Non-confidential description of company and nature of business:
Gentris Corporation is a global provider of pharmacogenomic testing and biorepository services. As pioneers in the field, Gentris has over 10 years of experience guiding pharmaceutical companies and clinical research organizations on how to effectively integrate pharmacogenomics into their drug development programs. Pharmacogenomic testing can facilitate the delivery of safer, more effective compounds to the market more quickly. With better characterization of patient populations, pharmacogenomics can help reduce drug failure rates by enabling drug companies to modify patients' exposure to drugs based on their genomic drug-response profile. This ensures that the right drugs reach the right patients at the right doses, and provides optimal benefits for their pharmacogenomic profile. We take a science-driven, focused approach to our client’s needs to develop customized pharmacogenomics solutions that will spur the next generation of personalized medicines. Gentris maintains the highest quality standards and provides confidence that data will meet requirements for submission to regulatory agencies. With over a decade of experience, Gentris is uniquely positioned to provide the guidance and expertise necessary to help our clients capitalize on the vast potential of genomic medicine.

Gentris partners with clients to create efficient solutions that will help propel clinical research efforts forward. Through its Biorepository, Gentris can preserve clinical samples and enhance their value by coupling validated sample handling and storage capabilities with dependable pharmacogenomic testing services. Clinical trial design assistance, IRB submission, genotyping platform and polymorphism selection, bioinformatics, and statistical analysis services are also provided to clients to offer a complete solution for their pharmacogenomic clinical trials.

We continue to invest in our model for driving innovation in clinical development through strategic collaborations with world class researchers, integration of cutting-edge technologies, and recruitment and retention of top talent. Gentris expanded 2-fold in employment and facilities in 2010-11 at our Morrisville site and a 20% expansion is anticipated in 2011-12. Genotyping and genomics technologies are regularly updated to meet our clients’ ever-changing needs. Gentris Corporation is also planning a site in China. By working with Gentris, our sponsors can gain access to unique clinical resources and expertise to advance drug development programs and gain valuable experience running clinical projects in China.

Non-confidential description of company’s core technolog(ies):
Clinical trials support, including pharmacogenomic and biorepository solutions, is provided using state of the art commercially-available instrumentation from vendors including Life Technologies (e.g. TaqMan, Sanger sequencing, next generation sequencing) and Affymetrix (e.g. DMET Plus, SNP 6.0). These technologies enable low- to high-plex genotyping and gene expression analysis. In addition, we provide clinical trial design and IRB submission support, and biorepository solutions, bioinformatics, and statistical analyses.

Proposed Scope of Work for Fellow:
The Fellow will be involved in the development of a novel pharmacogenomic assay for the Hepatitis C virus on a new next generation sequencing platform that will be marketed to pharmaceutical companies and clinical research organizations. Responsibilities will include the assessment of publically available literature, independent assay design, and hands-on methods development and validation. It will also include preparing business materials, a methods paper(s), and a possible patent claim. The project will be performed in a GLP and CLIA environment.

**Proposed Activities:**

Hepatitis C virus (HCV) is a genetically heterogeneous virus. The virus can be subdivided into genetically distinct strains called genotypes (e.g. genotypes 1 to 6) and subdivided further into subtypes (e.g. 1a and 1b) and mutations of the virus called “quasispecies”; the latter of which result from the virus’ error-prone RNA polymerase and its high replication rate.

Each patient typically shows viral population diversity and this is thought to contribute to vaccination failure, persistent infection, and resistance to antiviral drugs. Treatment of the virus can be tailored to a patient’s HCV genotype and several Gentris clients have expressed an interest in employing HCV genotyping in their clinical HCV antiviral trials. Next generation sequencing is ideal for HCV genotyping because it is high-throughput and has a higher sensitivity for the detection of rare variants (~1%) than Sanger sequencing and other methods presently used for HCV genotyping (>25%).

Gentris acquired an Ion Torrent’s Personal Genome Machine (PGM) (Life Technologies), a next generation DNA sequencing instrument, in 2011. The PGM uses a very simple method of sequencing based on the detection of hydrogen ions that are released during the polymerization of DNA. The PGMs ease of use, flexible and scalable protocols, and considerably shorter run times than other commercially available next generation sequencing platforms make it an ideal sequencing platform for clinical tests, including HCV genotyping. The Fellow will tasked with developing and validating a HCV genotyping test on the PGM.

Successful completion of the project will require working across multiple departments at Gentris. The Fellow will work with Business Development to ascertain the needs of our clients, which will shape the specifics of the assay that is ultimately developed. For assay development and validation, the Fellow will work closely with members of Research and Development and Quality Assurance. When the assay has been approved by Quality Assurance and ready for prime-time, the Fellow will train Operations personnel and develop an assay performance monitoring program. The Fellow will also work closely with the Accessioning group to track the patient samples and reagents through the study protocol using our Laboratory Information Management System (LIMS) and collaborate with the Bioinformatics team to design an analysis pipeline.

Working with the Scientific Marketing team, the Fellow will develop appropriate marketing materials to promote the new assay to our clients and work with the Study Directors who will manage the HCV clinical trials from beginning to end and client interactions. The Fellow will also develop a HCV genotype-therapy selection algorithm in collaboration with our academic partners that will also be marketed to clients and potentially the subject of a patent claim.

During the course of this fellowship, the Fellow will gain highly marketable skills in pharmaceuticals, next generation sequencing, and assay development in a GLP and CLIA environment. In additional to scientific skills, they will gain valuable skills in understanding all aspects involved in the development and commercialization process of biotech products; from inception to market deployment. Interactions with
our Business and Marketing group, our Quality Assurance group, and our Scientific and Operations group will give the Fellow a well-rounded view of the contract laboratory and pharmaceutical industries. It will also provide the Fellow with insights into the different career paths that are available in the Biotech industry.

Desired Qualifications of Fellow:
The Fellow will have a PhD in molecular biology, genetics, or a related scientific field. They must be highly motivated with proven experience in molecular biology techniques, particularly PCR and genotyping techniques, and have good oral and written communication skills. Prior experience in DNA sequencing is not required but is desirable, especially next generation sequencing methods. Virology research experience is also desirable. The applicant must be able to work independently and in a group and have the ability and desire to work in a fast paced environment.

Benefits Description:
Medical/Dental
Short term and long term disability insurance Life and Accidental Death and Dismemberment Insurance
Flexible Spending Account
401(k)
Supplemental Insurance
Fitness Center
Holiday and PTO

Gentris typically covers 70% of the coverage for medical and dental insurance (range of ~5K to 6.2K for employee only and $15K-18K for family. Gentris offers two medical/dental plans of which one is a basic plan and one is a buy-up plan. The cost to the employee is dependent on the number of individuals covered and the chosen plan type. The table below provides an estimate of the cost to the employee which is approximately 30% of the premium. All other benefits listed above are standard and at no cost to the employee.