Academic ingenuity and corporate partnerships: new models in human health ventures bring value to all

Many disapprove of science faculty at American universities procuring corporate ventures that support research, instead of primarily functioning as an instructor, mentor and basic researcher. This perception is most evident surrounding biomedical research at public universities. In addition, some object that corporate-funded projects involve student research. In contrast, harmony and accord with companies has been a staple at institutions with medical, engineering or technology within their venerable names.

By Professor Paul Agris

It is not surprising that current economic conditions have altered this public perspective of a university's basic science faculty. Federal and state funding for research has diminished and has become increasingly competitive. Federal and state award criteria now require statements about the research applications and relevance for the public good in order to be of considerable size and evaluated seriously by peers. With the fluctuating economy and shifting attitudes has come recognition that significantly different, new models of academic/corporate partnerships do yield success in a principled manner and acceptable process.

Many universities want to diversify their sources of income, as do private investors, to better navigate the rocky shoals of an uncertain economy. Many conducting basic science want to involve themselves in applied research and commercialisation to obtain licensing fees and royalties with the promise of blockbuster products. Unfortunately, most universities, particularly public institutions, do not have a history of engaging their basic science faculty in the commercial or entrepreneurial enterprise.

In instances where success is observed in academic collaborations with corporations, a university has demonstrated an uncompromising commitment to create a very small number of unique, niche entities. These centres of excellence or research institutes factor in the long-term potential of products and their commercialisation from basic and applied early-phase research programmes. This is a relatively new truism for those campuses of public universities that do not covet the titles nominally associated with medicine, engineering and technology. Large biotechnology and pharmaceutical companies no longer provide financial gifts without an iota of possible return on investment. A new reality of biomedical corporations seeking academic collaboration is here to stay. This is of benefit to the universities, the corporations, and most notably, the students and public-at-large. The ideas and the early-phase research and development of new drugs, diagnostics and the biotechnologies that bring them to market will be conceived at, and their development conducted through, partnerships with universities. Companies

cannot afford the intellectual and instrumental infrastructure and the overhead of novel ideas and early-stage R&D. Yet, they can and are willing to invest in university partnerships that yield shared intellectual property or offer them the opportunity to license it.

Models of corporate collaboration in the biomedical fields vary with the university and the novelty of the research. These direct partnerships lower risk and costs for the companies, and meet university research funding needs not being fulfilled through federal agencies. However, for university research to attract the attention of multinational and domestic corporations, particularly those interested in the commercialisation of products in the biomedical sciences, the research must be both innovative and contain a realistic potential for return on investment.

There are seven areas that are critical to success for the university, the corporation and the public-at-large. The RNA Institute at the State University of New York at Albany stands as a prime example of that success, though only three years in the making. It is a unique entity for basic science and its applications to technology development, drug and diagnostic discovery. The Institute represents a new, 'open source' model that is succeeding in many of the seven critical components, including:

- Uniqueness and value.
- Environment.
- Financial support/investment.
- Student engagement.
- Administrative independence.
- Ease of process.

Uniqueness and value

The distinctiveness and value of a university research enterprise must benefit the researcher/inventor, the university and the public, and ultimately be of commercial interest. The RNA Institute is unparalleled because its mission and vision provides value to the academic researcher, the University at Albany, SUNY system, New York State and beyond, while forging opportunities for corporate partnerships.

The Institute's mission is to be a national research resource in an innovative area of basic biology and biochemistry. RNA research has already demonstrated its application to difficult human health problems. RNA, or ribonucleic acid, is central to all biology. It controls the production of proteins in cells. Thousands of RNAs manage which genes encoded within our DNA are turned on, when and to what degree. Thus, understanding RNA has led to its potential as a tool, a target and even a therapeutic for human diseases that are near intractable by other approaches. The Institute has filled a void nationally and internationally for a centralised site of intellectual and instrumental capital in basic and applied research that operates in the manner of an 'open source' for ideas and development.

The Institute's 'open source' model of collaboration and commercialisation takes advantage of its intellectual capital and unique infrastructure. The Institute's new infrastructure, which opened June 11, 2013, was designed for creative RNA science, product innovation and entrepreneurship for the public good in attacking the most difficult diseases, notably drug-resistant bacterial and viral infections, neurodegenerative and cancers.

