



**REQUEST FOR PROPOSALS TO PARTNER (RFPP)**

WITH

**THE SICKLE CELL CURE FOUNDATION, INC. (SCCF)**

**A NON-PROFIT BIO-MEDICAL RESEARCH FIRM**

**TO CONDUCT TRIALS OF ITS PATENTED CURE**

FOR

**SICKLE CELL ANEMIA**

**A GLOBAL PLAN FOR A GLOBAL DISEASE**

THAT

**SUPPORTS SCCF MANAGEMENT**

AND

**STRENGTHENS ITS FINANCES**

*Electronic Response Deadline: August 6, 2009*

## **Abstract - United States Patent # 7,517,669 Issued April 14, 2009**

A method is described for regulating gene expression related to iron metabolism to ameliorate diseases that include sickle cell, cancers, neurodegenerative diseases, Friedreich's ataxia, and other neuromuscular disorders, and atherosclerosis. This approach is illustrated by recent findings that show that ferritin-H, an iron-binding protein that is present in cell nuclei can repress the human  $\beta$ -globin gene, the gene that is mutated in sickle cell disease. Increased expression of ferritin-H or a related ferritin-family peptide, given to mutated cells either as the peptide itself (or a part thereof), as an expression clone of the ferritin-H-subfamily gene, or via a gene regulator that increases expression of the ferritin-H-subfamily gene itself, prevents or ameliorates expression of the disease state in disorders where increased availability of iron is implicated in the etiology of the disease, including those named above.

[Underlined text presents the essential argument and finding.]

## **Sommaire du Brevet No. 7,517,669 des Etats-Unis Emis le 14 avril 2009**

Une thérapie est décrite pour régler l'expression génétique afférant au métabolisme de fer afin d'améliorer les symptômes des victimes de certaines maladies telles que la drépanocytose, des cancers, des maladies neurodégénératives, l'ataxia de Friedreich, autres désordres neuromusculaires, et l'athérosclérose. Des découvertes récentes illustrent que cette thérapie à base de la ferritine-H, une protéine qui fixe le fer et qui se trouve dans les noyaux des cellules, peut réprimer le gène humain  $\beta$ -globine, le gène qui porte la mutation drépanocytaire. L'expression accrue de la ferritine-H ou d'une peptide liée à la famille des ferritines, donnée aux cellules mutées -- soit sous forme d'une peptide (ou d'une partie en conséquence), soit comme une expression clone du gène de la sous-famille ferritine-H, soit par voie d'un gène régulateur qui fait accroître l'expression du gène de la ferritine-H lui-même empêche l'expression ou améliore les symptômes des maladies dans les cas où une disponibilité accrue du fer est impliquée dans leur étiologie y compris les désordres cités en haut.

[Le texte souligné présente l'essentiel de la chaîne de raisonnement et la découverte.]

## “DREPAVIE” CHAT BOX EXCERPTS - SEPTEMBER 2008

Hello everyone. I'll soon be 22. My mom and dad are Greek and Camerounian. My husband comes from Guadeloupe. Our sweet little angel has just turned 20 months. He inherited both SS genes from us despite our two very different backgrounds.

Never in my wildest imagination did I think such an illness existed hidden inside us. The Apocalypse has arrived in my family. Everything changed after our little boy's first month. He's already taking blood transfusions to keep his numbers in the proper range. It is really very difficult to see nurses coming at your child with needles. He is totally traumatized.

He screams out, but there's nothing we can do. Since birth he's had to be admitted to the Nantes Hospital --- often in reaction to the standard battery of childhood immunizations which his weakened immune system cannot tolerate. I'll never forget that landmark day when at his one-year old birthday "party" he seemed so sleepy and tired, that I let him take a nap. I had to wake him. As I lifted him up into my arms, he felt like a limp cat. Hospitals frighten me: needles, oxygen masks.

Emergency facilities were all brought to bear on this child who seemed like no more my own. His numbers were low and wrong. I overheard the doctors saying that "She hadn't done him in, yet." What a horror to realize that my personal fears had almost killed my son. I'm so sad. This illness never ends. Lots of fresh, cool water seems to be the only comfort we can offer. I can't work to bring in much needed money. What do they expect me to do? Leave a two-year old locked in the apartment? If only my big family were here to help us. I can't stop crying.

When I think of my son's future, all I see is excruciating pain and death. They say there's force in numbers. What can we do to fight back? I guess joining this chat-box is the first step. Please help me, anyone.

Contribution by a young mother.

You gotta drink two big glasses of water per day, even three. When I'm feeling good and forget I have sickle cell, I can easily slip into a crisis mode and cause a lot of heart ache. You've gotta be careful to avoid crises. The pain can rock and roll between your knees and arms and just attack the hell out of you. Morphine shots have no effect. You can't stop the pain once it gets started. Most hospitals won't even admit you until your pain exceeds "7" on their pain scale.

