



MUNICIPAL OFFICE COMPLEX  
8401 W. MONROE STREET  
PEORIA, AZ 85345

**CITY COUNCIL SPECIAL MEETING &  
STUDY SESSION  
NOTICE & AGENDA  
Tuesday, May 31, 2011  
5:00 PM  
PINE CONFERENCE ROOM**

**CITY COUNCIL:**

Mayor  
Bob Barrett

Mesquite District  
Cathy Carlat, Vice Mayor

Acacia District  
Tony Rivero

Ironwood District  
Dave Pearson

Palo Verde District  
Ron Aames

Pine District  
Carlo Leone

Willow District  
Joan Evans

City Manager  
Carl Swenson

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**CONVENE:**

**PLEDGE:**

**ROLL CALL:**

**FINAL CALL TO SUBMIT SPEAKER REQUEST  
FORMS:**

## **STUDY SESSION AGENDA**

### **Subjects for Discussion Only:**

1. Presentation on the Peoria Medical Device Incucelerator

## **CONSENT AGENDA**

**CONSENT AGENDA:** All items listed with "C" are considered to be routine or have been previously reviewed by the City council, and will be enacted by one motion. There will be no separate discussion of these items unless a Councilmember so requests; in which event the item will be removed from the General Order of Business, and considered in its normal sequence on the Agenda.

### **CONSENT – New Business:**

#### **1C Authorization to Hold an Executive Session**

Pursuant to A.R.S. § 38-431.03: Discussion and possible action to authorize the holding of an Executive Session for the purpose of discussion with Legal Counsel for legal advice pertaining to the City's position on a proposed Economic Development Incentive and Investment Agreement pursuant to the City's Economic Development Incentive and Investment Policy (EDIIP) with an undesignated applicant that proposes to establish a commercial business operation in the vicinity of Vistancia Boulevard and the Loop 303. (Pursuant to A.R.S. § 38-431.03(A)(4)).

**(Executive Session will be held after the Regular Meeting)**

## **REGULAR AGENDA**

### **NEW BUSINESS**

#### **2R Redistricting**

Discussion and possible action to provide direction to staff to have the City of Peoria's redistricting consultant prepare one or more maps leaving all Council members in their own district.

### **CALL TO THE PUBLIC: (NON-AGENDA ITEMS)**

Your comments pertaining to City Council business are welcome. However, if you wish to address the City Council, please complete a Speaker Request Form and return it to the clerk before the call to order for this meeting. The City Council is not authorized by state law to discuss or take action on any issue raised by public comment until a later meeting.

### **ADJOURNMENT**

**NOTE:** Documentation (if any) for items listed on the Agenda is available for public inspection, a minimum of 24 hours prior to the Council Meeting, at any time during regular business hours in the Office of the City Clerk, 8401 W. Monroe Street, Room 150, Peoria, AZ 85345.

***Accommodations for Individuals with Disabilities.*** Alternative format materials, sign language interpretation, assistive listening devices or interpretation in languages other than English are available upon 72 hours advance notice through the Office of the City Clerk, 8401 West Monroe Street, Room 150, Peoria, Arizona 85345 (623)773-7340, TDD (623)773-7221, or FAX (623) 773-7304. To the extent possible, additional reasonable accommodations will be made available within the time constraints of the request.

**CITY OF PEORIA, ARIZONA  
STAFF REPORT**

**RPT #: SS1**

**Date prepared: May 23, 2011**

**Council Meeting Date: May 31, 2011**

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**TO:** Carl Swenson, City Manager  
**THROUGH:** Susan J. Daluddung, Deputy City Manager  
**FROM:** Scott Whyte, Economic Development Services Director  
**SUBJECT:** Presentation on the Peoria Medical Device Incucelerator

**SUMMARY:**

This presentation on the Peoria Medical Device Incucelerator is a follow up to the May 3 study session which presented options to growing high-wage technology jobs in Peoria by focusing on start-up companies.

The focus and recommendation of this presentation will be the formation of a medical device incubator at Plaza del Rio, in partnership with BioAccel and the Plaza Companies.

**ATTACHMENT:**

The attachment includes the business plan for the Peoria Medical Device Incucelerator.

**CONTACT:** Maria Laughner at 623-773-5121

Business Plan of the

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CITY OF PEORIA

***BioDEVICE INCUCCELERATOR***

*“INNOVATE ... INCUBATE ... ACCELERATE”*

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A partnership between BioAccel, a non-profit organization and the City of Peoria; dedicated to producing measurable economic outcomes through the commercialization of promising biotechnologies.

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**BioAccel**<sup>®</sup>  
Catapulting Arizona Bioscience

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# March 2011

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## **Incucelerator Overview**

### **1.1. INTRODUCTION**

The objective of this project is to create a business incubation center in the City of Peoria. This new entity will be focused on incubating companies that develop medical devices and will actively promote development of a new industry sector in Peoria by accelerating new company creation and job creation resulting in positive economic growth within the City of Peoria. The incubator will be referred to as the “City of Peoria, BioDevice Incucelerator”; bringing together the ideas of ... -Innovation -Incubation and -Acceleration. For the purposes of this Plan, we will refer to the new entity as the “Incucelerator”, to emphasize that we plan to innovate, incubate and accelerate.

The City of Peoria will partner with BioAccel, a non-profit firm that is creating positive economic impact by accelerating the commercialization of late stage discovery research. BioAccel addresses the Valley of Death challenge faced when developing new technology by offering resources that include funding and management of companies developing products and services in the life sciences. BioAccel will utilize its existing business development resources to attract, assist, and help grow companies in the program addition. BioAccel will also professionally manage the Incucelerator for the City of Peoria.

This partnership with BioAccel provides both structure and function to this project that is not found in other Business Accelerators or Incubators; whether they exist in the Phoenix area, statewide or beyond. Companies who enter the Center can increase their potential for success through the utilization of these services and network of partners. BioAccel provides important services such as Business Plan review, Technology review, Regulatory (FDA) assistance and even access to pre-qualified prototyping and manufacturing firms. These services will not only propel the Incucelerator tenants forward in their quest for Commercialization, but also increase their chances for success as a viable new company.

This Business Plan sets in place a 5-year objective. A commitment to this time period is crucial to meeting the goals of the City of Peoria and the Incucelerator, which are to impact local job growth as well as to ignite a business culture where Medical Device companies are attracted to locate in Peoria.

### **1.2. CITY OF PEORIA DISTINCTIVE**

The City of Peoria has long been identified as one of the most live-able cities in the US. With a population over 150,000 (and growing), Peoria offers the type of amenities many people desire, such as:

- Sports facilities (MLB Spring Training), and other entertainment

- Shopping
- Diverse, affordable housing in award-winning master-planned communities
- Highly ranked schools
- Stunning parks and recreational areas

The City has a strong health care focus as indicated by having 20% of its jobs in that field. With the largest off-hospital campus in Arizona, it is uniquely positioned to host the BioDevice Incucelerator.

It is clear, that people love living in Peoria. However, most commute (sometimes long distances) to their place of employment. The Incucelerator seeks to reverse this trend by providing incentives to Bio-related companies that would locate in Peoria.

### 1.3. BIOACCEL DISTINCTIVE

Simply put, BioAccel’s mission is to drive economic development in Arizona through the commercialization of innovative research in the life sciences. BioAccel, a non-profit organization, accomplishes this mission by focusing on late stage research and technology; transforming research discoveries into new business opportunities with a focus on diagnostics, therapeutics, medical devices, tools, and services. The organization provides:

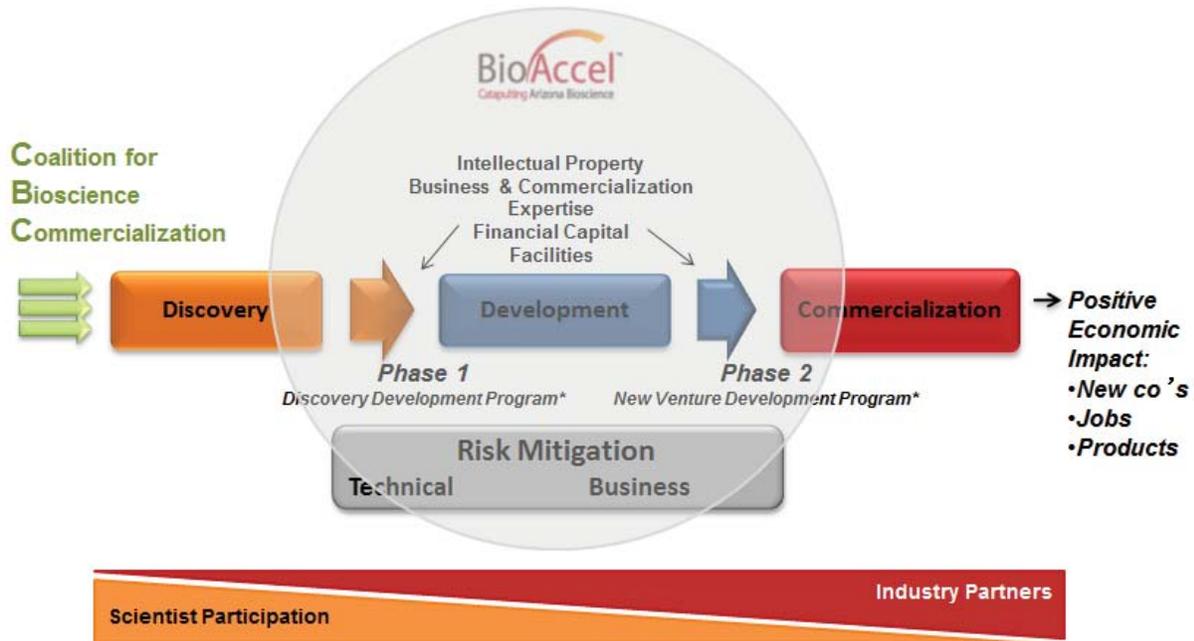
- Proof of concept funding for commercially viable research projects
- Hands-on technical and business mentoring, strategic planning and support services to assist entrepreneurs and early-stage companies to accelerate research outcomes towards commercialization, and,
- Educational opportunities to entrepreneurs, scientists, students, and philanthropists to help them better understand the integrated system necessary to transform a life science discovery into commercial success.

