Arrayit Corp
Form 10-K
April 15, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-K

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þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2013

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from: _____ to _____

_____

Arrayit Corporation
(Exact name of registrant as specified in its charter)

_____

Nevada	001-16381	76-0600966
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

927 Thompson Place, Sunnyvale, CA 94085

(Address of Principal Executive Offices) (Zip Code)

408-744-1331

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $0.001 par value per share
OTCQB

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes o No þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

The issuer's revenues for the most recent fiscal year ended December 31, 2013 were $2,902,135.

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter was $3,853.000.

As of April 14, 2014, there were 32,260,815 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

PART I

PART II

PART III

PART IV

PART I

ITEM 1. BUSINESS

CERTAIN STATEMENTS IN THIS ANNUAL REPORT ON FORM 10-K CONSTITUTE "FORWARD LOOKING STATEMENTS" WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1934, AS AMENDED, AND THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995 (COLLECTIVELY, THE "REFORM ACT"). CERTAIN, BUT NOT NECESSARILY ALL, OF SUCH FORWARD-LOOKING STATEMENTS CAN BE IDENTIFIED BY THE USE OF FORWARD-LOOKING TERMINOLOGY SUCH AS "BELIEVES", "EXPECTS", "MAY", "SHOULD", OR "ANTICIPATES", OR THE NEGATIVE THEREOF OR OTHER VARIATIONS THEREON OR COMPARABLE TERMINOLOGY, OR BY DISCUSSIONS OF STRATEGY THAT INVOLVE RISKS AND UNCERTAINTIES. SUCH FORWARD-LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS, UNCERTAINTIES AND OTHER FACTORS WHICH MAY CAUSE THE ACTUAL RESULTS, PERFORMANCE OR ACHIEVEMENTS OF ARRAYIT CORPORATION (THE "COMPANY", , “ARRAYIT”, “TELECHEM”, “AVANT DIAGNOSTICS”, “ARRAYIT MARKETING”, “ARRAYIT SCIENTIFIC SOLUTIONS”, "WE", "US" OR "OUR") TO BE MATERIALLY DIFFERENT FROM ANY FUTURE RESULTS, PERFORMANCE OR ACHIEVEMENTS EXPRESSED OR IMPLIED BY SUCH FORWARD-LOOKING STATEMENTS. YOU SHOULD NOT UNDULY RELY ON THESE STATEMENTS. FACTORS, RISKS, AND UNCERTAINTIES THAT COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE IN THE FORWARD-LOOKING STATEMENTS INCLUDE, AMONG OTHERS:

our ability to raise capital,
our ability to provide our products and services at competitive rates,
our ability to execute our business strategy in a very competitive environment,
our degree of financial leverage,
risks associated with our acquiring and integrating companies into our own,
risks related to market acceptance and demand for our services,
the impact of competitive services, and
other risks referenced from time to time in our SEC filings.

With respect to any forward-looking statement that includes a statement of its underlying assumptions or bases, we caution that, while we believe such assumptions or bases to be reasonable and have formed them in good faith, assumed facts or bases may vary from actual results, and the differences between assumed facts or bases and actual results can be material depending on the circumstances. When, in any forward-looking statement, we or our management express an expectation or belief as to future results, that expectation or belief is expressed in good faith and is believed to have a reasonable basis, but there can be no assurance that the stated expectation or belief will result or be achieved or accomplished. All subsequent written and oral forward-looking statements attributable to us, or anyone acting on our behalf, are expressly qualified in their entirety by the cautionary statements. Except as required by applicable law, including the securities laws of the United States and/or if the existing disclosure fundamentally or materially changes, we do not undertake any obligations to publicly release any revisions to any forward-looking statements to reflect events or circumstances after the date of this report or to reflect unanticipated events that may occur.

REFERENCES IN THIS FORM 10-K, UNLESS ANOTHER DATE IS STATED, ARE TO DECEMBER 31, 2013.

INDUSTRY DATA

In this Form 10-K, we may rely on and refer to information regarding the biotech industry from market research reports, analyst reports and other publicly available information. Although we believe that this information is reliable, we cannot guarantee the accuracy and completeness of this information, and we have not independently verified it.

