From: Derek Schorzman [mailto:Derek.Schorzman@liquidia.com]
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To: amtech
Cc: Doug Mar; Shawn Glidden; Kyle Chenet; Neal Fowler; Bruce Boucher; Jonathan Smith; Frank Malinoski
Subject: AMTech Comments

Please find attached Liquidia Technologies' response to NIST's request for information regarding the proposed AMTech Consortia. Liquidia also recently submitted (September 26, 2011) a potentially relevant whitepaper to the NIST Technology Innovation Program (TIP) entitled "Translating Nanomaterial Promise into Products", that we can send upon request. Please do not hesitate to contact me, or any of my colleagues at Liquidia, with further questions or comments.

Best Regards,

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Response to Request for Information on Advanced Manufacturing Technology Consortia (AmTech) from National Institute of Standards and Technology (NIST), Department of Commerce, Docket #110620345–1331–02

Submitting Organization

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Advanced manufacturing technologies are vital for economic recovery and maintaining US leadership in key areas of strategic national interest. Our aim in this RFI response is to focus on the particular aspects of *nanomanufacturing technologies*. Taken as a whole, these new and exciting capabilities show great promise for transformative impact in a broad spectrum of applications, many in areas of critical national need: medicine, energy, defense and national security, to name a few. Despite a decade of investment, the full commercial benefits of nanotechnology are far from being realized, because of the unique technical and funding challenges faced by nanomanufacturing technologies in their commercialization. Our response to the US Department of Commerce is intended to suggest ways in which the AmTech Initiative can be better structured to develop a robust domestic nanomanufacturing industry, with tools and techniques for fabricating the basic nanoscale materials and cost-effectively producing these nano-enabled materials in quantities orders of magnitude greater than currently achievable: from milligrams to grams, kilograms and metric tons.

The establishment of advanced manufacturing consortia represents a unique opportunity to build on the investments in nanotechnology made by the US in establishing the National Nanotechnology Initiative over a decade ago. Through the work of the NNI and its member agencies, the Federal Government has begun to leverage the investment of the last decade in basic and applied nanotechnology R&D, and to apply resources towards transitioning the knowledge gained into commercializable nano-enhanced products. Having recently identified nanomanufacturing as a critical program area, the NNI has encouraged direct Federal investment in public-private partnerships, leading to manufacturing processes that are now being developed for scalable production of nanomaterials and integrating them into systems and protocols that can take advantage of the technology. These development efforts are currently being implemented in diverse but restricted scale forms in the U.S., and they will need to be refined continuously to leverage investments made to date and to realize fully the benefits of industries being able to manufacture and use nanotechnology products. Such leveraging is exemplified by the NIST Technology Innovation Program (TIP), through which federal funds are invested in research and development of innovative technologies in areas identified as critical national needs. Of the 36 projects currently funded under this program, more than a third of them directly involve nanotechnology in some form, and of these, nearly all have as a primary goal the cost-effective volume production of nanomaterials. In some cases, nanotechnology products are now moving into commercialization phases. Cost structures are better understood, and nanotechnology in general is developing. Broad and transformative impact is slowly being realized, but there are remaining barriers to nano-commercialization.

While it is likely that nanomanufacturing technologies will find niche commercial applications, the goal is to leverage the investment in existing nanotechnology development programs to realize the widest possible impact in the shortest possible time. Commercialization efforts have been hindered by a lack of available prototype nano-engineered materials that can be tried in multiple applications across multiple industries. Broad applicability demands the production of nanomaterials that are flexible, with engineered characteristics that enable them to be readily modified and tailored for downstream products. This product development can be best achieved by those companies with direct knowledge of the desired end-use, but introducing novel materials to these companies is a fragmented and inefficient

exercise. To streamline this process, there must be widespread commercial availability of consistent, affordable product for use in research and development. Among the factors limiting the pace of market entry is the lack of nano-engineered material sets that are flexible, controllable, and of consistent quality. Such materials, if available at reasonable cost, could quickly impact multiple industries as prototype testbed materials for rapid exploration. Promising directions could then be followed up with more focused development to achieve the required properties in the commercial end use. We suggest that organizations and mechanisms that can provide such "clearinghouse" or "foundry" functions would greatly accelerate the commercialization of nanomaterials and nanomanufacturing technologies. In addition, advanced manufacturing consortia could serve effective roles in developing regulatory guidelines, and solutions to common problems across multiple technologies, such as high throughput nano-analytical techniques. Consortia, if well resourced and managed, can play vital roles in all of these areas, and help accelerate the commercialization of nanomaterials and nanomanufacturing technologies.

Below, we respond to specific questions in the AmTech RFI.

