

## ANNUAL REPORT

Quadrant Biosciences Inc.



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In this Annual Report, the terms “Quadrant”, “the company”, “we”, “us” and “our” refer to Quadrant Biosciences Inc. and its consolidated subsidiaries. The company, having offered and sold Common Stock pursuant to Regulation Crowdfunding under the Securities Act of 1933, as amended (the “Securities Act”) is filing this annual report pursuant to Rule 202 of Regulation Crowdfunding for the fiscal year ended December 31, 2021. A copy of this report may be found on the company’s website at [www.quadrantbiosciences.com/financials/](http://www.quadrantbiosciences.com/financials/).

### FORWARD-LOOKING STATEMENTS

**This report may contain forward-looking statements and information relating to, among other things, the company, its business plan and strategy, and its industry. These forward-looking statements are based on the beliefs of, assumptions made by, and information currently available to the company’s management. When used in this report, the words “estimate,” “project,” “believe,” “anticipate,” “intend,” “expect” and similar expressions are intended to identify forward-looking statements, which constitute forward looking statements. These statements reflect management’s current views with respect to future events and are subject to risks and uncertainties that could cause the company’s actual results to differ materially from those contained in the forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. The Company does not undertake any obligation to revise or update these forward-looking statements to reflect events or circumstances after such date or to reflect the occurrence of unanticipated events.**

## **BUSINESS SUMMARY**

### **Overview**

Quadrant Biosciences Inc. is a medical technology company focused on the research and development of molecular diagnostics, virtual care solutions, and therapeutic products and services.

The company was founded to improve lives through the development of more accurate and timely medical solutions for large-scale health issues; these include Autism Spectrum Disorder (“ASD”), Parkinson’s disease (“PD”), mild traumatic brain injuries (“mTBI” or “concussion injuries”), and most recently SARS-CoV-2 infections (“COVID-19”). In addition to developing solutions for these conditions, the company is actively engaged in proprietary research and development efforts related to molecular diagnostics for other chronic, degenerative and developmental diseases and disorders.

The company has research relationships with more than 100 academic medical or clinical sites in North America, Central America and Europe; these sites recruit research study participants and collect biological specimens, medical histories, phenotypic characteristics and demographic data.

For its development of novel molecular diagnostics, the company has accumulated biological specimens and data related to hundreds of thousands of patients, ranging in age from new-born to over 90 years and including nearly every racial and ethnic background. The company analyzes these biological samples using next-generation sequencing technology for epigenetic and genetic content and further analyzes the results of this sequencing, along with medical histories, phenotypic characteristics and demographic data of the patients, using proprietary artificial intelligence and machine learning tools developed by the company to identify molecular profiles which accurately differentiate patients with the subject disorder or disease from those without it.

For each disorder or disease, these newly discovered molecular profiles are the foundation of the company’s molecular diagnostic development pipeline. In certain cases, the company believes the molecular profiles discovered through this process may yield appropriate targets for the development of new therapeutics.

The company has developed proprietary epigenetic and genetic research systems which align and quantify certain human and microbial molecules which may play a significant role in gene expression and observed phenotypic characteristics. The company extensively utilizes cloud-computing and database storage facilities offered by Amazon Web Services.

The technology pioneered by Quadrant has translated into the development of clinical diagnostic tools which are based on identifying certain profiles of biomarkers in biological samples, such as blood and saliva, that are highly correlated with medical conditions and can be used as part of the diagnostic workup of patients who may be affected by the conditions. The most important biomarkers used in the Quadrant tests consist of certain nucleic acid transcript sequences for microRNA and other small non-coding RNAs produced by the patient (human transcripts) and by the microbes present in the patient’s mouth (microbial transcripts). The technology consists of:

- Methods for determining sets of biomarker human transcripts and microbial transcripts that are present in different amounts in patients with certain conditions as compared to patients who do not have the condition, and;
- Specific ways of implementing the methods to identify the set of biomarker human transcripts and microbial transcripts that are most highly correlated with a particular condition.

To better serve its molecular diagnostics clients, the company now operates two high-throughput, CLIA high-complexity laboratories located in Syracuse and Buffalo New York. The company markets its molecular tests under the brand name “Clarifi”.

In response to the global COVID-19 pandemic, the company has been working in conjunction with SUNY Upstate Medical University and other State University of New York (“SUNY”) researchers, to develop testing for the detection of SARS-CoV-2. This work began in March 2020, and on September 22, 2020, the company was granted an emergency use authorization (“EUA”) for its COVID-19 test “Clarifi COVID-19 Test” from the U.S. Food and Drug Administration (“FDA”). The Clarifi COVID-19 Test is a saliva-based, quantitative polymerase chain reaction (“qPCR”) test for the presence of the SARS-CoV-2 virus. The company believes that the Clarifi COVID-19 Test presently is the most sensitive

saliva test available in the United States, based on its limits of detection on the standard reference panel provided by FDA. Currently, the company receives revenues from the three methods of COVID-19 testing:

- A test for individuals - a saliva-based test to facilitate the diagnosis of individuals infected with the SARS-CoV-2 virus;
- A test for pooled specimens - a cost-effective and time-efficient means of testing up to 12 saliva specimens at one time (if the pool tests negative for the SARS-CoV-2 virus, all 12 specimens are considered negative; if a pool test positive for the SARS-CoV-2 virus, all 12 specimens are retested on an individual basis to determine which are positive); and
- A test to analyze wastewater – a method that allows for the monitoring of wastewater produced by the residents of a defined geography or congregate living facility, for the purpose of detecting the SARS-CoV-2 virus and measuring any changes in the amount of SARS-COV-2 virus present in the wastewater over time.

For the individual saliva test, pooled saliva testing and wastewater surveillance testing, the company has entered into exclusive global license agreements with the Research Foundation for the State University of New York.

In April 2022, the New York State Department of Health approved use of Quadrant’s Clarifi COVID AB Test, a semi-quantitative, saliva-based assay which identifies and quantifies the presence of human antibodies specific to the SARS-CoV-2 virus in individuals who have received a vaccine to SARS-CoV-2, had a previous SARS-CoV-2 infection, or both. A CPT code and CMS reimbursement rate for this type of test has already been established; the Company is developing a commercialization plan for this test.

In addition to sales of its COVID testing products and services, the company has sold Clarifi ASD and the ClearEdge® Brain Health Toolkit (“ClearEdge” or “ClearEdge Toolkit”), both developed and validated in cooperation with the SUNY Upstate Medical University and the Penn State College of Medicine:

- Clarifi ASD is a molecular diagnostic test that provides clinicians with objective support for an earlier diagnosis of Autism Spectrum Disorder, when treatment is most effective. While regulators approved Clarifi ASD as a Laboratory Developed Test (“LDT”) pursuant to the Clinical Laboratory Improvement Amendments (“CLIA”) in November 2019, many of the company’s resources were subsequently diverted toward COVID-19 initiatives; as expected, sales of Clarifi ASD were limited. During the pandemic, the company continued to pursue several strategic initiatives related to Clarifi ASD, including (i) application to the FDA for “Breakthrough Device” designation (granted in April 2021) and (ii) ongoing implementation of the company’s insurance reimbursement strategy. Recent milestones for our insurance reimbursement strategy include: issuance of a unique CPT® PLA code for Clarifi ASD by the American Medical Association, and; establishment of a payment rate of \$1,755 for Clarifi ASD by the Centers for Medicare and Medicaid Services (“CMS”). The company is now pursuing state and federal health insurance coverage for Clarifi ASD.
- The ClearEdge Toolkit is a suite of tests and assessments healthcare providers use to measure and track a patient’s balance and cognitive reaction time. The ClearEdge Toolkit initially consisted of a cognitive reaction time assessment module, which was a Class II medical device licensed from Anthrotronix and a balance module developed by the company, which was a Class I medical device. An improved version of the balance module was subsequently cleared by the FDA as a Class II medical device in October 2019. Due to limited clinical demand for the product and the company’s increased focus on molecular diagnostics, sales of the ClearEdge Toolkit were discontinued in late 2020.

The intellectual property associated with our molecular diagnostics technology includes:

- Two patents issued in 2022, in the US and South Korea respectively, with claims covering an epigenetic test to aid in the diagnosis of Autism Spectrum Disorder and potential patent rights (in the form of patent applications which have been filed) in the methods of using the key biomarkers that are associated with a particular condition, such as Autism Spectrum Disorder, Parkinson’s Disease, or concussion injuries, together with the associated know-how necessary to implement the methods;
- Trade secret rights in the specific algorithms that use the human and microbial RNA biomarker transcripts as inputs, and produce the best correlation with the target condition; and
- Trade secret rights together with the associated know-how necessary to implement our COVID-19 tests, and how to implement those tests on a high-throughput basis.

In addition to its molecular diagnostics platform, in 2020 the company began development of virtual care solutions to better serve its communities. Since that time, the company implemented a virtual care solution to facilitate patient access to its saliva-based PCR test for SARS-CoV-2 infections and is now finalizing development of pediatric virtual care clinics specializing in the early diagnosis of Autism Spectrum Disorder. These virtual care clinics will employ evidence-based medicine technologies and are expected to launch in the Northeast US in mid-2022 with the intent of providing services on a national basis by late-2023.

The company intends to further expand its clinical offerings related to Autism Spectrum Disorder through the provision of evidence-based therapeutic services. In March 2022, the company acquired Frazier Behavioral Health LLC, an Ohio-based provider of behavioral health services with the intent to expand this business throughout Ohio and the Northeast.

The company was incorporated in Delaware on March 13, 2015 as Motion Intelligence Inc. On August 6, 2015, Motion Intelligence LLC, a New York limited liability company merged into Motion Intelligence Inc. The company changed its name to Quadrant Biosciences Inc. on September 7, 2017. The company is principally located at the Institute for Human Performance at the State University of New York Upstate Medical University and is a participant in the New York State START-UP NY economic development program, which provides the company and its employees with substantial tax and other benefits under New York law.

Quadrant has been recognized for numerous awards and accolades, including:

- In 2019, the company was selected as the Technology Business of the Year by the New York State Small Business Development Center and was selected by the National Institutes of Health for inclusion in their Commercialization Accelerator Program (“CAP”).
- In 2020, the company was selected as the Small Business of the Year by the CenterState Corporation for Economic Opportunity.
- In 2021, the company’s COVID-19 test development and deployment efforts were selected as the Project of the Year by MedTech for its “singular and demonstrable positive impact on public health”. Further, the company was selected as the Large Business of the Year by the CenterState Corporation for Economic Opportunity and the company’s CEO Richard Uhlig was recognized as one of the top 50 Healthcare Technology CEOs by the Healthcare Technology Report. Finally, official proclamations were presented to Quadrant Biosciences by County Commissioners from Erie and Onondaga counties, as well as the NYS Assembly, for our significant contribution in combating the COVID-19 pandemic.

As of December 31, 2021 the company has seven wholly owned subsidiaries:

- Motion Intelligence LLC sold ClearEdge toolkits to end users utilizing distributors and agents.
- Quadrant Epigenetics LLC records the revenue from epigenetic activities.
- Quadrant IP Holdings LLC houses the company’s patents.
- Quadrant Vision Technologies LLC was created to partner with a health provider, but has not yet engaged in any business activities.
- Quadrant Viral Testing LLC sells the wastewater testing services and the Clarifi COVID-19 Test kit to CLIA approved laboratories.
- Quadrant Biosciences Canada Ltd was created to facilitate the company’s expansion into Canada, but has not yet engaged in any material business activities.
- Quadrant Laboratories LLC operates and administers two CLIA high-complexity clinical laboratories in which diagnostic medical testing and related commercial activities are conducted.

## Principal Products and Services

### COVID-19 Testing

Since March 2020, the company has been focusing on ways to utilize its technology to develop a comprehensive approach to detecting and diagnosing COVID-19, in coordination with local, state and regional health care policies and directives. The company currently has three COVID-19 products:

- A test for individuals - a test facilitating the diagnosis of individuals infected with the SARS-CoV-2 virus;
- A test for pooled specimens - a cost-effective and time-efficient means of testing up to 12 specimens at one time (if the pool tests negative, all 12 specimens are considered negative; if a pool test positive, all 12 specimens are retested on an individual basis to determine which are positive); and
- A test to analyze wastewater – a method that allows for the monitoring of wastewater produced by the residents of a defined geography or congregate living facility, for the purpose of detecting SARS-CoV-2 and measuring any changes in the amount of SARS-COV-2 present in the wastewater over time.

For individual testing, pooled saliva testing and wastewater surveillance testing, the company has entered into exclusive global license agreements with the Research Foundation for the State University of New York.

### *Individual Tests*

On September 22, 2020, the company received an FDA EUA for its individual COVID-19 diagnostic test. This is the culmination of work started in March 2020, where the company, in conjunction with SUNY Upstate Medical University and other SUNY researchers, started to develop a diagnostic test for COVID-19. The Clarifi COVID-19 Test kit is a non-invasive and easy to administer saliva swab, and a kit of reagents for extraction of viral RNA and performing qPCR testing to determine the presence or absence of SARS-CoV-2 viral RNA. The Clarifi COVID-19 Test kit contains the saliva collection device and the reagents needed to run the analysis, together with detailed instructions regarding performing the testing method / procedure. The Clarifi COVID-19 Test kit is available for use by high-complexity clinical laboratories serving patients through physicians' offices, urgent care clinics and hospitals. The company's FDA EUA for this test was amended on May 6, 2021, to allow for pooling of up to 12 specimens, multiple saliva collection devices, an array of different PCR systems, and self-collection of a saliva specimen. An additional amendment is under review by the FDA to add at-home saliva specimen collection and updated variant analysis. The company believes that the Clarifi COVID-19 Test is presently the most sensitive saliva test available in the United States (as measured using the FDA SARS-CoV-2 Reference Panel).

### *Pooling of Specimens*

The company's FDA EUA has been amended to allow for the pooling of saliva specimens, a cost-effective and time-efficient method of screening large populations of people for the presence of SARS-CoV-2 viral RNA. The company has contracts with SUNY Upstate Medical University to facilitate pooled saliva specimen testing for nearly all State University of New York (SUNY) campuses as well as many other colleges/universities, K-12 schools, nursing homes, municipalities and other clients. In addition to these services, the company opened and operated as many as 43 community test sites throughout New York State in late 2021 and early 2022; these sites were established in response to the proliferation of the Omicron variant of SARS-CoV-2 and at the request of the New York State Commissioner of Health Dr. Mary Bassett. The company is supplying SUNY with test components as well as consulting services, inclusive of the staffing, management and oversight of two CLIA high-complexity clinical laboratories. This pooled testing approach involves collecting saliva samples from a small group of individuals (for example 12) and combining them into one test. A negative test means that all individuals in the pooled group are presumed to be coronavirus-free. A positive test result for the pool would mean every person in that group would need to be individually tested. Screening groups of twelve individuals at a time greatly reduces the cost of supplies, staffing and time required to perform tests.

### *Wastewater Surveillance*

In mid-2020, the company's environmental laboratory was selected by the New York State Department of Health to work in collaboration with SUNY ESF, SUNY Upstate Medical University, Syracuse University and global civil engineering firm Arcadis, to collect and analyze wastewater from county and municipal sewer systems for the presence of the SARS-

CoV-2 virus. Results from the wastewater tests are used by local and state authorities to modify public health policies and allocate resources to areas as the virus appears in wastewater several days before infected individuals enter the healthcare system for diagnosis. The company has executed contracts with New York State and other municipalities, colleges, and universities to perform wastewater tests at more than 330 sites throughout New York, Pennsylvania and Vermont.

### Clarifi ASD

Clarifi ASD has been designed and developed to assist clinicians in providing a diagnosis as to whether children aged 18-83 months have ASD. Clarifi ASD is an easy to administer, non-invasive, molecular test that improves the specificity of tests that are used to screen for ASD. Such screening tests generate many false positive results and Clarifi ASD aids in distinguishing between the true positive and false positive results. This facilitates earlier diagnosis of ASD, when treatment is most effective.

ASD is one of the most commonly diagnosed developmental disabilities in the United States; however, the current clinical diagnostic workup takes time to identify and address ASD. The average child waits well over a year for a diagnostic evaluation. The inadequacy of existing screening tools is causing pediatricians to over-refer patients for ASD evaluations. The availability of developmental specialists is limited (both by number and geography); this causes wait times for evaluation to exceed 12 months on average and may exceed 18 months in some locations. Autism is being diagnosed on average in the fourth year of life, but it should be reliably diagnosed earlier to expedite access to intervention services to maximize their effectiveness.

