

## **PROPOSED PROJECT**

ECI is currently evaluating the expansion of the company's product portfolio to include the development and production of a Controlled Release Technology specific to extended release /sustained release prescription solid dose Formulations, as well as Prescription Powder Formulations. Company management are considering several states for the expansion including Texas, Kentucky and Tennessee. The management team recognizes and is also evaluating the potential of outsourcing both components of the expansion to a Contract Research Organization and/or a Contract Biologic Manufacturer, as those options are readily accessible and equipped to support those functions independently.

The economic feasibility of the project is contingent upon being approved for the Qualified Targeted Industry (QTI) tax refund, as each phase of the expansion would require a significant capital infusion. To maximize the incentive's impact on the project, the investment structure of the expansion has been designed to parallel the incentive payout for each subsequent growth period. The vast majority of those costs are centric to the purchase, validation and relocation of equipment necessary for the additional research, quality assurance and production.

Once all R&D and Manufacturing equipment has been fully qualified for operation, the development of several predetermined products will proceed. At this point, ECI has plans to initiate the employment process, which will consist of recruiting individuals proficient in formulation development, industrial laboratory production, stability protocols, and finally the compilation of New Drug Application (NDA's) or Abbreviated New Drug Applications (ANDA's) for submission to the FDA. ECI has begun negotiations with Workforce One to provide assistance with employee recruitment, screening and training if the expansion takes place in Fort Lauderdale.

Upon approval of a NDA or ANDA from the FDA, ECI will then start the rigorous and labor-intensive Process Validation of the product. This entails an approved protocol to demonstrate the manufacturing process can be duplicated several times, proving the process rugged and robust from batch to batch. This is also accompanied with excessive laboratory testing to provide the analytical data required to prove these processes. Only when this completed Process Validation Report has been issued, can the manufacturing facility begin the last step, which would be the actual production and distribution of the of the new product line(s).

ECI Pharmaceuticals LLC will continually need to meet certain standards and requirements for Quality Systems, which are delegated through Quality Assurance, Quality Control, Document Control, Regulatory and Compliance. All manufacturing procedures must remain compliant within the guidelines governed by the FDA under the Code of Federal Regulations.

If ECI Pharmaceuticals LLC meets its hiring target of 20 employees over the next three years in the City of Fort Lauderdale (average salary of \$48,690-115% of the Broward County annual average wage) the City's share of the QTI would be a total of \$12,000 paid out over a six-year period. The City's payment will only be triggered if each annual milestone is met.