Item1. BUSINESS

General Business Description, Operations and Changes in Control

Overview of the Business:

Founded in November 1999, Arrayit Corporation, a Nevada Corporation, is a leading life sciences technology company providing innovative products and services that empower scientists and clinicians to study all living things, from humans, animals, and plants, to viruses and bacteria. This research is being performed in thousands of government, university, pharmaceutical, biotechnology, and agrigenomics laboratories around the world, where scientists seek to expand our knowledge of the biological functions essential for life. Beginning at the genetic level, where our tools are used to elucidate the correlation between gene sequence and biological processes, life science research expands to include the study of the cells, tissues, organs, systems, and other components that make up living organisms. Novel insights into the function of genes and proteins, early stage disease diagnostics, better and safer medicines, and safer and more nutritional crop plants are some of the many aspects of human health empowered by Arrayit technology. Arrayit has secured its position in the industry by leveraging the company's widely used patented microarray manufacturing platform and revolutionary VIP™ genotyping technology. Since 1999, Arrayit has built a powerful portfolio of patents, trade secrets, and more than 650 life sciences products. The company was featured on the television series NOVA in 2001, received successive appointments to the Inc. 500 list of fastest growing private companies in 2002 and 2003, and has received numerous local awards including the Rising Star award from the City of Sunnyvale and the Silicon Valley Top 50 award in 2003.

Arrayit has proven expertise in three key areas: the development and support of microarray tools and components, custom printing and analysis of microarrays for research, and the development of diagnostic microarrays and tools for early detection of treatable disease states. The Company's patented tools and trade secrets provide the performance, throughput, cost effectiveness and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information. The Company believes this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery, drug development and clinical research, allowing diseases to be detected earlier and permitting better choices of drugs for individual patients.

Arrayit strives to increase shareholder equity by inventing, developing, manufacturing and selling sophisticated life sciences products and services to an extensive customer base spanning 50 countries. Our corporate philosophy is put into action by a highly skilled, multidisciplinary team of scientists, business professionals, engineers, investors, executive and support staff, all of whom place shareholder value, product quality, customer service and price competitiveness as our highest priorities. Arrayit technology empowers decisive strategic advantage and return on investment in the basic research, pharmaceutical diagnostic, and health care markets. We presently conduct operations through two wholly owned subsidiaries, one majority owned subsidiary, and one minority owned subsidiary as outlined below:

TeleChem International, Inc., a wholly owned subsidiary

Arrayit Marketing, Inc, a wholly owned subsidiary

Arrayit Scientific Solutions, 98% majority owned subsidiary

Avant Diagnostics, Inc., 38.46% minority owned subsidiary, of which the Company has no voting rights

Effective Thursday, March 19, 2009, Arrayit Corporation's common stock began trading on the OTC Bulletin Boards as "ARYC". The authorized common shares of the Company are 480,000,000 and the authorized preferred shares of the Company are 20,000,000.

Arrayit has a December 31 year end.

Arrayit's principal office is located at 927 Thompson Place in Sunnyvale, California. Arrayit presently has seven employees.

Arrayit Products and Services

Since 1999, Arrayit has focused on developing microarray laboratory instruments, glass substrate slides, kits and reagents using an open platform strategy, in contrast to the closed platform formats of its largest competitors. Arrayit's patented printing technology has become an industry standard for microarray manufacturing, allowing customers to manufacture microarrays of all types including DNA, protein, patient DNA, antibody, antigen, peptide, carbohydrate, whole cell and many others. This flexibility differentiates Arrayit's microarray technology from competitors, who are generally limited to DNA microarrays. Arrayit sells both small-scale microarray manufacturing robots (SpotBot®) and high throughput versions (NanoPrint™). The SpotBot® and NanoPrint product lines have been further enhanced to accommodate more stringent requirements for manufacturing protein microarrays. Arrayit also offers personal microarray scanners (SpotLight™) as well as high-end scanning instruments (InnoScan®). As the industry continues to grow, Arrayit is providing more fully integrated platforms such as the company's Platinum, Gold, Silver and Bronze Variation Identification Platform™ (VIP) genotyping systems, including cleanroom and laboratory versions. Arrayit is expanding its pre-printed microarray content to complement its flagship H25K Whole Human Genome Microarray, which is a premium product for biomarker discovery and drug compatibility testing. Arrayit is expanding its Microarray Services capabilities in connection with increased demand for microarrays of all kinds, and a trend toward outsourcing high end technical manufacturing. With the investment proposed in its business plan, Arrayit will create a variety of microarray based diagnostic tests using Arrayit's patented VIP Healthcare technology and related proprietary approaches. As microarrays move into clinical diagnostics and genetic screening applications, the Company expects to earn license and royalty fees in these areas. A full microarray product list with descriptions, scientific publications, protocols and pricing is available at http://arrayit.com.