BioAccel is addressing the key issues surrounding the challenge of commercializing life science devices by providing assistance in funding, partnerships and high-level mentorship. The graphic below captures an overview of how BioAccel helps companies move from discovery, through development and into the marketplace. Their focus is to bridge the gaps between development and commercialization – to ensure that each company will be successful and relocate into the City, expand, add jobs and create positive economic impact.

### The BioAccel Business Model

## ***Bio*business *Acc*elerator**

... bridging the Discovery to Commercialization Gap



\* BioAccel Programs



BioAccel® recognized the need to have a pipeline that identifies technology to create critical deal flow and founded the Coalition of Bioscience Commercialization (CBC). The organization consists of eight research-performing institutions from across the state along with the Science Foundation Arizona. The CBC ensures that experts in the field of bioscience commercialization are provided access to technology and participation in a technical assistance network that provides review assistance, mentoring and access to business and legal expertise. The CBC will be expanding to include the Incucelerator and other Accelerator/Incubator organizations in order to leverage existing assets and expertise across the state. BioAccel® has also established partnerships and strategic alliances with local angel groups, venture funds, incubators and other entities that are important components of the commercialization life science ecosystem.

Integration and leveraging of Incucelerator and BioAccel Programs:

BioAccel® currently operates Arizona’s only statewide, **Bio**business **Acc**elerator that incorporates proof of concept as a platform to build strong, sustainable companies. BioAccel and its innovative **Bio**business **Acc**elerator provide both the model and resources necessary to address the issues noted above by bridging the financial, technical, business and mentoring

gaps that exists when transforming early-stage technology into a commercial enterprise. The **Bio**business **Accelerator** focuses on helping to mitigate both the science and business risks associated with expedited new company formation. The knowledge, expertise and program structure will serve as the platform to build the Peoria Incucelerator. The existing program includes a multi-stage approach that ensures both a pipeline for new company formation as well as the ability to identify new companies to incubate within the Incucelerator. The programs includes support of proof of concept projects to ensure an ongoing pipeline for technology development (Phase 1), along with a program that can establish new companies and/or support early stage start-up companies (Phase 2) that can be located within the Incucelerator.

Phase One funds research projects that have progressed to a point where a potential commercial product can be envisioned, but additional development efforts are required to validate the initial discovery and commercial potential. Projects that require proof-of-concept, validation, pre-clinical data, or prototype development are examples of projects eligible for Phase One funding. This funding provides a mechanism that allows these projects to progress quickly to the next stage of commercialization, while also increasing the technology's value for the inventing institution. BioAccel® provides hands-on management and oversight to these projects to ensure that focused milestones result in accelerated outcomes. A typical Phase One project should require less than \$100,000 and be completed within six months.

Phase 2 activities and funding create new companies graduating from Phase One that show clear commercial potential, as well as supports very early stage companies (less than a \$3M valuation and in operation for less than 2 years) that require management, technical development and funding to validate their core technology. Phase Two provides assistance in launching the company, forming the management team, identifying facilities, and providing mentorship for the entrepreneur through the initial stages of the company's formation. These new companies are typically too early in development to attract Angel Investor or Venture Capital financing and BioAccel® programs help to address this gap. Phase Two support may include up to \$300,000 of funding.

These programs already include a focus on medical device identification, development and commercialization and can easily be integrated into the creation of the full service and support Incucelerator that is under design.

Additionally, unlike the management of other existing incubator operations, BioAccel's comprehensive and integrated assets, along with a network of medical device experts, will be brought to bear on creating, operating and sustaining the Peoria Incucelerator. BioAccel and its innovative programs provide both the model and resources necessary to address the challenges

of starting this new initiative by bridging the financial, technical, business and mentoring gaps that exists when transforming early-stage technology into a commercial enterprise.

#### 1.4. PEORIA INCUCCELERATOR FOR MEDICAL DEVICES

##### 1.4.1. ORGANIZATION STRUCTURE (LEGAL)

A new corporate entity will be created, based on input from the City of Peoria, to formalize the existence of the new BioDevice Incucelerator and to oversee its governance. BioAccel is recommending the formation of a non-profit Limited Liability Corporation (LLC) as the corporate structure. The formation of an LLC is important for the City to maintain the Incucelerator's existence as an independent entity and to be prepared for its growth and evolution over time. The Incucelerator facility will be housed at 13660 N. 94<sup>th</sup> Drive, Building D in Peoria, with initially 7,300 square feet of space available to support 5 to 8 new companies as well as central support services and equipment necessary to jump start medical device startup companies. A proposed floor plan of the Incucelerator is contained in Section 4.2 as well as the Appendix.

##### 1.4.2. BOARD OF MANAGERS

A Board of Managers for the LLC will be appointed by the Peoria City Council and BioAccel to provide the necessary governance of the new operation. The Board will include representatives from the City of Peoria, BioAccel®, the Core Institute, [others to be determined], and will meet on a quarterly basis. This group will oversee and monitor the metrics that have been established by the City of Peoria to assure that the expected economic development milestones and targets are being met. This group will also oversee the process that will be used to review and select technologies and companies that will be housed in the Incucelerator. The Board will review operating policies to provide ongoing input as well as participate in strategic planning and business development activities to assure the ongoing success of the Incucelerator and its new companies.

With an emphasis on medical devices, it will also be important to build a network of organizations and consultants representing academia, research, clinical and industry. This network will be represented by the organizations included in the following chart:

<p><b>Academia:</b></p> <p>Arizona State University Northern Arizona University University of Arizona SFAz Arizona Biomedical Research Commission</p>	<p><b>Clinical:</b></p> <p>The CORE Institute Sun Health Research Mayo Clinic Catholic Healthcare West</p>
<p><b>Research Institutions</b></p> <p>TGen Mayo Clinic</p>	<p><b>Industry Connections</b></p> <p>Regulatory Experts Quality System Experts Pre-qualified manufacturing sources Existing device companies for partnering Talent Recruiters Private Equity/Venture Capitalists</p>

Representatives from this Network will be asked to serve on a Scientific Advisory Board, described in section 1.4.3, which will be assembled to provide ongoing direction to the Incucelerator operations as well as to serve as Advisors to the new companies that are formed and/or located in the facility.

1.4.3. ADVISORY BOARD

In order to maintain ongoing input from experts in the BioDevice field a science and technical advisory board will be formed. It is recommended that this Board consist of individuals from the key identified areas:

- Research Institutions – as a direct feeder of potential technologies, and technical expertise
- Clinical Institutions – gaining access to Clinical Review Boards and clinical trial sites
- Industry – individual(s) who has had direct technology commercialization experience, preferably in the US.
- Medical Device Investors – Capital and business expertise

#### 1.4.4. BioDevice Focus:

The focus of the Peoria BioDevice Incucelerator is to identify promising, undeveloped medical device technology and provide the company tangible resources along with business nurturing so that they can successfully make it to the marketplace. There will also be an active effort to identify existing companies, both in and out of the state, that are still in the incubation stage and require a support structure to grow and prosper. Companies that graduate from the Incucelerator will be expected (possibly required) to re-locate within the City of Peoria.

The BioDevice Incucelerator has been strategically conceived to focus on medical devices. Within Life Sciences, there are two primary sectors: Pharmacological (drug development) and Medical Devices. The development path for a new drug is very long, the FDA approval process extremely arduous and is therefore highly capital intensive. For Medical Devices, these hurdles are much lower, allowing a quicker entrance into the marketplace, depending on the type of device and therefore a much better target for accelerated economic development efforts.

By definition, a “medical device” can range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include instrumentation used in surgical procedures, in vitro diagnostic products and testing lab equipment and reagents as well as orthopedic implants. These are some of the well-known “medical devices.”

There are several compelling reasons for the Incucelerator to focus on medical devices:

- At an estimated \$94.9 billion in 2010, the US medical device market is the world’s largest. The total world market for all medical devices is roughly \$450 billion. Most medical devices are in fast growing markets, with certain medical devices, such as biomaterial-based devices, growing at nearly 21% per year.
- The regulatory (FDA) requirements are lower than drug development – allowing a greater number of companies to enter and graduate from the Incucelerator.
- By definition, medical devices is a very broad field – therefore a much wider scope and type of company can associate with the Incucelerator
- A vacuum exists for an Incucelerator focused on medical devices in the Phoenix metro, as well as the State of Arizona – providing a first-to-market position for the Incucelerator.

- The Incucelerator can capitalize on the opportunity in the rapidly growing field of personalized health devices to further capitalize on ongoing activities in this sector, locally and across the state.

#### 1.4.5. Management and Operation:

The City will contract the management of this comprehensive BioDevice Incucelerator to BioAccel, leveraging their existing capabilities to assemble the necessary experts to execute a successful and novel initiative. The leveraging of existing assets and integration with programs will allow an accelerated launch and growth of the Incucelerator. BioAccel will bring together a staff and operation that is:

- Experienced in creating and managing medical device companies
- Experienced in managing a bioscience accelerator
- Capable of performing overall management of the day-to-day operations and oversee the various services required to support a device-focused incubator.
- Have experience and a network to identify and assess viable prospects as a pipeline into the incubator and to provide the necessary support to both create new companies and/or support existing small start-ups that require assistance.
- Can provide or make available the essential services such as proof of concept support, scientific advisory board members, IP protection and patent services, back-office support, regulatory assistance and introductions to downstream investors.
- Experienced in developing commercialization and business plans that will foster successful device-based companies in Peoria
- Able to introduce technologies/companies to the clinical environment to obtain user-based feedback and testing.
- Able to market and promote the Incubator to both the community and to potential new companies.
- Has strong relationships with the National Institutes of Health (NIH) and the Food and Drug Administration (FDA)

#### 1.4.6. KEY MEASUREMENT METRICS

Measuring the success of the Incucelerator is critical and will be monitored carefully. The following key metrics will be closely monitored and evaluated for each Incucelerator-based company:

*Adherence to the Technology Development Plan:* Every Company, upon entering the Incucelerator, must have a well developed Technology Development Plan, or TDP. This document becomes the guiding force behind each project (in essence the “Operations Manual”) and contains many/most of the approval criteria that was reviewed and approved upon entrance to the Incucelerator.

*Specific Technology Evaluation:* this metric focus' on the specific technology being developed and how it is proceeding toward a product or service that can be marketed and sold.

*Budget and Overall Financial Health:* Many companies fail in the first several years because of insufficient funding and misuse of funding. BioAccel can directly and indirectly assist the company to make sure that development capital is available and used wisely.

