Drug Development Working Group Report: Analysis of Existing Strengths, Critical Gaps, and Opportunities for Collaboration
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1.***Analysis.*** *Biopharma - Focused on innovation with clinical application.* Universities will play an increasingly large role in driving innovation in the biomedical industry for the foreseeable future. In New Jersey, there are several major biopharmaceutical and >350 smaller biotechnology and related companies with one or more employees. The recent integration of Rutgers creates a unique opportunity to align the University's considerable drug discovery and development strengths. A directed effort of this sort would greatly enhance the capabilities of the University and enable University research to synergize with the biopharma industry, broadly defined. Although there have been shifts, mergers, and acquisitions in the New Jersey biopharma industry, the biopharma industry has continued to thrive. In 2003, the NY/NJ biopharma region had 17 companies with valuation >$100 M; in 2013 this region had still had 16 such companies. Moreover, the region is still vibrant: it continues to be home to large biomedical corporations, startups, entrepreneurs, and the world center for finance and capital. New Jersey also has quality industrial laboratory space, an ecosystem populated by a talented and experienced work force that has made New Jersey the "medicine chest of the world," and an unparalleled opportunity to combine these factors in biopharma ventures that build on partnerships between Rutgers University and industry. Indeed, the primary difference between now and 15 years ago is that the present industry now is willing to reach out in a highly dynamic fashion. Rutgers is uniquely positioned to step forward as the premier university leader in biomedical innovation and development in the region.

Rutgers Core Competencies in Platform Technologies and Disease-Focused Translational Research. All drug discovery and development companies, regardless of therapeutic focus, use platform technologies to bridge the gap between clinical need and translational innovation. Rutgers has core competencies in these technologies: **1) structural biology; 2) biologics, proteins, and polypeptides; 3) drug delivery; 4) computational biology and structure based drug discovery; 5) molecular synthesis; and 6) translational science**. Rutgers also has established and emerging competencies in disease-focused translational and discovery research. These additional competencies are: **7) oncology; 8) infectious disease; and 9) neurological disease.** We also have the opportunity to build a complementary and supporting capability in **10) pharmacoepidemiology**. Beyond these, Rutgers has considerable strengths in a wide scope of discovery biology that we have not designated as core competencies, including metabolomics, fibrosis, inflammatory disease, and neurotrauma.

Funding and Faculty. The below tables summarize the highly collaborative faculty and funding represented in the core competence areas of drug discovery and development. The list, though not comprehensive, captures the essence of the strengths and capabilities of Rutgers in drug discovery and development. The following sections describe the strengths and gaps of the core competencies in technologies and disease areas, and identify opportunities for collaboration.

Table 1: Biomedical Funding for Legacy Rutgers and UMDNJ Organizations 2011-13

	Legacy Rutgers	Legacy UMDNJ	Total
Faculty members*	25	75	100
Funding FY2011 – FY2013	$135,154,588	$69,157,153	$204,311,741
Publications			~2,000

*This list is not comprehensive.

Table 1: Total funding for drug discovery research obtained by faculty members from the legacy Rutgers and UMDNJ organizations over the three most recent fiscal years for which data is available. The total number of faculty in this analysis is 100. Over this three year period, the mean funding per faculty member engaged in drug discovery research is $2 M. Approximately 2,000 articles were published over the course of five years at a rate of ~4 per year.

Table 2: Biomedical Funding by Source 2011-2013

Funding – Biomedical Faculty*	FY 2011	FY 2012	FY 2103
Federal Government	$49,323,238	$54,005,904	$60,493,712
State Government	$1,312,192	$344,713	$1,059,459
Corporations	$3,661,730	$3,203,206	$3,717,685
Foundation	$1,277,641	$2,614,589	$3,485,458
Associations and Other Sponsors	$1,203,526	$1,163,181	$1,219,369
Institutes of Higher Education	$5,402,415	$4,882,784	$5,946,938
Total	$62,180,742	$66,214,377	$75,922,621

*This list is not comprehensive.