Early diagnosis leads to early intervention. It is imperative to initiate early intensive behavioral intervention (“EIBI”) therapy as early as the second year of life, a dynamic period of brain growth and neuroplasticity. As has been demonstrated in hundreds of clinical research studies since 1987, between 45% and 50% of children on the autism spectrum who have the benefit of EIBI therapy are functionally and cognitively indistinguishable from their peers by the first grade. This outcome dramatically improves the quality of life for ASD children and their families.

Clarifi ASD may be utilized by pediatricians, family physicians, and other clinicians with patients (18 months through 83 months of age) with a positive screening test or a clinical suspicion of ASD. The goal of Clarifi ASD is to accelerate the autism diagnostic process, with results available in 3 to 6 weeks, and thereby assist medical professionals in identifying the likelihood of an ASD diagnosis. This will ultimately help provide children earlier access to important services.

During the pandemic, the company has taken steps in developing a strategy for Clarifi ASD insurance reimbursement. Attaining a unique CPT® PLA code in 2020 was a major step toward reimbursement for Clarifi ASD. On Sept 21, 2020, CMS (Centers for Medicare and Medicaid Services) released a payment rate determination of \$1,755. With these now established, the company is pursuing state and federal health insurance coverage for Clarifi ASD.

More recently (April 2021), the FDA designated Clarifi ASD a “Breakthrough Device”; the FDA Breakthrough Device Program is intended to help patients and health care providers receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. As part of the FDA regulatory approval process for Clarifi ASD, in November 2021 the company entered into a \$6.2 million Research Support Agreement with Autism Speaks Inc. This agreement utilizes the Autism Care Network and facilitates the collection of one or more biological specimens from over 6,600 children at risk of an autism spectrum disorder diagnosis along with their demographic and phenotypic information from 17 clinical research sites located throughout the United States.

### Laboratories

On July 1, 2021, the company’s subsidiary received CLIA Accreditation and NY State Department of Health CLEP permits for its two laboratories located in Syracuse and Buffalo, New York, see “—Regulation -- New York State Department of Health - Clinical Laboratory Evaluation Program and CLIA” below. These laboratories have performed all of the company’s COVID-19 testing and it is anticipated that they will also perform future tests that the company develops or other third-party tests that are consistent with the business and operations of such laboratories.

### Clinical Diagnostic Products Under Development

The company believes its molecular diagnostic solutions that are currently under development will help accelerate advances in healthcare. Market trends which have facilitated the company's development efforts include:

- Reduced cost of genetic sequencing technology,
- Increasing availability and access to data through cloud computing, and
- Ongoing developments in artificial intelligence and machine learning.

The company is currently developing certain tests, products and services and other assets relating to the measurement and interpretation of epigenetic control of biochemical and metabolic pathways that are altered in patients with certain medical conditions. Biochemical and metabolic pathways are directly controlled by proteins, such as enzymes. These proteins are made by translation of messenger RNA, which is in turn made by transcription of genetic DNA. MicroRNAs are involved in controlling, via epigenetic mechanisms, the making of proteins by translation of messenger RNA. MicroRNAs therefore can be used as biomarkers to derive information about how epigenetic control mechanisms are altered in patients with a particular medical condition. In addition to Clarifi ASD, epigenetic diagnostic aids currently in development by the company include tests to evaluate the human and microbial transcripts associated with Parkinson's Disease and the microRNA profiles associated with concussion injuries. These tests are needed to provide clinicians with objective support in the diagnosis and management of these health conditions.

In addition to its self-funded research, the company has been awarded National Institutes of Health ("NIH") grants in excess of \$4.8 million to facilitate the company's research and development of molecular diagnostics for Autism Spectrum Disorder and concussion injuries:

- In June of 2016, the company was awarded a Phase I Small Business Technology Transfer ("STTR") grant from the NIH for \$225,000 to develop an objective, saliva-based diagnostic tool to facilitate the early diagnosis of Autism Spectrum Disorder. The grant supports research to further refine a saliva-based diagnostic test previously developed by the company, Penn State Medical Center and SUNY Upstate Medical University, with the objective of improving timely access to therapeutic services for children on the autism spectrum.
- In September of 2018, the company was awarded a Phase II STTR grant from the NIH for \$2.0 million to validate an objective, saliva-based diagnostic tool to facilitate the early diagnosis of Autism Spectrum Disorder. The company is partnering with Penn State College of Medicine, SUNY Upstate Medical University, Nationwide Children's Hospital, Cincinnati Children's Hospital, University of Missouri School of Medicine and Baylor University College of Medicine in this study.
- In June of 2019, the company was awarded a Supplemental STTR grant from the NIH for \$330,000 to validate an objective, saliva-based diagnostic tool to facilitate the early diagnosis of Autism Spectrum Disorder; this supplemental award is for whole-exome sequencing of study participants in the company's Phase II ASD study.
- In September of 2020, the company was awarded a Fast Track (Phase I/II combined) STTR grant from the NIH for \$2.3 million to develop an objective, saliva-based diagnostic tool for detecting concussions in children and adolescents. The grant supports research to further refine a saliva-based diagnostic test previously developed by the company, Penn State Medical Center and SUNY Upstate Medical University, with the objective of improving care for school-aged children and young adults who are particularly vulnerable to head injuries and their potential lasting effects. The company will be partnering with Penn State, SUNY Buffalo, SUNY Upstate, Arkansas Children's, and Children's Hospital of Michigan in this study.

### **Intellectual Property**

The company's epigenetic technology is based on research originally conducted at SUNY Upstate Medical University and the Penn State College of Medicine and is licensed from the Research Foundation for the State University of New York and the Pennsylvania State Research Foundation ("Foundations"). The intellectual property associated with the technology includes:

- Two patents issued in 2022, in the US and South Korea respectively, with claims covering an epigenetic test to aid in the diagnosis of Autism Spectrum Disorder
- Potential patent rights that may be obtained through the patent applications (together with associated know how) that are invented and owned by the Foundations, and

- Trade secrets that are created and owned by the company.

The patent applications presently consist of non-provisional patent applications in a number of jurisdictions, and the non-provisional applications must then be prosecuted at the USPTO, as well as select international patent offices, to attempt to obtain issued patent rights.

The company has entered into License Agreements with the Foundations, which grant the company the exclusive right to practice certain existing joint patent rights and Foundation-owned patent rights in fields of use consisting of products and services for the evaluation of ASD, Parkinson’s Disease, and TBI. The company’s ASD, Parkinson’s, and TBI License Agreements have the same terms and conditions regarding the earned royalties payable, the term, and early termination by the Foundations.

Under the License Agreements, earned royalties are payable at the rate of 4% of revenue from licensed products if the licensed technology includes an issued patent, and at the rate of 2% of revenue if no patents are issued and the licensed technology includes only the know-how created in development of the technology covered by the License Agreement.

Further, each agreement requires Quadrant to pay a minimum amount of royalties per year, and if earned royalties are less than the minimum amount for a particular year, a minimum royalty payment is required so that the minimum amount is paid to the Foundations. The minimum royalties are:

| Year   | ASD License Agreement | Parkinson’s License Agreement | TBI License Agreement |
|--|-----------------------|-------------------------------|-----------------------|
| 2021   | \$ 25,000             | \$ 10,000                     | \$ 5,000              |
| 2022   | \$ 50,000             | \$ 25,000                     | \$ 10,000             |
| 2023   | \$ 50,000             | \$ 25,000                     | \$ 10,000             |
| 2024   | \$ 50,000             | \$ 25,000                     | \$ 10,000             |
| 2025 through expiration (estimated to be 2038) | \$ 50,000             | \$ 25,000                     | \$ 25,000             |

The total estimated payments, assuming the company pays the minimum royalty payment through expiration (estimated to be 2038), for the ASD, Parkinson’s and TBI Licenses are \$875,000, \$443,000 and \$385,000, respectively.

Further, each License Agreement requires Quadrant to begin selling licensed products by the following agreed upon commercialization deadlines: Parkinson’s licensed product, December 31, 2020 and TBI licensed product, December 31, 2022. Both Quadrant and the Foundations acknowledge the difficulties associated with conducting clinical research during the COVID-19 pandemic and have agreed in principle to a two-year extension of these commercialization deadlines; a definitive agreement is expected. Quadrant has already begun commercialization of the ASD licensed product. Quadrant has the option to extend the commercialization deadlines by a maximum of three six-month extensions, for the following fees: \$25,000 for the first extension; \$50,000 for the second extension, and \$100,000 for the third extension.

The term of the License Agreements, which include one or more issued patents, extends until expiration of the last issued patent. Issued patents expire 20 years after the earliest filing date, and most of Quadrant’s patent applications have effective filing dates in 2018. The term of any License Agreement that covers only know-how is 10 years after the first commercial sale of the licensed product that embodies the know-how.

The Foundations can terminate the License Agreements early if the company fails to commercialize licensed products by agreed upon deadlines or the company fails to make required payments. The License Agreements presently are in good standing.

Quadrant has also entered into two license agreements with the SUNY Research Foundation (“SUNY RF”) in relation to its COVID-19 testing technology, one for testing saliva samples and one for testing wastewater. The technologies embodied in the Clarifi COVID-19 Test for saliva and the test for wastewater were both jointly developed by Quadrant and SUNY Upstate Medical University personnel, and are therefore co-owned by Quadrant and SUNY RF.

The saliva testing technology consists of inventions and know-how related to the method of testing saliva samples for the presence of the SARS-CoV-2 virus, and the test kit of materials and reagents that are used in the testing method. The testing



method involves extraction of the SARS-CoV-2 viral RNA and amplification and detection of the viral RNA using a qualitative polymerase chain reaction. SUNY RF has granted Quadrant an exclusive worldwide license of SUNY RF's ownership interest in the COVID-19 Test technology in consideration for Quadrant's payment of a royalty in the amount of the following percentages of the net revenue realized on sales of products or services that embody the COVID-19 Test technology for the associated time periods: 10% until December 31, 2021, 8% from January 1, 2022 through June 30, 2022, and 6% for the remainder of the term of the license. The wastewater technology consists of inventions (covered by a US patent application) and know-how related to a method of identifying the SARS-CoV-2 virus in wastewater and estimating the quantity of SARS virus present in relation to the amount of other viral RNA typically present in wastewater. SUNY-RF has granted Quadrant an exclusive worldwide license of this technology in consideration or a royalty of 10% of net revenue. The terms of both of these licenses extend for the entire time period during which Quadrant sells any product or service that embodies the COVID-19 Test technology, and wastewater technology, respectively. SUNY RF has the right to terminate the licenses if Quadrant defaults in performance of its obligations under the license, for example failing to pay royalties when due, and if Quadrant declares bankruptcy or becomes insolvent.

In 2021 and 2020, the company incurred royalty expense due to SUNY RF of \$7,833,833 and \$858,614, respectively, with respect to the COVID-19 testing technology, and these license agreements with SUNY RF presently are in good standing.

The company has filed patent applications with the United States Patent and Trademark Office ("USPTO") in relation to intellectual property related to some significant epigenetic diagnostic tools it is developing based on the research conducted at one or both of the Foundations. The company believes it is a leader in the development of intellectual property, products and services and other diagnostic-related assets relating to human and microbial transcripts.

Quadrant has two granted and 22 pending patent applications. Issued patents are US 11,242,563 B2, issued February 8, 2022, and KR 10-2359013 issued January 28, 2022 both entitled Analysis of Autism Spectrum Disorder. The pending patent applications as of April, 2022, are grouped below in the following 8 patent families:

- Methods of determining the probability that a child is affected by ASD, using RNA biomarkers obtained from a sample of saliva; 5 applications: Japan, Australia, European Patent Convention, Canada, and New Zealand
- Methods of determining the probability that a patient is affected by mild traumatic brain injury, using RNA biomarkers obtained from saliva; 7 national applications, in the same jurisdictions identified above
- Methods of determining the probability that a patient is affected by Parkinson's Disease, using RNA biomarkers obtained from saliva, 1 PCT application, to be nationalized subsequently
- Methods of determining the probability that a patient is affected by Anorexia Nervosa, using RNA biomarkers obtained from saliva, 1 US application
- Methods of applying machine learning techniques to develop a system that classifies a set of RNA biomarkers according to patterns of relative abundance that are associated with a target medical condition, and methods of using the classification system to test samples of the biomarkers; 1 PCT application, to be nationalized subsequently
- Methods of normalizing micro RNA (miRNA) biomarkers to account for circadian variations in any testing process based on differentially expressed miRNAs; 5 national application: US, Australia, New Zealand, European Patent Convention, and Canada
- Methods of normalizing miRNA biomarkers to account for variations caused by exercise in any testing process based on differentially expressed miRNAs; 1 US application
- Methods of quantifying virus from wastewater; 1 US application

Quadrant has actively pursued the registration of the "Clarifi" mark, filing 34 applications in the U.S. and numerous countries. The current status of these efforts (and a brief, general, description of the terms "registered", "filed and pending", and "approved") follows:

- Registered – i.e. the certificate of registration has been issued and is in force: Australia, Canada, China, Brazil, European Union, Great Britain, Hong Kong, Indonesia, India, Japan, Korea, Norway, New Zealand, Saudi Arabia, Singapore, Switzerland, Taiwan, Thailand, United Arab Emirates, United States, and Vietnam.
- Filed and pending/allowed – i.e., in this context the term "pending" means the application is in the examination process but has not yet been approved or allowed, and "allowed" means the examiner has approved/allowed the

application but it has not yet been registered (it could be waiting for the opposition period to pass or for a Statement of Use to be filed (as in the U.S.): China (1 Registered, 1 Pending), Malaysia (pending).

An amended filing with the USPTO was made to include the Clarifi word mark, as well as expand the scope of the defined services.

Every country conducts trademark examinations differently; some are limited to a formalities exam only (i.e., they do not look for conflicts).

### **Market - COVID-19**

Due to the scope, nature and severity of the ongoing pandemic, there is ongoing need for fast, efficient, non-invasive individual COVID-19 diagnostic tests. We anticipate the need for these tests will persist as SARS-CoV-2 variants continue to infect large portions of populations around the world.

Despite current reductions in US cases from peaks experienced in January 2022, the risk of (i) a resurgence of infections, and (ii) an increase in mortality rates, persist. For the next 6-12 months, the company believes that laboratory testing will remain a critically important tool for limiting individual transmission of the virus to others and tracking geographic migration of the virus.

The company's view is informed by a growing body of published research and its own observations and analysis of data derived from its COVID-19 testing platform, including ongoing variant analysis. There are several risks associated with a potential resurgence of SARS-CoV-2 viral transmissions in the US, including but not limited to the following:

- Immunity May be Temporal. The percentage of a community with natural immunity from infection (resulting from prior infection) or acquired immunity (resulting from vaccination) is dependent on (i) the durability of each individual's immune response, and (ii) the applicability of derived antibodies to new variations of the virus. The latter of these is believed to be a material risk, particularly given the ongoing emergence of SARS-CoV-2 Variants of Concern (as defined by the US Centers for Disease Control and Prevention ("CDC")) in the US and elsewhere. Further, while US vaccination efforts may ultimately be successful in reducing infections in the near-term, the virus continues to spread widely in many other countries; for this reason the risk of mutations which enhance transmissibility and allow the virus to evade natural or acquired immunity is high.
- Recently Observed Declines in US Cases may be Predominantly Seasonal. The 7-day moving average of US cases has declined significantly from a peak of approximately 800,000 cases/day (January 2022). While vaccinations and prior infections are believed to play a role in this reduction, a majority of the decline remains unexplained. There is growing evidence that SARS-CoV-2 infections may be seasonal, similar to infections observed from other coronaviruses. A seasonal resurgence of US cases in the Fall of 2022 is possible.

### **Market - Epigenetics**

The global epigenetics market is a new and developing market. According to Grand View Research, Inc., the global epigenetics diagnostic market size was \$5.5 billion in 2018 and is expected to reach \$21.7 billion by 2026.

The target market for our different products will depend on the specific focus of the product, as outlined below:

#### Autism Spectrum Disorder

For Clarifi ASD, we believe our target market is the subsection of children who, based on clinical observations, are at risk to have an Autism Spectrum Disorder diagnosis. Of the nearly 4 million children born in the United States every year, nearly 1 in 6 will have a developmental delay. Currently, children with a wide range of developmental delays are referred for an ASD diagnosis; these children represent the target market for Clarifi ASD.