I tire very fast when playing soccer. My eyes turn yellow. I just promised I'd make a big contribution to the sickle cell disease telethon this year. I hope they hurry up and find the cure. I hate this fucking disease.

Teenager's contribution to Drepavie.

## **CRITICAL DATES GOVERNING THE RFPP**

Proposals will be received and evaluated

during National Sickle Cell Month

September, 2009

Saturday June 20, 2009 --- SCCF issues RFPP at SCCF website  
on "First World Sickle Cell Disease Day"

Wednesday August 19, 2009 --- Deadline for potential partners to submit  
letters of intent (LOI) and pose questions

Tuesday Sept. 1, 2009 --- Deadline for potential partners to submit  
proposals electronically.

Wednesday Sept. 30, 2009 --- SCCF and highest ranked offer(s)  
conclude partnership agreement for Stages 4  
and 5 (incl. clinical Phases I and II) management  
and funding

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## REFERENCES

- A. World Health Organization. Executive Board 117/Recommendation 3 on Sickle-Cell Anemia January 23-28, 2006.
- B. Sources, References, and Footnotes: General and Critical. SCCF Business Plan. August 2008.
- C. European Union Approved Patent Application EP1-724-339-A1 Gene Regulation Therapy Involving Ferritin, 26-Jul-06 (initially issued in 10 countries).
- D. Thérapie de Régulation Génique Comprenant la Ferritine. Le Bulletin Européen des Brevets No. 06/32. le 9 août 2006.
- E. United States Patent No. 7,517,669. "Gene Regulation Therapy Involving Ferritin" issued April 14, 2009.
- F. Proceedings of the National Academy of Sciences, USA. Vol. 98, pages 9145 -9150 (31 July 2001).
- G. Radio Interview. 10 KTOK AM. Oklahoma City, OK. April 11, 2009.  
(Double click the icon below and wait ten seconds to listen to the 20-minute embedded radio interview.)



Broyles-KTOK  
Interview 18-Apr-09.

## I. INTRODUCTION

### The Challenge – Disease Burden:

Every day a thousand infants are born with full-blown sickle cell disease (SCD). Many will die before their second birthday, most before age 5, totaling approximately 350,000 deaths per year. Today over 107,000 SCD survivors - almost exclusively in Europe and North America - receive “standard” SCD treatment at an average cost of \$14,000/year only to die an early death at age 42-45 after decades of agony.

SCD is a global problem. About 5% of the world’s population carries the recessive sickle gene. In 2006, the Executive Board of the World Health Organization urged its member states to increase awareness of SCD, to develop technical protocols for treatment, and to encourage ongoing research. (Reference A)

As the most common genetically transmitted disease in the world and the first disorder to have its cause traced to the molecular level, SCD touches the lives of millions. “Sickle cell disease is by far the most common genetic disease in France with over 300 symptomatic newborns each year.” (<http://www.viva.presse.fr> 9/9/2008) Yet, in Burkina Faso, a poor, land-locked country with only 20% the population of France, an estimated 14,000 newborns present with SCD symptoms each year (Appendix B - Global Report on Birth Defects, March of Dimes, 2006 as manipulated using United Nations World Population Prospects, 2006.) People of at least five racial groups and numerous ethnic origins carry the recessive sickle gene. Classified as a “tropical” disease, it is most common among populations living in the malaria belt that encircles the globe in the lower latitudes.

SCD occurs most frequently in Africa (which has about 75% of the cases), in Mediterranean countries, in the Middle East, and in India, with significant numbers in the Caribbean, Brazil, and Oceania. Migrations of people from these regions have resulted in significant numbers of SCD sufferers in the temperate zones: North America, South America, and Europe.

The prevalence and continued high incidence of sickle cell is due in large part to resistance to the chronic effects of malaria that is conferred by the presence of sickle hemoglobin in the red blood cells of asymptomatic carriers.

Compared to non-carriers, healthy carriers of recessive genes for sickle cell anemia, thalassemia, and G6PD deficiency have a well-documented survival advantage against the lethal effects of malaria. As a result, asymptomatic carriers are more likely to reach reproductive age. Over time, this has led to an increase in the population prevalence of these genes in tropical regions (Gilles and Warrell, 1993). March of Dimes. Global Report on Birth Defects, p. 21.

However, the benefits of carrying the recessive sickle trait come at a very high price for those who inherit two copies of the sickle gene – one from each parent. In such cases, SCD is a devastating disorder. It brings with it pain “crises” that are frequent and often severe. As SCD progresses, it impacts the proper functioning of major organs and imposes limitations on the daily lives of sufferers and their families. In the Third World short on comprehensive medical care, a diagnosis of SCD is a death sentence that terminates life early, often within the first two years.