Table 2: Breakdown of annual funding expenditures for drug discovery faculty by source for the fiscal years 2011-2013. The number of faculty in this analysis is 100. These data are from the same source as Table 1.

Strengths.

1. Structural Biology. One of the key contributing technologies to drug discovery is structural biology, especially protein structure determination. Rutgers is among the premier institutions worldwide in structural biology. Rutgers is the home of the Research Collaboratory for Structural Bioinformatics Protein Data Bank (www.rcsb.com), the sole global repository for biological macromolecular structure data. Rutgers structuralbiology has extensive X-ray expertise, as well as NMR and information management expertise and capabilities. Distributed throughout the university are clusters of instrumentation for protein structure determination and characterization, including X-ray diffraction, NMR spectroscopy, mass spectrometry, protein/nucleic acid biophysical characterization tools, and hardware for high performance computing. Given a protein target, structure-based methods represent powerful ways to initiate drug discovery and understand mechanisms of action.

The strengths of this core competency focus on the ability to reliably conduct structure determination on single protein targets as well as on large biomolecular complexes. There is considerable expertise in structure determination on a broad range of protein targets. Transcription, including viral and bacterial targets, complexes of DNA with polymerases and transcription factors, chromatin structure, collagen, and many additional targets, and target-ligand complexes, are focus of study. Discovery and translational research includes macromolecular level analysis, fragment screening, and iterative structure-based drug design in oncology and infectious diseases.

2. Biologics, Proteins and Polypeptides. Peptides and proteins for therapeutic applications have emerged as a major area of drug discovery and development. In 1997 there were few biomolecule drugs, and none of them were on the top ten list. Only 15 years later, 7 out of the top ten selling drugs were biomolecules. This area is an important core competency for Rutgers University. In addition to peptide and protein modeling and engineering, these macromolecules are being developed at Rutgers against clinically significant targets and as promising technologies for delivery and enhanced efficacy strategies. The combined structural biology capabilities at Rutgers allow for hypothesis testing by characterization with the therapeutic target.

Strengths in peptide and protein therapeutic applications include the ability to prepare and analyze macromolecules (e.g., x-ray crystallography, binding assays, and stability assays), validate targets, screen compound libraries using in vitro and in vivo models, and conduct proof-of-concept studies to validate biologic therapies using *in vivo* disease models. Discovery and translational capabilities involve targeting influenza, type II diabetes, protein trafficking disorders, and specific cancers; delivery strategies; multifunctional nanoparticles; cell membrane and blood-brain-barrier penetration; and biomaterials for wound healing and spinal cord regeneration.

3. Drug Delivery. Drug delivery therapeutic strategies have emerged as a major area of drug discovery and development, and Rutgers houses several leaders of the drug delivery field. This core competency is focused on strategies and methods for targeted drug delivery, drug release, and the development of biocompatible and biodegradable medicinal materials

Additional strengths in drug delivery technologies include the ability to prepare and analyze nanocarriers and other macromolecules for drug delivery, as well as non-viral nanoscale-based delivery systems for antisense oligonucleotides, siRNA, peptides, and related biologics. Discovery and translational capabilities cover a range of research with an emphasis on drug delivery in dermatology, oncology, and infectious disease, including treatments for non-small cell lung cancer, breast cancer invasivity, melanoma,

and HIV. These capabilities also extend to proof-of-principle studies for therapy validation using *in vivo* disease models and to preclinical evaluation of therapies.

4. Computational Biology and Structure-based Drug Discovery. Rutgers is a world leader in the field of computational biology, particularly in structural bioinformatics. This is due in part to the Protein Data Bank and Nucleic Acid Data Bases, advanced computer science technology, and complementary strengths in biochemistry, molecular biology, and genetics. Computational biology at Rutgers aims to understand the complex molecular interactions that link the individual biomolecules to cellular function, disease processes, novel diagnostics, the design of drug lead compounds, and treatment strategies.

