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Background and Company Performance

Industry Challenges

Cancer continues to be one of the leading causes of mortality globally. The World Health Organization (WHO) reports that cancer caused 8.8 million deaths in 2015. Technologies enabling earlier cancer diagnosis and improved treatment management can be useful for addressing challenges related to lowering cancer morbidity and mortality. Insights across cancer genomics and tumor pathogenesis have led to the discovery of several novel biomarkers that have the potential to transform cancer management. However, the precision oncology industry is still largely challenged by the limited availability of clinically validated biomarkers and a lack of sensitive screening assays and accurate quantitation technologies that can be used for the detection and monitoring of a wide range of cancers.

While rapid technological advances and plummeting gene sequencing costs have fueled the discovery of a wide range of biomarkers, especially relevant to oncology, few of those biomarkers currently have direct applications in a clinical setting. Only clinically relevant markers, or those known to have an impact on human health, are likely to have a significant impact on early diagnosis and disease management. Therefore, new cancer detection and monitoring technologies need to leverage biomarkers that provide actionable clinical insights, and especially insights for early detection or that may guide targeted treatment decisions.

The scarcity and inaccessibility of tumor tissue for analysis of solid tumors is also a growing challenge faced when testing and validating new cancer biopsy methods. Fortunately, with the discovery of new biomarkers detected in blood or other body fluid samples, there is a growing preference for the use of noninvasive or minimally invasive techniques for cancer screening. However, these liquid biopsies are often limited by assay sensitivity due to low levels of biomarkers in the fluid samples. Tumor-derived, cell-free DNA (cfDNA)—one of the most commonly evaluated biomarkers across liquid biopsy assays—is difficult to quantitate due to its low abundance in blood samples. There remains a significant need for non-invasive biopsy technologies that accurately measure biomarkers from body fluids for oncological screening and monitoring.

Technology Attributes and Future Business Value

Industry Impact

US-based Cancer Genetics, Inc. (CGI) is a leading provider of precision oncology technologies that enable early cancer detection, treatment management, and the development of novel cancer immunotherapies. CGI offers a wide range of genomic and biomarker-based products and services that have the potential to transform cancer management and reduce cancer morbidity and mortality worldwide. CGI has developed a global footprint of laboratories in the US, India and China. The laboratories are organized as “centers of excellence” focused on specific aspects of precision oncology, and the reference laboratories in the US are both Clinical Laboratory Improvement Amendments (CLIA)-certified and College of American Pathologists (CAP)-accredited.
CGI offers a range of technology platforms for oncology biomarker testing that enable precision treatment and targeted patient management by providing diagnostic, prognostic, and theranostic information including predicting treatment efficacy and potential adverse events. Their comprehensive offering not only helps to predict patient outcomes but also aids in the development of new therapies through clinical trial support and drug discovery. Solutions comprise genotyping assays for a wide range of genomic and immuno-oncology related biomarkers, and can be used across several therapeutic classes in oncology, including: hematological cancers, solid tumors, and hereditary-related cancers. CGI also offers several pharmacogenomic service packages for predicting patient responses to treatment and for classifying enrollees in clinical trial studies.

**Product Impact**

Frost & Sullivan recognizes the significant impact of CGI’s technology in precision oncology. In the past two years, the company has launched multiple innovative assays and technologies, continuing to deliver on its “bench to bedside” mission.

In 2016, CGI developed and launched a comprehensive immuno-oncology (IO) testing portfolio, utilizing multiple technology platforms. The CGI portfolio of IO tests includes the full range of FDA-approved immunohistochemistry (IHC)-based complementary and companion diagnostics (CDx) for paradigm-changing IO drugs, including Dako 28-8 PharmDx for Bristol Myers-Squibb’s Opdivo (nivolumab), Dako 22C3 PharmDx for Merck’s Keytruda (pembrolizumab), Ventana SP142 for Roche’s Tecentriq (atezolizumab), and Ventana SP263 for AstraZeneca’s Imfinzi (duralumab). CGI’s most recent addition to its constantly expanding IO portfolio is its Complete::IO™ test – a unique and comprehensive flow cytometry panel for novel IO therapies across both blood cancers and solid tumors. In addition to the complementary and CDx tests, the company also offers a comprehensive menu of hundreds of antibodies for various IHC markers.

