).

STATEMENT OF WORK

A. BACKGROUND and PROGRAM OBJECTIVES

The Developmental Therapeutics Program(DTP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI), supports the NCI's Experimental Therapeutics (NExT) and other programs to facilitate novel drug discoveries into clinical trials of new cancer therapeutic agents. One of essential parts of the program's mission involves the manufacture and supply of bulk chemicals/drugs that are prepared under the current Good Manufacturing Practice (c-GMP). The bulk materials will be used to support pre-clinical studies and to prepare clinical products that are necessary to support human clinical trials under the NCI sponsorship or investigator initiated Investigational New Drug Applications (IND).

The Pharmaceutical Resources Branch (PRB), DTP, DCTD, NCI is seeking Contractors that will provide services, personnel, equipment, and facilities as required to perform synthesis of bulk materials under c-GMP conditions. The quantity of a given material synthesized may range from multi-grams to multi-kilograms. The materials are of very high purity and well characterized. They are intended for formulation development, pharmacology, toxicology and clinical use.

The overall objective is for the preparation of bulk chemicals/drugs that are needed by the NExT and other programs. The required materials are not readily available in the quality or quantities needed from the original supplier or on the open market.

Major aspects of the contract work scope will include: (1) GMP process development to transform a laboratory scale to larger scale production ; (2) synthesis of bulk chemicals/drugs on multi-grams to multi-kilograms scale as needed; (3) analysis for ensuring the purity, identity and quality of the prepared compounds including QA/QC for the GMP batches; and (4) additional studies such as solubility/stability when required. Technical reports submitted by the Contractors may be used to support IND applications to the FDA.

B. DESCRIPTION OF WORK

The Contractor shall furnish all of necessary services, qualified personnel, materials, equipment, laboratory supplies, and facilities for scale up manufacture and analysis of GMP bulk materials as detailed below:

The Contractor shall:

1. Provide and operate material preparation facilities for:

    a) synthesis of varying amounts of materials either under laboratory, R&D and c-GMP conditions in the quantity and/or quality needed. The desired materials will involve a wide variety of well-characterized small molecules including short peptides and oligomers. The Project Officer will instruct priorities for preparation, standards of purity and quality specifications. The amount of any assigned preparation ranges from few gram to multi-kilogram quantities.

    b) process development or improvement of existing processes for scale-up or optimization of the processes. Methods of synthesis or literature citations will be available for many but not all assignments. Development of new and/or existing synthetic procedures and process development for scale up to large size lots will be frequently required.

    c) occasional assignment of preparation of gram quantities of research grade compounds of special interest to the DTP.

2. Provide pertinent analytical data to adequately assess purity, quality and identity of all materials prepared or purchased. The data should include elemental analysis, proton/carbon-NMR, MS, IR, UV, melting point, solubility, HPLC purity, residual solvents, etc, as requested by the Project Officer.

3. Retain and/or provide samples of synthetic intermediates prepared during the manufacture of target compounds in the amounts required by the Project Officer.

4. Prepare data sheets and description of preparative methods for all materials. The preparative methods shall be sufficiently detailed for filing with the FDA as bulk manufacturing processes. This includes details of sources, purities and lot numbers of all raw materials and solvents used, their acceptance data and quantities used. Detailed methodology including the reaction conditions, the isolation and purification procedures used for all intermediates and the target compound, and the acceptance criteria used for each should be provided.

5. Provide itemized costs of process development and preparation for each target material.

6. Deliver the materials, data sheets, preparative methods, and cost information in accordance with the instructions of the Project Officer. Material Safety Data Sheet (MSDS) for the material should be prepared and included with all shipments to the Government's repositories or other facilities as instructed by the Project Officer.

7. Additionally, upon specific instructions from the Project Officer, the Contractor shall:

    a) Procure, purify (if necessary) and characterize substances from commercially available sources.

    b) Perform preliminary stability, solubility and characterizations of materials produced or procured by the Contractor or by the Government.

c) Conduct preliminary stability or safety studies in the handling and storing of substance accepted as an assignment. The Contractor shall provide the necessary data as a guide for the proper handling and storage of such substances.

d) Prepare analytical reference standards if requested by the Project officer.