The Microarray Industry

Arrayit's core business is in the life sciences research market, with customers in laboratories at universities, medical research centers and government institutions, as well as biotechnology and pharmaceutical companies. Researchers at these institutions use Arrayit products and services in a broad spectrum of scientific activities such as genotyping and gene expression, basic research into the function of genes in plants and animals, research on the human genome, development of diagnostics for personalized medicine, and diagnostic screening tools for drug development programs that identify toxicity patterns in patient populations. Arrayit products are cited in more than 4,700 scientific publications to date.

Health Care Industry Segment

Arrayit Corporation believes that the analysis of genetic variation and function will play an increasingly important role in molecular biology, and that by empowering genomic and proteomic analysis, our tools and trade secrets will advance disease research, drug development, and the creation of molecular diagnostic tests. In addition to developing all types of microarray-based solutions for life science, applied science, and consumer markets, Arrayit is facilitating the transition to the clinic, by supporting and carrying out clinical trials to gather data for regulatory submissions in the US and globally, and establishing infrastructure to offer products designed and manufactured in compliance with global quality standards for medical devices.

As personalized medicine progresses, it has become apparent that millions of people will need to be tested for various diseases or traits in order to identify whether or not a disease is present, or to determine compatibility with specific drug treatments. However, testing millions of patient samples, one at a time, would overwhelm laboratory testing facilities and be cost prohibitive. To solve this problem, Dr. Mark Schena developed and patented a method to place up to 100,000 individual patient samples on a single microarray substrate slide. That slide is then immersed in a solution that contains the known markers for a specific disease, such as congenital hearing loss, Parkinson's Disease, Alzheimer's Disease, etc. The results are as easy as reading a traffic signal. Should any one of those 100,000 patient samples contain the marker for the disease being tested, a red spot appears, and if not, a green spot appears. This procedure can also identify carriers as yellow spots. Because of the sophistication of this patented invention, one lab could test hundreds of thousands of patient samples a day after receiving a sample of DNA from each patient. It is the only method available to the industry that can accomplish this. Dr. Schena's multi-patient genotyping procedure is protected by the following patents:

US Patent 6,913,879

Australia 2002218740

Europe 1343911

Korea 10-0756015

New Zealand 523560

Singapore 94899

Taiwan I280282

Israel 153848

Other worldwide patents pending

Strategic Relationships and Licensing Arrangements

As of December 31, 2013, Arrayit Corporation owns 19.5 million shares in Avant Diagnostics, Inc. The shares basically have no voting rights as Avant Diagnostics, Inc. has issued Preferred Stock controlled by insiders at Avant with controlling voting rights. Avant was originally a 100% subsidiary of Arrayit Corporation. It was created as a vehicle to finance the FDA approval process and sales and marketing for Arrayit Corporation's microarray based test for ovarian cancer. Arrayit Corporation developed, manufactures, processes, and owns its ovarian cancer test and OvaDx® registered trademark. Arrayit Corporation conferred the right to sell an ovarian cancer test upon FDA approval to Avant Diagnostics, Inc, and Avant was tasked with raising $3-5 million for the FDA approval process and sales and marketing. After 5 years, Avant remains unsuccessful at raising $3-5 million for the FDA approval process. So, in the fourth quarter of 2013, Arrayit Corporation requested that the right to sell an ovarian cancer test be returned to Arrayit Corporation. The parties discussed various settlement arrangements, but were unable to reach an agreement. On March 31, 2013, Avant Diagnostics, Inc sued Arrayit Corporation. Arrayit Corporation is preparing a counter suit against Avant.

Arrayit Corporation decided to engage the services of DOCRO, the top diagnostic oncology research organization in the United States, to assist with the pre-IDE and 510(k) submissions for FDA approval of OvaDx®, as well as for CLIA approval of Arrayit's new microarray clean room laboratory facility in Sunnyvale, CA. Arrayit believes it is in the best interests of the Company and its shareholders to follow through with DOCRO and advance OvaDx® toward commercialization despite the failure of Avant to fund these obligations as previously required. We believe Avant is in complete default of any agreements with the Company and seek to remove Avant from any rights to an ovarian cancer test and OvaDx®.

Human noroviruses cause up to 21 million cases of foodborne disease in the United States annually and are the most common cause of acute gastroenteritis in industrialized countries. To reduce the burden of foodborne disease associated with viruses, the United States Department of Agriculture and Arrayit Corporation used Arrayit's colorimetric microarray platform to develop a method of simultaneously genotyping multiple norovirus strains associated with foodborne disease. USDA's findings led them to conclude that the use of Arrayit's microarrays enabled the accurate and rapid detection of norovirus genogroup I and II strains. Arrayit intends to license USDA's patent in this area and commercialize this product.