In 2016, CGI also commercially launched Focus::Oncomine™, a CLIA-validated next generation sequencing (NGS) panel for diagnosis and treatment selection applications in solid tumors. The NGS panel comprises 52 key genes that are not only targets for several marketed oncological drugs, but have also been identified as clinically relevant by the American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN), and College of American Pathologists (CAP). The Focus::Oncomine™ assay is capable of detecting clinically relevant biomarkers by simultaneously using genomic and transcriptomic methods. It has a rapid turnaround time and can be used to sequence 35 hotspot genes, 23 fusion genes, and 19 genes that have been linked to copy number variants using a single workflow. The assay leverages Thermo Fisher Scientific’s Ion Torrent™ NGS and Ion AmpliSeq™ library preparation technologies to address tissue scarcity challenges. The panel uses minimal tumor tissue sample amounts that may be derived from various tumor sample types, including fine needle aspirates and small biopsies, yielding accurate and reliable results.

The same year, CGI launched two additional comprehensive and powerful NGS assays, Focus::Lymphoma™ and Focus::Renal™. These CLIA-validated proprietary assays were developed in collaboration with leading research centers and academic institutions in the
field of oncology. Focus::Lymphoma™ is the most comprehensive and clinically actionable NGS panel in the field, sequencing 220 genes, with the ability to customize reporting that provides clinically actionable information to guide treatment decisions for patients with various forms of B-cell lymphomas. Focus::Renal™ provides precision information for the diagnosis, prognosis, and therapy selection in renal cancers. Focus::Renal™ is a highly-sensitive NGS panel, able to detect mutations in 76 renal cancer-related genes, as well as genome-wide copy number changes, all in a single test. CGI is currently collaborating with biopharma and academic partners to implement Focus::Renal™ for liquid biopsy samples so that this critical test can also inform cancer care directly from a single blood draw.

In 2017, CGI announced multiple agreements and collaborations to develop liquid biopsy programs with leading biopharma companies. The programs range across a variety of cancers including breast, lung, renal, prostate, and gastrointestinal. The paradigm changing lung cancer liquid biopsy test, Liquid::Lung-cfDNA™ has already been CLIA-validated and commercially launched by CGI, and is able to detect lung tumor-derived cell-free DNA (cfDNA) obtained from the plasma fraction of blood. Liquid::Lung-cfDNA™ is an NGS panel and is based on ThermoFisher Scientific’s Oncomine™ Lung cfDNA assay. Liquid::Lung-cfDNA™ analyzes 150 major hotspots and 11 critical genes clinically relevant for lung cancer, and can be performed for both patient care and for clinical trials. This groundbreaking assay is highly sensitive, offering a limit of detection (LOD) of 0.05% for both tissue and blood specimens.

In 2017, CGI also entered into the comprehensive hereditary cancer testing field for breast and ovarian cancers through its launch of a hereditary panel, branded Focus::HERSite™. Focus::HERSite™ analyzes the 16 genes most commonly associated with breast and ovarian cancers, and provides comprehensive coverage of BRCA1 and BRCA2.

The most recent addition to CGI’s test menu is ThermoFisher’s FDA-approved universal CDx for lung cancer, Oncomine Dx Target Test. This test is the first NGS-based CDx test that simultaneously screens tumor samples for biomarkers associated with three FDA-approved therapies for non-small cell lung cancer (NSCLC). CGI is one of the first laboratories, and one of only three in the US, to offer the Oncomine Dx Target Test. Approved by the FDA on June 22 of 2017, the Oncomine Dx Target Test simultaneously evaluates 23 genes clinically associated with NSCLC. Following FDA approval, results from analysis of three of these genes can now be used to identify patients who may be eligible for treatment with one of the following: AstraZeneca’s EGFR inhibitor Iressa (gefitinib), Pfizer’s ALK and ROS1 inhibitor Xalkori (crizotinib), and the combination therapy of Novartis’ MEK inhibitor Mekinist (trametinib) and RAF inhibitor Tafinlar (dabrafenib). With this test, physicians can now match patients to these therapies within days instead of the several weeks’ time it would take when screening samples for one biomarker at a time.