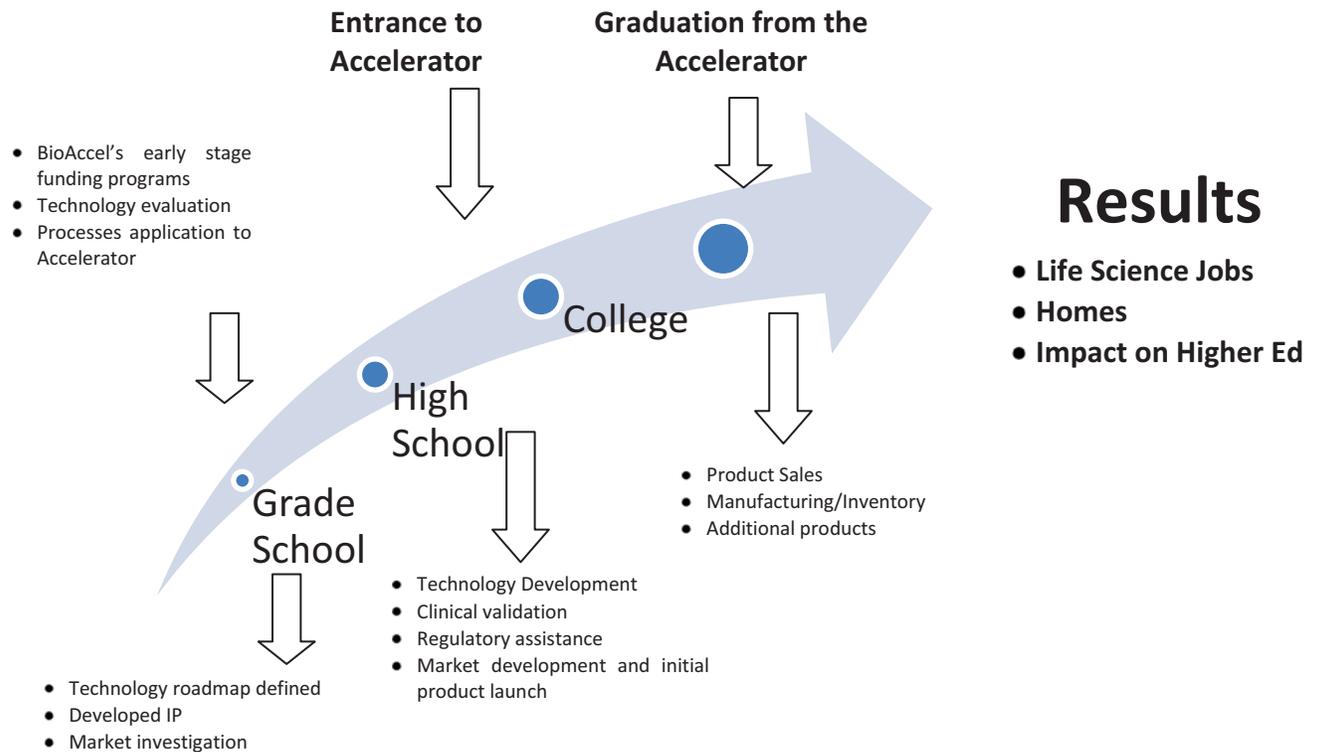
Likewise, the overall success of the Incucelerator will be tracked by these metrics:

- Companies identified and recruited to Incucelerator
- Company retention in the program
- Additional IP developed in the Incucelerator-based companies
- Number of Graduates
- Number of jobs created
- Number of medical devices commercialized
- Time period: from company entrance to the Incucelerator – to graduation
- Positive Economic Indicators

#### 1.5. GRADUATION

The goal of the Incucelerator is that companies entering the program would “graduate;” move to their own space within the City of Peoria and continue their path of growth. The Incucelerator plays a role much like an educator and trusted instructor – developing skills in the student so that they graduate and become a productive and model citizen in the community. At each stage of the process, the Incucelerator will help foster the company’s development until they can graduate and stand on their own – independently supporting their company operations and bringing additional jobs to the City of Peoria.

The different stages could be represented in the following diagram.



Creating a technology pipeline for new company development is a first step. It is important that the companies succeed not only while in the incubator, but more importantly once they have graduated and become business entities in the City of Peoria. BioAccel, working with the City, will create a business eco-system to support these companies that will include but not limited to potential partners, venture financing, technical/business experts, etc. This will ensure the success of the Incucelerator as well as its positive impact on economic development.

#### 1.6. COST, TIMELINES AND ECONOMIC IMPACT

BioAccel and the City of Peoria recognize the importance of this 5-year Plan and commitment. BioAccel is providing a proven structure of evaluating candidates and high level mentorship; along with unprecedented access to a highly qualified medical device network – both locally, across the state.

Costs to start the Incucelerator can be broken down into several areas:

- Facility Build-out \$ 426,000 (Landlord Contribution)
- Operations budget, 5-years \$ 11,977,00 (see yearly breakout in Section 6)

During this 5-year period, companies will enter the Incucelerator’s programs – starting with Phase 1, moving to Phase 2 and then graduating. The following schedule is a possible representation of the number of companies in each Phase:

	<i>Year 1</i>	<i>Year 2</i>	<i>Year 3</i>	<i>Year 4</i>	<i>Year 5</i>
Phase 1	3	4	4	4	4
Phase 2	2	2	3	2	3

It is expected that a company will need 2 to 3 years to move from Phase 2 to graduation. Depending on how quickly the companies actually move through the Phases, by the end of year 5, the Incucelerator could graduate roughly 5 to 8 companies with roughly 100 to 150 new jobs.

**2. PRINCIPLES OF SUCCESS**

2.1. A UNIQUE MISSION

The mission of the Peoria Incucelerator is to become known as Arizona’s premier incubator of companies developing medical devices. This focus on medical devices is highly needed in Arizona and represents a significant opportunity to positive economic impact.

To achieve this mission, we have become acutely aware of the reasons why most companies, and thusly, most incubators fail:

<ul style="list-style-type: none"> <li>● Lack of early stage funding</li> <li>● Under-developed technology roadmap</li> <li>● Lack of IP development</li> <li>● Lack of focus</li> <li>● No access to highly qualified industry network</li> </ul>	<ul style="list-style-type: none"> <li>● No access to pre-clinical testing/feedback</li> <li>● Lack of business plan review by qualified, senior business executives.</li> <li>● Lack of access to competitive roadmaps</li> <li>● Lack of qualified business leadership.</li> </ul>
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The partnership with BioAccel brings to the Peoria venture structure, people, connections and know-how; which constructs a specific path to success – even before a company is allowed into the Incucelerator. This is a key differentiator from most other Incubators/Accelerators that have been conceived and started.

2.2. PRINCIPLES FOR SUCCESS

Recognizing the above pitfalls, the Incucelerator Management has constructed the following “Keys to Success.” These Keys follow “best practices” compiled from personal experience, from

in-depth discussions with other Accelerators and from their experience in operating business within the Life Sciences.

*Safe place to vet and exchange ideas:*

The Incucelerator will become a “safe zone” for vetting and discussing technology. Studies have clearly shown that when technology development occurs in a “vacuum,” mistakes are prevalent. This Incucelerator has assembled an important pool of experts that Incucelerator companies will have access to – in a protected and professional environment. Companies will be enabled to get early feedback on their device such as; feedback from clinicians that would use the device, challenges and expenses associated with the ramp-up phase of manufacturing; how to put together a distributorship network, etc. Providing such high-level access to individuals and organizations to start-up companies is one of the most valuable Keys to Success.

*Market-based Validation of Technology:*

Many start-up companies developing technology, especially technology out of Research Institutions, do so without much market-based information or feedback. Knowing how well a technology could compete against other developed, or even developing, technologies, will be crucial for entrance to the Incucelerator. All Incucelerator technology will be investigated in three areas; what is being developed within academic research (white papers), what is being developed within private research organizations, and what is being developed within industry. This provides a good competitive technology landscape. In addition, a constant eye on how the technology is/will be accepted by the marketplace will also be maintained.

*Fully vetted Business Plan:*

Another key of success is a well-scrubbed business plan. BioAccel provides Plan evaluations through in-house personnel as well as expert consultants who can review and provide helpful comments on the Plan.

*Experienced Management/Technical Team:*

Highly qualified, experienced people to manage and lead the company are known to be an important key for success. In many start-ups, the technology developer – by default – becomes the primary decision maker; this can be problematic. The Incucelerator will look for companies that have well balanced, experienced business-makers in leadership. For companies that are weak in this area, staff within BioAccel and their network will provide ongoing business and operational support to ensure success.

*Defined Market Opportunity/Strategy:*

In today's competitive marketplace, technology rarely "sells itself." Companies in the BioDevice Incucelerator will develop highly defined market niches along with a plan on how to most effectively reach this audience.

*Access to business and technical expertise:*

A key to developing successful companies within the Incucelerator will be how to network the companies to business and technical expertise. This expertise will streamline solutions the company needs in areas such as:

- Insider market information – testing the technologies acceptance and solution-solving abilities
- Clinical application – gaining feedback on how clinicians and/or clinical settings would use the product/service.
- Manufacturing – early feedback on barriers to manufacturing, costs and ramp-up scenarios
- Sales Channel development – strategies for direct vs. representative networks, distributorships, etc.

*Regulatory strategy:*

One of the most important keys to success is gaining a clear understanding for how the product, test, services, etc. would be cleared by both USA (FDA) and foreign regulatory bodies. The Incucelerator will provide very high level expertise that can evaluate, develop and oversee the regulatory path. The FDA is currently going through many changes that can have both positive (shorter regulatory paths) and negative (longer, more expensive paths) effects on technology development. This is one "key" area that must be aggressively and professionally managed – something the Incucelerator can and will provide. BioAccel has already made contact with key staff at the FDA to seek them as partners in this initiative.

*A Culture of Commercialization:*

Technologies (companies) being developed within the Incucelerator will benefit from a "culture of commercialization." This culture is developed to build an atmosphere that breeds success and energized the commitment to best practices. The Incucelerator accomplishes this Key by offering numerous seminars, informal gatherings – in spaces to meet within Incucelerator facility. For example, holding a seminar on FDA Regulatory issues will be something that every company within the can attend and take away information to immediately implement. These meetings will also bring attention to Peoria and its initiative in creating a state of the art Accelerator.