ASD is a developmental disability that can cause significant social, communication and behavioral challenges. According to the US CDC:

- As of 2021, approximately 1 in 44 children has been identified with Autism Spectrum Disorder according to the most recent estimates from CDC's Autism and Developmental Disabilities Monitoring ("ADDM") Network (2020).
- The reported prevalence of ASD has increased significantly: in 2002, this statistic was 1 in 150; in 2006, prevalence was 1 in 110; in 2010, prevalence was 1 in 68; and in 2020 the prevalence was 1 in 54.
- ASD is reported to occur in all racial, ethnic, and socioeconomic groups.
- ASD is about 4 times more common among boys than among girls.
- Studies in Asia, Europe, and North America have identified individuals with ASD with an average prevalence of between 1% and 2%.

### Parkinson's Disease

For our early-stage Parkinson's Disease diagnostic (in development), we believe our target market is those adults who, based on clinical observations, are at risk to have a PD diagnosis. In clinical research, movement disorders such as tremor and parkinsonism are observed in approximately 21% of adults aged 50 or more; these adults represent the target market for our PD diagnostic. For the US population of nearly 330 million, approximately 115 million are aged 50 or older.

According to the CDC, PD is the second most common neurodegenerative disease after Alzheimer's disease. Population prevalence of PD increases from about 1% at age 60 to 4% by age 80. Early symptoms of PD include tremor, rigidity, and difficulty walking; cognitive decline is common at later stages. The underlying pathology of PD is selective death of dopamine-generating cells in the substantia nigra, a part of the brain involved in movement, reward, and addiction. Treatment of PD with levodopa temporarily controls motor symptoms but does not slow disease progression. Like other common diseases, PD is thought to arise from complex interactions between genetic and environmental factors.

### Concussion Injuries (Mild Traumatic Brain Injuries)

For our acute concussion injury diagnostic (in development), we believe our target market is children and adults who have experienced some form of trauma and, as a result, are at risk to have a concussion (or mild traumatic brain injury) diagnosis. In 2014, there were approximately 2.87 million traumatic brain injury-related emergency department visits, hospitalizations, and deaths in the US, including over 837,000 of these health events among children.

A concussion is a type of traumatic brain injury caused by a bump, blow, or jolt to the head or by a hit to the body that causes the head and brain to move rapidly back and forth. This sudden movement can cause the brain to bounce around or twist in the skull, creating chemical changes in the brain and sometimes stretching and damaging brain cells.

According to the CDC, traumatic brain injury is a serious public health problem in the United States. Each year, traumatic brain injuries contribute to a substantial number of deaths and cases of permanent disability. Further information about the causes of TBIs:

- In 2014, falls were the leading cause of TBI. Falls accounted for almost half (48%) of all TBI-related emergency department ("ED") visits. Falls disproportionately affect children and older adults:
  - Almost half (49%) of TBI-related ED visits among children 0 to 17 years were caused by falls.
  - Four in five (81%) TBI-related ED visits in older adults aged 65 years and older were caused by falls.
- Being struck by or against an object was the second leading cause of TBI-related ED visits, accounting for about 17% of all TBI-related ED visits in the United States in 2014.
- Over 1 in 4 (28%) TBI-related ED visits in children less than 17 years of age or less were caused by being struck by or against an object.

### **Competition**

There is a deep market need for improved diagnostic tools across a wide range of human health conditions and diseases and the company expects competition to increase, especially with respect to diagnostic tests related to ASD, Parkinson's Disease and traumatic brain injury. Further, due to the exigent nature of the COVID-19 pandemic, there is a significant need for fast, effective, and non-invasive diagnostic tools. The company expects to face significant competition from both emerging medical device, biotechnology and healthcare companies, and established market participants, some of whom may be larger and have more resources than the company.

## **Suppliers**

The company purchases the reagents and materials used in the chemical reactions incorporated into our processes, as well as the sequencers and equipment that we use in our laboratory operations from a variety of suppliers. Currently, several reagents and materials are sourced from sole suppliers. For instance, DNA Genotek is the sole supplier of saliva swabs used in our Clarifi COVID-19 and Clarifi ASD test kits and Illumina is the sole supplier of sequencers and various associated reagents used in testing the saliva collected, and is the sole provider of maintenance and repair services for these sequencers.

## **Customers**

The company has received predominantly all of its revenue from COVID-19 products from state and local entities of New York State.

## **Research and Development**

The amount expended for research and development for the year ended December 31, 2021 was \$206,092 and for the year ended December 31, 2020 was \$521,875.

## **Employees**

As of December 31, 2021, the company has 126 full-time employees. All company employees are “at will”; however, the company has employment agreements with basic confidentiality, proprietary rights and non-compete provisions with all employees.

## **Regulation**

Medical products and devices are regulated by the FDA in the United States and can be regulated by foreign governments for devices sold internationally. The Federal Food, Drug and Cosmetic Act and regulations issued by the FDA regulate development, manufacturing, packaging, and marketing of medical devices.

Unless an exemption applies, each medical device or product we wish to distribute commercially in the United States will require marketing authorization from the FDA prior to distribution. These devices may require premarket notification, also called 510(k) clearance, or in cases where that is not available, premarket approval (“PMA”). However due to the exigent nature of the COVID-19 pandemic in the US, on February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) upon determining that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the detection and/or diagnosis of COVID-19. This emergency use authorization (“EUA”) approval is needed to distribute and/or use in vitro diagnostic tests for COVID-19 in the United States.

Since our epigenetic diagnostic tests are developed and performed in a single laboratory, we believe that these tests are LDTs that are subject to FDA’s enforcement discretion for LDTs and do not require FDA notification or authorization. Notification requirements and the related exemptions are discussed in more detail below.

Our manufacturing processes and facilities are also subject to regulations, including the FDA’s Quality System Regulation (“QSR”) requirements. These regulations govern the way we manufacture our products and maintain documentation for our manufacturing, testing and control activities. Although the FDA has waived compliance with some parts of the QSR for COVID-19 tests that are granted EUA, other parts of the QSR do apply to the assembly, packaging, and tracking of COVID-19 diagnostic assays that are distributed to purchasers. In addition, to the extent we manufacture and sell products abroad, those products are subject to the relevant laws and regulations of those countries.

Finally, the labeling of our products and devices, our promotional activities and marketing materials are regulated by the FDA and various state agencies. Violations of regulations promulgated by these agencies may result in administrative, civil or criminal actions against us or our manufacturers by the FDA or governing state agencies.

### Pre-market clearance

To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is “substantially equivalent” to a device legally marketed in the United States that is not subject to PMA approval, commonly known as the “predicate device.” A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more.

### 510(k) Clearance

On October 22, 2019, ClearEdge Balance was cleared by the FDA as a Class II medical device under product code LXV (K18366). ClearEdge Balance assesses changes in balance using our proprietary Edge™ Sensor, a wireless inertial measurement unit worn on the patient’s lower back, at the approximate center of mass. On November 1, 2021, the ClearEdge Toolkit containing ClearEdge Balance was discontinued from use.

### FDA EUA Application for COVID-19 Test Kit

The FDA has prescribed templates to be used for submissions to obtain EUAs for COVID-19 test kits, which enumerate the detailed information that FDA requires to issue the EUA. The information required includes the intended use of the test kit, the materials and reagents comprising the test kit, the step-by-step testing procedure in which the test kit is used, including laboratory equipment required to perform each step, and all laboratory and clinical testing that is required to demonstrate the accuracy of the test. The process to obtain an EUA typically consists of two phases, an initial Pre-EUA submission that is used to identify and resolve any significant problems that would preclude issuance of an EUA and a final EUA submission. The final EUA submission addresses the details that the FDA will require to demonstrate that the COVID-19 test kit will have acceptable sensitivity (to detect a high percentage of people who are infected) and specificity (to not generate a positive test result for someone who is not infected; i.e. limit false positive results). The company obtained an EUA from the FDA for its Clarifi COVID-19 Test Kit on September 22, 2020. Subsequently an amendment to this EUA was granted on May 6, 2021 to further expand the product’s clinical use. As of April 22, 2021, an additional amendment was under review by the FDA

### Laboratory-Developed Tests

Laboratory developed tests (LDTs) are clinical laboratory tests that are developed, validated and manufactured, and used by a single laboratory and then only performed in that laboratory (the test is not shipped to other laboratories). Historically, the FDA has exercised enforcement discretion with respect to most LDTs, and not required the CLIA-certified laboratories that perform such tests to comply with the agency’s requirements for medical devices (e.g., establishment registration, device listing, QSR, premarket clearance or approval, adverse event reporting).

On April 13, 2022, Quadrant Laboratories received approval from NYSDOH CLEP for the LDT submission of an ELISA-based method for SARS-CoV-2 total antibody (IgM, IgG, IgA) detection in saliva collected samples. Although the approval is granted for an indefinite period, it is subject to demonstration of ongoing compliance with NYSDOH CLEP regulations and standards.

In recent years, the FDA has indicated that it intends to end its policy of enforcement discretion and begin regulating LDTs as medical devices. In October 2014, the FDA published two draft guidance documents describing a proposed risk-based framework under which it might regulate LDTs. The FDA’s draft framework proposed, among other things, premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared diagnostics currently on the market. Subsequently, on January 13, 2017, the FDA published a “discussion paper” in which the agency outlined a substantially revised “possible approach” to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it does not represent the agency’s “formal position”; rather, the discussion paper represents the latest iteration of the agency’s thinking on LDTs, which the agency posted to “spur further dialogue”. In August 2020 the Department of Health and Human Services announced that FDA would no longer require premarket review of LDTs unless and until it went through the notice and comment rulemaking procedure required by the

Administrative Procedure Act. However, on November 15, 2021, HHS reversed its course once again and provided that the FDA may begin oversight of LDTs. It is unclear at this time when, and how, the FDA will provide oversight over LDTs. We believe that the epigenetic tests that we initially intend to offer are considered LDTs.

Further, a relatively new type of LDT consists of tests that use software algorithms to analyze the results of next generation sequencing of nucleic acids, known as bioinformatics analysis. The Clarifi ASD test is an example of this new type of bioinformatics LDT. It is often the case that the bioinformatics and next gen sequencing parts of LDTs are performed at separate facilities, because of the inherent differences in the equipment and personnel who process specimens to extract the nucleic acids and sequence them and the equipment and personnel who design and implement the analytic software algorithms. FDA's regulation of bioinformatics LDTs is in its infancy, and there are not well-defined requirements regarding the joint control of the distributed sequencing and bioinformatics parts of these LDTs. There is therefore uncertainty about the risk that FDA may seek to regulate bioinformatics LDTs, such as Clarifi ASD, as medical devices.

If the FDA withdraws its enforcement discretion with respect to the Clarifi ASD test, it is likely that the Clarifi ASD test would be considered an In Vitro Diagnostic Device ("IVD"). IVDs are typically Class II devices, and there does not appear to be any existing IVD classification that would fit the Clarifi ASD test. While there is a device class for pediatric autism spectrum disorder diagnosis aids, the technology used in this class is not an in vitro diagnostic test, and it is not clear whether this class would be deemed to cover the Clarifi ASD test. If Clarifi ASD is not covered by the existing pediatric autism spectrum disorder diagnosis aids, there is no predicate device which could be used to obtain 510(k) clearance for the Clarifi ASD product, by demonstrating that Clarifi ASD was substantially equivalent to the predicate. Based on information gathering communications with the FDA, we believe that it would be possible to use what is known as the de novo regulatory pathway to seek and obtain classification of the Clarifi ASD test as a Class II IVD medical device and obtain clearance to market and sell the Clarifi ASD test based on requirements very similar to the 510(k) process. If the de novo regulatory pathway is undertaken, it is not certain how long it will take to obtain de novo clearance to market the Clarifi ASD test.

In the unlikely scenario in which the de novo regulatory pathway cannot be used to obtain clearance to market Clarifi ASD, the Clarifi ASD test would be a Class III medical device, and it would be necessary to use the PMA process to obtain authorization to market the Clarifi ASD test. The PMA process is much more costly and time consuming than the 510(k) clearance pathway, because while 510(k) clearance requires demonstrating substantial equivalence to an existing predicate device by comparison to the predicate, the PMA process requires demonstrating the safety and efficacy of the candidate device by valid scientific evidence regarding its technology and clinical utility. If the PMA process were required for Clarifi ASD, it is uncertain whether we have the resources necessary to obtain approval or whether approval could be obtained within a feasible time frame for our business.

Legislation has been introduced in previous Congresses, and is being drafted in the current Congress, that would clarify FDA's role in the oversight of LDTs. For example, a congressional bill entitled the Verifying Accurate Leading-Edge In Vitro Clinical Tests Development (VALID) act, would create a new type of regulated product, called In Vitro Clinical Tests, which would be subject to regulation by the FDA. We expect that new legislative proposals will be officially introduced from time-to-time. That being said, the likelihood that Congress will pass any such legislation – and the extent to which such legislation would give the FDA authority to regulate our LDTs – is unclear at this time.

#### *New York State Department of Health - Clinical Laboratory Evaluation Program and CLIA*

All clinical laboratories located in New York State, and laboratories conducting clinical or forensic testing on specimens originating in New York State, regardless of location, must hold a New York State Department of Health ("NYSDOH") clinical laboratory permit pursuant to Title V, Section 574 of the New York State Public Health Law.

The Clinical Laboratory Reference System ("CLRS") was established by the NYSDOH to assist clinical laboratories and blood banks applying for licensure with the New York State Department of Health and to serve as a reference and a resource to all participants. CLRS is administered by the Clinical Laboratory Evaluation Program ("CLEP"), a function of the NYSDOH public health laboratory the Wadsworth Center. Mandated activities include collaborative research, method development and test approval, laboratory inspection, and monitoring of proficiency testing participation to ensure that laboratory services provided to health care providers in the state meet performance standards for good patient care. CLRS outlines the policies and procedures by which the Clinical Laboratory Reference System meets the following objectives: (i) to monitor, improve, and broaden the clinical capabilities of participating laboratories and blood banks, (ii) to provide

guidelines, quality control standards and procedures to be used by permit-holding clinical facilities, and (iii) to provide continuing education opportunities for technical personnel involved in the operation of clinical laboratories through training and remediation programs.

In recognition of the fact that CLRS has requirements that are equal to or more stringent than the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”), the program was granted exempt status by the federal Centers for Medicare and Medicaid Services (“CMS”) in 1995. As a result, laboratories located in New York State meet CLIA accreditation requirements, as documented by a valid New York State permit, which includes a CLIA number. Laboratories must enroll in a CMS-approved proficiency testing program to meet CLIA proficiency test requirements. Laboratories located in New York State are still subject to validation inspections performed by CMS staff and all records maintained by New York State regarding a laboratory are subject to disclosure to CMS. Eligibility for CLIA certification for laboratories located outside New York remains the responsibility of each state’s regional CMS office.

The two clinical laboratories operated by the company each hold a NYSDOH clinical laboratory permit, meet CLIA accreditation requirements and have been assigned a CLIA number. The laboratories have demonstrated 100% scores in proficiency testing performance over the last four required testing cycles. The laboratories also conduct periodic internal audits to further review and refine processes consistent with applicable standards. The laboratories are permitted to accept clinical specimens for testing in all 50 states.

**Litigation**

From time to time, the company may be involved in legal proceedings. The results of such legal proceedings and claims cannot be predicted with certainty, and regardless of the outcome, legal proceedings could have an adverse impact on the company’s business because of defense and settlement costs, diversion of resources and other factors.

As a result of the company’s novel discoveries in medical diagnostics, the company and its advisors have been, and remain involved in, ongoing discussions with regulatory authorities. While the company considers these continuing inquiries to be ordinary course in light of the nature of the company’s projects, any failure by the company to satisfy regulatory authorities that it is in compliance with all applicable rules and regulations could have a material adverse effect on the company. At this time, the company is not aware of any proceedings against it which are expected to have a material adverse effect on its financial position or operations.

**THE COMPANY’S PROPERTY**

The company does not currently own real property. We lease office and lab space in (i) Syracuse, New York at SUNY Upstate Medical Center and at a local biotech accelerator affiliated with SUNY, (ii) Buffalo, New York at the University at Buffalo (SUNY), and (iii) San Antonio, Texas in a commercial office building. The lease for laboratory and office space at the University of Buffalo expires in February 2022. All other office and laboratory space rentals are on a month-to-month basis. Additionally, a finance lease has been entered into for laboratory equipment in Syracuse, New York, with payments through October 2025. We expect our month-to-month lease contracts for our office space in Syracuse and San Antonio to continue with similar terms. During the years ended December 31, 2021 and 2020, rent expenses were recognized associated with operating and finance leases as fixed rent expense of \$147,797 and \$87,583 respectively.

**DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES**

The company’s executive officers, directors and significant employees as of April 1, 2021 are listed below. The executive officers and significant employees are full-time employees.

| <u>Name</u>               | <u>Current Position</u>           | <u>Age</u> | <u>Date Appointed to Current Position</u> |
|---------------------------|-----------------------------------|------------|---|
| <b>Executive Officers</b> |                                   |            |   |
| Richard Uhlig             | Chief Executive Officer           | 56         | August 2015                               |
| Rita Romano               | President - Quadrant Laboratories | 56         | February 2021                             |

|                     |  |    |               |
|---------------------|--|----|---------------|
| Kayla Wagner, MS    | President - ASD Diagnostic Products                | 29 | April 2021    |
| Benjamin Perry, MS  | President - mTBI Diagnostics                       | 31 | November 2019 |
| Richard Bongo       | Chief Financial Officer                            | 60 | April 2018    |
| Andrew Brindle      | Executive Vice President Research & Development    | 40 | April 2016    |
| Ira Fedder, MD      | Executive Vice President Corporate Strategy        | 68 | December 2021 |
| Thomas Frazier, PhD | Executive Vice President Virtual and Clinical Care | 46 | May 2020      |
| Nicholas Gianadda   | Chief Technology Officer                           | 40 | April 2021    |
| Bryan Greene        | Chief Operating Officer                            | 40 | July 2019     |
| David MacLean, JD   | Chief Marketing Officer                            | 61 | August 2015   |
| Rita Marble         | Executive Vice President Human Resources           | 51 | June, 2021    |
| Wakaba Tessier, JD  | General Counsel                                    | 42 | October 2021  |
| Kortney West, MD    | Executive Vice President Virtual Medicine          | 35 | January 2022  |

## Directors

|                 |          |    |              |
|-----------------|----------|----|--------------|
| Richard Uhlig   | Chairman | 56 | August 2015  |
| Richard Bongo   | Director | 60 | October 2017 |
| Peter Cohen     | Director | 76 | April 2018   |
| James Croke, JD | Director | 63 | April 2018   |
| Ira Fedder, MD  | Director | 68 | October 2017 |
| Andrew Rock     | Director | 58 | August 2015  |
| Mary Ann Tyzsko | Director | 64 | August 2015  |

## Biographies of Executive Officers and Directors

### *Richard Uhlig*

#### *Chairman & Chief Executive Officer*

Richard has been our Chairman and CEO since 2015. He has more than 30 years of business experience focused on the design and development of innovative products across various industries, Richard's management capabilities range from ownership of regional retail businesses to the start-up and management of major corporate divisions with domestic and international product sourcing and sales experience. Prior to serving as Chairman and CEO of Quadrant Biosciences, he was the Sole Member of Motion Intelligence LLC, a biotechnology company he founded in 2012 and which was merged into Quadrant in 2015. Previously, he was the Chairman and Chief Executive Officer of Morgan Stanley Bank, the principal banking subsidiary of Morgan Stanley, and was the Chief Investment Officer at Merrill Lynch Bank. He held other significant posts in the financial industry and served as an Executive in Residence at Cornell University's Johnson Graduate School of Management. Richard received a Bachelor of Science degree from Cornell University.

### *Rita Romano*

#### *President - Laboratory Services*

Rita has more than 30 years of clinical laboratory experience. Prior to joining Quadrant in February 2021, she was Director of the Operations Center for Laboratory Alliance of CNY, a locally owned, independent reference laboratory, a position she held since 2011. In this role, she had technical and regulatory oversight of clinical laboratory services performing over 10 million tests/year. She developed strategic partnerships with both larger and smaller institutions to improve the delivery of laboratory testing for a clinically integrated network of health care providers in a cost-effective manner. Rita earned her Bachelor of Science in Medical Technology and her Masters of Arts in Strategic Leadership from St. Bonaventure



University. She is certified by the American Society of Clinical Pathologists. Rita serves as the President of the Central New York Chapter of Clinical Laboratory Management Association and chair of the membership committee.

*Kayla Wagner*

*President - ASD Diagnostic Products*

Kayla's career originates from a research background in clinical psychology, where she conducted research investigating many areas of child psychopathology, including autism spectrum disorder, ADHD and 22q11.2 deletion syndrome. More specifically, Kayla's published research has a translational focus, with her interests surrounding early identification of autism, management of the comorbidity between autism and ADHD, and targets for intervention aimed at improving social outcomes for individuals with neurodevelopmental disorders. Kayla joined Quadrant in May 2017. Until her promotion to President of ASD Diagnostic Products in April 2021, Kayla led the development and commercialization of Clarifi ASD as VP of Product Management. This followed her role as VP of Research where she developed and led the Clinical Research Department, overseeing Quadrant's research portfolio and grants in excess of \$5 million. Prior to Quadrant, Kayla worked in academic medical settings for over 5 years conducting and managing grant funded research, including most recently at Syracuse University and SUNY Upstate Medical University (August 2014 - May 2017). In her clinical work, she provided diagnostic and psychological counseling services as a therapist focused on improving functioning and well-being for children and adolescents with autism and other psychiatric disorders. Kayla earned a BS in neuroscience and psychology and an MS in Clinical Psychology at Syracuse University.

*Benjamin Perry*

*President - mTBI Diagnostic Products*

Benjamin's career originates from a technical background, where he spent over ten years in the software development industry. During that time, he both led and contributed to several successful projects in the public, private, and academic sectors. Benjamin's expertise revolves around a wide breadth of disciplines including cloud computing architecture, blockchain technology, and agile project management, where his experience spans all facets of the product development lifecycle. He strives to build both human and technical systems that are accessible to all, and scale rapidly with demand. Ben has been with Quadrant Biosciences since April 2016. Until his recent promotion to President of the company in November 2019, he served as the Chief Technology Officer for both Quadrant and our subsidiary Motion Intelligence LLC. Prior to 2018, he was the Vice President of Technology at both organizations. Prior to Quadrant Biosciences, Benjamin led projects for the federal statistical system and public opinion domain. More specifically, he was a software developer for the Cornell Institute for Social and Economic Research from June 2013 – April 2016, where his metadata management software was installed within the US Census Bureau as part of an NSF grant. In addition, Benjamin ran a consulting business that provided data management expertise, and software development services. He received his master's degree in Information Science from Cornell University.

*Richard Bongo*

*Chief Financial Officer & Director*

Richard has over 30 years of finance experience while working at many major Wall Street firms. Richard has been our Chief Financial Officer since May 2018. He most recently was a Managing Director at BNP Paribas (April 2006 through April 2018), one of Europe's largest banks, and has also worked at such firms as Lehman Brothers, Credit Suisse, Merrill Lynch and Bank of America. Richard's experience spans several different disciplines in structured finance including structuring, trading and sales at the institutional level, where he helped to usher in several cutting-edge financial investment products such as Collateralized Mortgage Obligations and Commercial Mortgage Backed Securities and Collateralized Loan Obligations. Richard began his career at Coopers & Lybrand (PricewaterhouseCoopers) where he received his CPA. He holds degrees in both Computer Information Systems and Accounting from Kings College.

*Andrew Brindle*

*Executive Vice President - Research and Development*

Andrew brings a strong background in hardware design and development to the Quadrant Biosciences team, where he has been since April 2016. Prior to that, he ran his own engineering consulting business with a focus on commercial manufacturing and medical devices (August 2013 – April 2016), where he had many clients, including Quadrant. His career has included over 12 years in the defense industry working on sophisticated radar systems such as the DARPA FORESTER, the Army's AN/TPQ-49, and radar antennas for drone helicopters. Andrew developed and holds patents on new technologies involving efficient heat transfer, and has a strong background in algorithm development having created algorithms for deep-sea underwater sensors and sports performance technologies. Andrew received a BS in Mechanical Engineering with a minor in Mathematics from Clarkson University.

*Ira Fedder, MD*

*EVP Corporate Strategy & Director*

Ira is a fellowship trained orthopedic spine surgeon practicing at the University of Maryland, St. Joseph Medical Center in Towson, Maryland. Ira is Board Certified by the ABOS as well as the ABSS and an active member of a number of professional organizations. Ira has participated in a number of clinical trials, has published widely in both the orthopedic and pharmacology literature, and has been an active lecturer speaking about the current and future use of stem cells and other biologics in orthopedics. Dr Fedder received his Doctor of Pharmacy degree from the U of Maryland School of Pharmacy in 1979. Subsequently, Ira completed a fellowship in Clinical Pharmacology at Thomas Jefferson University School of Medicine. After teaching at Northeastern University College of Pharmacy and the Veterans Administration in Boston, Ira then returned to the University of Maryland where he graduated from the School of Medicine in 1986. After completing his residency in Orthopedic Surgery at the University of Maryland he completed a fellowship at St Joseph Medical Center in Towson. He has practiced as an orthopedic spine surgeon since 1992.

*Thomas Frazier*

*Executive Vice President - Virtual and Clinical Care*

Dr. Frazier is a licensed clinical psychologist who received his Ph.D. from Case Western Reserve University in 2004. He joined Cleveland Clinic in 2006 and from 2013-2017 was the director of the Cleveland Clinic Center for Autism. In 2017, he was hired as the Chief Science Officer at Autism Speaks, overseeing all science and service programs before joining John Carroll University in January 2020 as a Professor of Psychology. Over the last decade, Dr. Frazier has maintained an active clinical practice and research programs focused on the evaluation and treatment of autism, ADHD, and related conditions. He has published more than 120 scientific papers and has ongoing collaborations across the US and internationally.

*Nicholas Gianadda*

*Chief Technology Officer*

Nick has 20 years of experience in the software development, Information Technology, and security fields. Prior to joining Quadrant in April 2021, he held leadership roles managing diverse teams of project managers, developers, quality assurance testers, and support personnel. His experience includes serving as the Director of HIT Solutions at HealthConnections where he oversaw the technical operations of the organization related to grant work and value based billing products and applications (September 2017 - March 2021) and as CTO at FieldNimble, a software startup focused on the small to medium sized contractor market, where he lead all technical operations for the organization (September 2016 - September 2017). Nick's experience in developing software in the healthcare industry includes applications for single sign-on, patient data access for providers, referral & case management tools, and quality measure calculation. Nick has a long history of building highly performant teams and coordinating successful product launches. He received a BS in Computer Science from Canisius College.

*Bryan Greene*

*Chief Operating Officer*

Bryan brings more than 15 years of experience in medical device operations, manufacturing, validation and new-product introduction at both large multinational and start-up corporations. He has been in charge of our operations since October 2015. He has a proven track record of successfully introducing Class I, II and III products at Life Technologies (Thermo Fisher Scientific), Pall Corporation and ImClone System (Eli Lilly). Most recently, Bryan was the manufacturing and operations leader during establishment and implementation of an FDA 21CFR820 compliant system at Rheonix, a medical device start-up (January 2013 – July 2015) and production and operations quality manager (July 2015 – October 2015) at Unilife Corporation. He received a BS in Chemical Engineering from Clarkson University.

*David MacLean*

*Chief Marketing Officer*

David has more than 25 years of business, research and legal experience. He recently produced two award-winning feature and documentary films and founded an MMA website and clothing company. David was the co-owner of a mixed-martial arts promotion company and co-owner of a medical-device sales distribution company, MacLean Surgical Instruments, which he managed for over 20 years prior to joining us as our chief marketing officer in August 2015. Previously, he was a litigator at the firms of LeBoeuf, Lamb, Lieby & MacRae, and Nixon Hargrave Devans & Doyle. Earlier, he was a research biologist for the Cornell University Lab of Ornithology. David earned a BS from Cornell University and a JD from the University of Buffalo Law School, where he was a member of the Law Review.

*Rita Marble*

*Executive Vice President - Human Resources*

Rita has more than 20 years of leadership experience in the field of Human Resource Management. Her areas of expertise include: recruitment & training, labor cost management, benefits design and administration and staff development. Prior to joining Quadrant Biosciences, she was most recently Director of Employer Solutions with a high growth PEO. In this role, Rita led in Business Development, HR Infrastructure design, onboarding and implementation of HR service plans for local and national organizations. She says she is most energized by making a meaningful impact for the organization and team she serves. Rita holds the certification of Senior Certified Professional from the Society for Human Resource Management and channels her knowledge and enthusiasm into her community as a New Venture Mentor for the Tech Garden and subject matter resource for companies affiliated with the WISE Women's Business Center for the SBDC.

*Wakaba Tessier*

*General Counsel*

Throughout her career, Wakaba has focused on regulatory compliance and privacy issues facing healthcare providers. Prior to joining Quadrant Biosciences, Wakaba was a Partner at Husch Blackwell LLP, an AmLaw 100 law firm. While there, Wakaba focused her practice on state and federal health privacy law, federal fraud and abuse issues related to the Stark Law, the False Claims Act and the Anti-Kickback Statute, and complex issues facing pharmacies and laboratories. She also led various business development initiatives and Associate recruiting activities on behalf of Husch Blackwell. Wakaba obtained her B.A. from Wellesley College and her J.D. from Washington University in St. Louis School of Law.

*Kortney West*

*Executive Vice President - Virtual Medicine*

Dr. West is a board-certified pediatrician. Prior to joining Quadrant, she worked for a pediatric clinic in Gonzales, LA, opened a concierge pediatric medical practice serving the greater Baton Rouge Area, and practiced at Reading Pediatrics. After noting the sizable gaps in mental healthcare for youth in the US, Dr West later founded Clear Water Health, which focuses on management of behavioral and mental health disorders. She has long been an advocate for early autism diagnosis

and intervention - she received training to utilize STAT MD while in residency and continued to offer autism diagnostic appointments at each of the aforementioned practices. Additionally, she served on the board of The Emerge Center, an autism center located in Baton Rouge where she was vice-chairwoman. Dr. West received her undergraduate degree with Honors from Louisiana State University, her medical degree from LSU Medical School in Shreveport, and completed her pediatric residency at the University of Texas -Southwest in Dallas.

*Peter Cohen*

*Director*

Peter was Chairman of the Board of Cowen Inc., a well-known diversified financial services firm and its predecessor Ramius Capital from 1994 to 2017. From November 1992 to May 1994, Peter was Vice Chairman and director of Republic New York Corporation, as well as Chairman of Republic's subsidiary, Republic New York Securities Corporation. He was Chairman of the Board and Chief Executive Officer of Shearson Lehman Brothers from 1983 to 1990. From 1970 to 1983 he held various management roles within the company. Over his career, Mr. Cohen has served on a number of corporate, industry and philanthropic boards, including the New York Stock Exchange, The Federal Reserve International Capital Markets Advisory Committee, The Depository Trust Company, The American Express Company, Olivetti SpA, Telecom Italia SpA, and Kroll Inc. He was a Trustee of Mount Sinai Medical Center for 30 years and is currently Vice Chairman and Lead Director of the Board of Directors of Scientific Games Corporation, Chairman of PolarityTE Inc, Chairman of Andover National Corporation, Chairman of Peter Cohen LLC, Chairman of the Museum of American Finance, and Director of Gift of Life Marrow Registry. Mr. Cohen received a Bachelor of Science from The Ohio State University in 1968 and his Master of Business Administration from Columbia University in 1969.

*James Croke*

*Secretary and Director*

Jim was our General Counsel from January 2018 through early November 2021 (when Wakaba Tessier assumed that role). Jim continues to serve the company as its Secretary and as a Director. He is currently a principal at The Law Office of James Croke, LLC where he has been since April 2014. Jim was previously a structured finance/banking partner at Chapman & Cutler, Orrick Herrington, Cadwalader Wickersham & Taft, and Hunton & Williams. Throughout his career, he served as counsel to underwriters and issuers in U.S. and global public offerings and private placements. Jim has been a member of the board of directors of the American Securitization Forum and a faculty member of the Practicing Law Institute. He has written and lectured on a variety of topics regarding legal and regulatory issues and annually served as a guest lecturer regarding U.S. corporate and finance law at The Universidad Panamericana in Guadalajara, Mexico. Jim practiced U.S. law in London from 1999 - 2004, as the head of Cadwalader, Wickersham & Taft LLP's London capital markets department. Jim earned his undergraduate degree in Mathematics from the University of Kentucky (in three years) and his J.D. degree from the University of Notre Dame Law School.

