

**III. Executive Summary** (limited to one page)

We propose establishing a North Dakota Economic Development Center of Excellence (ED-COE) in Biopharmaceutical Research and Production (CBRP, The Center) to perform economically significant and market-driven research and development of biopharmaceuticals like vaccines that address commercially relevant, industrial problems for companies located in North Dakota. The Center would help move the most innovative research from NDSU's College of Pharmacy, Nursing & Allied Sciences into business to create new jobs for North Dakota. With \$2,080,237 of ED-COE funding, CBRP efforts will lead to new or enhanced products that can increase revenue, market share and profitability for ED-COE partner companies which, in turn, should stimulate corporate growth, promote the creation of new jobs, and lead to further economic development in North Dakota. The proposed CBRP projects are new, market driven research activities dictated by industrial needs of such North Dakota companies as Aldevron, Clinical Supplies Management (CSM), ParaClin, PRACS Institute (PRACS), and MeritCare. The Greater Fargo-Moorhead Economic Development Corporation (GFMEDC) has great interest in potentially providing future funding for the Center. We estimate the creation of about 40 new professional and technical jobs within the private sector partners, including 15 new jobs by direct hires in CBRP at NDSU. The Center will become self-sustaining by generating and maintaining multiple revenue streams from both public and private sectors. The Center's synergistic and sustainable relationship with academic, industry, federal funding agencies and the community will fuel biopharmaceutical and life sciences sectors to discover and develop new vaccines and other biopharmaceuticals to treat some of the most challenging diseases facing humankind.

# **Revised Budget for the proposed Center for Biopharmaceutical Research and Production**

## **REQUESTED FROM THE ND ED-COE PROGRAM:**

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Total</b>
Personnel (faculty, staff, technician, Post-doctoral fellow, graduate students)	\$305,363	\$320,631	\$336, 663	\$962,657
Equipment	\$737,343			\$737,343
Supplies	\$75,000	\$75,000	\$75,000	\$225,000
Operating	\$25,000	\$25,000	\$25,000	\$75,000
<b>Total Fund Requested</b>	<b>\$1,142,706</b>	<b>\$420,631</b>	<b>\$436,663</b>	<b>\$2,000,000</b>

## **MATCHING FUND**

<b>Private-sector cash matching for projects</b>				
Aldevron	\$16,666	\$16,667	\$16,667	\$50,000
<b>Private-sector in-kind matching for projects</b>				
Aldevron (manpower and facilities)	\$147,334	\$147,333	\$147,333	\$442,000
CSM	\$50,000	\$100,000	\$100,000	\$250,000
<b>Federal Funds Facilitated with Private Sector</b>				
Aldevron	\$1,166,666	\$1,166,667	\$1,166,667	\$3,500,000
<b>Federal Funds Facilitated with NDSU</b>				
Dept of Pharmaceutical Sciences	\$166,666	\$166,667	\$166,667	\$500,000
<b>Total Matching Fund</b>	<b>\$1,547,332</b>	<b>\$1,597,334</b>	<b>\$1,597,334</b>	<b>\$4,742,000</b>

## **Appendix B: Narrative Budget Explanation**

### **Personnel:**

Dr. Charles Peterson and Dr. Jagdish Singh will co-direct the Center during the transition period for the first six month, or until which time a high profile scientist at a full professor level is hired to direct the research and development of the Center. Salary support (\$180,000 per year including 30% fringe benefit) is requested for the director. The Center requests salary support for an administrative secretary (\$40,000 per year), a Postdoctoral Fellow (\$40,000 per year), a technician (\$26,000 per year), and a graduate student (\$20,400/year). The director will be responsible for directing, coordinating and overseeing the CBRP private-sector-partnered projects. Academic and graduate student salaries are increased by 5% from second to third years of the project. The above personnel salary includes fringe benefits. Fringe benefits for academic staff are 30%. The fringe benefits for secretary, technician and postdoctoral fellow are 35%. Fringe benefits for graduate student are 2%.

### **Equipment:**

Equipment start up funds is requested for developing well equipped CBRP. It includes major equipment such as Cellerty<sup>TM</sup>, MALDI-TOF, and Real Time PCR. Cellerty is a fully automated solution for cell culture, including the proven Robot Manipulator arm. MALDI-TOF and RT-PCR would be used in proteomics work of biopharmaceuticals.

### **Supplies:**

The funds requested (\$75,000/year) are to allow acquisition of several articles essential for the successful and efficient performance of the proposed work, including biopharmaceutical research supplies, vaccine adjuvants, and small animals.

### **Operating:**

We request \$25,000 per year for three years to meet expenses for office supplies, postage, marketing, and travel for three years. It will meet the expenses for domestic travel for the Center staff for new business development as well as trips to national research symposium for presentation of results and general Center advertisement. It also includes expenses for market analysis, consultant and patent attorney fees, and business plan development.

### **Private-Sector Matching**

The matching is based on commitments noted in the letters of commitment and business plan of Aldevron and CSM.

### **Federal Matching Funds**

The federal matching funds from the private sector (Aldevron) are funds from US department of defense and National Institutes of Health. Aldevron would contribute a minimum of \$3,500,000 to conduct research and develop infrastructure to advance the Center. The NDSU Department of Pharmaceutical Sciences will match \$500,000 over three years from the federal funds (NIH and NSF).

### **A Tentative Timelines:**

**Year 1:** Recruitment of a high-profile faculty at professor level to direct the Center, administrative secretary, technician, post-doctoral fellow and two graduate students for the Center; purchasing equipment (Cellerity, MALDI-TOF, Real Time PCR and miscellaneous items) to establish the Center and begin biopharmaceutical development work; Conducting biopharmaceutical and vaccine development work with Aldevron; Conducting preclinical animal work to test biopharmaceuticals activity and efficacy, and begin to prepare with CSM for conducting clinical studies.

**Year 2:** Continue the biopharmaceutical development and preclinical animal studies; Develop Intellectual Property; Plan to conduct efficacy and safety of biopharmaceuticals in humans with participating companies (MeritCare, CSM, and PRACS); Apply for funding from the federal agencies and private sectors to expand the Center; Help develop start-up companies; Travel to present findings to national symposia and advertisement of the Center; business development plan.

**Year 3:** Continue the biopharmaceutical development, preclinical and clinical studies; Continue to develop Intellectual Property; Apply for funding to the federal agencies and private sectors to sustain the Center; Help develop start-up companies; Travel to present findings to national symposia and advertisement of the Center; Develop relationships with private sectors and potential licensees interested in the market potential of specific products and technologies developed by the Center.