1. *Should AMTech consortia focus on developments within a single existing or prospective industry, or should its focus be on broader system developments that must be supplied by multiple industries?*

Transformative technologies should not be tied to a single industry or a single critical national need. Particularly in the case of the inherently broad field of nanomanufacturing, where the nanomaterial products add value to a wide range of unrelated industries, limiting the scope of a consortia to a single industry would limit the impact. Moreover, consortia should focus on getting novel new materials into the hands of multiple industries to enable value-addition assessment of existing products. There are several examples of nanomaterials being incorporated into existing commercial products in ways that improve performance and value of the newly nano-enabled product. Adoption of new materials in a broad array of existing industries will maximize impact and create the largest demand for US-based manufacturing. It should be noted that the National Nanotechnology Initiative (NNI) efforts over the previous ten years have already created a pipeline of new, enabling nanotechnologies, and this commitment could potentially be maintained through the AMTech consortium.

2. *Who should be eligible to participate as a member of an AMTech consortium? For example, U.S. companies, i.e., large medium, and/or small; institutions of higher education; Federal agencies; state, local, and tribal governments; and non-profit organizations?*

The focus of the AMTech consortia should clearly be on U.S. based companies. It is suggested that U.S. companies of various sizes lead and participate in the consortia, and participation membership be extended to international companies, federal agencies, etc. Academic institution leadership of consortia

is unadvisable due to inherent lack of product-based focus, but academic inclusion has multiple benefits: providing early research, the rapid invention or adoption of new analytical techniques, and the training of a nano-ready workforce.

3. *Should AMTech place restrictions on or limit consortium membership?*

As described for question number 2, the focus of and leadership of the consortia should be on U.S. companies, but further membership need not be artificially limited.

4. *Who should be eligible to receive research funding from an AMTech consortium? For example, U.S. companies i.e., large, medium, and/or small; institutions of higher education; Federal agencies; state, local, and tribal governments; and non-profit organizations?*

Academic institutions should not be eligible to receive direct funding, but rather as sub-prime through U.S. companies to promote product-based focus. Restrictions should NOT be placed on working with additional national laboratories, as has been the case with previous federal programs. Small, medium, and large companies should be considered for funding based on the stage of the technology. A broad focus which advances companies and technologies at various stages of the value-chain (i.e., nanomaterials, nano-intermediates, *and* nano-enabled products), will create the most balanced and sustainable portfolio for the AMTech consortia. It is also important to note that the time to adoption will vary greatly depending on the position of the individual company/technology in the value-chain, which will result in a wide range of support requirements.

5. *What criteria should be used in evaluating proposals for AMTech funding?*

Criteria should include technical merit, various degrees of risk, potential market impact, and ability to utilize unique US resources such as talent pool and intellectual property protection to ensure creation of a sustainable, US-based product pipeline.

6. *What types of activities are suitable for consortia funding?*

Research, development, and commercialization of U.S. based innovations, and creation of supporting programs/institutions as needed to accelerate adoption of new, US-based technologies. These could include public-private partnerships, programs and services with broad applicability, streamlined processes for standardization and regulation, and mechanisms for cross-fertilization between industries.

7. *Should conditions be placed on research awards to ensure funded activities are directed toward assisting manufacturing in the U.S.?*

Yes, but they should not unduly burden the ability of work to be conducted, for example placing limitations on interaction with foreign sub-contractors, academic labs, and federal institutions.

8. *What are ways to facilitate the involvement of small businesses in AMTech consortia?*

Waive the requirement of in kind contributions from small institutions, coupled with appropriate oversight by AMTech.

9. *What are best practices for facilitating the widest dissemination and adoption of knowledge and technology through consortia?*

The NNI has successfully achieved this by hosting workshops and other technical, commercially focused events with broad representation from industry, academics and government, to enable face-to-face communication. Additionally, subsidized travel and other incentives would encourage the broadest participation.

10. *While it is expected that the research efforts of AMTech consortia (including participants from the Federal, academic, and private industry sectors) will take place largely at the pre-competitive stage in the development of technologies, the generation of intellectual property is possible, even likely. What types of intellectual property arrangements would promote active engagement of industry in consortia that include the funding of university-based research and ensure that consortia efforts are realized by U.S. manufacturers?*

With respect to patentable inventions, AMTech could pre-arrange a non-exclusive cross-license structure such that each participating party has access to the base technology, thus removing the fear of being blocked from practicing the base technology. The remaining challenge will be how to protect confidential and/or trade-secret information working between entities with such different objectives (corporate for-profit entities as compared to public universities). To ensure a true competitive advantage for the U.S. manufacturers, retaining the information as trade-secret information will be preferable, if not necessary, however, it will be difficult to accomplish such approach while working with universities devoted to the dissemination of information and knowledge. Therefore, early stage research should be the focus of the university role in these consortiums with timely removal of the manufacturing technology to private sector prior to optimization and implementation, which should remain trade-secret.