*Andrew Rock*

*Director*

Andrew earned a reputation as a successful serial entrepreneur in the global medical technology industry. He is co-founder of K2M Group, a medical device developer based in Leesburg, Va., which became listed as a publicly traded company on NASDAQ on May 5, 2014. While at K2M, Andrew developed over 18 utility and method patents for the treatment of complex spine pathologies including scoliosis, tumor and trauma, as well as for minimally invasive implants. Before his involvement in K2M, Andrew was a member of the executive management team at American Osteomedix, where he co-developed a minimally invasive approach to access and treat osteoporotic compression fractures and tumors in the thoracic spine. From 1993 to 2003, he was Chairman and CEO of Rock Surgical Associates, Inc., a distributor of Orthopedic and Neurosurgical Products in the Mid-Atlantic region. Currently, Andrew is the Chairman and CEO of Minneapolis-based St Teresa Medical Inc., a developer of nanotechnology-based hemostatic and dural sealants; he is also the founder and managing partner of Neuro Spine Ventures LLC, an 82-member global angel investor group. Andrew is also a Co-Founder and Executive Director of DP Enterprises Group Inc., which provides product development and global marketing services for med-tech companies. Andrew also serves as the Chairman of Woven Orthopedics, LLC, which specializes in fixation and osteoporotic and osteopenic, and of Virtual Healthcare partners, a wellness focused digital healthcare company. Andrew

serves on the Board of Directors for several corporations, including St. Teresa Medical, Woven Orthopedics, 7D Surgical, Inc., a machine vision surgical navigation company, and Quadrant Biosciences, Inc., which focuses on brain health and epigenetics diagnostics. He is on the board of advisors for Indianapolis-based Recovery Force, LLC, and a pioneer in wearable technology for the medical, sports and defense industry sectors. Andrew graduated from Linsly and West Virginia University.

*Mary Ann Tyszko*

*Director*

Mary Ann has over 30 years of experience in leadership, strategy development, business development, program execution and management. She served as Chief Executive Officer and President of SRCTec Inc. from its inception until August 2010. Prior to that, she served as an Executive Vice President, Operations for SRC, responsible for the day-to-day management and financial results of SRC's four business centers. Mary Ann also served as Vice President for Strategic Business Development and Innovation for Syracuse University. Her office integrated the activities of technology transfer, corporate relations and technology incubation to facilitate the commercialization of university technologies and support faculty entrepreneurship. She served on the board of Excell Partners, Inc., a VC fund investing in seed and early stage high-tech startups in New York State. Currently, Mary Ann is chair of the board of Symphoria, Central New York's professional orchestra. Formerly Mary Ann was Chair of the Greater Syracuse Chamber of Commerce Board of Directors, and a Member of Le Moyne College Management Division Advisory Board. She is a National Director of the Association of Old Crows (AOC) and a Member of the Armed Forces Communications and Electronics Association (AFCEA), the Association of the United States Army (AUSA), the United States Field Artillery Association (USFAA), and the National Association of Corporate Directors (NACD). Mary Ann also has been Corporate Chair of Go Red for Women, American Heart Association, as well as a Board Member of Manufacturers Association of Central New York (MACNY). She received her MBA and MS in Computer Science from Syracuse University and a BS in Biology from Le Moyne College.

## **INTEREST OF MANAGEMENT AND OTHERS IN CERTAIN TRANSACTIONS**

None.

## **RISK FACTORS**

*The SEC requires the company to identify risks that are specific to its business and its financial condition. The company is still subject to all the same risks that all companies in its business, and all companies in the economy, are exposed to. These include risks relating to economic downturns, political and economic events and technological developments (such as cyber-attacks and the ability to prevent those attacks). Additionally, early-stage companies are inherently more risky than more developed companies. You should consider general risks as well as specific risks when deciding whether to invest.*

### **Risks Related to the Company's Business**

***We are an early stage revenue producing company and our net income to date was due to our COVID-19 initiatives; we may not be able to maintain profitability.***

Fiscal year 2021 was the first year that we have not incurred losses from operations; as of December 31, 2021, we had an accumulated deficit of approximately \$6.1 million. Sales of our ClearEdge Toolkit have not provided us with any significant revenue, and are unlikely to, as we have ceased sales of this product. Sales of Clarifi ASD commenced in December 2019 and have not yet resulted in material revenues. To date, our only significant revenue has come from COVID-19 testing, which may be reduced significantly if transmissibility or virulence of the SARS-CoV-2 virus changes or public health policy relative to the SARS-CoV-2 virus changes. We expect to continue to incur significant expenses for the foreseeable future. We expect that our expenses may increase substantially as we continue to develop and expand a number of products and the scope of uses of our products, including as we:

- conduct additional clinical research related to Clarifi ASD, expand the clinical utility of the Clarifi COVID-19 Test, develop a market for our recently approved, saliva-based, semi-quantitative COVID antibody test, and expand our COVID-focused wastewater surveillance efforts, our currently offered commercial products;
- conduct additional research and development and verification and validation testing in relation to a possible EUA submission for additional COVID-19 products and of our other saliva-based epigenetic diagnostics in mild traumatic brain injury and Parkinson’s disease;
- seek to expand our saliva epigenetic diagnostic platform to other diseases and disorders to discover and develop additional product candidates;
- seek regulatory clearances or approvals (where required) for any product candidates that successfully complete verification and validation testing;
- continue to build a sales, marketing and distribution infrastructure and scale up diagnostic laboratory capabilities, either internally or externally to commercialize any epigenetic products;
- maintain, expand and protect our intellectual property portfolio, bioinformatics and machine learning platforms, including through licensing arrangements;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our growth;
- experience any delays or encounter any issues with any of the above, including, but not limited to, failed verification and validation testing, complex results, safety issues or other regulatory challenges; and
- if and as necessary, enforce our rights under a note purchase agreement, dated as of November 12, 2018, between Quadrant and a corporate lender organized in the Cayman Islands by a Hong Kong based venture capital firm (“Lender”).

As explained above, our revenues in 2021 were primarily related to the sale of COVID-19 products. The need for these products will depend on many factors beyond our control, including the prevalence and success of the vaccines and trajectory of the pandemic.

Our ability to continue operations is dependent upon our ability to generate sufficient cash flows from operations to meet our obligations and/or to obtain additional capital financing.

***Our current revenues are concentrated from one client***

In 2021, 80% of Clarifi COVID-19 Test kit sales, 100% of product assembly services and 100% of Lab Test Revenue were to one customer, New York State (inclusive of the State University of New York system). If we were to lose this customer it would have a material adverse effect on our company.

***The company has a limited operating history, which makes it hard to evaluate its ability to generate revenue through operations.***

The company’s limited operating history may make it difficult to evaluate its current business and future prospects. The company has encountered and will continue to encounter risks and difficulties frequently experienced by growing companies in rapidly developing and changing industries. Investors should consider the company’s business and prospects in light of the risks and difficulties it faces as an early-stage company focused on developing products in the fields of medical devices and laboratory-developed tests.

**The company is dependent on the global supply chain and has experienced supply chain constraints, as well as increased costs on components and shipping resulting from the COVID-19 pandemic, the continuing conflict in Ukraine and other macroeconomic factors.**

The company has experienced supply chain constraints and delays as a result of several factors, including but not limited to, the COVID-19 pandemic, the impact of the continuing conflict in the Ukraine, U.S. workforce participation issues and unanticipated price change issues due to inflation. These supply constraints include, difficulties obtaining the supplies needed for our individual COVID-19 saliva test, and for our COVID wastewater test work (where we have already experienced some supply chain shortfalls which have limited our ability to satisfy demand for such testing) and our COVID-19 pooled screening work, and further may affect our ability to produce, market and sell our existing products. In addition, the company has also faced increased costs of components and freight resulting from these supply chain issues. Further, current or future governmental policies may increase the risk of inflation, which could further increase the costs of raw materials and components for our business. Similarly, if costs of goods continue to increase, our suppliers may seek price increases from us. If we are unable to mitigate the impact of supply chain constraints and inflationary pressure through price increases or other measures, our results of operations and financial condition could be negatively impacted. Even if we are able to raise the prices of our products, consumers might react negatively to such price increases, which could have a material adverse effect on, among other things, our brand, reputation, and sales. If our competitors substantially lower their prices, we may lose customers and mark down prices. Our profitability may be impacted by lower prices, which may negatively impact gross margins. Even though we are working to alleviate supply chain constraints through various measures, we are unable to predict the impact of these constraints on the timing of revenue and operating costs of our business in the near future. Raw material supply shortages and supply chain constraints, including cost inflation, have impacted and could continue to negatively impact our ability to meet increased demand, which in turn could impact our net sales revenues and market share. The increased cost of components and freight as well as ongoing delays in receiving raw materials and components for production are likely to have an impact on sales and profitability throughout 2021 as well as 2022 and 2023.

***If the company loses certain senior management and key personnel or are unable to attract and retain skilled employees when needed, it may not be able to operate successfully.***

The success of the company depends largely on its management team, including its founder, Richard Uhlig. The company does not maintain any life insurance coverage on Mr. Uhlig or any other member of its management team. The death of Mr. Uhlig, or an extended illness or the occurrence of any other event which might prevent him from regularly performing his duties as chief executive officer of the company, or the loss of any key member of the management team, may substantially limit the company's ability to execute its business plans.

***The company may face substantial competition from a number of known and unknown competitors as well as the risk that one or more of them may obtain patents covering technology critical to the company's businesses.***

The company believes that a number of organizations are or may be working to develop human health and disease diagnostic and preventative mechanisms and or other novel technologies that may be competitive with its own technology. Some or all of such organizations and/or their respective purchasers have substantially greater resources than the company has, and many of them appear to be attempting to patent technologies that may be competitive with or similar to the technology the company has developed. The company does not have access to detailed information about the technologies these organizations and/or their respective purchasers may be attempting to patent. If one or more other persons, companies or organizations obtains a valid patent covering technology critical to the company's existing or prospective businesses, the company and the other entities that need the relevant technology in order to enable the company's existing or prospective businesses to be successful and to operate as intended might be unable or unwilling to license the technology, which could have a material adverse effect on the company.

***We rely on a limited number of suppliers or, in some cases, sole suppliers for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers.***

We rely on several sole suppliers, including Illumina and DNA Genotek, for certain products and substances used in the chemical processing of saliva to prepare it for sequencing, and reagents, sequencers, equipment, and other materials which we use in our laboratory operations. For instance, we rely on DNA Genotek as the sole supplier of saliva swabs used in our Clarifi ASD test kits, our individual COVID-19 Test Kits and our pooled COVID-19 surveillance work, and

we rely on Illumina as the sole supplier of sequencers and various associated reagents, and as the sole provider of maintenance and repair services for these sequencers. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing these or any other of our products, reagents, sequencers, or other laboratory materials, and if we cannot then obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations, and reputation.

Further, we believe that there are only a few other equipment manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials furnished by these replacement suppliers would require us to significantly alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, would likely affect the performance specifications of our laboratory operations, and would require that we revalidate our products currently under development. We cannot assure you that we would be able to secure alternative equipment, reagents, and other materials, and bring such equipment, reagents, and materials online and revalidate them without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and reagents we require for our products, our business, financial condition, results of operations and reputation could be adversely affected.

Should the company be unable to supply the swab, or to satisfy our demand for swabs in relation to our opportunities to commercialize such tests, our ability to provide the test may be diminished or delayed or we may not be able to engage in saliva testing for COVID-19 at all.

***The technology upon which the company relies for its operations may malfunction; company methodologies may produce unanticipated consequences.***

The technology relied upon by the company may not function properly, which would have a material impact on the company's operations and financial conditions. There are few alternatives available if such technology does not work as anticipated. This technology may malfunction because of internal problems, the current verification and validation testing could fail to establish the performance of our products or as a result of cyberattacks or external security breaches. The technology employed by the company in relation to the development of its saliva-based epigenetic diagnostic aids is novel and the methodology developed by the company in relation thereto may be subject to unanticipated consequences. For example, in the course of clinical trials it was discovered that if several saliva samples were taken in succession from a subject, the RNA composition of samples subsequent to the first sample could be altered by the sample collection itself. This unexpected discovery led to modifying the directions for sample collection to include a waiting time between successive sample collections to allow time for the RNA composition to come back into equilibrium so that it represented the patient's true steady state. These types of technological problems, failures and unanticipated consequences, if not timely corrected or cured, could adversely impact the company's business and operating results.

***Our business and operations would suffer in the event of system failures.***

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future verification and validation testing could result in delays in our regulatory efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

***The company and its subsidiaries are subject to cyberattacks, security risks and risks of security breaches.***

The company and its subsidiaries are all subject to cyberattacks, security risks and risks of security breaches. An attack on any of them or a breach of security of any of them could result in a loss or corruption of private data. In addition, a breach



of personally identifying information may require notice to affected individuals and government authorities, may result in fines or other penalties, and may result in costs for mitigation measures for affected individuals.

***If we are unable to support demand for our existing and our future products, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage the evolution of our bioinformatics platform, our business could suffer.***

As our volume grows, either through the use of third parties or internally, we will need to continue to increase our workflow capacity for sample intake, customer service, billing and general process improvements, expand our internal quality assurance program, and extend our bioinformatics platform to support comprehensive epigenetic analyses at a larger scale within expected turnaround times. The company or our third-party partners will need additional certified laboratory scientists and technicians and other scientific and technical personnel (as applicable) to process higher volumes of our products. Portions of our process are not automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up, and validate, and increase our software and computing capacity to meet increased demand. We cannot assure you that any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements will be successfully implemented, or that we or our third-party partners will have adequate space to accommodate such required expansion.

As we commercialize additional products, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. For example, we may procure additional laboratory space internally or externally to allow us to further develop new products. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business.

***The company has a convertible note that it is treating as debt.***

In October 2018, Quadrant entered into a convertible note purchase agreement (“NPA”) with a lender pursuant to which Quadrant initially borrowed \$5,000,000 and had the right to borrow an additional \$2,500,000 on each of March 31 and June 30 of 2019. When we exercised our right to borrow \$2,500,000 on March 31, 2019, the lender failed to fund us and defaulted on its obligation to do so, which we believe constituted a material breach of the NPA. In consultation with our outside counsel and independent auditors, we concluded that the breached NPA is no longer in effect or binding on Quadrant. Accordingly, we believe that other than our obligation to pay the principal amount outstanding and interest upon it (less costs and damages resulting from the breach), we have no further obligations under the NPA and related note, including conversion rights, board appointment or exclusive licensing rights for our intellectual property in the Asia-Pacific region. In our financial statements, we have accordingly treated our obligation to the lender as debt. To date, the lender has not asserted any claims under the NPA and related note; however, should the lender do so, it may lead to costly and extended litigation or other adversarial proceedings. If, notwithstanding the lender’s breach of the NPA, the lender were to pursue such a course of action and was able to reinstate its conversion rights under the NPA, it would be entitled to convert its \$5,000,000 loan into our Common Shares at a strike price of \$1.50 per share (3,333,334 shares). This increase of Quadrant’s outstanding shares would be dilutive of Quadrant’s existing stockholders’ interests.

***New product development involves a lengthy and complex process, and we may be unable to successfully commercialize any other products we may develop on a timely basis, or at all, and the development and commercialization of additional products may negatively affect the commercialization of existing products.***

We believe the clinical research data to date for our epigenetic diagnostic technologies are promising. In April 2021, Quadrant was granted a Breakthrough Device designation by the Center of Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) for a future version of the Clarifi ASD® autism saliva test, which would be in the form of an in vitro diagnostic device (IVD), that could be marketed and sold to third party commercial laboratories.

The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health. In early 2020, we began selling Clarifi ASD as a Laboratory Developed Test (LDT) in collaboration with Admera Health; however, due to the onset of the pandemic many of the company's resources were diverted toward COVID-19 initiatives. As expected, our sales of Clarifi ASD have been limited to the first quarter of 2020; additionally, for a variety of reasons we chose not to renew our contractual relationship with Admera Health. We hope to successfully re-introduce and commercialize an improved version of Clarifi ASD as an LDT that we perform in a company operated clinical laboratory, but we cannot assure you that we will meet this goal. With respect to our other products currently in earlier stages of development, including the epigenetic tests for traumatic brain injury ("TBI") and Parkinson's Disease, it will take time to successfully commercialize them, and we cannot assure you that that these products will be successful for a variety of technical and market reasons.

We cannot assure you that our new products will be capable of reliably diagnosing the diseases we are pursuing. Before we can commercialize any new products, we will need to expend significant funds in order to:

- conduct substantial research and development, including validation studies and potentially clinical trials;
- identify and/or build additional laboratory space for new products;
- further develop and scale our laboratory processes to accommodate different products; and
- further develop and scale our infrastructure to be able to analyze increasingly large amounts of data.