Environment

Since basic biological and chemical sciences and entrepreneurship are not synonymous, both faculty

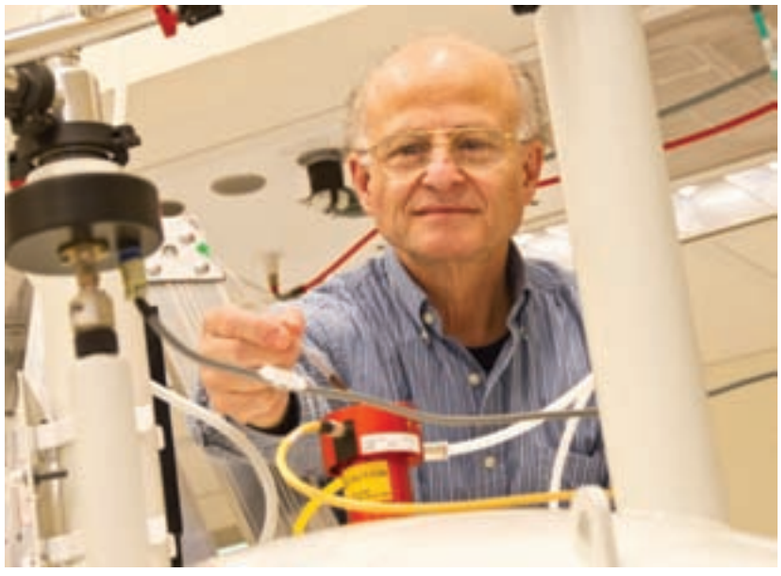
and corporate scientists and their management realise the potential of collaboration within the context of a modern academic research resource poised to do business. Increasingly, biopharmaceutical and biotechnology companies have outsourced development of their ideas to contract research manufacturers. With outsourcing, molecules are moved to drugs and technology prototypes to commercial instruments on the way to the marketplace in less time and with less investment. Small companies do not even have the finances to create the intellectual and capital resource environment required for success. Years of increasingly expensive product development in-house, failures and restarts have compromised profits. In pulling back from R&D, corporations also have compromised their abilities to be continually creative, a characteristic of American ingenuity and corporate success. Thus, they are looking more often to academia for new ideas and collaborations to lower costs and risks.

Academic entrepreneurship does not just blossom from the traditional academic enterprise; a practical idea requires a nurturing atmosphere. A centre based in fundamental science must encourage and engage faculty and students alike, in the enterprise of applied research. For instance, students earning their doctorates are confronted with pressures from their faculty mentor and academic departments, to be creative in their research. Discovery of the novel is what a thesis is all about and important to a budding career. Yet, these same students are not taught to recognise that within the creativity of their thesis pursuits they may have crafted a tool or method, adapted an instrument that is an accepted, commercially viable product. The fault here lies within the historical environment of the traditional academic department.

The RNA Institute is a new kind of academic centre with specifically designed modern space and capital instrumentation within the relatively new research field of RNA-based applications. The 'open source' model welcomes corporate partnerships. As with other successful university centres nationwide, the Institute is where corporations can find practical solutions to RNA science, technology development and drug and diagnostic discovery, as well as a place where company scientists can discuss and support implementation of novel ideas at a fraction of the cost of in-house and out-sourcing.

Financial support/investment

Investment in biomedical technology development, pharmaceuticals and diagnostics has always been particularly expensive. Competition is worldwide, so risk is greater than ever before. As corporate



investment in research and development continues to shrink, these same multi-national companies are looking toward universities to supply the innovation and early phase development of putative commercial products, new drugs and diagnostics. Yet, academic investigators have a diminished ability to respond to corporate interest in a difficult economy, despite it being for public interest.

For almost a century, the National Science Foundation (NSF), the National Institutes of Health (NIH), the Department of Energy (DOE) and the Department of Defense (DOD) have invested in academic science, technology development and its applications to human health. NSF-, NIH-, DOE- and DOD-funded research and development has made the US the lead nation with a model the envy of the world. However, national funding priorities have shifted and economic woes are sacrificing US stature and competitiveness. The result is that federally-funded innovation has suffered as financial decisions become considerably more conservative and the agencies become risk adverse. In addition, agencies are piling on layers of communication, rules, regulations and formalities for individual investigators and their institutions. These actions are stifling the very ingenuity the federal government set out to promote and which made the US the innovation economy of the world.

Conservative thinking and risk aversion at early stages of product development are counterproductive. Moving a technological idea to design and instrument prototype requires a year, possibly more. Moving a putative drug molecule through

early-phase *in vitro* and in cell culture testing, redesign, retesting, animal and clinical phase testing, requires many years. And there is risk in both. However, a public university research centre with a focused and specific mission is fertile ground for new ideas and early-stage testing, creating highly skilled jobs and a comparable workforce attractive to companies. Academic success in obtaining federal funding, as well as the attraction of corporate interest and finances, is dependent on data coming from modern infrastructure and pilot research programmes funded locally, by the university and the state.

The RNA Institute has been fortunate to receive initial federal, state and university funding for creating the only infrastructure of which we are aware that is exclusively designed for working with fragile, small and large RNA molecules as tools, targets and possible therapeutics. The Institute is designed with mobile benches and walls to change its geometry and capabilities with the needs of the research field. The Institute has a growing University at Albany faculty committed to RNA research in the most difficult of human diseases, and has requested future faculty that bridge boundaries between the basic sciences and business and public health. In addition, the Institute has set aside a 1,000sq ft laboratory for visiting academic and corporate scientists and engineers to be involved in the commercial enterprise of applied science, as well as a modern computation and imaging lab for predicting drug design and visualising their effects on cells and tissues. The uniqueness of the Institute has produced a programme of more than 50 academic labs and some 375 researchers nationwide-literally an intellectual powerhouse attractive to corporations wanting new products, drugs and diagnostics in the RNA world.