Frost & Sullivan research found that CGI addresses the growing need for biomarker screening platforms, leveraging sensitive quantitation techniques for the analysis of clinical actionable cancer biomarkers both in tissue samples and liquid biopsies.
Scalability

CGI has developed a global footprint with locations in the US, India and China. Its state-of-the-art reference labs in the US are CLIA-certified and CAP-accredited and have licensure from several states including New York State. The company’s global infrastructure, which has been developed through strategic acquisitions, and its unique business model, which incorporates routine clinical testing for cancer patients and fee-for-service solutions for biotech and pharmaceutical companies, have positioned CGI for diversified growth and access to the oncology community. This has allowed the company to develop a durable platform from which to commercialize its oncology programs and testing capabilities.

CGI offers scalable platforms and services that can be used across both clinical trial and patient testing applications. Its SelectOne® Clinical Trials solutions offer a comprehensive range of services that integrate genetic testing for Phase I to Phase III clinical trials, and support for trial logistics, bioinformatics, and biorepository requirements. SelectOne® includes services for cytogenetic testing, NGS, gene expression analysis, nucleic acid extraction and purification, flow cytometry, and genotyping, addressing the need for new biomarkers that are likely to enhance trials for emerging, targeted therapies. The platform has a global technological availability, as it is offered in the United States, India, and China.

Frost & Sullivan believes SelectOne® will drive the development of targeted therapies and new companion diagnostics.

Application Diversity

CGI is a technology-agnostic company with comprehensive diagnostic capabilities. It is a certified service provider for various companies, such as Affymetrix, ArcherDx, etc., and offers full NGS capabilities with both Illumina and Thermo Fischer platforms, providing a mix of proprietary panels and off-the-shelf assays. CGI is driven by a passion to transform cancer treatment, provide the highest quality testing services, add value to health care providers, partner in patient care, and help clinicians fulfill the promise of precision medicine. It is uniquely positioned, with the combination of its global infrastructure and its foundation built on innovation, to provide for both the development and delivery of diagnostic testing to support hematology/oncology needs from bench to bedside. The company constantly strives for diversity and innovation, successfully balancing the two pillars – a balance not easy to attain.

CGI’s clinical testing applications have the potential to transform personalized treatment across diverse cancer indications. CGI’s advanced testing platforms can be leveraged by biotech and pharma companies to develop diagnostic assays and targeted therapies. The technology-agnostic comprehensive solutions can be used across solid and hematological malignancies. CGI offers flow cytometry, immunohistochemistry (IHC), karyotyping, fluorescent in situ hybridization (FISH), microarray-based comparative genomic hybridization (array CGH), NGS, and other molecular diagnostic technologies for holistic coverage of different patient profiles and applicable to different sample types.
CGI works with biotech and pharma companies to develop novel diagnostic assays for various cancer indications. Its NGS platforms, for example, are being explored for liquid biopsy applications across colorectal, breast, and kidney cancer indications. In 2017, CGI announced a partnership with Ventana Medical Systems, a member of the Roche Group, to enhance patient access to the FDA-approved VENTANA PD-L1 (SP263) Assay. Importantly, CGI is also listed by Merck as a National Reference Laboratory for Keytruda (pembrolizumab) CDx testing. The partnership with Ventana and the recognition by Merck as well as various other recent developments are reflective of CGI’s leading role in enabling precision diagnostics in the immuno-oncology field across novel cancer immunotherapies. CGI also has ongoing partnerships with innovative companies utilizing artificial intelligence (AI) and big data, including Lantern Pharma and Mendel Health, to accelerate AI-driven drug development and informed clinical trial patient matching.

Financial Performance

CGI’s technological leadership is reflected in the company’s remarkable revenue growth. In 2016, CGI recorded full-year revenue of $27 million—50% more than its 2015 full-year revenue of $18 million. Full-year gross-profit margins in 2016 were 37%, up from 22% in 2015. CGI’s cash and equivalents, as of 31 December 2016, were reported to be $9.5 million. In March 2017, CGI closed a debt financing round of $12 million, while additionally raising $1 million in non-dilutive capital.

CGI’s recent financial statements also look impressive. Sustained organic growth fueled CGI’s Q1 2017 revenue to $7.0 million, an increase of 15% from Q1 2016. Frost & Sullivan believes CGI’s recent product launches, such as Liquid::Lung-cfDNA™, Complete::IO™, and Focus::HERSite™, will fuel new business opportunities in immuno-oncology, while its continued commitment to precision oncology innovations and operational improvements will ensure strong financial growth.