*Management Control:*

Another Key to Success is the importance of ongoing management and oversight. This is done through the use of a knowledgeable Board that includes experienced business people, experts in the industry, as well as effective daily management of operations, financials, product development, etc. BioAccel and the on-site Accelerator Team will both participate and provide ongoing guidance in this area.

*Not an Entitlement Program:*

The next important Key to Success is complementary to the aforementioned Key ... Culture of Commercialization. Companies should clearly understand that involvement with the Accelerator is not some form of an “entitlement program.” This Accelerator is NOT a place where technologies are “conceived,” where basic research can be pursued. The focus must be on the shortest, most effective path to commercialization. Companies chosen to benefit from the Accelerator will have a high bar to maintain – constantly demonstrating to the Accelerator Management that they are progressing in their Plan, utilizing their resources efficiently and planning for graduation.

**2.3. DISCIPLINED APPROACH**

Each company entering the Incucelerator will understand that a highly disciplined approach is needed for success. Therefore, specific Objectives, Tasks, Deliverables and Milestones will be developed for each project and/or product. BioAccel leadership will work with each company to craft these four metrics:

- Objectives
- Tasks
- Deliverables
- Milestones

The Incucelerator’s management uses these four metrics as the contents a Technology Commercialization Plan (or TCP). This TCP shall be written and updated by the Accelerator companies, providing a structured means to evaluate specific progress. Managing this TCP on an ongoing basis keeps projects on track and/or provides a basis to make mid-stream adjustment when needed, before they become significant problems that the company must overcome.

**3. SERVICES**

In Section Two, the Keys to Success were introduced, along with how Technology Commercialization Plans are constructed and followed. The Incucelerator acknowledges that providing the companies assistance is critical for the companies, which can mean the difference

between success and failure. Unlike most other Incubators/Accelerators – that provide simply space, this Accelerator will provide a level of service ongoing basis that directly impacts the company’s developmental progress on an. These services are crucial for developing successful medical devices, and will be offered by Accelerator staff members that have significant product development experience. Many companies and incubators have failed because of a lack of resources in this area. Each area of service is listed and described below Section 4.1.

3.1. SERVICES FOR INCUCCELERATOR CLIENTS

Specific service programs are designed to assist the companies and increase their success rates. These services include:

**Competitive Analysis:**

The Incucelerator will provide a thorough and insightful competitive analysis that is valuable during the development of technology. The analysis should occur early in the process and should be visited several times during commercialization.

**Intellectual Property and Trade Secrets:**

Tenants will be offered assistance in protecting their technology through a process of applying for patents, copyrights and trademarks or through carefully documented trade secrets. BioAccel has assembled resources, such as law firms and patent attorneys, familiar with working on early-mid stage technology. This preferred provider network provides the talent needed and prices that are affordable.

**Product Manufacturing analysis and services:**

This particular service area will be a key feature of the Incucelerator and one of the most valuable services. Manufacturing vendors, interested in serving the Accelerator will be researched, evaluated and recommended. These vendors will comply with the Incucelerator’s requirements in areas such as quality, project management and business systems.

Some examples of the areas where pre-qualified manufacturing resources will be made available are:

<ul style="list-style-type: none"> <li>● Rapid Prototyping</li> <li>● Plastic Injection molding</li> <li>● Low volume production and assembly</li> <li>● Circuit board design/prototyping/production</li> </ul>	<ul style="list-style-type: none"> <li>● Oligo development, supply and manufacturing</li> <li>● Sample storage devices</li> <li>● Microfluidic development/prototyping</li> <li>● Packaging design, prototyping and production</li> </ul>
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The Incucelerator's management, through BioAccel and other individuals, has carefully identified companies that will fulfill the requirements of a vendor and could become trusted partners. These companies will be contacted upon the official opening of the Incucelerator.

***Regulatory Analysis, Research and Submission:***

Achieving the right to market a medical device in the USA depends upon approval from a FDA panel, or if outside the USA, CE in Europe, etc. The BioDevice Incucelerator will work with its companies to develop a comprehensive plan for submitting to the FDA. Services shall include:

- Researching and defining the FDA Product Code
- Researching and defining the Device Class (I, II or III)
- Providing Guidance Document packets for specific devices
- Providing key contacts within the FDA, germane to the products area of application
- Preparation and submittal of pre-IDE's (Investigational Device Exceptions)
- Assisting in face-to-face meetings with the FDA
- Preparation and submittal of final IDE's.
- Follow-up services to address any potential AI Letters (Additional Information letters)

***Pre-Clinical and Clinical Preparation:***

As a medical device finishes in-house testing, the next step in commercialization is to complete pre-clinical testing. During this testing phase important information about the device can be obtained from the potential clinical user.

Similar to the manufacturing assistance, the Incucelerator shall provide its clients with access to contacts, organizations and testing labs, which can streamline this process such as:

- Biomechanical Testing for orthopedic devices
- Access to qualified (and certified) animal testing
- Access to clinical equipment, used in conjunction with the device
- Biochemistry laboratories

Some of these testing labs and clinical resources are identified and listed in Section 1.4.1 These organizations are recognized as some of the best labs in the nation and access to them shall become a valuable asset to companies in the Incucelerator.

### 3.2. PROGRAMS FOR ENTREPRENEURIAL ASSISTANCE

Becoming an entrepreneur and business owner within the environment of the Accelerator can provide many benefits. The provision of on-going training, along with access to business-related services. Topics may include:

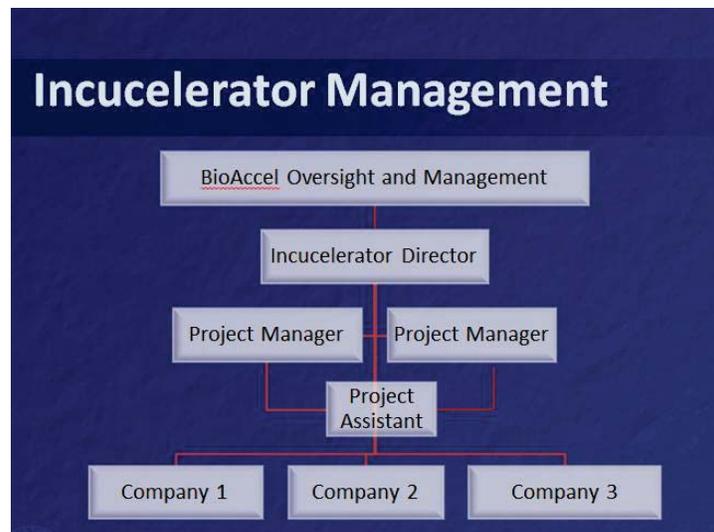
- How to set up your business with a HR services vendor (payroll – taxes – etc.)
- How to access SBIR/STTR grants
- How to network with other Bio-related organizations such as CBC, AZBio, etc.
- How to work with a business law firm
- How to apply for patents and trademarks
- How to fund your business for the next stage

## 4. OPERATIONS

### 4.1. AREAS OF OPERATIONS

#### 4.1.1. PROJECT MANAGEMENT

Careful oversight and ongoing project management are key building blocks for success at the Incucelerator. The figure below depicts the oversight, staffing and the project management structure as it relates to managing the tenants and operation:



#### 4.1.1.1. DIRECTOR OF THE INCUCELERATOR

BioAccel provide ongoing oversight of the Incucelerator and will hire the Director of the Incucelerator. The Incucelerator will get the added advantage of having immediate access to all of the BioAccel staff. Such access allows a controlled hiring of new staff to fit the needs of the Incucelerator. The Director shall be the primary liaison between BioAccel Management, the City of Peoria and shall also be responsible for managing all aspects of the Incucelerator and implementing the vision. A key role of this individual will be business development to identify technology and new companies for the Incucelerator. The Director will also serve an important role in networking the tenants with the community to grow their businesses.

#### 4.1.1.2. PROJECT ASSISTANT

A project assistant will be hired when required, with BioAccel staff providing services as needed. The assistant will provide:

- Telephone answering and initial information to those interested in making application to the Incucelerator
- Coordination of meetings/teleconferences/etc.
- New company formation assistance
- Master scheduler for Incucelerator's facilities (conference room, equipment usage, etc.)
- Assist in marketing efforts, as directed
- Assist in the coordination of equipment maintenance issues
- Coordinate needs of tenants with pre-qualified list of vendors, etc.
- Project management services support as required

#### 4.1.1.3. PROJECT MANAGERS

The Director may hire Project Managers or share Project Managers with other BioAccel programs. Initially these duties will be performed by the Director and BioAccel staff.

- Assisting in the management of Commercialization projects
- Collecting and communicating relevant information between the company, the city and the incubator
- Manage the Technical Assistance Network (TAN)
- Assess and report progress of tenant

### 4.2. APPLYING TO THE BIODEVICE INCUCCELERATOR

#### 4.2.1. APPLICATION PROCESS

Application to the Incucelerator and its programs shall be an "open process;" meaning that all interested candidates are encouraged to submit an application profile to BioAccel. Initially, potential candidates will be reviewed for suitability. If positive, the candidate can then begin to move through the staged process; outlined in the following diagram:

## BioAccel Review Process

Proposal Solicitation	Application Intake	Stage 1 Triage	Stage 2 Technical Review	Stage 3 Business Review	Stage 4 Board Approval	Project Management
Website	Inquiry from Applicant	Review Proposal	From Database Identify Reviewer	From Database Identify Reviewer	Compile Technical & Business Review Evaluations	Track Board Meeting updates and action steps
Face to Face Meeting	Application Submission	Initial Due Diligence	Contact Reviewer, COI Clearance and prepare and send package	Contact Reviewer and send package	Develop SWOT and Dashboard	Finalize commercialization development plan
Technology Alert- ABOR	Application Review	Market Unmet Need	Collect Reviewer evaluation	Collect Reviewer evaluation	Final Analysis against portfolio	Track progress against plan
Word of Mouth	Follow-up Q & A	Preliminary Financial Modeling	Review Evaluation	Review Evaluation	Submit for Board Consideration	Anticipate and mitigate issues
Scientific/ Investor Meetings		Other Investigational Areas	Review Evaluation	Comprehensive Financial Modeling		Coordinate TAN Support
Targeted RFP's						
Initial assessment		If pass go to next step, if not respond to submitter	If pass go to next step, if not respond to submitter	If pass go to next step, if not respond to submitter		

### 4.2.2. SELECTION AND SCREENING PROCESS

Utilizing the BioAccel model, the Incucelerator will complete due diligence in (at least) 18 critical areas. Some of the screening criteria (see below) are broad – such as “Technology” – which is further broken down into specific key elements – see 4.2.4.