Arrayit provides a variety of customized solutions for its life science and pharmaceutical customers. We are the sole provider of custom microarray glass manufacturing services to a major life sciences tools company on an OEM basis. Our microarray manufacturing technology and substrates are being used to create the first allergy microarrays approved for the Taiwanese and Chinese markets. Arrayit is also providing OEM microarray manufacturing services for a breast cancer test, and CE approval was granted in 2013.

Product and Services Categories

Arrayit's revenues are generated through the following major product lines:

Patented Printing Technology

Arrayit manufactures the world's most widely used microarray printing technology consisting of Professional, 946, Stealth and ChipMaker® pins and printheads. Arrayit's patented printing technology allows the high-speed manufacture of DNA, protein, antibody, lipid, carbohydrate and other types of microarrays for research and diagnostic applications including gene expression, genotyping, protein profiling and many more.

Instrumentation

Automated microarray manufacturing instruments including NanoPrint™, SpotBot Titan, SpotBot Extreme, and SpotBot® Protein and Personal microarrayers. NanoPrint™ allows high-end, high throughput manufacturing, whereas SpotBot® systems are the only personal microarrayers in the industry that enable affordable benchtop use.

Other instruments include SpotLight™ CCD fluorescence scanners, SpotWare® colorimetric scanners, InnoScan® laser scanners, TrayMix™ Hybridization Stations, ArrayMix Hybridization Stations, high speed centrifuges, air jets, and vacuum products. Laboratory tools and bioinformatics computers complete the instrumentation line which are all designed to facilitate the quality and speed of microarray research.

Consumables

Arrayit manufactures and provides the microarray industry with variety of laboratory consumables, including glass substrates and slides, reagents, solutions, kits and clean room supplies.

Arrayit Super Microarray Substrates have been adopted by major Life Science companies and are used industry wide. They are polished atomically flat glass surfaces with proprietary coupling chemistry that afford high signal intensities and low background noise for premium quality microarray experimentation.

Arrayit buffers and solutions are optimized to increase the quality of microarray manufacturing, processing, and use. Purification kits provide both a high yield and superior purity. Applications include: DNA microarrays, fluorescent microarray purification, sequencing and others. Arrayit kits utilize proprietary binding membranes and purification chemistries for optimal performance.

Healthcare Platforms

Arrayit's patented Healthcare technology, the Variation Identification Platform (VIP), allows diagnostic tests to be performed by depositing as many as 100,000 patient samples onto a single microarray. VIP platforms enable the manufacture of extremely high-quality microarrays with superior precision and accuracy. These microarrays containing 100,000 individual features allow the simultaneous genotyping of 100,000 different patients in a single test, which dramatically reduces the cost of manufacturing and processing such genotyping tests by more traditional means.

Arrayit Opportunity in Diagnostics and Personalized Medicine

With the completion of the human genome sequencing project, genetic researchers have focused on identifying the variations in the DNA of specific genes in the genome. These DNA variations are partly what define individual characteristics, including disease states or a statistical propensity for disease as well as compatibility with specific pharmaceutical compounds. In addition to DNA analysis, it is now possible to identify messenger RNA (mRNA) and protein markers or biomarkers in the blood stream that provide definitive early warning signs for diseases such as Parkinson's Disease and ovarian cancer. Arrayit technology uniquely allows the analysis and identification of all of the major classes of molecules in the human body (DNA, mRNA and protein) using a single patented and proprietary microarray technology platform. The implications of this capability are far-reaching and impact not only the research community, but will also impact individual patients and medical and insurance providers in the near future. Diagnostic tests that detect diseases very early in their progression provide options for earlier treatments that may improve patient quality of life and prognosis by delaying or preventing disease progression or even death. The health care enterprise will incur major cost savings by avoiding costly late stage disease treatments.

We intend to pursue opportunities to license diagnostic markers that were developed using our platform and to acquire businesses that increase our disease diagnostic capability and expand our geographic reach. We also intend to acquire manufacturers of other highly engineered and customized ancillary or complementary products that will further our penetration into the life sciences, diagnostics and health care markets and our customer base served by these sectors. We favor academic and commercial candidates that have core competencies and business characteristics similar to our own, and those that we expect will benefit from some of the major positive trends occurring in our industry.