8. Provide cost estimate and lead time required for performance and completion of each assignment.

9. Comply with c-GMP regulations for bulk production and Government health and safety regulations:

a) FDA requirements

The Contractor shall be registered with the FDA as a manufacturer of bulk drugs. Facilities shall meet FDA standards in accordance with c-GMP regulations. If inspections by the FDA during the term of the contract cite deficiencies which are not addressed satisfactorily to the FDA in timely manner, such citations could be the basis for termination of the contract.

b) OSHA, EPA and DOT regulations

The Contractor shall comply with all Occupational Safety and Health Administration (OSHA) and Department of Transportation (DOT) regulations. The Contractor shall comply with all Environmental Protection Agency (EPA) regulations regarding the discharge of water and air pollutants and assure that disposal of all chemical residues meet current EPA regulations.

10. The chemicals and drugs to be prepared or handled under this contract are to be regarded as proprietary in nature. Under no circumstances are chemicals or drugs or any information associated with these chemicals or drugs to be released or divulged to the public without prior written approval of the Project Officer.

11. Under certain conditions, the Contractor may be eligible for filing for patent protection to protect any inventions that they may have made during the course of their contract performance. When the drug comes from an external collaborator with the NCI the collaborator's original discovery needs to be protected.

C. EXPERIMENTAL PROCEDURES AND GUIDELINES

The desired materials will involve a wide variety of compounds. Methods of synthesis or literature citations will be available for many but not all assignments. Development of new and/or existing synthetic procedures and process development for scale up to large size lots will be frequently required.

All materials submitted must be analyzed and checked for identity and purity by accepted procedures. HPLC analytical method for GMP materials may be provided by the NCI when it is available. Projects and the priorities are assigned by the Project Officer consistent with the needs of the drug development program. Since this is a very dynamic and continually changing process, an advance list of the assignments which may be made to the Contractor is not available. The Project Officer continually makes new assignments as needed consistent with the availability of technical labor hours, skills of the Contractor, and the complexity of each project. All materials produced or procured shall be accounted for, will remain Government property, and shall be delivered and distributed only as directed by the Project Officer. Organizations will not be permitted to scale up preparations of assigned materials for commercial purposes without prior written approval of the Project officer. Appropriate laboratory safety controls and procedures must be followed in carrying out the activities of this project. Unexpected events, such as accidents resulting in loss of work time greater than one day, rashes, changes in personnel, etc., should be reported within 48 hours to the Project Officer.

D. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use in humans without the prior written approval of the Project Officer.

E. CONFIDENTIALITY INFORMATION

All data provided to the Contractor and developed by the Contractor under this contract must be treated confidentially. When compounds are assigned to the Contractor, "discreet" compounds will be identified by the letter "D" as a prefix to the compound's NSC number. Under no circumstances are chemicals or drugs or any information associated with these chemicals or drugs, including data generated under this contract can be released to the public without prior written approval of the Project Officer.

F. TRAVEL REQUIREMENTS

The Principal Investigator or a designated staff scientist will be permitted to attend one relevant scientific meeting per year with prior approval of the Contracting Officer. Any other technical trips to be charged to the contract must also have prior approval by the Contracting Officer. Estimates for any anticipated travel of this type should be shown in the cost section of the Proposal.

G. WORK ASSIGNMENTS

Work assignments (WA) will be issued under cost-reimbursement, completion-type contracts resulting from this solicitation. Work assignments will be initiated by the Project Officer, who will forward a request (see Part I in WA form) to the Principal Investigator stating the period of performance, the specific work to be performed, and deliverables. Within the specified period, the Contractor will submit to the Project Officer a detailed description of the technical approach to be used in carrying out the work assignment, and an estimate of the required effort and cost (see Part II in the WA form). With the concurrence of the Project Officer and approval of funding, the Contracting Officer will then execute the work assignment. No later than one month after completion of the work assignment, the Contractor shall forward to the Project Officer a work assignment completion report (see Part III in the WA form) providing a listing of the actual labor and cost for the work assignment and the stated deliverables. Upon the recommendation of the Project Officer, the Contracting Officer will then approve the work assignment for completion.

At the time of award of a contract, an administrative work assignment shall be initiated for the first year of performance. This work assignment will cover the effort and expenditures necessary for administration of the contract (other that the conduct of specific assigned project). Tasks specifically applicable to the administrative work assignment will consist of and be limited to: (1) preparation of responses to subsequent work assignments; (2) preparation of monthly reports; (3) preparation of final work assignment reports, technical reports, annual reports, and final contract reports; and (4) allowable miscellaneous expenditures.