### The Response:

The Sickle Cell Cure Foundation, Inc. (SCCF) is committed to alleviating this terrible disease in as many sufferers as can be reached. SCCF has a **global** plan for distribution of the cure at a cost that 80% of the sufferers in the world can afford without subsidy. The plan combines safety and clinical trials with a cost-effective business plan that includes a “north-south” dialogue and “west-east” cross subsidies from advanced economies to economically less affluent regions in such a way that all victims may receive the “cure” at a cost much lower than what the affluent now pay for inferior, “standard” treatments.

The cure for SCD is genetically based, non-invasive, and molecular. To date it has no observed side effects, is 100% effective, and is expected to cost far less than the price of today’s standard care. Presentations to the world’s scientific community are noted in Reference B, the SCCF Business Plan, available at the SCCF website, e.g., attached PDF of the 11 June 2009 talk at the IBIS World Congress, Porto, Portugal, including 30 countries.

### Scientific Basis for the Cure and Addressing Credibility Issues:

SCD has attracted its share of charlatans. It has weathered many a false start. In the wake of broken promises, parents and research colleagues have grown suspicious. In fact, disbelief and denial have come to characterize the SCD community in North America. Families of victims ask, “Sure. Your ‘cure’ may work in theory, but does it work in practice?” Medical colleagues remind us, “Just because it works in the laboratory doesn’t mean it’ll work in the real world.” SCCF welcomes such expressions of doubt. They form the scientific basis for responsible medical research: independent replication, peer review, and clinical trials.

The message is simple. ***In nature, fetal hemoglobin (HbF) has been shown to prevent sickle cell disease.*** Many laboratories around the world in many repeated experiments and patient trials have over the last 30 years confirmed this fact. Yet, with a few noteworthy exceptions, most newborns cease HbF production by the 12<sup>th</sup> month of life in favor of “adult” hemoglobin.

It is a known fact that newborns with sickle cell present no symptoms during their first 3 to 4 months of life precisely because residual HbF protects them by blocking the polymerization of hemoglobin S which causes the rigidity of red blood cells.”  
(Dr. Dora Bachir. “Les Nouveaux Traitements de la Drépanocytose”,  
[http://asso.oepha.net/SOSGLOBI/cgi-bin/pages/HYDREA\\_DR\\_Dora-Bachir.php](http://asso.oepha.net/SOSGLOBI/cgi-bin/pages/HYDREA_DR_Dora-Bachir.php).)

The challenge has been how to re-stimulate HbF production in humans without irreversible gene therapy, a bone marrow/stem cell transplant, or the use of toxic drugs - all of which are dangerous, expensive, and available to only 1% of the world's SCD sufferers in any event – hardly a “standard” to emulate. In 2006 Dr. Broyles demonstrated how to activate and sustain the HbF “trigger” – a discovery that forms the operational basis for the SCCF project. The foundation’s discovery provides **a phenotypic “cure” for SCD and may also confer a resistance to malaria** in so far as it promotes HbF production.

The effective cure involves ferritin-heavy chain (FtH), a protein that occurs naturally in the body. It has been shown to deactivate the mutant sickle cell gene and to reactivate a dormant, healthy replacement gene. Yet, FtH does not permanently alter the genes. The cure addresses the embedded genetic cause of SCD – not its external symptoms. The cure is specific to the ailment and easy to administer. Quite stable, FtH requires no refrigeration. Thus, FtH should be easier to market and distribute in tropical, developing countries where electrical service and distribution systems can be unreliable but ironically where over 90% of SCD sufferers reside. The drug’s detailed identification, its mode of application, and salutary effects described in References B, E, and F are unique, proprietary, and patent-protected.

## II. STAGES 1, 2, AND 3 ACHIEVEMENTS

We use the term “Stage” with Arabic numerals to indicate progressive steps leading to commercialization. The term “Phase” with Roman numerals corresponds to the three major steps in bio-medical inquiry: Phase I - human safety trials, Phase II human efficacy trials, and Phase III large-scale field testing leading to licensing. See Attachment 3 – Illustrative Budget Layout.

**SCCF has found a safe, low-cost way to induce the fetal HbF switch.** A natural, small, stable human protein has induced the HbF switch in many settings: in test tubes, in living primate and human cells, in transgenic mice carrying and expressing the human ferritin-H gene, and in formative red blood cells donated from pediatric sickle cell patients.