Specific strengths in this core competency comprise: molecular and macromolecular structure calculations, modeling of biomolecule interactions with natural and synthetic ligands, genomic and proteomic analysis, including networks, computational biochemistry, and complex cellular dynamic modeling. These tools benefit from the capability to develop and apply quantum mechanical and molecular dynamical methods. The development and application of computational tools for translational research in medicine encompass, for example, bioinformatics approaches to identify cancer subtypes, biomarkers, tissue-level modeling, and population genetics of cancer. Multiple software platforms are being actively developed and used at Rutgers for the modeling of pharmacological and toxicological activity, the design of drug lead compounds, and molecular simulation.

5. Molecular Synthesis. The cornerstone of the drug discovery process is the ability to design and prepare molecules with biological function, and this is unlikely to change in the foreseeable future. Rutgers has considerable strength in this core area. These capabilities are distributed across the university in more than 20research active laboratories that focus on either the development of synthetic methods or the synthesis of target compounds, conjugates, and constructs with desirable biological function. Importantly, this group includes several faculty members with extensive biopharma experience.

Specific strengths in this core competency includes expertise in the preparation of the major classes of bioactive compounds and hybrid structures, for example: traditional drug-like heterocyclic compounds, the major natural product classes – peptides, nucleic acids, carbohydrates and polysaccharides, lipids, steroids, polyacetates and polypropionates, terpenes, alkaloids, and related compounds, as well as the synthesis and optimization of chemical probes, and parallel and solid support-based synthesis. This expertise covers the range of therapeutic areas, especially cancer, infectious diseases, neurologic disease, and immune modulators. Moreover, several groups have expertise in hit exploration, target identification and validation, lead optimization, process chemistry research, and clinical advancement of drug candidates.

6. Translational Science. During the last 8 months, Rutgers has consolidated core competencies in translational science, including specific expertise and capabilities in drug discovery and development, under a single, central entity independent of academic units and schools: Office of Research and Economic Development (ORED). ORED enables researchers at Rutgers to locate and access expertise in drug discovery and development, sets Rutgers apart from other universities who have created centers that are tied to, and dependent on, single departments or units. The independence of ORED fosters coordination and synergy and builds bridges across the biomedical sciences.

ORED strength in translational science is currently derived from four key areas: medicinal chemistry, molecular imaging, compound screening, and animal models of disease. (1) *Medicinal Chemistry:* In addition to the core competency at Rutgers in academic groups which conduct molecular synthesis, Rutgers has scientists with experience and commercial success in the design and synthesis of drug candidates. The ORED Translational Synthesis Laboratory is equipped for early drug discovery, to interface with biology faculty and startup companies, and to provide consultation in drug discovery with seasoned NJ-biopharma industry veterans. (2) *Molecular Imaging*: Rutgers is able to conduct a wide variety of imaging studies in vivo, including PET/CT, MRI, X-ray, optical, and ultrasound imaging. Imaging facilities exist at the medical schools and in Newark, in particular at the Rutgers University Brain Imaging Center, which conducts human and animal imaging studies with a 3T MRI. Additionally, in vivo fluorescent/luminescent imaging is available in the NJMS-MSB vivarium and the Newark Cancer Center vivarium. (3) *Compound Screening*: Small-molecule screening is being carried out by a number of groups. For example, the NIH-funded Center of Excellence in Translational Research antibacterial-drug-development team is building a screening workflow and developing multiple translational programs. There are focused screens with compounds (100-1000) in assays with drug-resistant bacterial pathogens, including both priority public-health pathogens and priority biodefense pathogens. Rutgers University also has access to ultra-high-throughput screening (UHTS) capabilities at Venenum BioDesign. Ongoing efforts are in progress to build on our fragment-based and medium-throughput screening technologies. (4) *Animal Models of Disease:* Vivaria are located throughout Rutgers, including the NIH-funded Regional Biocontainment Laboratory (RBL), which is located at the International Center for Public Health in