Competition within the Microarray Research and Development Industry

Arrayit competes with large and small, public and private companies. The industry has been historically dominated by Affymetrix which achieved strong market penetration by being the first public company to commercialize and promote microarray applications. Over the past few years, Illumina has taken significant market share from Affymetrix. However, both competitors face mid to long term scientific and technological challenges because they are limited by what they can deposit onto a microarray--DNA. Arrayit's patented printing technology can deposit any kind of molecule into a microarray, including DNA, proteins, antibodies, diagnostic elements and other compounds. These next generation microarrays represent the largest growth opportunity in the industry. Arrayit has a long-term advantage in its unique line of personal and high throughput microarray printers, highest sensitivity microarray scanners, top quality consumables, patented diagnostic methods, collaborative corporate culture, and competitive pricing. Arrayit's main competitors are:

Name and Location	Trading Symbol	Price per Common Share	Market Capitalization
Agilent Technologies, Inc., Santa Clara, California	NYSE: A	$52.77	$18.48B

Agilent provides bio-analytical and electronic solutions to the communications, electronics, life sciences and chemical analysis industries. The microarray division is a small portion of their total business. Agilent's process places spots in a microarray by means of an ink jet technology and is limited to DNA microarrays.

Affymetrix, Inc., Santa Clara, California	NasdaqGS: AFFX	$6.37	$539.26M

Affymetrix provides consumables and systems for genetic analysis in life sciences. Their process creates a microarray by means of photolithography and is limited to DNA microarrays.

Illumina, Inc., San Diego, California	NasdaqGS: ILMN	$135.24	$21.12B

Illumina provides a line of products and services to serve the sequencing, genotyping and gene expression markets. Their process places chemically reacted beads into a microarray format, and is limited to DNA microarrays.

(1) Share price and market cap values as of April 11, 2014. Source http://otcmarkets.com.

Research and Development

During 2013 we spend $63,534 on Research and Development, none of which was borne directly by our customers.

Advertising, Marketing and Sales

Arrayit has become a recognized brand through major broadcast television news media, full page advertisements in top scientific journals, trade shows and workshops, vendor fairs, direct mail campaigns, feature articles in major trade publications and via e-mail newsletters. All advertising and marketing efforts drive traffic to the Arrayit.com website and web based store resulting in sales. The Arrayit.com web site regularly receives more than 815 unique visitors per day and 26,000 visitors per month and over 685,000 hits per month. Because of the wealth of scientific information and protocols on the site, many consider it be the scientific portal of the microarray industry.

The Company's sales strategy relies on providing exceptional customer service and technical support. Arrayit has developed a network of more than 50 international distributors in Eastern and Western Europe, Asia, the Middle East, South Africa, India and other locations world-wide. These global distributors purchase directly from Arrayit for resale on net 30 day terms, and represent approximately 54% of the Company's 2013 revenues. These foreign receivables are insured through Atradius Trade Credit Insurance, Inc.

Facilities

Arrayit's corporate offices and research facilities are located at 927 Thompson Place, Sunnyvale, California 94085. The corporate headquarters covers 15,000 square feet which in addition to the executive offices, shipping and receiving, include 1,500 square feet of clean room space, preparation and packing facilities, and quality control and quality assurance work stations. The base rent is $19,500 per month plus a monthly operating expense charge of $3,750. The lease expires on December 31, 2021.

Avant Diagnostics, Inc operates from corporate offices located at 8561 East Anderson Drive, Suite 104, Scottsdale, AZ 95255.

Management believes these facilities are suitable and adequate for its current operations.

Regulatory Matters

We and our customers are subject to various government regulations, and we may incur significant expenses to comply with, and experience delays in our product commercialization as a result of, these regulations.

The FDA must approve certain in-vitro diagnostic products before they can be marketed in the United States. Certain in-vitro diagnostic products must also be approved by the regulatory agencies of foreign governments or jurisdictions before the product can be sold outside the United States. Commercialization of our and our collaborative partners' in-vitro diagnostic products outside of the research environment may depend upon successful completion of clinical trials. Clinical development is a long, expensive and uncertain process and we do not know whether we, or any of our collaborative partners, will be permitted to undertake clinical trials of any potential in-vitro diagnostic products. It may take us or our collaborative partners many years to complete any such testing, and failure can occur at any stage. Delays or rejections of potential products may be encountered based on changes in regulatory policy for product approval during the period of product development and regulatory agency review. Moreover, if and when our projects reach clinical trials, we or our collaborative partners may decide to discontinue development of any or all of these projects at any time for commercial, scientific or other reasons. Any of the foregoing matters could have a material adverse effect on our business, financial condition and results of operations.

