NellOne
THERAPEUTICS

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March 25, 2009

Office of the Assistant General Counsel
for Technology Transfer and Intellectual Property
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585
Attn: Technology Transfer Questions

Subject: Questions Concerning Technology Transfer Practices at DOE Laboratories (Federal Register/Vol. 73, No. 229/ November 26, 2008 /Notices)

Dear Mr. Gottlieb,

Thank you for the opportunity to respond to the questions published in the Federal Register. As Chief Executive Officer of NellOne Therapeutics, a spin-out company which is in the process of licensing technology from Oak Ridge National Laboratory (ORNL), I found the questions to be highly relevant to our experiences. While many great technologies and capabilities reside in the National Laboratories there are many challenges related to commercializing them yet they hold promise in improving American competitiveness and building new technologies and capabilities to address our nation's critical needs in the future.

The success of technology commercialization can be measured in many ways and it is unclear from the posting how DOE will measure the success of its efforts. As AUTM (the Association of University Technology Managers) states, "Early numerical measures include the number of patents filed, license agreements executed and new companies formed. Later numerical measures include revenues from license fees, royalties and cash from equity investments paid to the [academic] institutions and the numbers of products successfully introduced to the market. Success is also demonstrated by the impact the products have on our lives." It is important to consider that without a successful path to commercialization which is cognizant of the needs of those who chose to license and commercialize the technologies, the later measures will not be realized and the impact of the products developed will not be felt. In the case of NellOne, we are attempting to develop regenerative therapeutic products to treat cardiovascular and musculoskeletal conditions. If successful, we hope to improve human health and well-being for decades to come.

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In response to Question 1 regarding contracting mechanisms, consider that when the technology which is being licensed from Oak Ridge was first identified, further in vivo studies needed to be completed to validate whether there was in fact merit to the claims of efficacy. NellOne Therapeutics utilized a Work For Others (WFO) agreement to complete this work and simultaneous exercised an option to license the existing intellectual property from UT-Battelle, the Laboratory's contractor. The advance-payment feature required by the WFO was challenging for a start-up, venture-backed company like ours. We paid for each of our three phases in advance of the work beginning tying up precious cash for six month periods at a time. Having been involved with several university-based start-ups, include some which have utilized third-party private contract development organizations, this advance payment feature is non-standard and does disadvantage the DOE. If the Department wishes to conduct contract work in its vastly capitalized facilities, it should consider more standard terms, such as a down-payment with either a fixed payment schedule as work is completed or a pro rata payment schedule. In the cases of high risk technology development, a start-up company tries to minimize its expenditures early on and a method allowing for work to be paid as completed, but not an entire program paid months in advance.

As proposed in Question 2, also challenging for NellOne, both in regards to the WFO and in licensing the intellectual property (IP), is the prohibition on licensing future IP. In early stages of development, it is typical (almost predictable) that IP will be developed as early investigation of a technology is conducted. As such, a company like ours would like to know that our future is not at-risk for future IP being developed which would fall outside an existing license. Such future IP could invalidate or supersede the existing IP allowing the Laboratory or its contractor to hold the company "hostage" for new and more aggressive terms. While I would not suggest DOE give carte blanche to a potential licensee, it is conceivable, and standard practice in many universities, that pre-set terms be defined for future IP related directly to the existing license including field of use where the same principal investigator is involved. This allows the Laboratory to capture value for IP created but keeps the financial risk to the licensee measurable which supports future fundraising efforts.

While supportive of sustaining and even improving U.S. competitiveness, I would caution DOE to consider that the marketplace, particularly for health and life science technologies is truly global. It takes over $100M and over 10 years to develop a drug in the United States alone. Very few large pharmaceutical companies exist that can support that type of investment and regulatory pathway, many of whom are based outside of the United States. For a small company such as ours, it is most likely that our products will be licensed to or our company will be acquired by one of these large pharmaceutical companies before the products receive FDA approval. Regulations already exist relating to the manufacture and testing of therapeutics, so restrictions as indicated in Question 3 would only further inhibit our company's ability to be successful (i.e. if we are biased against selling or licensing to companies and partners outside the United States). Given the size and financial strength of the U.S. marketplace, I believe the ultimate licensee of this technology will manufacture product here creating jobs and improving

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the health of our citizens. However, if strict limitations are placed on us in our license such that we may only sublicense or transfer the license to a U.S. company, this could impact the long-term success of our efforts and the "impact" may not be experienced at all. I would encourage DOE to adopt less stringent terms and conditions and only tighten them in cases of national security or other special circumstance.

As I mentioned previously, our company utilizes a WFO in our work with ORNL. Given that we as a sponsor pay all costs for this work, I believe it is only appropriate that any resulting intellectual property be owned by NellOne. As stated previously, as a small company, the intellectual property that is the basis for our company is our most significant asset and must be protected and developed to the best of our ability. If a sponsor is to fund work with a Laboratory, the resulting data and IP should belong to that sponsor. This way the company is not at risk for IP being developed and owned by the Laboratory or its contractor forcing the sponsor to then negotiate and in-license. Ambiguity over the control of IP and related "costs", such as license fees and royalties further inhibits a start-up's ability to raise capital and further develop technologies. If the IP of sponsor-funded work is at risk (i.e. does not belong to the sponsor), I believe this would significantly negatively impact the private-sector engagement with the National Laboratories in the future. I encourage DOE to maintain the provision as stated in Question 4 in the Registry.

Finally, Question 6 asks about other things DOE can do to improve technology transfer. While I do not know the specifics as to what specific steps must occur between the contractor and the local DOE field office, the paperwork and redundancy of putting our WFO in place, navigating our option agreement, and now working through a license agreement, is incredibly time consuming and frustrating. What strikes me about DOE is that the amount of paperwork (versus on-line) required to establish a program or contract, the processing of it and tracking of programs is enormous and inefficient. I would encourage DOE to revisit its policies and procedures with an eye toward efficiency and so long as an agreement is "standard" within a range of acceptable terms, remove many steps and sign offs to better facilitate consummation of a transaction. Such efforts would greatly improve private partnership relationships in working with the Laboratories. Consider, as an example, the National Institutes of Health, which has a wonderful website that outlines its standard agreements, graphically depicts the process for licensing technologies, and supports a good portal for identifying technologies. While not transparent, there is some comfort in knowing what to expect and how long the process may take.

Again I thank you for the opportunity to comment on these questions. It is my sincere hope that DOE will consider these recommendations as I believe there to be great potential in the technologies and researchers resident in the National Laboratories. With lower barriers to commercialization, the benefits of our significant investment in these institutions can be realized in the near and long-term.

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Sincerely,

Tracy S Warren

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Chief Executive Officer
NellOne Therapeutics, Inc.