All in all, SCCF collaborators have performed almost 200 experiments of 50 different types/designs with each experiment replicated two to ten times by two, three, or even five different investigators. All the experiments consistently point to the same conclusion: adult hemoglobin production can revert to fetal hemoglobin production – at least partially --thereby wiping out the symptoms of SCD. SCCF has even devised four ways to deliver this cure! During Stages 1, 2, and 3, this discovery was patented in 13 countries: Albania, Australia, Canada, France, Germany, Greece, Italy, Luxembourg, Portugal, Spain, Turkey, the United Kingdom, and the United States. SCCF continues to monitor the patent environment to protect its discovery on a worldwide basis.

### III. STAGE 4-5 OBJECTIVES

#### Experience and Money:

We realize that a host of specialists are required to move this discovery “from lab bench to boardroom to bedside”. So far, SCCF resources have been limited to pro bono professional hours, patents issued in 13 countries, individual cash donations, short-term credit, and personal signature loans. Of the 12 board positions established under SCCF By-Laws, two are currently vacant. SCCF has had to slow its research agenda in response to limited funding availability.

To accelerate the momentum towards product development and distribution, SCCF seeks to partner with larger, more experienced entities that can attract seasoned business managers and garner more funds. We need new partners versed in finance, law, fund-raising, accounting, and tax regulations with a common emphasis on the “bottom line”. We are eager to move to Stage 4: animal trials and to Stage 5, Phase I/II trials for human safety clinical efficacy.

While we can provide the hope, confirm the science, and report on the safety of our discovery, two elements are missing to launch Stages 4 and 5: proven business experience and money.

Later, under Stage 6 we would move to global human trials and solicit licensing approvals from the U.S. Food & Drug Administration (FDA) and the European Medicines Agency (EMA) to distribute and sell the cure on a sustainable commercial basis. However, please note that Stage 6 is not part of this request.

#### Objectives of This Request:

##### Mandatory ----

1. To help SCCF develop, write, time, and cost out recommendations for its management, finance, and fund-raising structures and systems compliant with the latest charitable documentation requirements so as to facilitate SCCF's mid-term purposes and long-term goals.
2. To produce a single homogenous test batch of patented treatment products, including storage, packaging, distribution, and shipping protocols.
3. To establish SCCF laboratories from which safety and efficacy tests in animals and humans will be performed and/or directed.

##### Optional ---

1. Negotiate the content and the funding for SCD awareness and fund-raising campaigns.
2. Pay patent fees incurred during Stage 3.
3. Lift SCCF's debt burden.
4. Pay patent fees that become due during Stages 4 and 5.
5. Strengthen the spirit of cohesion and teamwork among SCCF board members.
6. Support Awardee staff.

Awardee Inputs and Their Estimated 48-Month Value:

Mandatory ----

1. Personnel Identification, mobilization, and related costs: management advice, financial expertise, fund-raising guidance, plus short-term consultations related thereto (months 0-48).  
\$2,800,000
2. Product: contract to deliver test materials packaged as specified in experiment protocols (months 0-2).  
\$1,000,000

Note: SCCF is now conducting experiments to determine the doses of ferritin-H required to produce 30-50% fetal hemoglobin (HbF) in the forming erythrocytes of SCD patients. The findings of this ongoing research are expected to influence the decision on how much ferritin-heavy chain to produce in the first experimental batch and therefore the estimated cost per dose. This information should inform a more accurate estimate of the cost to produce the first batch. SCCF will advise applicants of any material changes in this area.

3. Acquisition of laboratory technician services, laboratory equipment, and out-sourced specialty services, and rental space scoped and selected by Dr. Broyles (months 0-48).  
\$922,000

Optional ----

4. Fund-raising plan to solicit grant-funding (months 1-48)  
\$278,000
5. Pay invoices for patent-related, European legal services (months 0-2), \$60,000, and for new advice (months 3-48), \$150,000.  
\$210,000
6. Assumption of three Outstanding SCCF-related expenses (months 0-2)  
\$90,000:
  - a. Floyd-Broyles personal loan (months 0-3) with any accrued interest.  
\$35,000
  - b. Payment to Dr. Broyles for technical information, guidance, and orientation such that the estimated post-tax "net" equals the outstanding credit card balance for SCCF-related charges (months 0-3).  
\$20,000
  - c. Pay for present and continuing patent-related, American legal services (months 0-9).  
\$35,000
7. Pay 48 months of all relevant, worldwide patent rights on behalf of SCCF. (months 0-48)  
\$130,000
8. Pay per diem and round-trip travel costs. (months 0-48).  
\$230,000

9. Pay administrative support (office rental, furnishing, maintenance, computers and related services, software, and consumables, plus overhead as deemed necessary by the Awardee for its own staff and consultants (months 0-48).  
\$120,000
10. Evaluation and /audit services (months 0-48).  
\$251,000
11. Contingency (months 0-48).  
\$201,000

SCCF's Contributions to Stage 4-5 Objectives:

- New primary research papers
- Continuing efficacy/safety research in human cells and animals
- New and pending patent applications
- Business Plan
- New Board Memberships
- Recommended locations for human safety and clinical efficacy trial locations in the United States, Europe, and the Third World

#### IV. PLANS TO SUPPORT MANAGEMENT

As a fledgling non-profit with a global outlook, SCCF's plan is to secure full-time management start-up advice, half-time reliable financial talent, and part-time, seasoned fundraising expertise in exchange for partnership status leading eventually to the sharing of royalties. SCCF seeks to partner with multilaterals, non-profits, and/or for-profits to create a team with the business skills, the medical knowledge, the multi-cultural sensitivity, the timely funding, and – above all – the passionate commitment so vital to ensure the delivery to humanity of this long-awaited cure.

##### SCCF Foundation Creation and Legal Status:

SCCF is a bio-medical research firm established July 28, 2006 and located in Oklahoma City, USA. SCCF is directed by a volunteer board following cooperative management principles to reach consensus. Dr. Robert H. Broyles and colleagues established the SCCF in the wake of Dr. Broyles' laboratory discovery of a genetic regulatory treatment that promises to control the symptoms of SCD. Under his leadership, SCCF has secured patents in 13 countries for a cure to sickle cell disease, humanity's oldest and most frequent genetic disorder. The U.S. Internal Revenue Service (IRS) accorded 501c3 status on February 12, 2007 to SCCF as a tax-exempt, non-profit, independent medical research foundation. The cure tentatively branded DREPAC © treats the cause instead of the symptoms.

April 14, 2009 the U.S. Patent Office issued patent #7,517,669 on "Gene Regulation Involving Ferritin". This important validation of the SCCF cure has encouraged the foundation to pursue its global program more aggressively. While SCCF's immediate aim is to bring the SCD cure to market, the foundation's broader, far-reaching aim is to pursue a research agenda centered on gene regulation therapy.

##### SCCF Management Style:

SCCF focuses primarily on investigations and discoveries and intends to pursue basic and translational research.

SCCF's co-op management style has often been characterized as philanthropic entrepreneurship. We call it "more-than-non-profit". Five goals encompass our vision:

- to market drugs worldwide at affordable prices reducing prices as soon as feasible
- to maximize distribution first and profits second
- to share independent research as a north-south norm
- to educate the public
- to strengthen the foundation's asset and talent base.

These "more-than-non-profit" goals reflect our policy that basic health care is a social obligation and a citizen's right – not a corporate option or a special privilege.

Our "more-than-non-profit" cooperative management style defines our mission, guides our global development plan, and provides the context for our business relationships. Would-be partners – either non-profit or for-profit – will need to share these social goals. Specifically, we seek a systematic reduction in cost per dosage and the maximization of patients under treatment. Realizing this vision with seasoned partners will prove critical to our success.

### Vision, Mission Statement, and Business Opportunity

- **Vision** - conduct and sponsor basic/translational medical research, pursue breakthroughs in medical knowledge and technology, and apply for patents on health-related intellectual property that can be licensed for commercialization and distribution in exchange for royalties and/or non-taxable considerations on an affordable and accessible basis consistent with World Intellectual Property Organization (WIPO) guidance.
- **Mission Statement** – expand patented Gene Regulation Therapies (GRT) in hopes of spear-heading a series of gene-based discoveries and treatments; to make the findings of this research available to other non-profits consistent with WIPO guidance.
- **Business Opportunity** – to commercialize as many SCCF medical discoveries as possible, especially those amenable to GRT; to negotiate the commercialization of DREPAC © as part of a genomic treatment to stop the expression of SCD. This would be the world's first clinical application of GRT, a patented procedure developed by Dr. Broyles.

## V. PLANS TO STRENGTHEN FINANCES

### Risks and Rewards:

The SCCF Business Plan (Reference B) indicates an attractive projected internal rate-of-return, a substantial net present value, and short break-even durations. In this connection, applicants are urged to scrutinize the finance section of the Business Plan available at the SCCF website and to present their own assumptions, hypotheses, and cost-benefit analyses. Of course, by the close of Stage 4-5 trials, the high-to-low range of estimated cost projections is expected to narrow. Accurate costing information will then become central to the work to be conducted under Stage 6 field trials and will impact scale-up and distribution strategies. SCCF's preliminary scenarios and assumption set at the close of Stages 1-3 indicate a 96% reduction in standard treatment costs and a quadrupling of patients able to be served.

The entrepreneurial spirit to shoulder the risks associated with the uncertainty of early pharmaceutical trials and first-time business start-ups warrants commensurate compensation. The manner in which a would-be partner hopes to recoup its investment will affect the ranking of the partnership proposal with near-term, more certain compensation plans receiving lower scores. Conversely, a prospective partner willing to forego compensation over longer periods of profits will receive higher evaluation scores. The proposal review panel will evaluate the magnitude and duration of the proposed support.