As with a business venture, corporate America is attracted to the university research enterprise if the university and the state have demonstrated a substantial and sustaining commitment to success, financial and otherwise. Though new, The RNA Institute has a half-dozen corporate research partnerships and is adding more each year. These arrangements require a public university to have an increasingly flexible approach, enabling the relationship to be fashioned for the mutual benefit of the university, the public and the corporation. Without flexibility to negotiate, the promise of return on the university's and state's investments is moderated.

Students engagement as value-added education

There is risk and promise when young scientists are involved in applied research, though this has been common to the engineering sciences for decades. One risk prominent in the minds of student and mentor is the delay in publications and presentations in which the student or postdoctoral fellow is the first author. The delay is a consequence of the publication or presentation producing a commercially viable product that first must be legally protected. Delayed publications inhibit young careers and also hamper the faculty mentor in acquiring funding. Thus, having students and postdoctoral fellows engaged in applied science has been frowned upon, especially in mentoring young scientists into academic careers. Yet it is documented that faculty now retire later rather than earlier for many reasons, leaving fewer positions for young scientists. Research training in the basic biological, chemical, physical and computational sciences now leads to many more careers than academia alone. Centres such as The RNA Institute promote the diversity of career opportunities. In collaboration with the University at Albany School of Business, the Institute developed a Student Venture Fund, a successful model for engaging science students and faculty in entrepreneurship. PhD science

graduate students, postdoctoral fellows and faculty, together with MBA students, are challenged to be creative and practical in a course in entrepreneurship. The goal of the course is for class teams comprised of both scientists and MBAs to compete in developing a novel scientific invention of potential commercial value, of which a prototype could be designed and implemented in 12 months with $50,000. Supported by the biotechnology company, Thermo Fisher Scientific, this programme has yielded at least one commercially-viable prototype and a second under consideration for further developmental funding in less than 12 months.

Centres such as The RNA Institute at a public university are responsive to training those members of our society who are historically underrepresented in the application of basic sciences to human health problems. For nearly three years, The RNA Institute's University-funded, Interdisciplinary Pilot Research Program has funded inventive and more risky and applied research of faculty and their students at the University at Albany and collaborating institutions.

Administrative independence

Independence of choice and flexibility of process enable centres of basic science to apply fundamental knowledge to technology development and to be innovative in doing so. Importantly, a degree of independence is key to initiating competitive and unique collaborations between the public university and private corporations. The success of a centre of applied research excellence necessitates manoeuvrability coupled to the speed of the corporate world. Unfortunately, this freedom and speed of process usually makes public university administrators uncomfortable. With a degree of independence, The RNA Institute has been able to muster University influence and prestige to form beneficial public-private partnerships not otherwise achievable. The Institute markets the intellectual prowess of the associated faculty and technical staff, along with its research infrastructure competitively and within the context of a product- and profit-driven economy. University administrators successfully entering the world of public-private partnerships for the advancement of research and education will acknowledge that opportunities are made through the independence of their centres and institutes. The RNA Institute occupies an important niche within an 'RNA market economy'.

Ease of process

With university and state support, a centre of applied science must abide by policy, conflict of interest and law with faculty and student creativity, and company spin-outs from faculty research and public-private partnerships. Yet, without a centralised organisation in place, both on-campus and within the state, the process can be overwhelming and ultimately devastating to achieving the desired goal. The RNA Institute has taken an unfunded initiative to guide faculty and students through the many steps in creativity and its protection on campus. Some states, North Carolina in particular, have moved aggressively to better enable biomedical entrepreneurship. This is

achieved by centralising both the information and the process for biomedical spin-offs from universities and other start-up companies. 'One-stop-shopping' enables entrepreneurs to obtain start-up-company funding, a list of capable and interested candidates for CEO and other administrative roles (including retired successes), legal and accounting support from local firms and extremely important entré into a very different world. This quickly releases the inventor to do what he or she does best – invent and develop.

More than ever before, America's innovation economy is dependent on a nexus of university and corporate collaborations. The roles of faculty in the basic sciences have surpassed the traditional classroom and research mentor, to one of a welcome, invited contributor who can provide solutions for some of the most difficult health issues through translational biomedical science.

Biomedical and biotechnical corporations worldwide have recognised that investing in university intellectual and instrumental capital has significant value to their bottom line and represents the future. New models of academic/corporate partnerships are successful at universities that have an uncompromising commitment to a small number of unique research enterprises. These centres of excellence succeed because they demonstrate value, engage students in multiple career choices and support a creative environment leading to practical solutions with corporations. As such, they are worthy of continued university financial support, an administrative independence and ease-of-process to establish lasting, synergistic public-private partnerships. DDW

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