Technology Licensing

CGI has several ongoing research collaborations with leading oncologists and cancer centers in the areas of kidney cancer, leukemia, non-Hodgkin’s lymphoma, and HPV-associated cancers. Its partners include Cleveland Clinic, Mayo Clinic, Memorial Sloan-Kettering Cancer Center, National Cancer Institute, Beth Israel Deaconess Medical Center, the University of Iowa Cancer Center, and Columbia University.

In 2017, CGI’s hereditary breast and ovarian panel, Focus::HERSite™, was selected by a global biopharmaceutical company for a large-scale clinical study of more than 1,000 patients. This worldwide study spans several years and is likely to enhance the stratification and management of breast cancer patients. CGI’s cancer diagnostic portfolio and clinical market share are likely to witness sustained growth as the company continues to expand its technological and research collaborations with biotech and pharma companies.
Conclusion

Cancer Genetics, Inc. offers leading technological platforms for enhancing precision oncology innovations. The company leverages advanced genomic and molecular technologies for the accurate and sensitive quantitation of clinically relevant biomarkers in blood and tissue samples that provide valuable insights across cancer diagnostics and treatment management. Its comprehensive product and service offerings are likely to drive the paradigm shift towards early cancer detection and personalized treatment strategies.

With its strong overall performance, Cancer Genetics, Inc. has earned Frost & Sullivan’s 2017 Technology Innovation Award.
Significance of Technology Innovation

Ultimately, growth in any organization depends upon finding new ways to excite the market and upon maintaining a long-term commitment to innovation. At its core, technology innovation, or any other type of innovation, can only be sustained with leadership in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

• Acquire competitors’ customers
• Generate awareness and interest
• Increase market share
• Grow the overall size of the market
• Balance price with profitability
• Increase brand equity
• Establish a strong brand identity
• Inspire customers
• Build a reputation for innovation
• Push the envelope

Understanding Technology Innovation

Technology innovation begins with a spark of creativity that is systematically pursued, developed, and commercialized. That spark can result from a successful partnership, a productive in-house innovation group, or a bright-minded individual. Regardless of the source, the success of any new technology is ultimately determined by its innovativeness and its impact on the business as a whole.
**Key Benchmarking Criteria**

For the Technology Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—Technology Attributes and Future Business Value—according to the criteria identified below.

**Technology Attributes**
- Criterion 1: Industry Impact
- Criterion 2: Product Impact
- Criterion 3: Scalability
- Criterion 4: Visionary Innovation
- Criterion 5: Application Diversity

**Future Business Value**
- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Technology Licensing
- Criterion 4: Brand Loyalty
- Criterion 5: Human Capital

**Best Practices Award Analysis for Cancer Genetics Inc.**

**Decision Support Scorecard**

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows our research and consulting teams to objectively analyze performance, according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation. Ratings guidelines are illustrated below.

**RATINGS GUIDELINES**

The Decision Support Scorecard is organized by Technology Attributes and Future Business Value (i.e., These are the overarching categories for all 10 benchmarking criteria; the definitions for each criterion are provided beneath the scorecard.). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.
The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, we have chosen to refer to the other key participants as Competitor 2 and Competitor 3.

<table>
<thead>
<tr>
<th>Measurement of 1–10 (1 = poor; 10 = excellent)</th>
<th>Technology Innovation</th>
<th>Future Business Value</th>
<th>Average Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competitor 2</td>
<td>8.0</td>
<td>8.0</td>
<td>8.0</td>
</tr>
<tr>
<td>Competitor 3</td>
<td>7.0</td>
<td>7.0</td>
<td>7.0</td>
</tr>
<tr>
<td>Cancer Genetics, Inc.</td>
<td>9.5</td>
<td>9.5</td>
<td>9.5</td>
</tr>
</tbody>
</table>

**Technology Attributes**

**Criterion 1: Industry Impact**
Requirement: Technology enables the pursuit of groundbreaking ideas, contributing to the betterment of the entire industry.

**Criterion 2: Product Impact**
Requirement: Specific technology helps enhance features and functionalities of the entire product line for the company.