#### 4.2.3. SCREENING CRITERIA

The following chart depicts the 18 general areas where due diligence is completed:

<b>Investigational Areas</b>	
Management & Personnel	Tax Status
Product or Service	Contracts & Agreements
Property & Equipment	Governmental Regulations
Market & Marketing	Litigation
Strategies	Research & Development
Operations	Other Company Information
Technology	Corporate Documents
Financial	Previous Securities Issuance
Valuation	Intellectual Property

When considering these investigational areas, the primary assessment drivers for the information will be:

1. Critical Assumptions
2. Validity of Assumptions
3. Success/Failure Factors
4. Impact

#### 4.2.4. TECHNICAL ASSESSMENT OF THE INVESTIGATIONAL AREAS

BioAccel then breaks down each investigational area into numerous key elements to obtain a thorough knowledge of the company's position:

# Due Diligence Checklist

18 Investigational Areas  
132 Key Elements

Investigational Areas	
Management & Personnel	Tax Status
Product or Service	Contracts & Agreements
Property & Equipment	Governmental Regulations
Market & Marketing	Litigation
Strategies	Research & Development
Operations	Other Company Information
Technology	Corporate Documents
Financial	Previous Securities Issuance
Valuation	Intellectual Property

Decision Assessment:  
1. Critical Assumptions      2. Validity  
3. Success/Failure Factors    4. Impact

**Intellectual Property**

- ✓ Patentability
- ✓ Freedom to Operate
- ✓ Claim Coverage
- ✓ Ownership
- ✓ Title

## **Technology Evaluation:**

Specific to the medical device industry, the following technology readiness levels are also incorporated into the evaluation process. A summary of each level is provided below; while a more detailed explanation of the TRL's can be found in the Appendix.

TRL1 – Qualitative Research and Review of Scientific Knowledge Base

TRL2 – Quantitative Research; Define Hypothesis and Experimental Designs

TRL3 – Define, Identify and Characterize Product /Technology fit

TRL4 – Optimization and non-GLP tests for Safety and Efficacy

TRL5 – Advanced optimization; Initiate GMP Process Development

TRL6– GMP Pilot Lot Production, Regulatory, Phase 1 Clinical Trials

TRL7– Scale-up, GMP Process Validation, Phase 2 Clinical Trials

TRL8– Regulatory Approvals, Final clinical and Manufacturing

#### 4.2.5. FINAL ASSESSMENT, APPROVAL AND START-UP

Once the information in the Application is assembled the last stage in the approval process is a review by the Board. If approved, the Director will send an acceptance letter to the candidate, followed up with a discussion regarding the facility requirements and move in dates.

Additional terms and conditions for acceptance into the Incucelerator include but are not limited to the following

- Term - 24 – 36 months, extendable based on business justification
- Rent - Minimal charge (TBD) for the first 24 months, then an escalating rent every quarter thereafter
- Incucelerator rights – Incucelerator gets observation rights (or a least a quarterly report) to review the companies progress and continued eligibility to stay in the Incucelerator
- Agreement to stay in the City of Peoria for a minimum of [needs to be determined] years or reimburse the Incucelerator for all rent/benefits received (unsubsidized rate)
- Willingness to participate in economic impact studies and other reports for the City of Peoria
- Willingness to participate in networking, mentoring (giving and receiving), and advisory groups with fellow Incucelerator tenants.
- Participation (if eligible) in SBIR/STR programs
- Required to use preferred vendors

#### 4.3. GRADUATION EXPECTATIONS

It is the goal of the Incucelerator that every company entering the facility will “graduate” and relocate within the City of Peoria. It is anticipated that the time between acceptances into the Incucelerator, to the time the company graduates would be 2-3 years. The exact time for a company to graduate will vary from case to case, however, several criteria can be suggested:

- Regulatory Process: a company’s revenue stream from the medical device depends upon the FDA’s certification of that device. Some companies will gain European (CE) approval first, as it is a shorter and less stringent process. Having some kind of regulatory clearance will allow the company to start selling its product.
- Sales and Marketing Plan: does the company have a plan and can it be implemented?
- Proper funding: once the company exits the Accelerator, additional fixed costs will begin.

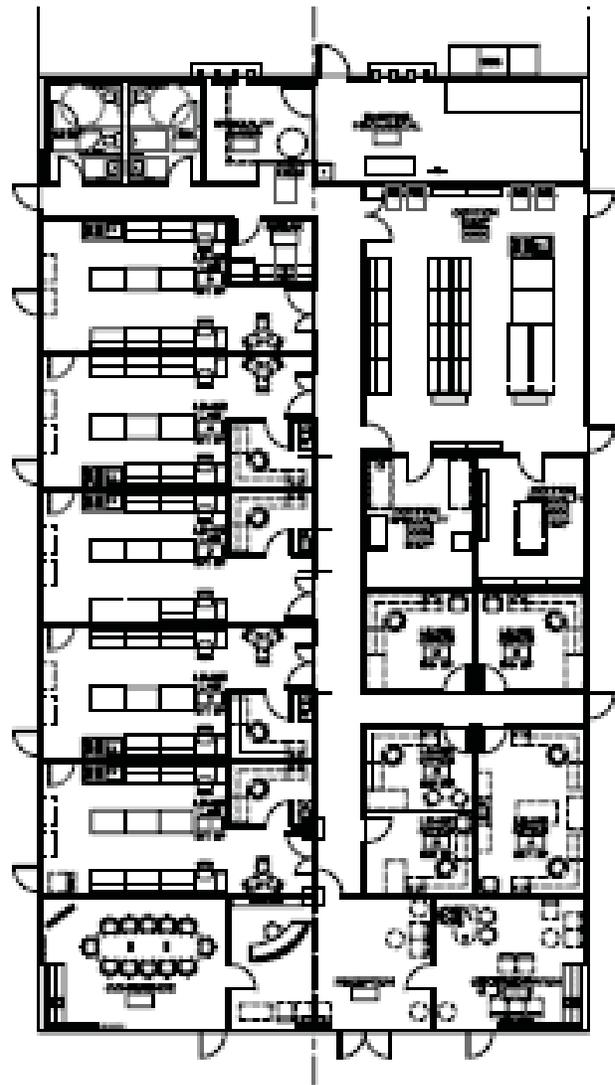
#### 4.4. FACILITY

##### 4.4.1. DESCRIPTION

The BioDevice Incucelerator is located at 13660 N. 94<sup>th</sup> Drive, Building D in Peoria. The Plaza Companies, a long proponent of the project, has made available a 7,300 square foot facility with can be put under contract to house the Incucelerator. Plaza Companies have also contracted with Cawley Architects to draw initial concepts of the building and how the internal structure would be laid out.

A smaller snapshot of the facility is shown below. The primary features planned for the Incucelerator facility are:

- The overall presentation of the facility must be foremost a Class 2 business distinctive. This is not “high-tech laboratory” facility that is normally associated with basic research development. The presence should communicate a level of maturity that visitor would conclude; “these are companies who have entered the marketplace and are ready to promote their device.”
- An impressive and warm reception area shall greet visitors who come to meet with the Incucelerator tenants.
- A fully functional conference room shall be constructed and shared by Incucelerator tenants.
- A “Collaboration Room” (secondary conference) will be available and shared. This room would allow the tenants to hold key strategy meetings, corporate meetings as well as a place to meet with vendors. This room shall have a large white-board running the entire length of one wall, to best facilitate brainstorming meetings.



- Incucelerator tenants can choose a combination of multi-purpose lab space as well as traditional office space to meet their needs.
- A common shop area is also provided, where tenants can utilize for use of shared equipment such as drill presses, lathes, etc. as well as light assembly.
- The design of the space has been optimized to offer tenants maximum flexibility, access to multiple use office/labs and yet be respectful of security related issues.

#### 4.4.2. DRAWINGS/LAYOUT

The space design is shown above. Final modifications can be made to accommodate tenants, however the locations for the labs and common shop area will be completed as shown.

A full size drawing can be found in the Appendix.

#### 4.4.3. EQUIPMENT

As stated above, the Incucelerator will provide some basic equipment that could be placed in the shared/common shop area – and used by the tenants. These might include:

- Metal working equipment such as drill presses, lathes, sheet metal fabrication, etc.
- Table/hood – welding station
- Circuit board design/prototyping/etc.
- Packaging testing; vibratory table, etc.
- Material characterization; tensile tester, etc.
- Microfluidic testing station, pumps, etc.
- Plastic fabrication

It is important to remember that companies developing medical devices can require a very broad need for specific equipment. The Incucelerator will seek, whenever possible, to provide the type of equipment that might be shared across the tenants. However, the needs of companies can vary; for example, the needs of a company developing bio-materials may be very different from a company developing a microfluidic card for cell separations. Therefore, it is not the intention for the Incucelerator to provide ALL of the equipment a tenant would need.

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## 5. MARKETING THE INCUCELERATOR

### 5.1. FINDING QUALIFIED CANDIDATES

BioAccel, the managing entity, shall utilize its networking capability to find and screen, qualified candidates. The goal is to identify medical device technologies that have passed the basic research stage and now require validation, proof-of-concept, or prototype work to confirm a commercial potential. BioAccel will apply a rigorous review process that includes internal and external subject matter experts from across the United States to select the most promising technologies to support. To accelerate the process, BioAccel will structure this as an “open submission” process and the review is done in “real time” in order to reduce timelines and simplify the process.

As stated by the “Key to Success” as well as the metrics used to measure a tenants progress – the Incucelerator will not be simply a place to “park” your company. The atmosphere will be fast-paced and focused on progress! Therefore, the goal of marketing the Incucelerator is to find well-qualified candidates, not just a company looking for “free space.”

Presentations of the BioDevice Incucelerator shall be made with clear emphasis on its mission, purpose and philosophy. Every effort will be made to highlight the value-added services that have been clearly discussed in this Plan.