Newark and which provides high biosecurity and biocontainment levels up to biosafety level 3 (BSL-3), the recently renovated NJMS-Medical Sciences Building Vivarium, and facilities for producing genetically modified mice (NJMS and CINJ). Most of the vivaria have the ability to house mice and rats. Several also can house rabbits, and the NJMS-MSB vivarium in Newark and vivaria in Piscataway/New Brunswick also can house larger animals. The vivaria add significant capabilities in translational research, especially in developing and testing animal models of disease, specifically in the evaluation of molecules that affect physiological processes. Examples include research on treatments for cancer, infectious disease, tissue regeneration, reduction of cardiac infarct damage, and reduction of the metabolic effects of sepsis.

7. Oncology. The greatest strength of cancer research at Rutgers is that it houses an NCI-designated comprehensive cancer center (RCINJ), which is the only comprehensive cancer center in the State, and whose primary mission to facilitate translational research. Moreover, RCINJ has state-wide authority beyond the University matrix. As such, it offers a consortium of drug discovery and development researchers to the entire state and a direct entry point to biopharma and other academic institutions, such as Princeton University. Drug discovery research in oncology at Rutgers is extensive and cuts across the university.

The strengths of translational and discovery oncology, as they relate most directly to drug discovery and development, fall into two categories: basic research and major initiatives in drug development. Specific strengths in cancer at Rutgers include breast, head and neck, melanoma, myeloid and lymphoid leukemia, pancreatic, and prostate and related cancers. Drug discovery and development efforts focus, among others, on: (1) apoptosis, (2) autophagy and metabolism, (3) DNA damage and repair, (4) target identification and validation, (5) new chemical scaffolds (including chemical scaffolds derived from natural sources, designed based on structural data of the target, and arising from compound screening related molecules), and (6) development of new and repurposed anticancer agents, including new combined therapies. Major initiatives in drug development include, among others: (1) Phase I/Investigational Therapeutics Program, a multidisciplinary scientific group that develops new methods for treatment of cancer using the newest and most promising anti-cancer treatments; (2) Precision Medicine, comprising genomic analysis and biomarker assessment to develop personalized therapeutic regimens for cancer patients, including those with rare and resistant tumors.

8. Infectious Disease. Basic and applied research on infectious disease and antivirals research is one of Rutgers' greatest strengths and is the research area where significant commercialization of Rutgers intellectual property has taken place in recent years. The International Center for Public Health and NJ Medical School house a large group of researchers who have focused their research on diagnostics and therapies for infectious diseases. The adjacent Public Health Research Institute has a staff of over 20 researchers who are studying infectious disease and are wholly supported by grants and licensing income. This group recently received a large NIH Center of Excellence in Translational Research grant to develop countermeasures to drug-resistant bacterial pathogens.

Research on diagnostics for infectious diseases at Rutgers includes the development of Molecular Beacons. Molecular Beacons are best-in-class diagnostic tools and have been a source of significant revenue for Rutgers. The recent combination of this technology with quantitative PCR has led to the design of a diagnostic test for drug-resistant TB that has been endorsed by the World Health Organization and licensed by Rutgers to Cepheid, Inc. Research on therapeutic agents for infectious diseases at Rutgers includes the development of antibacterial drugs targeting bacterial cell division – which have been licensed to Taxis, Inc., a Rutgers University spinout company, for further optimization and development – antibacterial drugs targeting bacterial RNA polymerase and the development of anti-HIV therapeutics targeting HIV reverse transcriptase and anti-influenza therapeutics targeting influenza RNA polymerase.

9. Neurologic Diseases. Drug discovery and development in neurologic disease is an emerging core strength area at Rutgers. In addition to traumatic injury and repair, the primary focus of neuroscience-based drug development is in Parkinson's disease and Multiple Sclerosis. It is our expectation that translational science in neurologic disease will grow significantly over the next several years, since age-associated neurodegenerative disorders constitute a significant societal and economic burden, are increasing in prevalence with the aging population, and represent major unmet medical needs.