**Criterion 3: Scalability**
Requirement: Technology is scalable, enabling new generations of products over time, with increasing levels of quality and functionality.

**Criterion 4: Visionary Innovation**
Requirement: Specific new technology represents true innovation based on a deep understanding of future needs and applications.

**Criterion 5: Application Diversity**
Requirement: New technology serves multiple products, multiple applications, and multiple user environments.

**Future Business Value**

**Criterion 1: Financial Performance**
Requirement: Potential is high for strong financial performance in terms of revenues, operating margins, and other relevant financial metrics.

**Criterion 2: Customer Acquisition**
Requirement: Specific technology enables acquisition of new customers, even as it enhances value to current customers.

**Criterion 3: Technology Licensing**
Requirement: New technology displays great potential to be licensed across many sectors and applications, thereby driving incremental revenue streams.
**Criterion 4: Brand Loyalty**
Requirement: New technology enhances the company’s brand, creating and/or nurturing brand loyalty.

**Criterion 5: Human Capital**
Requirement: Customer impact is enhanced through the leverage of specific technology, translating into positive impact on employee morale and retention.

**Decision Support Matrix**
Once all companies have been evaluated according to the Decision Support Scorecard, analysts then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

<table>
<thead>
<tr>
<th>STEP</th>
<th>OBJECTIVE</th>
<th>KEY ACTIVITIES</th>
<th>OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Monitor, target, and screen</td>
<td>Identify Award recipient candidates from around the globe</td>
<td>Pipeline of candidates who potentially meet all best-practice criteria</td>
</tr>
</tbody>
</table>
|      |           | • Conduct in-depth industry research  
|      |           | • Identify emerging sectors  
|      |           | • Scan multiple geographies | |
| 2    | Perform 360-degree research | Perform comprehensive, 360-degree research on all candidates in the pipeline | Matrix positioning of all candidates’ performance relative to one another |
|      |           | • Interview thought leaders and industry practitioners  
|      |           | • Assess candidates’ fit with best-practice criteria  
|      |           | • Rank all candidates | |
| 3    | Invite thought leadership in best practices | Perform in-depth examination of all candidates | Detailed profiles of all ranked candidates |
|      |           | • Confirm best-practice criteria  
|      |           | • Examine eligibility of all candidates  
|      |           | • Identify any information gaps | |
| 4    | Initiate research director review | Conduct an unbiased evaluation of all candidate profiles | Final prioritization of all eligible candidates and companion best-practice positioning paper |
|      |           | • Brainstorm ranking options  
|      |           | • Invite multiple perspectives on candidates’ performance  
|      |           | • Update candidate profiles | |
| 5    | Assemble panel of industry experts | Present findings to an expert panel of industry thought leaders | Refined list of prioritized Award candidates |
|      |           | • Share findings  
|      |           | • Strengthen cases for candidate eligibility  
|      |           | • Prioritize candidates | |
| 6    | Conduct global industry review | Build consensus on Award candidates’ eligibility | Final list of eligible Award candidates, representing success stories worldwide |
|      |           | • Hold global team meeting to review all candidates  
|      |           | • Pressure-test fit with criteria  
|      |           | • Confirm inclusion of all eligible candidates | |
| 7    | Perform quality check | Develop official Award consideration materials | High-quality, accurate, and creative presentation of nominees’ successes |
|      |           | • Perform final performance benchmarking activities  
|      |           | • Write nominations  
|      |           | • Perform quality review | |
| 8    | Reconnect with panel of industry experts | Finalize the selection of the best-practice Award recipient | Decision on which company performs best against all best-practice criteria |
|      |           | • Review analysis with panel  
|      |           | • Build consensus  
|      |           | • Select recipient | |
| 9    | Communicate recognition | Inform Award recipient of Award recognition | Announcement of Award and plan for how recipient can use the Award to enhance the brand |
|      |           | • Present Award to the CEO  
|      |           | • Inspire the organization for continued success  
|      |           | • Celebrate the recipient’s performance | |
| 10   | Take strategic action | Upon licensing, company is able to share Award news with stakeholders and customers | Widespread awareness of recipient’s Award status among investors, media personnel, and employees |
|      |           | • Coordinate media outreach  
|      |           | • Design a marketing plan  
|      |           | • Assess Award’s role in future strategic planning |
The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan’s 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan’s research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.