### 5.2. STATE-WIDE EFFORTS

BioAccel will market the Incucelerator to the Bio-community within Arizona with special emphasis on:

- The Coalition for Bioscience Collaboration (CBC)
- Utilize the Accelerator’s Advisory Board’s
- The Flinn Foundation
- State of Arizona Universities; ASU (BioDesign Institute), UofA (Bio5 Institute), NAU
- Networking to Research Performing Institutes, or RPI’s such as TGen, Catholic Healthcare West (Barrow) Sun Health, Mayo Clinic, etc.
- Bio-business organizations; AZBio, etc.
- Other state-based incubators where existing assets can be leveraged.

### 5.3. MARKETING OUTSIDE OF ARIZONA

While the emphasis is focused on finding candidates from Arizona-based technology, it will be important to reach out of state, especially when collaborative efforts could lead to opening wider networking opportunities. Phoenix remains a destination location and winning ideal candidates from outside of Arizona adds up to significant economic development.

Targeted areas might include:

- Minneapolis, MN – as one of the largest bio-device manufacturers in the US, this area is rich with start-ups and boasts very highly qualified personnel. Many Minnesotans have ties to Phoenix, with many retiring here after highly successful careers in Life Sciences.
- Boston, MA – this area is one of the undisputed leaders in entrepreneurship and technology development.
- Southern CA – many initiatives are already underway to access technology developers from this region.

Of additional importance is the opportunity to market the Incucelerator's unique plan to companies and organizations outside the US. Life Science development is a large, active and global entity. BioAccel's network reaches to many potential partners in Europe that could consider a venture with the Incucelerator in Peoria.

## 6. FINANCIAL

### 6.1. PROPOSED BUDGET

**BioAccel Contract:**– This line includes salary to support the FTE used by BioAccel and the Core Institute to provide leadership, onsite technical and management support, technology identification, due diligence technical assistance services.

**Incubator Personnel Costs:** salary and benefits is included in support of full time Incucelerator staff.

**Non Personnel Costs:** Due Diligence Costs/Database/Company Formation Costs/Legal Costs: Support costs of researching the opportunity, market data, database for competitive as well as scientific comparisons, verification of IP and or prior art and the legal fees associated with starting a company. Consulting support: This will provide both ongoing and one-time expertise that will be needed by the Incubator to assist new companies in launching their enterprise. It is expected that companies will be responsible for paying for ongoing specialized services that they require over time. General Supplies/Services: Ongoing supplies and services by vendors to maintain the office and labs.

**Proof of Concept/Seed Funding:** Support Phase I and II program funding of projects and companies

**Capital Outlays:** On site lab and office equipment. Additionally, equipment costs to support a central support laboratory, as identified by CORE Institute, in included in Year 2. Lease costs are included.

## Incucelerator: Option A Budget (in '000s)

Cost Category	Year 1	Year 2	Year 3	Year 4	Year 5	Total Commitment
BioAccel Contract	\$302	\$275	\$236	\$208	\$208	\$1,229
Incubator Personnel Costs	\$125	\$163	\$260	\$297	\$297	\$1,142
Non-personnel Costs	\$399	\$404	\$453	\$456	\$453	\$2,167
Capital Outlays	\$503	\$332	\$197	\$201	\$243	\$1,439
Proof of Concept/Seed Funding	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$6,000
<b>Total Cost</b>	<b>\$2,529</b>	<b>\$2,374</b>	<b>\$2,345</b>	<b>\$2,362</b>	<b>\$2,403</b>	<b>\$11,977</b>

Consistent with the term of the building lease, a 5 year contract will be awarded to BioAccel® to support the creation, launch and maintenance of the Peoria Incubator for Medical Devices. BioAccel® will be responsible for any subcontract(s) required to obtain the necessary expertise to assure a successful medical device based incubator.



## 7.2. TECHNOLOGY READINESS LEVELS

The following guidelines help to define Technology Readiness Levels. These may be used by the Accelerator to assess the maturity level of the technology and how far along the Commercialization path it is.

### **Technology Readiness Level #1: *Qualitative Research and Review of Scientific Knowledge:***

The starting point for TRL1 is a clearly written technology description with possible application profile(s). This may/should include a brief overview of basic research history and the maturation into applied research.

From this information, the goal of TRL1 is to compare the Technology to active development found in related scientific knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies. A presentation of these findings is made to the IBCC representative/team.

### **Technology Readiness Level #2: *Quantitative Research; Define Hypothesis and Experimental Designs.***

The starting point for TRL2 is the Technology Definition Statement developed in TRL1. The objectives of TRL2 are to develop, define and propose a roadmap of research, hypotheses, and experimental designs for developing the technology – better than current ideas/products in the marketplace. Focus of this level is on collecting baseline data to support the practical applications based on the basic principles observed. When possible, use computer simulation or other virtual platforms to test application hypotheses. Basic quantitative evidence is developed to support the graduation to TRL3.

### **Technology Readiness Level #3: *Define Identify and Characterize Product/Technology Fit.***

The starting point for TRL3 is the basic quantitative evidence, gained from experimental data, which supports the effectiveness of the technology application. The objectives of this level are to fully define the product and/or technology in context of its commercialization. Begin research, testing, data collection, and analysis in order to test effectiveness. Identify and evaluate critical technologies and components, and begin characterization of the application. Preliminary efficacy demonstrated *ex vivo* and *in vivo* (if possible). Milestone is a clearly envisioned pathway to regulatory approval and how testing data will support a regulatory submission.

**Technology Readiness Level #4: *Optimization and non-GLP tests for Safety and Efficacy.***

The starting point for TRL4 is a clear characterization of the technology from in vivo and ex vivo experiments and a proposed regulatory pathway. The overall objectives of this level are to develop and define the integration of critical technologies to complete a “system” for technology deployment. Included in TRL4 is the initiation of animal model development as well as non-GLP in vivo toxicity and efficacy demonstration in accordance with the product’s intended use. Write protocols needed for any cadaver and/or human in vivo (clinical) experiments to test safety and efficacy per FDA Guidance Documents for your Product Code. Propose and secure IRB’s. Address potential manufacturing options.

**Technology Readiness Level #5: *Advanced Optimization – Initiate GLP testing for Safety and Effectiveness.***

This TRL begins with the approved protocols required to begin all safety and effectiveness testing, as defined and submitted in TRL4. The objective of this level then, is to continue any non-GLP *in vivo* studies, animal models and assay development (where applicable) so that GLP testing is begun. Establish draft Target Product Profiles. Develop a scalable and reproducible manufacturing process amenable to GMP. Open discussions with FDA and submit pre-IDE’s where applicable.

**Technology Readiness Level #6: *GMP Pilot Lot production, Regulatory, Phase 1 Clinical Trials.***

The starting point for TRL6 is the positive safety and effectiveness results from the testing under TRL5 as well as feedback from the FDA via pre-IDE’s. The objective of this level is to address the manufacturing issues assigned to the product. A GMP-compliant pilot run is to be initiated. Prepare and submit Investigational New Device/Drug (IDE/IND) package to FDA and conduct Phase 1 clinical trial(s) to determine the safety and pharmacokinetics of the clinical test article.

**Technology Readiness Level #7: *Scale-up, GMP Process Validation, Phase 2 Clinical Trials.***

The focus of TRL7 is to address manufacturing scale-up, business structure and completion of clinical trials. TRL7 would require a complete manufacturing scale-up and initiate validation of GMP manufacturing processes with ISO/QSR standards required by FDA. Finish animal efficacy studies as appropriate. Conduct Phase 2 clinical trial(s).

**Technology Readiness Level #8: *Regulatory Approvals, Final clinical, Manufacturing.***

The final TRL will guide the project through remaining clinical testing, regulatory approvals and finalize the GMP manufacturing process. Complete pivotal animal efficacy studies or clinical trials (e.g., Phase 3), and/or expanded clinical safety trials as appropriate. Prepare and submit NDA/BLA.

# Peoria Bio-Science Attraction Concepts

City of Peoria  
Study Session  
May 3, 2011



# Today's Presentation

- Stimulating economic growth in Peoria through Bio-Science development
- Critical elements in building a Bioscience industry in Peoria
- Value of a medical device focused approach
- Options to Consider
- Cost Estimates and Risk Profiles



# Impetus behind Peoria Bioscience industry

EDIS is the basis for Incubator Initiative

- Peoria has weak targeted business attraction competitiveness due to absence of technology companies
- Incubators grow technology companies from start-up thus establishing foundation for new industry
- Peoria has strength in health care
- Peoria has identified partners with expertise and experience in bioscience and medical devices

# Entrepreneurship = Job Growth

- A 2010 Public Policy Institute of California study showed that from 1992-2006, **only 1.9% of jobs gains** and 2% of job losses in an average year **came from business re-locations (zero sum gain)**
- In contrast, nearly 42% of job gains were derived from existing business expansions and more than **56% came from new enterprises.**



# Partnership with BioAccel

**Non-profit organization with mission to drive economic development through commercialization of bio-science research**

- Focus on late stage technologies
- Provide proof of concept and seed funding for new company formation
- Provide hands-on technical and business mentoring
- Provide network of expertise

# BioAccel Strengths:

- Experienced in technology development and managing an accelerator
- Established network for identifying prospects/creating robust pipeline
- Can provide start-up business infrastructure
- Understands medical device development, commercialization and regulatory strategy
- Strong relationships with NIH and FDA

# Partnership - Plaza Companies

Plaza Companies is a full-service real estate firm specializing in the development, leasing and management of medical office properties, technology and bioscience facilities.

- Based in Peoria, with a strong presence in the community
- Track record of successful projects
- Strong knowledge of bioscience and research projects



# Plaza Companies Strengths

- Experience in research/biotech projects includes SkySong, the ASU Scottsdale Innovation Center
- Biotech/research synergy taking place at Plaza del Rio already
- Has worked on several other biotech projects in Arizona



## Four Options Considered:

- Option A – Launch comprehensive incubator (“Incucelerator”)
- Option B – Focus on accelerating companies that have been incubated elsewhere
- Option C – Phased implementation - Accelerator to Incubator
- Option D – Do nothing

# Sharon Harper

## Plaza Companies



CITY OF PEORIA

# Bio-Device Focus

- \$94.9 Billion US market in 2010
- FDA requirements lower with quicker approvals with bio-devices than for pharma (drug manufacturing)
- Very broad field
- No other device-focused incubator in Arizona
- Capitalize on fast-growing personalized health devices

# Purpose of Incubators/Accelerators

- To foster new economic growth from technology, science, IP, research
- To jump start a local economy
- To fill gap in economic mix (i.e. retail, office, industrial)
- Promote entrepreneurship – job engine
- To create investment opportunities



# Economic Impact of Incubators

- Every \$1 in public operating subsidy for incubators generates about \$30 in local tax revenue
- NBIA members report 84% of incubator graduates stay in their communities.
- NBIA estimates that North American incubator clients and graduates have created approximately half a million jobs since 1980.
- Every 50 jobs created by an incubator client generates another 25 jobs in the community.