WA Form Part I, II and III

CONTRACT WORK ASSIGNMENT (W.A.)

Contractor:_____

W.A. Title:_____

Contract No:_____

W.A. No:_____ Modification No.:__0___ W.A. Originator:_____.

Contracted Task Area:_____ Date Prepared: _____

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Part I. INITIATOR'S REQUEST

A. Period of Performance: See the contractor's proposed period of performance
B. Task Description

C. Task Leader :

D. Deliverables :

E. W.A. Response Due Date: ASAP

CONTRACT WORK ASSIGNMENT (W.A.)

Contractor:_____ Contract No:_____

W.A. No: _____ Modification No: ____ Date Prepared:_____

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PART II. CONTRACTOR'S RESPONSE TO W.A. REQUEST

(The Contractor may attach additional sheets to this form to present requested data.)

A. Estimated Cost and Effort

1. Labor hours - list W.A. leader, specific individuals to be assigned, labor category, and estimated hours for each.
2. Labor costs - list by labor category and total.
3. Employee benefits.
4. Direct materials
5. Travel
6. Subcontracts
7. Other direct costs
8. Indirect costs
9. Total estimated costs for this Order

B. Detailed description of the approach to be used and of the deliverable(s). (Be specific.)

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APPROVAL TO PROCEED: The Contractor shall not exceed the estimated labor hours, estimated W.A. amount, or change the W.A. leader without the prior written approval of the Project Officer and the Contracting Officer.

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l. For the Contractor: _____ Date:
(Signature)

Typed name:

2. For the Government: _____ Date:
(Project Officer)

_____ Date:
(Contracting Officer)

CONTRACT WORK ASSIGNMENT (W.A.)

Contractor:_____ Contract No:_____

W.A. No:_____ Modification No: ____ Date Prepared:_____

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PART III. CONTRACTOR'S REPORT OF W.A. PERFORMANCE

(The Contractor may attach additional sheets to this form to present the requested data.)

A. Actual Cost and Effort

1. Labor hours - list specific assigned individuals, labor category, and actual hours worked.
2. Labor costs - list labor category, individual, and total amount.
3. Employee benefits
4. Direct Materials
5. Travel
6. Subcontracts
7. Other direct costs
8. Indirect costs
9. Total costs for this W.A.

B. Report of Deliverables

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REVIEW AND APPROVAL OF SATISFACTORY PERFORMANCE

The signatures below indicate that the services/products required under Work Assignment No. __ have been delivered, received and satisfactorily meet the requirements of this Work Assignment.

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l. For the Contractor: _____ Date:
(Signature)

Typed name:

2. For the Government: _____ Date:
(Project Officer)

_____ Date:
(Contracting Officer)

H. ESTIMATE OF EFFORT

It is anticipated that multiple awards of cost-reimbursement, completion-type contracts will be made for a period of one year with four option years as a result of this RFP. Each increment for these contracts will be for a period of 12 months.

To assist you in the preparation of your proposal, the Government considers the effort required to be approximately 9,375 hours per year. The estimate would be 5.0 full time equivalents (FTE) per year with completion and deliveries of the material targets of 10 to 15 assignments. A staff year is 1875 hours of direct labor per year excluding holidays and sick leaves. A direct cost for materials is estimated at approximately $ 25,000 per staff year.

A breakdown of the Government's estimated effort per year is as follows:

Labor category	Estimated hours per year
Principal investigator*	937.5 hours (0.5 FTE)
Professional (Senior staff) - Synthesis	3,750 hours (2.0 FTE)
Professional (Junior staff) - Synthesis	3,750 hours (2.0 FTE)
Other support **	937.5 hours (0.5 FTE)
Total hours per year	9,375 hours
* See Personnel section under Attachment # 15 ** Administration, Analysis including quality units, and etc.	

Your cost proposal should be based on the Government's estimated effort in each labor category accordingly. For clarification, senior staffs and junior staffs are professional scientists with Ph.D. degree and MS or lower degree, respectively.

PERIOD OF PERFORMANCE

It is anticipated that award will be made for a period of incrementally-funded one year with option for yearly extension up to four more years and these contracts will commence on approximately April 1, 2012.