### Possible Resultant Ownership Pattern:

The evolving allocation of SCCF ownership favoring this pro-risk orientation is projected as follows:

#### **Phase I Ownership (completed):**

Robert H. Broyles et al. (patent owners)– 100%

#### **Phase II Ownership (subject of this RFPP):**

Robert H. Broyles  $\leq$  66%

Broyles SCCF Associates  $\geq$  17%

Phase II Partners  $\geq$  17%

#### **Phase III Ownership (RFPP extension and/or new RFPP)\*:**

Robert H. Broyles/ SCCF Associates  $\geq$  51%

Phase II Partners  $\geq$  17%

Phase III Partners (manufacturers & distributors)  $\leq$  32%

\*Projections for royalties from Phase III trials are just one of many possible ways to share to share the benefits and effort.

### Authorities Retained or Shared:

SCCF's decision-making authority and rights of ownership rest exclusively with Dr. Robert H. Broyles, SCCF, its associates, and partners who will retain "rights of first option to buy" in the event SCCF, its associates, partners, and/or heirs and/or assignees seek to sell part or all of their ownership portion.

As patent holder and SCCF founder, Dr. Broyles intends to extend licensing and distribution rights consistent with WIPO guidance. SCCF anticipates awarding board memberships and royalty streams among a number of participating entities and individuals: licensee(s),

manufacturers, patent holders, non-governmental organizations, and participating non-profits or for-profits both local and expatriate.

We are searching for partners at home and/or abroad to provide goods and services currently estimated at \$6.232 million to help bring the cure through Stages 4 and 5. As indicated by the inclusion of an illustrative summary budget (Attachment 3), this RFPP is as much about finding compatible personnel as it is about a competitive budget.

We anticipate that pharmaceutical license holder(s) would conduct Stage 6 field trials. As such, their participation in Phase II activities can only serve to strengthen their competitive edge vis-à-vis Phase III.

However, proposals to transfer patent rights or to “buy out” the SCCF are not being encouraged at this time.

## VI. EVALUATION OF PROPOSALS TO PARTNER

Applicants/potential partners are asked to scrutinize the Evaluation Sheet (Attachment 2) to appreciate the points awardable for partnership relative to the proposed goods, services, and financing being sought.

Applicants/potential partners that do not retrieve and analyze closely the patent applications cited as References B, E, and F will place themselves at a distinct, competitive disadvantage.

Please note that certain line items are optional (although, encouraged). Applicants may – at their own risk -- choose not to respond to optional items. Mandatory items must be addressed.

## VII. ADVISORY NOTES TO WOULD-BE PARTNERS

### Strategic Advice:

#### 1. **Demonstrated Familiarity with the SCCF Patents, Business Plan, and Global Aspects of SCD:**

Competitive applications will demonstrate familiarity with the SCCF Business Plan, its spreadsheets, and graphs found at the SCCF website. Attractive entities and candidates will document a breadth of understanding of SCD that extends beyond Western medical centers and shall include a frank discussion of the hurdles associated with SCD patient outreach in remote rural areas of the Third World and how the applicant organization intends to overcome or manage these challenges. This RFPP is the first of a series of anticipated competitive solicitations to introduce a new standard form of therapy, GRT.

#### 2. **Partnership Agreement's Initial Duration & Optional Extensions:**

The Award is contemplated for 48 months starting September 1, 2009. However, the award may be extended beyond 48 months without further competition for a second and for a third period subject to mutual agreement on a revised budget, continuing need as documented in audits, evaluations, and budgeted funding availability.

#### 3. **Eligibility:**

RFPP competition is open to seven types of entities among which are six types of non-profit entities (foreign and/or domestic):

- multilateral organizations and agencies affiliated with the United Nations system, e.g. World Health Organization;
- a single applicant or a proposed consortium's prime entity headquartered in one of the 13 countries having issued a patent and be registered as tax-exempt pursuant to Section 501c3 of the IRS code, e.g. France;
- NGOs headquartered in one of the 13 countries that have patents in force to protect SCCF's discovery, e.g. Médecins sans Frontières (France);
- charitable groups (private voluntary organizations or local NGOs) in Third World beneficiary countries registered under their respective country's Charities Act or equivalent legislation, e.g. individual member of the Organisation Internationale pour la Lutte contre la Drépanocytose (OILCD) applying in tandem with one or more of the other types of entities;
- medical research firms headquartered in one of the patent-issuing states with a record of Third World development activities and/or relevant medical breakthroughs, e.g. The March of Dimes or The J. Craig Venter Institute;
- any combination of the five types of entities mentioned above;
- the traditional for-profit business model, e.g., Novartis, BD Biosciences.