The process of obtaining marketing authorizations, both in the United States and abroad, is expensive and may take many years. Our product development process involves a high degree of risk, and product development efforts may fail for many reasons, including:

- failure of the product to perform as expected at the preclinical stage;
- delays in clinical testing;
- failure to recruit, or timely recruit, eligible subjects to participate in clinical testing and clinical trials;
- suspension or termination of a clinical trial due to subject injury or other events;
- completion of preclinical studies and clinical trials without positive results and/or that fail to establish clinical utility;
- need for additional clinical trials, depending on the results of previous trials, and the type, complexity, and novelty of the product under development;
- failure to timely receive desired marketing clearances or approvals from applicable regulatory authorities (where required); and
- failure to obtain and maintain patent and trade secret protection.

Regulatory authorities have substantial discretion in the review process and may refuse to accept a marketing application as deficient or may decide that our data is insufficient for clearance or approval and require additional verification and validation testing. In addition, varying interpretations of the data obtained from verification and validation testing could delay, limit or prevent marketing authorization of a product candidate.

As we develop products, we will have to make significant investments in product development, marketing, and selling resources to maintain and grow an organization of scientists and businesspeople who can develop and commercialize our products. Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates and are currently principally focused on Clarifi ASD, our ASD diagnostic aid. As a result, we may forego or delay our pursuit of opportunities with other products or for other indications that later prove to

have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

***Our existing collaborations are important to our business, and future licenses may also be important to us. If we are unable to maintain any of these collaborations, or if these arrangements are not successful, our business could be adversely affected.***

We have entered into, or plan to enter into, collaborations with other parties, including, but not limited to, collaborations with the Foundations. If these collaborations fail for any reason, Quadrant's ability to develop the contemplated tests for evaluating patients for TBI and Parkinson's Disease would be significantly impaired because these collaborative studies are in their early stages. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of any product candidates or may elect not to continue or renew development or commercialization programs based on verification and validation testing results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay verification and validation testing, provide insufficient funding for such testing, stop such testing or abandon a product candidate, repeat or conduct new verification and validation testing, or require a new formulation of a product candidate for such testing;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we would potentially lose the right to pursue further development or commercialization of the applicable product candidates;
- failure to satisfy provisions of applicable license agreements, including those regarding milestones for commercialization of the licensed product or payment of minimum royalties, which would constitute default and permit our collaborators to terminate license agreements;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers; and
- we currently have, and in the future may have, a limited number of collaborations and the loss of, or a disruption in our relationship with, any one or more of such collaborators may harm our business.

If our collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed, and we may need additional resources to develop additional product candidates. Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business in the business and financial communities, and our stock

price, could be adversely affected. In addition, we have a limited number of collaborations and if our relationship with any one or more of such collaborators were to cease, our business would be harmed as a result.

We face significant competition in seeking appropriate collaborators and we may be unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all. If we are unable to do so we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, or delay its potential commercialization or reduce the scope of any sales or marketing activities.

We have only limited experience manufacturing our products at commercial scale, and if we decide to establish our own manufacturing facility, we cannot assure you that we can manufacture our products in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We presently conduct operations to assemble / accession, label, and package the Clarifi COVID Test kits. We have been successful in meeting the demand for the Clarifi COVID Test kits to date, but we have not yet demonstrated that we can continuously and reliably staff and efficiently work to meet the commercial demand for production of our Clarifi COVID-19 Test products and services.

***Any disruption or delay in the operations of our CLIA/CLEP certified laboratories could materially impact our ability to continue to offer and sell our diagnostics tests, including but not limited to COVID tests, which could significantly affect our business, financial condition, results of operations, and reputation.***

Our business may be negatively impacted if we are unable to successfully operate our laboratory facilities., . The inability to perform our tests for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, it would be difficult, time-consuming, and expensive to rebuild or switch facilities or license or transfer our proprietary technology to a third party, particularly in light of the licensure and accreditation requirements for a commercial laboratory. If we do utilize a third party with such qualifications to enable us to provide our diagnostic tests, we may be unable to negotiate commercially reasonable terms with such third parties.

***Even if any of our product candidates receives marketing clearance or approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

If any of our product candidates receive premarket clearance or approval (where required), it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Further, significant uncertainty exists as to the coverage and reimbursement status of our products and our product candidates, including those for which we must obtain regulatory clearance or approval. Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products (or services involving such products) will be available from third-party payors, such as government health administration authorities, private health insurers, and self-insured employers. Third-party payors decide which medical devices, and which procedures in which such medical devices are used, they will pay for and establish reimbursement rates for such items and services. If our product candidates do not achieve an adequate level of acceptance by the market, including third-party payors, we may not generate significant product revenues and we may not become profitable.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in verification and validation testing and to the use of our products sold commercially as well as product liability related to the potential commercialization of our COVID-19 saliva test under adverse conditions and on short notice. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of research study participants;
- significant costs to defend the related litigation;
- substantial monetary awards to research study participants and/or patients;
- delay in completing, or failure to complete, research study recruitment or research study endpoints;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold \$4 million in product liability insurance coverage in the aggregate, with \$4 million per occurrence limit, which may not be adequate to cover all liabilities that we may incur. Further, the commercialization of a COVID-19 test may significantly increase our exposure. Due to the contagious nature of COVID-19, if our test is flawed, both false negatives and positives could potentially expose us to liability. We may need to increase our insurance coverage as we expand our verification and validation testing or if we expand the commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

**We face risk that may arise from acquisitions and investments, which could result in operating difficulties, dilution, and other harmful consequences that may adversely impact our business, financial condition, and results of operations. Additionally, if we are not able to identify and successfully acquire suitable businesses, our results of operations and prospects could be harmed.**

We may pursue inorganic methods of growth, including strategic acquisitions and mergers in the future, to add complementary or strategic companies, products, solutions, technologies, or revenue. These transactions could be material to our results of operations and financial condition. We also expect to continue to evaluate and enter into discussions regarding a wide array of potential strategic transactions. The identification of suitable acquisition candidates can be difficult, time-consuming, and costly, and we may not be able to complete acquisitions on favorable terms, if at all. The process of integrating an acquired company, business, or technology may create unforeseen operating difficulties and expenditures. The related areas where we face risks include, but are not limited to:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- loss of key employees of the acquired company and other challenges associated with integrating new employees into our culture, as well as reputational harm if integration is not successful;
- difficulties in integrating and managing the combined operations, technologies, technology platforms, and products of the acquired companies, and realizing the anticipated economic, operational and other benefits in a timely manner, which could result in substantial costs and delays or other operational, technical, or financial problems;
- regulatory complexities of integrating or managing the combined operations or expanding into other industries or parts of the healthcare industry;
- assumption of contractual obligations that contain terms that are not beneficial to us, require us to license or waive intellectual property rights, or increase our risk for liabilities;
- failure to successfully further develop the acquired technology or realize our intended business strategy;

- uncertainty of entry into markets in which we have limited or no prior experience or in which competitors have stronger market positions;
- unanticipated costs associated with pursuing acquisitions;
- failure to find commercial success with the products or services of the acquired company;
- difficulty of transitioning the acquired technology onto our existing platforms and maintaining the security standards for such technology consistent with our other solutions;
- failure to successfully onboard customers or maintain brand quality of acquired companies;
- responsibility for the liabilities of acquired businesses, including those that were not disclosed to us or exceed our estimates, as well as, without limitation, liabilities arising out of their failure to maintain effective data protection and privacy controls and comply with applicable regulations;
- failure to generate the expected financial results related to an acquisition on a timely manner or at all; and
- potential accounting charges to the extent intangibles recorded in connection with an acquisition, such as goodwill, trademarks, client relationships, or intellectual property, are later determined to be impaired and written down in value.

Future acquisitions could also result in expenditures of significant cash, dilutive issuances of our equity securities, the incurrence of debt, restrictions on our business, contingent liabilities, amortization expenses, or write-offs of goodwill, any of which could harm our financial condition. In addition, any acquisitions we announce could be viewed negatively by customers, providers, partners, suppliers, or investors.

Additionally, competition within our industry for acquisitions of business, technologies and assets may become intense. Even if we are able to identify an acquisition that we would like to consummate, we may not be able to complete the acquisition on commercially reasonable terms or the target may be acquired by another company. We may enter into negotiations for acquisitions that are not ultimately consummated. Those negotiations could result in diversion of management time and significant out-of-pocket costs. If we fail to evaluate and execute acquisitions successfully, we may not be able to realize the benefits of these acquisitions, and our results of operations could be harmed. If we are unable to successfully address any of these risks, our business, financial condition, or results of operations could be harmed.

### **Risks Related to our COVID-19 Diagnostic Work**

***Though to date we have been able to commercialize our COVID-19 individual saliva Test Kit, our COVID-19 wastewater test work and our work in relation to pooled screening for COVID-19, the need for these tests may be limited in the future and/or we may fail to achieve and/or maintain the degree of market acceptance by local, state and federal authorities, physicians, patients, third-party payors and others in the medical community necessary for ongoing commercial success.***

The same is true with respect to our sales of the test components required for testing of pooled saliva samples for the presence of COVID-19. Further, the amount that any CLIA laboratory can be reimbursed by the Centers for Medicare and Medicaid Services (CMS) for an individual COVID-19 test is currently \$100. This amount includes our fees as well as the costs and fees of our laboratories or other laboratories administering our test. Further, the reimbursement rate could be lowered in the future. Our ability to continue to successfully commercialize our individual COVID-19 saliva Test Kit, and our pooled test for COVID-19 will depend, in part, on the extent to which insurance coverage and adequate reimbursement will be available from third-party payors, such as government health administration authorities, private health insurers, and self-insured employers. We may not be able to produce these tests to make them financially viable. In addition, due to the nature of the pandemic, to the extent that additional or more effective vaccines are successfully developed, made generally available and are received by the populace, the need for some of our products in the future may be limited. Further, to the extent we create additional products, including antibody testing, the success of that product may depend on a number of factors, including those described above under the heading “New product development involves a lengthy and complex process, and we may be unable to successfully commercialize any other products we may

develop on a timely basis, or at all, and the development and commercialization of additional products may negatively affect the commercialization of existing products.”

***Even if our COVID-19 saliva test is initially successful, mutations of the virus or competing tests may make our test obsolete.***

The SARS-CoV-2 virus is continuing to mutate with a growing list of Variants of Concern, as listed by the CDC ; these and other future variants may result in our COVID-19 saliva test no longer being useful in detecting the virus. If we are unable to modify our COVID-19 saliva test to detect new variants, we may no longer receive revenues from the test. Further, even if we were able to quickly adapt, we may have a large inventory of the older tests and we would not be able to recoup the costs related to the inventory. Further, we may also be left with inventory we will not be able sell, if the duration of the COVID-19 pandemic is shorter than anticipated or if other tests are developed that are improvement on our tests based on cost, speed and accuracy.

***The company’s focus on COVID-19 testing may divert the company’s attention and resources from its other diagnostic tests.***

We are currently a small company with limited resources and limited numbers of managerial and scientific staff. Our company’s recent focus on the COVID-19 testing over the past year has diverted attention and resources from our other products, some of which might otherwise be more lucrative, in the long term, than these new initiatives.

***The company may face substantial competition from a number of known and unknown competitors as well as the risk that one or more of them may obtain patents covering technology critical to the company’s businesses.***

The competition for products related to COVID-19 is robust. On February 29, 2020, the FDA issued an immediately in effect guidance with policy specific to this public health emergency. This guidance was updated on March 16, 2020. As of August 2020, there are at least 200 in vitro diagnostics that have received EUAs. Some or all of those organizations and/or their respective purchasers receiving EUAs have substantially greater resources than the company has. Further, there are many other organizations worldwide actively working to develop diagnostics to detect COVID-19. The other diagnostics developed may prove to be more marketable than ours, including for cost, accuracy, and speed. Further, even if our test proves to be more successful or viable, due to the exigent nature of the pandemic, we may not be able to protect our technology to the same degree we would under normal circumstances.

### **Risks Related to Government Regulation**

***We offer products that are subject to regulation as medical devices by the FDA. If we fail to comply with any applicable FDA regulatory requirements, it may have a substantially negative impact on our business, financial condition or results of operation.***

The company’s Clarifi COVID test kit and future medical device products, including In Vitro Diagnostic (IVD) devices (but excluding LDTs) are subject to regulation as medical devices by the FDA. As a result, we are currently subject to certain ongoing FDA regulatory requirements, including, but not limited to, establishment registration, device listing, quality system regulations, or QSR, adverse event reporting, correction and removal regulations, and certain record-keeping requirements. We are also subject to periodic inspections to assess our compliance with the QSR. Accordingly, we and the contractors with whom we work must continue to expend time, money and effort in all areas of FDA regulatory compliance, including manufacturing, production and quality control.

Moreover, to the extent required, the process of obtaining regulatory approvals to market a medical device can be expensive and lengthy, and applications may take a long time to be approved, if they are approved at all. Our compliance with the quality system, medical device reporting regulations and other laws and regulations applicable to the manufacturing of products within our facilities is subject to periodic inspections by the FDA and other governmental authorities. Complying with regulations, and, if necessary, remedial actions can be significantly expensive. Failure to comply with applicable regulatory requirements may subject us to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, halting product manufacturing, revocation of

approvals, exclusion from future participation in government healthcare programs, substantial fines, and criminal prosecution. If the FDA discovers problems with our products, our marketing materials, our marketing channels (including the usage of internal and third-party clinicians) and/or our procedures, and concludes that we have failed to comply with applicable regulatory requirements, the agency may take various types of enforcement action against us.

The company's COVID-19 Test Kit product is regulated by the FDA as an in-vitro diagnostic medical device. Due to the government's declaration of a Public Health Emergency caused by COVID-19, in-vitro diagnostic test kits and laboratory tests for COVID-19 can be marketed and sold pursuant to Emergency Use Authorizations (EUAs) issued by FDA, instead of the standard regulatory 510(k) clearance. EUAs permit marketing and sale of in-vitro diagnostic test kits and laboratory tests for COVID-19 only for the duration of the public health emergency. If the company desires to continue selling the Clarifi COVID-19 test kit after the end of the public health emergency, it will be required to seek 510(k) clearance. 510(k) clearance may be more difficult to obtain and there is no assurance that the company would obtain clearance even though it had obtained an EUA.

Some COVID-19 clinical work we are conducting could be prematurely terminated, or delayed for some time, if the FDA were to impose increased regulation of such work.

Further, if we were to market and sell our products in jurisdictions outside of the United States, we may be subject to similar regulatory requirements in such jurisdictions. Regulatory authorization procedures vary among jurisdictions and may require information and/or data beyond that required to comply with FDA requirements. We may not obtain the authorization(s) required to market our products outside the United States on a timely basis, if at all. Our failure or delay in obtaining required regulatory authorization to market our products in one or more countries may have a negative effect on our business.

***We perform epigenetic diagnostic tests that could, at some point in the future, be regulated by the FDA as medical devices. If the FDA decides to actively regulate tests like those that we offer, we may need to obtain FDA and/or other regulatory clearances or approvals, and comply with other regulatory requirements, which may delay, encumber or block us from commercializing these diagnostic tests.***

The Clarifi ASD test was designed to be offered as a laboratory-developed test ("LDT") that is available through a single CLIA certified laboratory. Historically the FDA has exercised enforcement discretion with respect to most LDTs and not required them to comply with the requirements for medical devices (e.g., premarket clearance, device listing, quality system regulations, and adverse event reporting). Despite its policy of enforcement discretion, FDA did in some cases decide that a particular LDT should be regulated as an IVD, which created considerable uncertainty in regulatory compliance. In August, 2020, the Department of Health and Human Services announced that FDA would no longer require premarket review of LDTs unless and until it followed the notice and comment rulemaking requirements of the Administrative Procedure Act. However, the Clarifi ASD test is a new type of bioinformatics LDT, which uses a software algorithm to analyze the results of next generation sequencing of nucleic acids. FDA's regulation of bioinformatics LDTs is in its infancy, and there is uncertainty about whether such bioinformatics LDTs, such as Clarifi ASD, will be regulated in the same way as general LDTs.

If the FDA regulates one or more of our epigenetic diagnostic technologies as a medical device, such a decision may materially impact our plans to develop and commercialize such test(s) and may require us to change our business model to come into and maintain compliance with these regulations. FDA oversight of our tests may significantly increase the time it takes us to bring such tests to market, may materially increase the costs of developing and offering such tests, and decrease the profitability of providing such tests. We cannot provide any assurance that FDA will not regulate any of our epigenetic diagnostic technologies in the future, whether through final guidance, regulations promulgated by the FDA under notice and comment rulemaking, or as instructed by Congress in new legislation. It is possible that legislation will be enacted into law, regulations could be promulgated, or guidance could be issued by the FDA which may result in increased regulatory burdens for us to offer our epigenetic tests. Moreover, if pre-market review is required by the FDA or if we decide to voluntarily pursue the FDA's pre-market review for any of our tests, we cannot assure you that our diagnostic tests will be cleared or approved on a timely basis, if at all. There is also no assurance that FDA will permit



marketing of our diagnostic tests for the clinical uses that we desire, and such limitations on marketing claims may adversely affect the adoption of and reimbursement for our tests. If the FDA regulates our epigenetic diagnostic technologies, our business could be negatively impacted.