*Information from the National Business Incubator Association*

# Why Companies Fail

- Lack of full commitment and early stage funding
- Under-developed technology roadmap
- Lack of IP development
- Lack of commercialization focus
- No access to highly qualified industry network
- No access to pre-clinical testing/feedback
- Lack of business plan review by qualified, senior business executives.
- Lack of adequate facilities and business support
- Lack of qualified business leadership



# **Incubator Provides Infrastructure for Success**

- **Safe place to vet and exchange ideas**
- **Market-based validation of technology created**
- **Fully-vetted business plan created**
- **Experienced mgt/technical team to assist start-ups**
- **Defined market opportunity strategy created**
- **Access to business/technical expertise**
- **Regulatory strategy created**
- **Culture of commercialization**
- **Management program services provided**
- **Proof of concept and path to FDA approval created**

# Local Competition

- 4 currently established in Valley (also AzCI in Tucson and NACET in Flagstaff)
  - Chandler Innovations – 120,000 SF for 30 bio tech companies
  - Surprise Techcelerator – 47,000 SF for 14 technology companies
  - SkySong – 300,000 SF with 50 companies (representing 11 countries)
  - West Mesa Business Incubator – targets health care, operated by West Mesa CDC
- 3 more expected to open in 2011
  - Tempe, Gateway Community College, City of Gilbert

# MaryAnn Guerra

## BioAccel



CITY OF PEORIA

# Option A: Peoria Medical Device Incubator

- Physical facility to house 5 medical device start-up companies
- An integrated, full service support system that identifies, validates, promotes technology commercialization pipeline and promising new companies
- Access to comprehensive technical, business and strategic partnerships to support new companies
- Reduces city investment risk by providing full service support to business and concept development

# Option A: Continued

- **Contract with BioAccel**
  - Identify and fund technology pipeline and start-ups
  - Identify and recruit companies; manage application process; vet and approve candidates
  - Operate incubator (manage budget and facility; oversee companies; provide on-site advisory assistance)
- **BioAccel will profit-share equity to create an evergreen fund to self-sustain Incucelerator operations**
- **5-year commitment to ensure success**

# Proposed Incubator Facility

- Located at Plaza del Rio
- 6,800 SF of space
  - 5-year lease with City's option to terminate after year 3.5, if needed.
- Office and medical research space
  - 5 offices
  - 5 labs
  - 3 common shop areas
  - Reception
  - Conference/meeting space

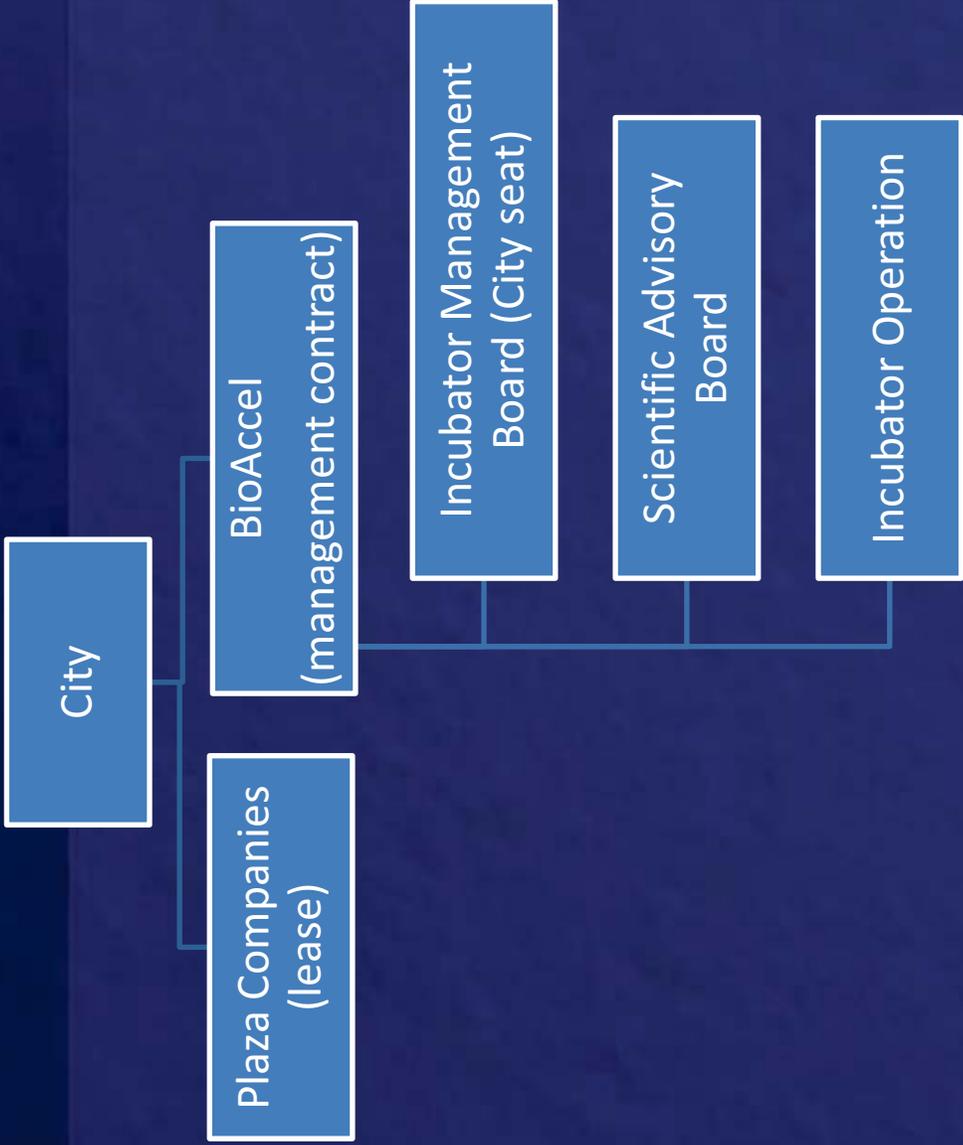
# Peoria Incuclerator Floor Plan



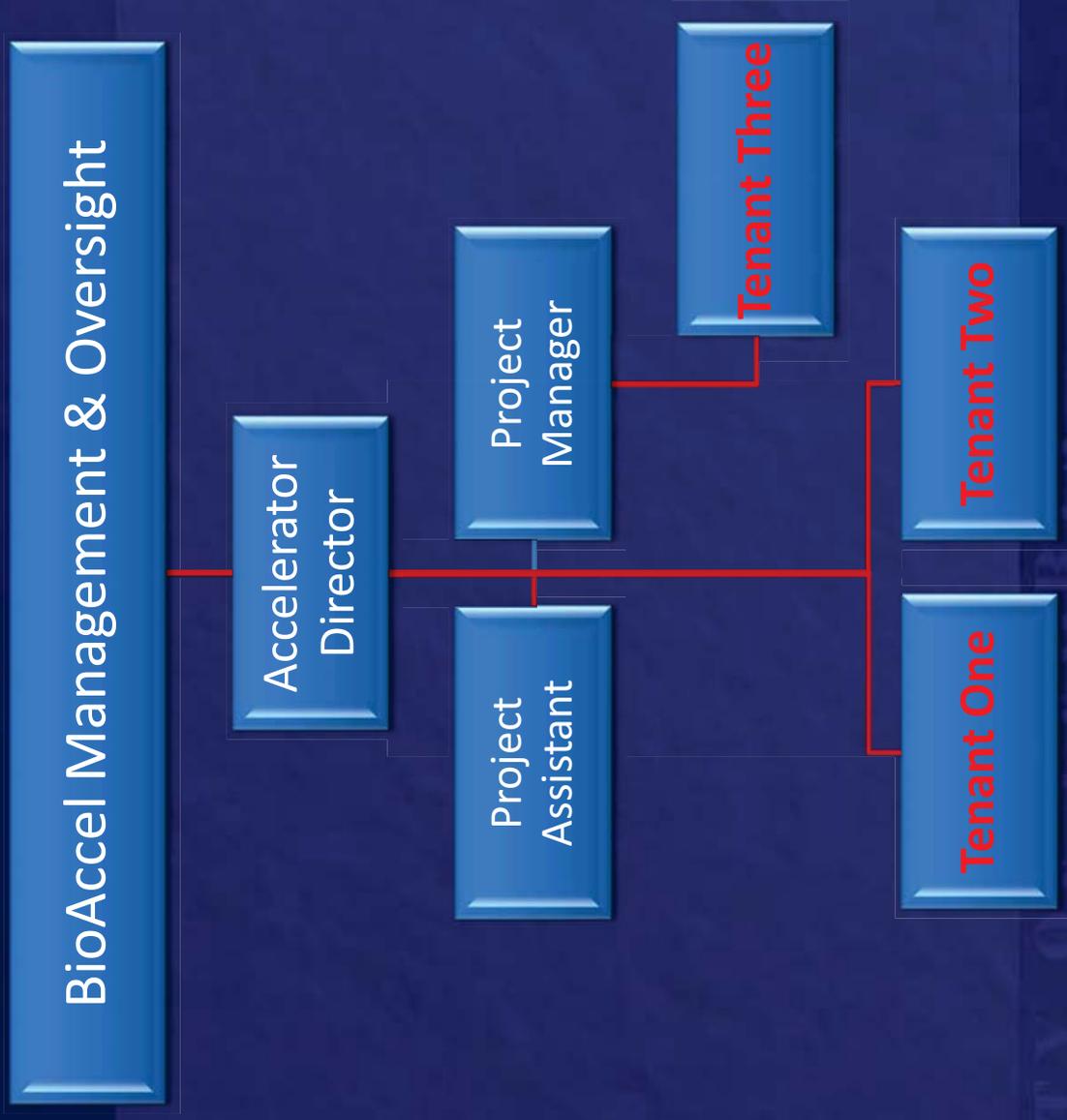
# Services Offered

- **Competitive analysis of new technology**
- **Intellectual property/trade secret counsel**
- **Product manufacturing assistance**
- **Regulatory analysis, research, submission to FDA and/or NIH**
- **Pre-clinical and clinical trial preparation**
- **Programs for business development**
- **Management support**