The strengths of this core spans drug discovery and development. Thus, this competency includes capabilities in target identification based on, for example, microRNA regulation, protein misfolding and neuronal death pathways mechanism of action, as well as target validation, cell-based drug testing, basic neuroimmunology, biomarkers of response to therapies, humanized transgenic animals, preclinical proof-of-concept animal model testing, collaborations with the Yerkes National Primate Research Center at Emory University, and phase I, II, III, and multicenter clinical trials. These capabilities are focused within the study of Parkinson's, atypical Parkinsonism, cognitive and behavioral aspects of Parkinson's, and/or Multiple Sclerosis. Moreover, this core competency includes the expertise to conduct clinical trials in stroke, epilepsy, ALS, and

Huntington's disease. This is in addition to advances in research on CNS trauma, spinal cord and brain injury.

10. Pharmacoepidemiology. This field of study, although in early stages at Rutgers, can play a key supporting role in drug discovery and development and other clinical studies, especially on mechanistic, preclinical, early clinical (safety), and with post-marketing safety evaluations. In addition to the considerable resources in computer science, significant data resources for pharmacoepidemiology research exist at Rutgers, for example at the Institute for Health, Health Care Policy and Aging Research, the Cancer Institute, and the School of Public Health.

A direct connection of pharmacoepidemiology research with drug discovery and development exists both in the area of regulatory science as well as in the ability of population-based observational studies to strengthen hypotheses for the repurposing of existing drugs for other indications. This research area thereby comprises an additional input into the drug discovery pipeline that is enabled by large data resources and drug discovery and development capabilities.

Critical Gaps. There are four gaps in drug discovery and development at Rutgers that, if closed, would transform both this cross-disciplinary research in early discovery and translational science across virtually all biomedical research in the university. These are: ***(1) the absence of enabling mechanisms for collaboration, coordination, and leadership of drug discovery research, (2) the absence of core facilities and instrumentation for drug discovery, and (3) the absence of training in core competencies critical to the drug discovery, and (4) the absence of mechanisms to establish and maintain relationships between University drug discovery researchers and NJ biopharma industry partners***. Additional specific critical gaps in core areas include:

- **Biologics, Proteins, and Polypeptides.** Rutgers does not: (1) have an active capability to manufacture compounds under GLP/GMP conditions or carry out preclinical IND-enabling studies; (2) have a strong recent track record of attracting corporate partners to collaborate, license, and/or develop potential drugs; (3) have a single core facility that consolidates existing biophysical characterization capabilities, including Surface Plasmon Resonance, Isothermal Titration Calorimetry, Differential Scanning Calorimetry, Ultracentrifugation, Circular Dichroism, Electron Microscopy, Biological Mass Spectrometry fluorometers, spectrophotometers, and other analytical tools essential to evaluate the performance of new molecules. The cost of GLP/GMP manufacturing and studies to file an IND is estimated at $3 M.
- **Molecular Synthesis.** All therapeutic areas and core competencies across the Drug Discovery spectrum need the expertise and resources of a molecular synthesis core. Synthesis is highly labor intensive. Simple molecules can be prepared in a timely manner by skilled undergraduates with suitable supervision and guidance, but other targets require extensive knowledge and expertise. Rutgers has the extensive infrastructure required, including instrumentation, resources, and laboratory space (NMR, MS, chemicals, hoods, etc.). However, there are currently few locations in the University that support modern molecular synthesis, and synthetic service capabilities are not well defined or widely known. Moreover, there are only three synthetic or medicinal chemistry tenure track faculty under the age of 50 and none under 40.
- **Translational Science**. *Compound screening:* The lack coordination of small-molecule screening across the biomedical research units is a critical gap, since it is one of initiation points in the drug discovery process. Moreover, we currently lack the expertise required to design, build, and maintain a state-of-the-art screening facility. Although it is appropriate and cost-effective to utilize the Molecular Libraries Probe Production Centers Network infrastructure, we lack: (1) specific screening capabilities (BSL-2 and BSL-3, zebrafish, phenotypic screens); (2) a medium-sized throughput collection of diverse small molecules for screening; (3) a substructure-searchable database to manage all of the relevant structural and biological data. *Pharmacology in vivo:* The role of CMR in maintaining and building in vivo facilities needs to be clarified and disseminated to researchers across the university. Hiring and retention of highly skilled animal handlers and technicians will be essential to preserving the highest quality results from the laboratories conducting research in vivo. Although Rutgers has a significant amount of vivarium space, certain equipment essential for performing research is lacking. For example, the NJMS-MSB vivarium has no X-ray facilities, which are essential for many surgical procedures and for insuring animal health.
- **Oncology**. The strength of RUCINJ as a designated comprehensive cancer center is not fully realized nor is its tremendous value generally appreciated within the University or the broader community as a research partner in drug discovery and development. The vitality of drug development-centered programs, for example the Investigational Therapeutics Program/Phase I Program, is greatly enhanced by industrial collaborations, and yet in some areas collaborative industrial engagement is lacking. Of course, industrial collaborations and partnerships are highly desirable across the drug discovery, development spectrum, as mentioned above. Research scientists and clinical investigator teams have not established collaborative