Purely philanthropic groups with no record of field-tested technical expertise are ineligible. Of course, entities and individuals with purely philanthropic intent may contribute directly by following the guidance found at the SCCF website.

## Managerial Guidance:

### 1. **Negotiable “Reach”:**

On the one hand, this RFPP does not require that SCCF enter into an agreement with any of the applicants. On the other hand, SCCF reserves its right to negotiate an award for only a portion of a single proposal or to try to merge two or more proposals in part or in whole. Likewise, individual candidates may appear in more than one proposal without prejudice to themselves or the proposing entity.

### 2. **Business Form:**

Proposals may rely on a variety of compatible non-profit business styles, *e.g.* cooperative agreement, partnership (merged budgets), consortium (parallel, separate budgets), grant, donation, and for-profit.

### 3. **Candidate Personnel:**

The RFPP calls for the Awardee to fill two professional slots in the SCCF management structure over a 48-month period: a full-time Vice-President for Management and a half-time Vice-President for Finance. Candidates are not required to be U.S. citizens. The Awardee will also identify one, two, or three fund-raising advisors (consultant and/or staff) working a combined total of two days per week on the average consistent with fund-raising events often held outside normal business hours. Applications must include for each candidate a one-page biodata-commitment sheet that is responsive to the evaluation sheet’s criteria with a signed closing “commitment” paragraph confirming the candidate’s availability to be on the payroll no later than 45 calendar days after the submission deadline and asserting each individual’s willingness to mobilize in Oklahoma City no later than 60 days after the submission deadline. “Job sharing” proposals are welcomed. Proposals with candidates already resident in the Oklahoma City metropolitan area will be accorded a small preference in ranking.

SCCF recognizes that the Internet and cyberspace have made it possible to sustain virtual business relations among colleagues many miles apart. Still, nothing can replace the nuances possible in face-to-face meetings and exchanges. SCCF is open to considering non-traditional management approaches.

If a candidate retracts his/her commitment in part or in whole, the applying entity is to notify SCCF immediately. The concerned entity will have ten calendar days to identify a replacement candidate with equal or superior qualifications in the opinion of the Review Panel. Failure to identify a satisfactory replacement may trigger application rejection in part or in whole. Retractions after the execution date of the partnership agreement may cause the invalidation of the contract in part or in whole and/or may result in negotiated damages for breach of contract.

## Administrative Instructions for a Proposal to Partner:

1. **Submission Deadline:** Complete submission no later than 10:00 AM Thursday August 6, 2009 Central Daylight Savings Time in Oklahoma City (same as 5:00 PM/17:00 August 6, 2009 Central European Savings Time in Geneva) as recorded using the electronic receipt stamp at the SCCF website. Each applicant is responsible for the timely transmission of its proposal including all attachments, graphs, and photos as well as for adherence to the interim question-and-answer schedule and deadline. Overly elaborate submissions and multi-color publicity materials more appropriate for annual

reports are discouraged. SCCF will not accept proposal substitutions or amendments after the submission deadline. However, at its sole discretion, SCCF may accept entirely new applications presented in “good form” but received late. In so doing, the SCCF Review Panel shall document the probable effects such a decision may have on actual or apparent competition.

**2. Electronic Submission Address:**

Each submission is to be submitted by e-mail as an attached document (preferably, as a PDF file) to the following email address: [robert.broyles@sicklecellcurefoundation.org](mailto:robert.broyles@sicklecellcurefoundation.org). Applicants must transmit their proposal electronically as this capability serves as one measure of the applicant’s ability to function smoothly in cyberspace.

**3. Cover Letter and Designation of Individuals Authorized to Negotiate:**

A cover letter on letterhead of the lead entity not to exceed two pages shall introduce the proposal. The cover letter shall identify the individual designated to be the applicant’s interlocutor to negotiate a tentative agreement and the individual empowered to execute the definitive contract, including title, e-mail, and phone. SCCF President and Chairman of the Board Dr. Robert H. Broyles will execute the definitive agreement on behalf of SCCF. E-mail: [robert.broyles@sicklecellcurefoundation.org](mailto:robert.broyles@sicklecellcurefoundation.org). Phone: 001-405-922-5774.

**4. Proposal Language, Format, Software, and Font :**

English must be used for the body of the proposal to partner, English or French may be used for references, graphs, appendices, or questions during the interim question-and-answer period. Proposals are to adhere to the following format parameters and to use the following software programs: single spaced, one-sided, with one blank line between paragraphs without indentation, justified on the left margin only. For word processing - Microsoft *Word* version 97-2003, for spreadsheets - Microsoft *Excel* version 97-2003 workbook, and for photos - pdf. or jpg. Concerning the font: Arial, pitch-11. Margins - 1.0 inch all around for 8.5 inch x 11.0 inch paper or 28 mm all around for European “A4” (210 mm x 297 mm) paper.