# Incubator Governance



# Incubator Management



# Approval and Start Up

- Graduation in 24 months
- Proof of Concept/seed stage
- Rent – minimal then escalating
- Agreement to stay in Peoria
- Willingness to participate: economic impact studies and networking/mentoring



# Graduation Expectations

- Expectation is 2-3 years based on criteria:
  - Regulatory Process
  - Sales and Marketing
  - Seed Funding Needs



# Option A – Budget (in ‘000s)

Cost Category	Year 1	Year 2	Year 3	Year 4	Year 5	Total Commitment
BioAccel Contract	\$327	\$265	\$336	\$340	\$340	\$1,611
Incubator Personnel Costs	\$125	\$125	\$214	\$214	\$214	\$892
Non-personnel Costs	\$389	\$548	\$597	\$600	\$597	\$2,731
Capital Outlays	\$400	\$175				\$575
Proof of Concept/Seed Funding	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$6,000
<b>Total Cost</b>	<b>\$2,441</b>	<b>\$2,313</b>	<b>\$2,347</b>	<b>\$2,354</b>	<b>\$2,351</b>	<b>\$11,809</b>

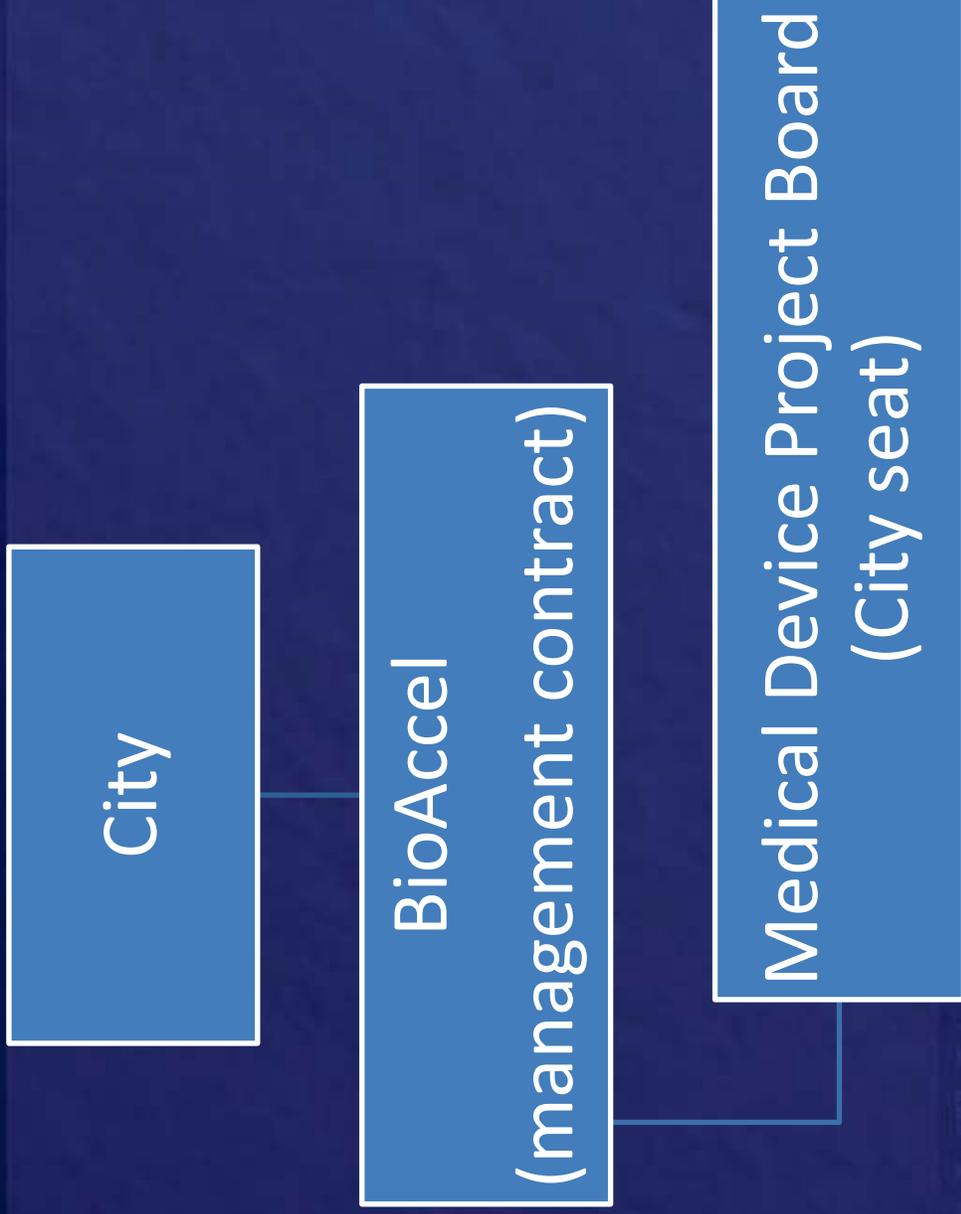
# Option A – Pros and Cons

- **Advantages:**
  - Provides full service approach to growing and supporting medical device companies
  - Creates a physical location branding Peoria as a bio-science location
  - Strong partnership with local experts
  - Best long term option to growing companies and culture of bio-science
  - Allows for full incubator-based economic impact outlined in earlier slide (\$1 subsidy  \$30 tax revenue)
- **Considerations:**
  - Managing City's investment exposure

# **Option B: Accelerator – Same Services, No Incubator Facility**

- **Contract with BioAccel**
  - Identify and recruit companies; manage application process; vet and approve candidates
  - Provide proof of concept and seed funding
  - Build pipeline and provide same services as Option A
- **Company must locate in Peoria to receive assistance**
  - BioAccel and City will facilitate location targeted at PDR
- **BioAccel will profit-share any equity to create an evergreen fund to self-sustain**
- **5-year commitment**

# Virtual Accelerator Governance



# Option B – Accelerator

Cost Category	Year 1	Year 2	Year 3	Year 4	Year 5	Total Commitment
BioAccel Contract	\$389	\$389	\$389	\$389	\$389	\$1,949
Incubator Personnel Costs						
Non-personnel Costs	\$325	\$264	\$268	\$271	\$268	\$1,398
Capital Outlays						
Proof of Concept/Seed Funding	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$6,000
<b>Total Cost</b>	<b>\$1,914</b>	<b>\$1,853</b>	<b>\$1,857</b>	<b>\$1,861</b>	<b>\$1,858</b>	<b>\$9,347</b>

# Option B – Pros and Cons

- **Advantages:**
  - **Reduced City financial investment**
  - **Focuses on later stage companies that have proven technology and approvals**
  - **Assisted companies locate in Peoria**
- **Considerations:**
  - **Does not create a culture of bio-science or physical bio-science location for Peoria**
  - **Peoria's competitive disadvantages may outweigh seed funding made available**

# Two more options: Hybrid or status quo



# Option C: Accelerator to Incubator

- Start with Accelerator approach (Option B)
- Implement programs outlined in Option A
- Launch incubator opening after 9 months once pipeline of prospects secured
- Launch incubator in two stages tied to pipeline to delay facility-related costs



# Option C – Accelerator to Incubator

Cost Category	Year 1	Year 2	Year 3	Year 4	Year 5	Total Commitment
BioAccel Contract	\$225	\$265	\$336	\$340	\$340	\$1,506
Incubator Personnel Costs		\$125	\$214	\$214	\$214	\$767
Non-personnel Costs	\$243	\$349	\$437	\$440	\$437	\$1,906
Capital Outlays	\$200	\$200				\$400
Proof of Concept/Seed Funding	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$6,000
<b>Total Cost</b>	<b>\$1,868</b>	<b>\$2,139</b>	<b>\$2,187</b>	<b>\$2,194</b>	<b>\$2,191</b>	<b>\$10,579</b>

# Option C – Pros and Cons

- **Advantages:**
  - Brings all the benefits of an incubator and accelerator in a phased approach
  - Reduces City’s initial investment while pipeline is created
  - Opens the incubator once eligible companies are ready for placement
- **Considerations:**
  - Delays the opening of the Peoria incubator



# Option D: Do Nothing

- **Contrary to approved EDIS action plan: Initiative #9 is “Medical Device Incubator”**
- **EDIS firmly establishes that there is no reason for technology companies to locate in Peoria**
  - **Peoria cannot compete with Phoenix, Tempe, Chandler, Scottsdale, and Gilbert**
- **Result is to stop efforts to attract Bioscience companies and jobs to city and refocus attention elsewhere**



## Next Steps:

- Make decision regarding approach towards investment in bio-science attraction
- Complete business plan for the concept which has the greatest potential for long-term success
- Execute required contracts as soon as possible



# For your deliberation...

- Is this the right concept and partnership for growing bioscience companies in Peoria?
- What is the best option going forward?
  - Incubator
  - Accelerator
  - Accelerator first and incubator second
  - Do nothing and refocus efforts



# Barry Broome

## GPEC



CITY OF PEORIA

**CITY OF PEORIA, ARIZONA  
COUNCIL COMMUNICATION**

CC: **2R** \_\_\_\_\_  
Amend No. \_\_\_\_\_

Date prepared: May 25, 2011

Council Meeting Date: May 31, 2011

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**TO:** Honorable Mayor and Council  
**FROM:** Steve Kemp, City Attorney  
**SUBJECT:** Direction to Redistricting Consultant

**RECOMMENDATION:** That if the Mayor and Council desire an additional map to be prepared as a redistricting concept which maintains all council members in their existing districts, the Mayor and Council direct staff appropriately.

**SUMMARY:** At the request of Councilmember Aames, the Mayor has placed this item on the open session for Council Discussion. If Council so directs, staff will have the consultant prepare a redistricting concept which maintains all council members in their existing districts. Such a concept must comply with the Federal Voting Rights Act and contain substantially equal population.

Staff will proceed based on Council's direction.

**FISCAL NOTE:** None

**ATTACHMENT:** None

**CONTACT:** Steve Kemp, City Attorney (623) 773-7321