partnerships with major pharmaceutical companies in areas of mutual interest.

- **Infectious Disease.** The critical gaps noted above in *Molecular Synthesis* and *Biologics, Peptides, and Proteins* are especially acute in the infectious disease area, since Rutgers researchers in the infectious disease have generally moved beyond discovery-stage research and are therefore dependent on the resources and expertise noted above under *Molecular Synthesis* or late-stage preclinical development (IND-enabling studies).
- **Neurological Disease.** The existing core competencies in target identification, target validation and translational research in neurologic diseases lack the expertise of experimental neuropathology that can bridge preclinical animal model testing to human postmortem studies. Additionally, capabilities in neuroimaging, including functional imaging, to support clinical phases of drug development are needed.

- **Pharmacoepidemiology**. Pharmacoepidemiology programs can be strong with a small number of faculty. With modest investment, Rutgers can create the standout program in pharmacoepidemiology in the Big Ten, and impact both the local biopharma cluster and the broader drug discovery and development community. Needed capabilities include: (1) a graduate education track in the Health Education and Outcomes Research (HEOR) program, (2) access to additional large claims or EHR databases, and (3) enhanced data infrastructure and programming capacity. Since pharmacoepidemiology programs can be quite strong with a small core faculty, two hires in this area should enable creation of a graduate program.