**5. Relocation:**

SCCF has recently relocated its physical address to 601 NW 13<sup>th</sup> Street, Oklahoma City, OK 73103 U.S.A. However, this relocation does not affect the electronic submission requirements and guidelines.

**6. Alternative Proposals:**

Applications must first respond to the mandatory items as detailed in the Attachments. Then and only then, may SCCF entertain alternative, supplemental, or divergent proposals. Each additional proposal must be presented in good form and in its entirety.

**PARTIAL CHECKLIST FOR A PROPOSAL TO PARTNER IN “GOOD FORM”**

1. Present your proposal following the content and sequence below.
2. Two pages or less -- Cover letter signed by the “prime” designating the authorized individual with whom SCCF would develop a partnership consensus
3. One page or less -- Sub-agreements among partners or consortia vis-à-vis their proposal.
4. As issued -- Government-issued certifications or certifications from multilateral agencies attesting to their official fiscal and charitable status.
5. As issued -- Copy of IRS Form 990 for U.S.-registered entities or equivalent financial data for non-U.S. organizations.
6. Eight pages – Demonstration of the applicant’s familiarity with current SCD issues covering following four areas:
  - a. two pages -- current SCD treatments, medical research, and administration in both advanced countries and Third World settings;
  - b. two pages -- commentary on the north-south dialogue including present and projected cost impact of SCD on public health budgets as well as costs covered via private insurance or out-of-pocket;
  - c. two pages – Applying organization’s record of fundraising, public awareness campaigns;
  - d. two pages -- Organization’s or candidates’ track record of business start-ups, especially those focused on testing of pharmaceuticals.
7. Magnitude of expenses that would-be partners are willing to absorb, proposed duration to recover investment, and percentage “take” of potential pre-tax royalties. See Evaluation Sheet for details. (Please quote in US dollars and cite exchange rate, if currencies other than US dollars are used.)
8. Two pages or less -- Assumption set and calculations to arrive at the estimated total costs for the production of a uniform, homogeneous batch of recombinant human Ferritin-H including method(s) of transmission, storage, distribution, quality control, shipping protocols to advanced and developing beneficiary countries. Calculations of internal-rate-of-return, net present value, and break-even durations (optional).
9. Detailed budget paralleling the eight Awardee line items identified in Section III.
10. Bio-Data and Commitment Form for Candidates (not to exceed one page per candidate) --
  - a. Professional Status: employment status vis-à-vis applying organization: staff or consultant, duration of past associations with applying organizations
  - b. History of working with non-profits
  - c. Description of candidate’s participation in efforts to introduce new pharmaceuticals
  - d. Patents, awards, academic degrees, post graduate research, membership in professional organizations
  - e. Record of publications (1995 to present)
  - f. Self-assessed language proficiency - 0-5 scale: English, French, and Spanish
  - g. Current residency in the Oklahoma City metropolitan area, willingness to relocate or lack thereof
  - h. Commitment to be available at least 45 calendar days from submission deadline date and willingness to begin a 18-month contract to be conducted primarily in Oklahoma City on payroll no later than September 1, 2009.
  - i. Signature of candidate

## Evaluation Scores

Note: All scoring factors are mandatory unless indicated as “optional”.

### MANAGEMENT (0-66) ---

- 0-18 VP for Management
- 0-9 VP for Finance
- 0-9 Fund-Raising Short-Termers

Above scores to reflect the following factors: employment status; history with non-profits; record of introducing new pharmaceuticals; patents, awards, degrees, and memberships; key relevant publications, 1995ff; length of relevant experience; team leadership; growing responsibilities; international experience; and Third World experience.

- 0-3 Oklahoma City Local Residence Points
- 0-10 description of lab equipment, services, and estimated costs (NTE 2 pages)
- 0-12 discussion of SCD issues (NTE 8 pages)
- 0-5 discussion on production of uniform batch of FtH and protocols (NTE 2 pages)

### **0-66 Sub-Total for Management**

### FINANCE (0-34) --

- 0-6 18-month budget in quarters (1 page)
- 0-7 Outline of fund-raising plan (2 pages)
- 0-7 Pay-off patent services to European legal firm (optional)
- 0-5 Quality of financial support, e.g. duration, amount, risk burden
- 0-3 Assumption of three outstanding debts (optional)
- 0-2 Pay 18 months of worldwide patent rights (optional)
- 0-2 Per diem and round-trip travel (optional)

### **0-34 Sub-Total for Finance**

## **0-100 (Maximum Possible Score = 100)**