Many of our products are labeled for research only. Even when a product is exempted from FDA clearance or approval, the FDA may impose restrictions as to the types of customers to which we can market and sell our products. Such restrictions may materially and adversely affect our business, financial condition and results of operations.

The FDA, the U.S. Department of Health and Human Services and foreign government regulators are increasingly focused on genetic analysis tools, including the use of microarrays that are labeled for research use only by cytogenetics labs, including labs certified under the Clinical Laboratory Improvement Amendments ("CLIA"). We cannot predict the extent of the FDA's future efforts in regulation and policies with respect to the sale and use of microarrays for the development of assays by CLIA laboratories, which are referred to as laboratory developed tests ("LDTs"). If new regulations restrict our customers' development of LDTs using our products labeled for research use only, or if we otherwise are required to obtain FDA premarket clearance or approval prior to commercializing these products, our ability to generate revenue from the sale of our products may be delayed or otherwise adversely affected. Moreover, our failure to comply with governmental rules and regulations related to our products could cause us to incur significant adverse publicity, or subject us to investigations and notices of non-compliance or lead to fines or restrictions upon our ability to sell our products.

Medical device laws and regulations are also in effect in many countries, ranging from comprehensive device approval requirements to requests for product data or certifications. The number and scope of these requirements are increasing. We may not be able to obtain regulatory approvals in such countries or may incur significant costs in obtaining or maintaining our foreign regulatory approvals. In addition, the export by us of certain of our products which have not yet been cleared for domestic commercial distribution may be subject to FDA or other export restrictions.

We have agreements relating to the sale of our products to government entities and, as a result, we are subject to various statutes and regulations that apply to companies doing business with the government. A failure to comply with these regulations might result in suspension of these contracts or administrative penalties, and could have a material adverse effect on our ability to compete for future government grants, contracts and programs.

Healthcare reform and restrictions on reimbursements

We are currently collaborating with our partners to develop diagnostic and therapeutic products. The ability of our collaborators to commercialize such products may depend, in part, on the extent to which reimbursement for the cost

of these products will be available under U.S. and foreign regulations that govern reimbursement for clinical testing services by government authorities, private health insurers and other organizations. In the U.S., third-party payer price resistance, the trend towards managed health care and legislative proposals to reform health care or reduce government insurance programs could reduce prices for health care products and services adversely affect the profits of our customers and collaborative partners and reduce our future royalties.

Handling of hazardous materials and other regulations governing environmental safety.

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation and storage of waste. We could discover that we or an acquired business is not in material compliance. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business. Our costs of compliance with environmental laws and regulations has been minimal, amounting to less than $6,000 during 2013.

Employees

As of March 21, 2014, we had 8 full time employees. We had no part-time employees. None of our employees are covered by a collective bargaining agreement with a union. We consider our relationship with our employees to be good.

Comment Letters Issued by the SEC

None

ITEM 1A. RISK FACTORS

Our business faces many risks. The risks described below may not be the only risks we face. Additional risks that we do not yet know of, or that we currently think are immaterial, may also negatively impact our business operations or financial results. If any of the events or circumstances described in this section occur, our business, financial condition or results of operations could be negatively affected to a significant extent. Our securities are highly speculative and should only be purchased by persons who can afford to lose their entire investment in our Company. The Company's business is subject to many risk factors, including the following:

Risks Related to the Growth of Our Business

We must continually develop and commercialize new or enhanced products and services to spur growth.

Our success depends in large part on our continual, timely development and commercialization of new or enhanced products and services that address evolving market requirements and are attractive to customers. The life sciences tools market is characterized by rapid and significant technological changes, frequent new product introductions and enhancements, evolving industry standards and changing customer needs. Standardization of tools and systems for genomic and proteomic research is ongoing. Other companies may introduce new technologies, techniques, products or services that render our products or services obsolete or less economical. If we do not appropriately innovate and invest in new technologies, then our technologies may become dated and our customers could move to new technologies offered by our competitors.

As a result, we are continually looking to develop, license or acquire new or enhanced technologies, products and services to further broaden and deepen our offerings. Some of the factors affecting market acceptance of our products and services include:

- availability, quality and price as compared to competitive products and services;
- the functionality of new and existing products and services;
- the timing of introduction of our products and services as compared to competitive products and services;