***If we fail to meet any applicable requirements of CLIA or state clinical laboratory licensure laws, that failure could prohibit and/or restrict the commercial sale of our epigenetic testing diagnostic technologies and otherwise cause us to incur significant expense.***

Our operations for conducting the COVID-19 tests, the Clarifi ASD test and other epigenetic tests, are and will be subject to federal and state laws and regulations applicable to the operation of clinical laboratories. The CLIA regulations impose a federal certification requirement for clinical laboratories, and establish standards for personnel, facilities administration, inspections, quality assurance, quality control, and proficiency testing, among other requirements. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include suspension, limitation, or revocation of the laboratory's CLIA certificate, requiring a laboratory to implement a corrective plan, imposing civil monetary penalties, injunctive suits, and/or criminal penalties.

Similarly, our clinical laboratories in development and any other clinical laboratory at which we perform our tests may be subject to certain state clinical laboratory licensure requirements. Such clinical laboratories may be required to obtain a state clinical laboratory permit from the state in which they operate. Moreover, several states require the licensure of out-of-state laboratories that accept specimens from those states (i.e., New York, California, Maryland, Pennsylvania, and Rhode Island) or from laboratories in those states (i.e., Florida). Furthermore, insofar as we intend to offer our tests as laboratory developed tests to patients in the state of New York, we are required to obtain a test-specific approval for such tests before we can perform tests on samples from the state of New York.

Complying with the CLIA and/or state licensure requirements for clinical laboratories may be expensive, time-consuming, and subject us to significant and/or unanticipated delays. Our failure to comply with such requirements may prevent us from offering our tests in certain jurisdictions or require us to modify or delay our activities in such jurisdictions. The prohibition, delay, or interruption of our plans to commercialize our test services may have a significant negative impact on our business.

***We are subject to federal and state healthcare regulations and laws relating to anti-bribery and anti-corruption, and non-compliance with such laws could lead to significant penalties.***

State and Federal anti-bribery laws, and healthcare fraud and abuse laws, dictate how we conduct the relationships that we and our distributors and sales representatives have with healthcare professionals, such as physicians and hospitals. We also must comply with a variety of other laws that protect the privacy of individually identifiable healthcare information. These laws and regulations are broad in scope and are subject to evolving interpretation, and we could be required to incur substantial costs to monitor compliance or to alter our practices if we are found not to be in compliance. In addition, violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in government healthcare programs.

***A violation of privacy, security or data protection laws could have a material adverse effect on the company and the value of the shares.***

Certain of our current and planned services, including the storage of the electronic epigenetics test results, including the Clarifi COVID-19 Test and Clarifi ASD, in a database controlled by the company as well as provision of telemedicine services to support our diagnostic products will be covered by various privacy, security and data protection laws. The most important of these laws is the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by The Health Information Technology for Economic and Clinical Health Act ("HITECH"). If our operations are found to be in violation of any of the federal and state laws or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business.

***Government regulations and other legal requirements affecting our company are subject to change. Such change could have a material adverse effect on our business.***

We operate in a complex, highly regulated environment. The numerous federal, state and local regulations that our business is subject to include, but are not limited to: federal and state regulation of medical devices; governmental payor regulations including Medicare and Medicaid; data privacy and security laws, internet privacy and security laws and regulations including HIPAA; the Affordable Care Act (“ACA”) or any successor to that act; laws and regulations relating to the protection of the environment and health and safety matters, including those governing exposure to, and the management and disposal of, hazardous substances; consumer protection and safety regulations including those of the Consumer Product Safety Commission; federal and state laws governing health care fraud and abuse; anti-kickback laws; false claims laws; and laws against the corporate practice of medicine. The FDA and state regulatory authorities have broad enforcement powers, including the ability to seize or recall products and impose significant criminal, civil and administrative sanctions for violations of these laws and regulations.

Changes in laws, regulations and policies and the related interpretations and enforcement practices may significantly affect our cost of doing business as we endeavor to maintain compliance with such new policies and laws. Changes in laws, regulations and policies and the related interpretations and enforcement practices generally cannot be predicted and may require extensive system and operational changes. Noncompliance with applicable laws and regulations could result in civil and criminal penalties that could adversely affect our business, including: suspension of payments from government programs; loss of required government certifications; loss of authorizations to participate in or exclusion from government programs, including the Medicare and Medicaid programs; and significant fines or monetary penalties. Any failure to comply with applicable regulatory requirements could result in significant legal and financial exposure, damage our reputation, and have a material adverse effect on our business operations, financial condition and results of operations.

***Our employees, independent contractors, principal investigators, contract research organizations, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could expose us to liability and hurt our reputation.***

We are exposed to the risk that our employees, independent contractors, principal investigators, contract research organizations, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates applicable laws and regulations, such as laws that require the reporting of true, complete and accurate information to the FDA, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are successful in defending ourselves, we may incur substantial legal expenses, damage to our reputation, and management’s attention may be diverted from the operation of our business.

***If we or our contract manufacturers or other third parties fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We and our contract manufacturers and other third parties with whom we do business are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and

flammable materials, including biological materials and chemicals. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. The failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for verification and validation testing outside of the United States, to sell our product candidates abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Our violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

### **Risks Related to our Intellectual Property**

***If we are unable to adequately protect our proprietary technology and intellectual property, or if we infringe on the intellectual property of others, it could have a material adverse effect on our business.***

Our success depends in large part on our ability to obtain, maintain and enforce intellectual property protection in the United States and other countries with respect to our proprietary epigenetic technology and products, as well as other product candidates, which are important to our business. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. Though we have filed joint patent applications with the United States Patent and Trademark Office ("USPTO"), as well as international patent agencies, related to the epigenetic diagnostic tools that we discovered and developed with our collaborators, we currently do not solely own any issued patents or pending patent applications. Patents may not be issued for any pending or future patent applications owned by or licensed to us, and the claims allowed under any issued patents may not be sufficiently broad to protect our technology. Further we may fail to file patents in a timely manner or fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Any issued

patents owned by or licensed to us may be challenged, invalidated or circumvented, and the rights under these patents may not provide us with competitive advantages. In addition, competitors may design around our technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture increased market position. We could incur substantial costs to defend ourselves in suits brought against us or in suits in which we may assert our patent rights against others. An unfavorable outcome of any such litigation could materially adversely affect our business and results of operations.

In addition to the protection afforded by patents, to maintain competitive position, we rely on methods of trade secret protection, including security measures and confidentiality agreements, to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees, advisors and consultants to assign their inventions to us, and we require all of our employees, consultants, collaborators, contract manufacturers, advisors and any other third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how, and other confidential information and technology will not be subject to unauthorized disclosure. Trade secret protection does not prevent others from independently developing technology that is substantially equivalent to our trade secrets, proprietary know-how, and other information and technology. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States.

Enforcing trade secret protections is difficult, expensive, and time consuming, and the outcomes of enforcement actions are unpredictable. Moreover, in cases where we prove a misappropriation of a trade secret, we may not be able to obtain adequate remedies for such breaches, and As a result, we may encounter significant problems in protecting and defending these trade secret assets globally. If we are unable to prevent unauthorized disclosure of these trade secret assets to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business and operations.

Third parties may assert that we are infringing on their intellectual property rights. In the event that a claim relating to intellectual property is asserted against us, or third parties not affiliated with us hold pending or issued patents that relate to our products or technology, we may seek licenses to such intellectual property or challenge those patents. However, we may be unable to obtain these licenses on commercially reasonable terms, if at all, and our challenge of the patents may be unsuccessful. Our failure to obtain the necessary licenses or other rights could prevent the sale, manufacture, or distribution of our products and, therefore, could have a material adverse effect on our business, financial condition and results of operations.

***Though we currently do not solely own any issued patents or pending patent applications, our goal is to either solely or jointly with our partners receive patent protection. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and ultimately unsuccessful.***

Though we currently do not solely own any issued patents or pending patent applications, in addition to patents we may file on our own behalf, we have potential patent rights that may be obtained through patent applications jointly invented and owned by the company and the Foundations or invented and owned by the Foundations. In the future, competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that one of our patents is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could materially and adversely affect us and our collaborators.

Any litigation to enforce or defend our intellectual property rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may

not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

***We rely on licensing agreements with the Research Foundation for the State University of New York and the Pennsylvania State Research Foundation.***

The company's epigenetic technology which is currently under development, as well as the technology embodied in the Clarifi COVID test kit and wastewater testing laboratory services, are based on research conducted at SUNY Upstate Medical University, as well as the Penn State College of Medicine, with respect to the epigenetic technology. These technologies are licensed from the Research Foundation for the State University of New York and the Pennsylvania State Research Foundation ("Foundations"). See, "The Company's Business – Intellectual Property." We have entered into a license agreement with the Foundations, which, among other things, grant us exclusive rights to practice the patent rights and associated know how in defined fields of use, comprising ASD, Parkinson's Disease, and TBI. Our failure to satisfy certain provisions of the License Agreement, including those regarding milestones for commercialization of the licensed product or payment of minimum royalties, would constitute a default thereunder and permit the Foundations to terminate the License Agreement. If our arrangement with the Foundations were to end, we would no longer be able to use the intellectual property covered by the patent, which could significantly affect our business.

***We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.***

Many of our employees were previously employed at universities or other biotechnology companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our representatives (employees, advisors and consultants) do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our representatives have used or disclosed intellectual property, including trade secrets or other proprietary information, of a representative's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our representatives who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such assignments with each party who in fact develops intellectual property for us. The assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that a representative performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, contractors and advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.***

We currently have rights to certain intellectual property, through licenses from third parties and under patents and patent applications that we own, to develop our product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of the more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. Moreover, our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

### **Risks Related to our Securities**

***Any valuation of the company at this stage is difficult to assess.***

The valuations for the securities sold in our Regulation A and Regulation CF offerings were established by the company. Unlike listed companies that are valued publicly through market-driven stock prices, the valuation of private companies, especially startups, is difficult to assess and you may risk overpaying for your investment.

***Future fundraising may affect the rights of investors, including the price of our common stock and the price at which the convertible promissory notes may convert to common equity shares of the company.***

In order to expand, the company is likely to raise funds again in the future, either by offerings of securities or through borrowing from banks or other sources. The terms of future capital raising, such as loan agreements, may include covenants that give creditors, including but not limited to secured creditors, greater rights over the financial resources of the company.

***Our convertible notes are unsecured indebtedness of the company and are subordinate to existing and future secured indebtedness of the company.***

The convertible notes represent unsecured indebtedness of the company, and are convertible, in most circumstances, to common equity interests in the company. This means that the convertible notes will rank junior to all existing and future secured indebtedness of the company and, if such notes are converted to common equity shares in the company such shares will rank junior to all existing and future indebtedness of the company and to other non-equity claims on the company with respect to assets available to satisfy claims on the company, including claims in liquidation. Any interest earnings on the convertible notes will not be payable but will instead accrete and increase the principal balance of a holder's notes. If the convertible notes are converted to equity, (1) any dividends thereon will only be payable when, as, and if declared by the Board, (2) dividends will not accumulate if they are not declared, and (3) because the company is a Delaware corporation, the company will be subject to restrictions on dividend payments and redemption payments out of lawfully available funds.

Further, the securities place no restrictions on the business or operations of the company or on its ability to incur additional indebtedness or engage in any transactions, subject only to the limited voting rights required under Delaware law which will only inure to holders' benefit if the securities are converted to common equity shares in the company.

***The company may default on its obligation to pay principal and/or interest on the convertible notes, and if such notes are converted to common equity shares in the company the company may not be able to declare and pay dividends on the shares of Common Stock.***

Subject to limitations under Delaware law, holders of Common Stock will be entitled to receive dividends, when, as and if declared by our Board of Directors, out of any assets at the time legally available for such dividends. We cannot assure you when dividends might first be paid, if ever.

***The amended and restated certificate of incorporation and the subscription agreement include forum selection provisions that require disputes to be resolved in specific forums regardless of convenience or cost to you, the investor.***

Investors in our Regulation CF and Regulation A offerings agreed to resolve disputes arising under the subscription agreement in any court of competent jurisdiction in the County of Onondaga, New York for the purpose of any suit, action or other proceeding arising out of or based upon the agreement. Further, the amended and restated certificate of incorporation, specifies that the Court of Chancery in the State of Delaware is the exclusive forum for certain lawsuits, see "Securities Being Offered – Forum Selection Provisions". Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. We believe that the exclusive forum provisions apply to claims arising under the Securities Act, but there is uncertainty as to whether a court would enforce such a provision in this context. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in Quadrant's amended and restated certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. You will not be deemed to have waived the company's compliance with the federal securities laws and the rules and regulations thereunder. This forum selection provisions may limit your ability to obtain a favorable judicial forum for disputes with us. Alternatively, if a court were to find either provision inapplicable to, or unenforceable in an action, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

***The holders of the majority of the outstanding shares of our capital stock may require other stockholders to participate in certain future events, including a sale of the company or the sale of a significant amount of the company's assets.***

Investors in our Regulation CF and Regulation A became parties to a stockholders' agreement which contains a drag along provision. Under this agreement, our stockholders (including but not limited to holders of convertible notes whose notes are converted to shares of Common Stock) will be subject to a drag-along provision related to a transaction in

stockholders holding shares representing more than 60% of our outstanding capital stock agree to sell the company to a bona-fide third party. If you do not approve the transaction, or even if the majority of our board of directors does not approve the transaction, but the holders of the majority of the outstanding shares of the company's capital stock vote in favor of the transaction, you will still be required to participate in the transaction; see "Securities Being Offered – Stockholders' Agreement" below. Specifically, investors will be forced to sell their stock in that transaction regardless of whether they believe the transaction is the best or highest value for their shares, and regardless of whether they believe the transaction is in their best interests.

Moreover, there is uncertainty as to enforceability of drag-along provisions under Delaware law. Since the rights of common stock are determined in general by statute as opposed to by contract, and the drag-along provision is a contractual term, the extent to which this provision would be upheld by the courts in Delaware is unclear. If this provision is challenged, a sale of the company might not be affected, and all the stockholders could miss an opportunity to realize the value of their investment.

***Investors in our Regulation A and Regulation CF may be subject to transfer restrictions.***

Investors in our Regulation CF and Regulation A offerings agreed to become a party to a stockholders' agreement which contains a "market stand-off" provision in the event the company has an underwritten public offering pursuant to an effective registration statement (e.g., an initial public offering), which may limit or delay an investor's ability to transfer shares for a period of time surrounding such an offering. See "Securities Being Offered – Stockholders' Agreement."

***There is currently no public market for the convertible notes or for our Common Stock, and a public market for the convertible notes and our Common Stock may never develop.***

The securities being sold in our Regulation CF offering are subject to restrictions on resale for one year. There is no formal marketplace for the resale of the convertible notes or our Common Stock. The convertible notes and our Common Stock may be traded over-the-counter to the extent any demand exists, but we have not (and may never) take steps necessary to permit such over-the-counter trading. These securities and our Common Stock are illiquid and there will not be an official current price for them, as there would be if we were a publicly-traded company with a listing on a stock exchange. Investors should assume that they may not be able to liquidate their investment for some time, or be able to pledge their convertible notes (or, if converted to Common Stock, their shares) as collateral. Since we have not established a trading forum for the convertible notes or the Common Stock, there will be no easy way to know what the convertible notes or the Common Stock is "worth" at any time. Even if we were to eventually list our Common Stock on Nasdaq or seek a quotation on the "OTCQX" or the "OTCQB" markets, there may not be frequent trading and therefore no market price for the Common Stock.



## SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN SECURITYHOLDERS

Our authorized capital stock consists of 125,000,000 shares, all of which are Common Stock with a \$0.0001 par value per share. As of December 31, 2021, there were 88,992,860 shares of our Common Stock issued and outstanding, all of which were fully paid, non-assessable and entitled to vote. Each share of our Common Stock entitles its holder to one vote on each matter submitted to the stockholders.