- ***Opportunities for collaboration.*** The cornerstone of success in drug discovery and development is close collaboration among scientists from theory and basic experimental science to clinical practice – and from academia to industry. The primary populations who will collaborate with faculty represented by the drug discovery and development group are researchers within the university, neighboring institutions, and the local biopharmaceutical, biomedical and diagnostics industries.
  - **Core Competencies form Collaborative Networks.** Drug Discovery and Development is a network of technology platforms and therapeutic expertise. There is a strong motivation for collaboration across the technology platform cores (*Structural Biology; Peptides and Biologics; Drug Delivery; Computational Biology and Structure-Based Drug Design; Molecular Synthesis; Translational Science; Pharmacoepidemiology*). Although collaborative research between the disease-focused cores (*Oncology; Infectious disease; Neurological Disease*) may be limited in scope because of specialization, there is tremendous synergy created when colleagues in the therapeutic cores collaborate with those in the technology platforms.
  - **Platform Technology Core Competencies Synergize with multiple RBHS Strategic Plan Working Groups and Signature Programs.** The platform technology cores present outstanding opportunities for collaboration with researchers that fall within potential signature areas, especially: (1) Cancer & Cancer Prevention; (2) Neuroscience; (3) Infectious Diseases, Immunity, Inflammation, HIV & TB; and (4) Clinical Research & Translational Research. Moreover, several of the cores we have described, whether technology platform or disease-focused, are synergistic with: (1) Big Data, Computation, Bioinformatics & Genomics; (2) Biomedical Imaging, Biomaterials, Devices, Diagnostics, Nanomedicine & Bioengineering; (3) Stem Cell & Regenerative Medicine.
  - **Core Technology Laboratories supported by the Office of Research and Economic Development (ORED)**. The platform technology capabilities in *Translational Science* serve to provide drug discovery and development expertise and capabilities beyond what is normally possible and supportable within academic units. These laboratories serve to promote collaboration between the biomedical and molecular sciences, facilitate preliminary data for grant applications, and increase value in biomedical research across the university. Laboratories that support academic and clinical research in drug discovery and development include Translational Synthesis, Chemical Biology, Molecular Imaging and Histopathology. These laboratories are staffed by non-tenure track veteran scientists from the pharmaceutical and biotechnology industries who are focused on adding value to faculty research through service research and collaboration, including collaborative grant applications as appropriate.
  - **Core Competencies Represent Synergistic Collaborative Opportunities with Biopharma and Neighboring Institutions.** With several major biopharmaceutical and >350 smaller biotechnology and related companies in New Jersey, the new integrated Rutgers has the opportunity to foster broad-based collaborative opportunities. The Core Competencies described here represent opportunities for research collaboration and partnerships with our counterparts in the private sector. Startup companies and smaller biotechnology companies have an urgent need to access high-end equipment, talent, and collaborators. Small company collaborations may be fundable by the NIH (e.g., SBIR, STTR). While large company collaborations may be high profile, such collaborations are generally built stepwise from smaller research

collaborations and are based on existing strengths. Another important collaborative connection is to build bridges with other academic institutions in this biopharma cluster. Regardless of the partner, rewarding collaborations require strong relationships and complementary capabilities.

Summary of Best in Class. Focused and strategic action by University leadership can establish Rutgers as first-in-class in drug discovery and development in the Big Ten within five years. Within the Big Ten, the Universities of Michigan and Minnesota have created centers around the broad theme of drug discovery, are strong in several components of the drug discovery pipeline, and like Rutgers, have a designated comprehensive cancer center affiliated with their institution. The University of Minnesota has received significant income from the important AIDS drug abacavir (Ziagen®), which is on the WHO list of essential medicines. Northwestern University currently has income of over $100M/year from sales of pregabalin (Lyrica®), which has found widespread use in the treatment of neuropathic pain and fibromyalgia. Rutgers University revenues from biomedical licensing alone in 2013 totaled $9.6M, placing it 6th in the CIC relative to the ***total*** revenues recorded by the Universities of Wisconsin, Illinois, Michigan, Minnesota and Northwestern University. None of these universities have programs that are as extensively integrated and strategic in scope as proposed here. In our opinion, they fail to effectively harness their own internal research and development potential. These universities also lag in core capabilities where Rutgers is particularly strong, for example, in structural genomics and infectious diseases.

There are approximately 100 self-described academic-based drug discovery centers in the US. The majority of these have a narrow focus and modest impact on their home institution as well as on the proximate economic environment. Of the top four biopharma clusters (Boston, San Francisco, San Diego, and New Jersey) only New Jersey currently lacks a comprehensive academic drug discovery and development center. Importantly, Rutgers is the only Big Ten School situated within a major biopharma cluster, housing an ecosystem replete with biopharma corporate stakeholders, access to extensive venture capital, financing instruments, as well as a uniquely experienced and entrepreneurial workforce. Building a broad drug discovery and development capability represents a major opportunity for Rutgers University, for potential partner institutions, for regional industry, and for the State of New Jersey. Taken together, these strengths place Rutgers on a trajectory to lead the Big Ten and to be among the leaders in drug discovery and development nationally. As outlined below, Rutgers University has the opportunity to leverage current strengths and create a signature program that will establish it as a national leader in drug discovery and development.