11. *Would planning grants provide sufficient incentive for industry to develop roadmaps and initiate the formation of consortia? If not, what other incentives should be considered?*

Roadmaps will not be productive enough to warrant funding, since they may quickly become obsolete. High risk, visionary technologies are fundamentally unpredictable, so it is recommended that AMTech focus on outcomes and allow the companies to chart the course

12. *Should each member of an AMTech consortium be required to provide cost sharing? If so, what percentage of cost sharing should be provided?*

The requirement of cost-sharing is a significant burden for small and in some cases medium sized companies in the current macro-economic environment. This would likely be an obstacle to full participation. For large companies, cost-sharing is appropriate.

13. *What criteria should be used in evaluating research proposals submitted to an AMTech consortium?*

As stated above, such criteria should include technical merit, various degrees of risk, potential market impact, and ability to utilize unique US resources such as talent pool and intellectual property protection to ensure creation of a sustainable, US-based product pipeline. To create maximum, sustained impact, AMTech should strive to maintain a highly diversified portfolio of programs and technologies, i.e. early vs. mid stage technologies, broad disciplines and market areas.

14. *What management models are best suited for industry-led consortia?*

There are two ways to interpret this question, management of individual consortia, and AMTech management of all consortia. For the former, it is suggested that one company serve as the lead, with representation from multiple companies. For the latter, management would be best served with representation from multiple disciplines (manufacturing, business, technology sectors, etc.) within individual topics (i.e. nanomanufacturing).

15. *Should the evaluation criteria include the assessment of leadership and managerial skills?*

Yes, but this should be done in a manner that does not unfairly exclude new players. It may be more pertinent to assess these skills for large awards and/or renewals.

16. *Should limitations be placed on the duration of consortia?*

Perhaps, but sufficient time must be provided to allow particular focus areas to reach fruition and become economically viable, especially since this nearly always takes longer than predicted for new technologies. Consortia durations may need to be shorter or longer than originally predicted due unanticipated technological and market developments, therefore a designed, perhaps annual, reassessment of consortia duration should occur

17. *How should an AMTech consortium's performance and impact be evaluated? What are appropriate measures of success*

Direct measures of success include U.S. jobs creation, revenues from commercialization, etc. Indirect measures of success include identification of new technologies in unpredicted fields, worldwide demand for US-generated products, growth of US skilled labor workforce, environmental impact of implementing sustainable and responsible technologies, US and global health, etc.

18. *What are the problems of measuring real-time performance of individual research awards issued by an industry-led consortium? What are appropriate measures of success?*

It is nearly impossible to predict invention or customer acceptance/adoption. It is also very difficult to accurately assess the final application, and therefore ultimate market value, at the early stages of a new technology. Additionally, the development and implementation of new technologies are often far more time consuming and expensive than predicted. It is crucial for AMTech consortia to be visionary and patient with new technologies in order to build enduring new industries and job growth in the US.

19. *How should the NIST AMTech program be evaluated?*

The AMTech program should be evaluated by the success of individual consortia as described previously. AMTech's ability to continually identify the *correct* consortia areas to focus on will be crucial in maximizing impact.

20. *What are lessons learned from other successful and unsuccessful industry-led consortia?*

One notable successful consortium is the Flat Panel Display Center (Arizona). This effort spanned many years and required patience to achieve technical success. However, the FDC demonstration of flexible OLED displays serves as an example of such potential.

21. *How can AMTech do the most with available resources? Are there approaches that will best leverage the Federal Investment?*

It is our opinion that the approach taken by the NIST-TIP program was an excellent mechanism of providing resources, although the cost-share match for small companies was more of a challenge versus what has been proposed here, especially due to the tightening of other funding sources in the current macroeconomic environment.

22. *How should AMTech interact with other Federal programs or agencies?*

One activity for AMTech could be to have a specific subgroup who's responsibility it is to explore ways to interact and the pursue such interactions where beneficial. Since there are many programs and agencies, defining explicit interactions prior to the creation of AMTech is difficult. In the case of nanotechnology, the NNI already serves an effective coordinating role that AMTech can take advantage of and build upon.

23. *What role can AMTech play in developing, leading, or leveraging consortia involving other Federal agencies?*

In addition to comments above, AMTech can play a critical role in coordinating proactive engagement of additional federal agencies. New technologies are always accompanied by needs in environmental and human safety analyses and subsequent regulation. In addition to promoting and encouraging new product development, it is suggested that AMTech proactively engage NIH, FDA, EPA, OSHA, NIOSH and others in generating these studies as new materials are developed, to accelerate the time to market for new products.