The following table sets forth information as of December 31, 2021, with respect to the beneficial ownership of our Common Stock (represented as the sum of Common Stock owned plus Common Stock acquirable through the exercise of options) by (i) each person or entity which holds a beneficial ownership of 5% or more of our Common Stock, (ii) the beneficial ownership held by our Executive Officers and Directors (as listed above), and (iii) the beneficial ownership held by our Directors (which includes four Executive Officers as noted above):

| <b>Name and address of beneficial owner (1)</b>          | <b>Number of Common Shares Owned</b> | <b>Number of Common Shares Acquirable (2)</b> | <b>Percent of ownership (3)</b> |
|--|--------------------------------------|---|---------------------------------|
| Richard Uhlig, Chairman and CEO                          | 32,779,154                           | 6,847,350                                     | 41.35%                          |
| Research Foundation for the State University of New York | 5,959,241                            | --  | 6.70%                           |
| James Croke, Secretary and Director                      | 2,020,398                            | 3,469,775                                     | 5.94%                           |
| Richard Bongo, CFO and Director                          | 1,184,266                            | 3,559,380                                     | 5.13%                           |
| All Directors and Executive Officers (18 total)          | 43,242,4383                          | 18,972,555                                    | 57.62%                          |
| All Directors (8 total)                                  | 38,997,772                           | 15,871,911                                    | 52.32%                          |

- (1) The address of each beneficial owner is in the care of Quadrant Biosciences Inc, 505 Irving Ave., Suite 3100 AB, Syracuse, New York 13210.
- (2) Represents shares of Common Stock acquirable upon exercise of options which are vested or which vest on or before March 1, 2022.
- (3) Percent of ownership includes a calculation of the amount the person (or group) owns now, plus the amount that person (or group) is entitled to acquire. That amount is then shown as a percentage of the outstanding amount of securities in that class if no other people exercised their rights to acquire those securities. The result is a calculation of the maximum amount that person could ever own based on their current and acquirable ownership, which is why the amounts in this column will not add up to 100%.

## RECENT OFFERINGS OF SECURITIES

We have made the following issuances of securities within the last three years:

- In July of 2018, we sold 10,449,367 shares of Common Stock in reliance on Rule 506(c) under Regulation D of the Securities Act, for consideration of \$13,061,709. The proceeds were used for working capital and a preference payment to convert all Preferred Stock to Common Stock.
- In September 2019, we sold 4,042,000 shares of Common Stock in reliance on Rule 506(b) under Regulation D of the Securities Act, for consideration of \$4,850,400. The proceeds of this offering were used for working capital.
- In February 2020, we sold 1,024,100 shares of Common Stock in reliance on Rule 506(b) under Regulation D of the Securities Act, for consideration of \$2,560,250. The proceeds of this offering were used for working capital.
- From March 9, 2020 through August 15, 2020, we sold 307,769 shares of Common Stock via Regulation A of the Securities Act, for consideration of \$923,307. The proceeds of this offering are being used for working capital.

- From September 2020 through February 18, 2021, we sold \$416,628 in 6% Convertible Notes that mature on August 25, 2025 in a Regulation CF offering. The proceeds of this offering were used for working capital.

## **DESCRIPTION OF CAPITAL STOCK**

### **General**

Quadrant offered Convertible Promissory Notes to investors in the Regulation CF offering.

The following description summarizes the most important terms of the company's capital stock. This summary does not purport to be complete and is qualified in its entirety by the provisions of Quadrant's amended and restated certificate of incorporation, as amended, and bylaws. For a complete description of Quadrant's capital stock, you should refer to the amended and restated certificate of incorporation, as amended, and bylaws and to the applicable provisions of Delaware law. Further, for a complete description of the Convertible Promissory Notes, you should refer to the Convertible Promissory Notes.

Under the certificate of amendment of restated certificate of incorporation of the company, adopted December 14, 2018, the company has 125,000,000 shares of Common Stock authorized.

As of December 31, 2021, 88,992,860 shares of the Common Stock are outstanding.

Investors in our Regulation A and Regulation CF offerings are subject to the Stockholders' Agreement and Forum Selection Provisions.

### **Rights, Preferences and Privileges of Our Common Stock**

#### ***Voting Rights***

Each holder of our Common Stock will be entitled to one vote for each share held of record by such holder on all matters submitted to a vote of the holders of our Common Stock, including the election of directors. Subject to a quorum requirement of one-third of shares entitled to vote at any meeting the affirmative vote of a majority of the shares present or represented by proxy at the meeting and entitled to vote will be the act of the holders of our Common Stock (except with respect to elections of directors, which will be determined by a plurality of the votes of shares present in person or represented by proxy at the meeting).

#### ***Dividends***

Subject to limitations under Delaware law, holders of our Common Stock are entitled to receive dividends, when, as and if declared by our Board of Directors, out of any assets at the time legally available for such dividends. Holders of Common Stock will be entitled to receive ratably those dividends, if any, when, as and if declared from time to time by the board of directors out of legally available funds, when, as and if declared by our Board of Directors. We cannot assure you when dividends might first be paid, if ever.

#### ***Other Rights and Preferences***

Holders of Common Stock have no preemptive, conversion or subscription rights. However, holders of Common Stock will be subject to drag-along provisions, see "Stockholders' Agreement" below. There are no redemption or sinking fund provisions applicable to our Common Stock.

### **The Convertible Promissory Notes**

The company sold \$416,628 in convertible promissory notes in its Regulation CF offering. The convertible promissory notes bear an interest rate of 6% per year, computed on the basis of a year of 365 days, and have a maturity date of August 25, 2025. Interest will accrue on the outstanding principal amount of the convertible promissory notes (i.e., it will

not be periodically paid) until the notes are paid in full or converted. At maturity, the principal and accrued and unpaid interest thereon will convert to common equity shares of the company.

While the convertible promissory notes are still outstanding, the convertible promissory notes will convert into common equity shares at the earlier of a "change of control" (such as the sale, merger or acquisition of the company in which more than fifty percent (50%) of the company's voting power is transferred, or the sale or transfer of all, or substantially all, of the company's intellectual property) or a "qualified equity financing" (which is an initial public offering of the company's common stock or an equity financing through which the company raises more than \$15 million).

The price at which the convertible promissory notes sold in the Regulation CF offering will convert will be:

- If conversion takes place prior to a qualified equity financing (e.g., at maturity or in a change of control): (i) in the case of a change in control, at a 20% discount to the share price at which such change in control occurred, and (ii) at maturity, at a 20% discount to the offering share price at which the company last sold \$500,000 or more of the company's Common Stock; or
- If the conversion takes place pursuant to a qualified equity financing, at a discount of 20% to the share price in the qualified equity financing.

If the company ever fails to timely pay principal or interest on the convertible promissory notes, or if the company becomes subject to certain bankruptcy or related insolvency/reorganization proceedings, the company's obligation to pay principal and interest on the notes will be accelerated and be then due and payable.

#### **Stockholders' Agreement**

Holder of Common Stock (including holders of convertible notes which are convertible to Common Stock) will enter into the Stockholders' Agreement with the company, pursuant to which such holders will have drag-along and market stand-off obligations. Under the market stand-off provision, in the event the company has an underwritten public offering pursuant to an effective registration statement (e.g., an initial public offering), a holder's ability to sell or transfer their shares may be limited for up to 180 days plus such reasonable period to accommodate certain regulatory restrictions following the date of the final prospectus of such offering. Under the drag-along provision, if at any time, any unaffiliated third party makes a *bona fide* fully-financed good faith offer to purchase all or substantially all of the outstanding capital stock of the company and holders of more than sixty percent (60%) of the issued and outstanding shares of common stock of the company accept, then, upon not less than 30 days' written notice from the company or the selling stockholders to all stockholders of the company and the company, each stockholder shall be obligated to accept the terms of such transaction, and shall sell, transfer and deliver, or cause to be sold, transferred and delivered, to such offer, the shares pursuant to the terms of such transaction.

#### **Forum Selection Provisions**

The subscription agreement includes a forum selection provision that requires any claims against the company based on that agreement to be brought in a state or federal court of competent jurisdiction in the County of Onondaga, New York for the purpose of any suit, action or other proceeding arising out of or based upon that agreement. Further, the amended and restated certificate of incorporation includes a forum selection provision that requires any claims against the company based on the agreement to be brought in the Court of Chancery in the State of Delaware, for the purpose of any (i) any derivative action or proceeding brought on behalf of the company, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee to the company or the company's stockholders, (iii) any action asserting a claim against the company, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or the company's certificate of incorporation or bylaws or (iv) any action asserting a claim against the company, its directors, officers or employees governed by the internal affairs doctrine. Although we believe the provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies and in limiting our litigation costs, to the extent it is enforceable, the forum selection

provision may limit investors' ability to bring claims in judicial forums that they find favorable to such disputes and may discourage lawsuits with respect to such claims. The company has adopted the provision to limit the time and expense incurred by its management to challenge any such claims. As a company with a small management team, this provision allows its officers to not lose a significant amount of time travelling to any particular forum so they may continue to focus on operations of the company. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. We believe that the exclusive forum provision applies to claims arising under the Securities Act, but there is uncertainty as to whether a court would enforce such a provision in this context. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision in the amended and restated certificate of incorporation will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Investors will not be deemed to have waived the company's compliance with the federal securities laws and the rules and regulations thereunder.

### **What it means to be a minority holder**

As an investor in convertible promissory note of the company, you do not have any rights in regards to the corporate actions of the company, including additional issuances of securities, company repurchases of securities, a sale of the company or its significant assets, or company transactions with related parties. Even if your securities convert to equity of the company, holders of convertible promissory notes will hold minority interests, potentially with rights less than those of other investors, and will have limited influence on the corporate actions of the company.

### **Dilution**

Dilution means a reduction in value, control or earnings of the shares the investor owns.

#### **Immediate dilution**

An early-stage company typically sells its shares (or grants options over its shares) to its founders and early employees at a very low cash cost, because they are, in effect, putting their "sweat equity" into the company. When the company seeks cash investments from outside investors, like you, the new investors typically pay a much larger sum for their shares than the founders or earlier investors, which means that the cash value of your stake is diluted because all the shares are worth the same amount, and you paid more than earlier investors for your shares.

#### **Future dilution**

Another important way of looking at dilution is the dilution that happens due to future actions by the company. The investor's stake in a company could be diluted due to the company issuing additional shares. In other words, when the company issues more shares, the percentage of the company that you own will go down, even though the value of the company may go up. You will own a smaller piece of a larger company. This increase in number of shares outstanding could result from a stock offering (such as an initial public offering, another crowdfunding round, a venture capital round, or an investment by a private equity investor), employees exercising stock options, or by conversion of certain instruments (e.g. convertible bonds, preferred shares or warrants) into stock.

If the company decides to issue more shares, an investor could experience value dilution, with each share being worth less than before, and control dilution, with the total percentage an investor owns being less than before. There may also be earnings dilution, with a reduction in the amount earned per share (though this typically occurs only if the company offers dividends, and most early stage companies are unlikely to offer dividends, preferring to invest any earnings into the company).

The type of dilution that hurts early-stage investors most occurs when the company sells more shares in a "down round," meaning at a lower valuation than in earlier offerings. An example of how this might occur is as follows (numbers are for illustrative purposes only):

- In June 2021 Jane invests \$20,000 for shares that represent 2% of a company valued at \$1 million.

- In December the company is doing very well and sells \$5 million in shares to venture capitalists on a valuation (before the new investment) of \$10 million. Jane now owns only 1.3% of the company but her stake is worth \$200,000.
- In June 2022 the company has run into serious problems and in order to stay afloat it raises \$1 million at a valuation (before the new investment) of only \$2 million (the “down round”). Jane now owns only 0.89% of the company and her stake is worth only \$26,660.

This type of dilution might also happen upon conversion of convertible notes into shares. Typically, the terms of convertible notes issued by early-stage companies provide that in the event of another round of financing, the holders of the convertible notes get to convert their notes into equity at a “discount” to the price paid by the new investors, i.e., they get more shares than the new investors would for the same price. Additionally, convertible notes may have a “price cap” on the conversion price, which effectively acts as a share price ceiling. Either way, the holders of the convertible notes get more shares for their money than new investors. In the event that the financing is a “down round” the holders of the convertible notes will dilute existing equity holders, even more than the new investors do, because they get more shares for their money. Investors should pay careful attention to the amount of convertible notes that the company has issued (and may issue in the future), and the terms of those notes.

If you are making an investment expecting to own a certain percentage of the company or expecting each share to hold a certain amount of value, it’s important to realize how the value of those shares can decrease by actions taken by the company. Dilution can make drastic changes to the value of each share, ownership percentage, voting control, and earnings per share.

### **Valuation**

The company determined the valuation cap, discount, and interest rate of the convertible promissory notes in its Regulation CF offering internally based on its own assessment of the company's current and future value, as well as relative risk for investors investing in similarly situated companies. The convertible promissory may convert to equity securities of the company in the future if the company engages in prescribed future equity financings, as described herein. At that time, the valuation of the company will be determined through negotiations with prospective investors. Those prospective investors may determine the value of the company through one or multiple methods which include:

*Liquidation Value* — The amount for which the assets of the company can be sold, minus the liabilities owed;

*Book Value* — This is based on analysis of the company’s financial statements, usually looking at the company’s balance sheet; and

*Earnings Approach* — This is based on what the prospective investor will pay (the present value) for what the prospective investor expects to obtain in the future.

### **Transfer Restrictions – Regulation Crowdfunding**

Securities purchased through a Regulation Crowdfunding offering, including any securities into which they convert, are not freely transferable for one year after the date of purchase of the securities, except in the case where they are transferred:

1. To the company that sold the securities
2. To an accredited investor
3. As part of an offering registered with the Commission
4. To a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser, or in connection with the death or divorce of the purchaser.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included in this report. The following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Unless otherwise indicated, the latest results discussed below are as of December 31, 2021.

### Overview

The company was incorporated in Delaware on March 13, 2015 as Motion Intelligence Inc. On August 6, 2015, Motion Intelligence LLC, a New York limited liability company merged into Motion Intelligence Inc. The company changed its name to Quadrant Biosciences Inc. on September 7, 2017.

Quadrant is a biotechnology company focused on the research, development and commercialization of molecular diagnostics, therapeutics and related products and services.

The company was founded to improve lives through the development of more accurate and timely diagnostics for large-scale health issues; these include Autism Spectrum Disorder, Parkinson's disease, mild traumatic brain injuries (or concussion injuries), and most recently SARS-CoV-2 infections. In addition to these conditions, the company is actively engaged in proprietary research and development efforts related to other chronic, degenerative and developmental diseases and disorders.

The company operates primarily in the United States. Markets served include the healthcare, educational institution, laboratory services and sports management fields. The company's commercial technology results from the translation of basic science developed by the company and in conjunction with academic partners.

Due to the pandemic in 2020, the company pivoted from its principal focus on the development and commercialization of epigenetic diagnostic tests and developed COVID-19 diagnostic products, including an individual diagnostic test for which it obtained a Food and Drug Administration ("FDA") emergency use authorization ("EUA") in September 2020. The company's 2020 and 2021 financial revenues are primarily derived from its COVID-19 products and services.

In addition to its commercialized products, the company is also developing a molecular analysis platform for mild traumatic brain injury ("mTBI") called Clarifi mTBI. Clarifi mTBI provides both diagnostic capabilities for mTBI, as well as a prognostic indicator for persistent post-concussion symptoms ("PPCS"). In September of 2020, the company received a \$2.3 million Small Business Technology Transfer ("STTR") grant from the National Institute of Health ("NIH") to develop a saliva-based diagnostic for concussions. Five research sites around the country are funded by this grant to collect additional data for Clarifi mTBI which will support future regulatory submissions. In addition to the company's NIH funding, Clarifi mTBI was also selected by the Technical and Business Assistance ("TABA") Needs Assessment Program. The TABA Program evaluates a product's go-to-market potential and is exclusive to NIH grant recipients. The company received a final report detailing an optimal commercialization strategy in July of 2021. Currently, the company is pursuing additional research sites, and well as gathering clinical utility data to help influence payor coverage and clinical adoption.

The company's COVID-19 related work includes as follows:

- Test Kits for CLIA Laboratory Use: Producing the "Clarifi COVID-19 Test Kit" a non-invasive and easy to administer saliva swab that determines the presence or absence of SARS-CoV-2 viral RNA. For the Clarifi COVID-19 Test Kit the company receives revenue both from the sale of the kits as well as product assembly services as such services are requested by its customers;
- Community/Municipal Wastewater Surveillance: Performing tests on municipal wastewater samples for SARS-CoV-2, principally in New York State;

- **Clinical COVID-19 Screening and Diagnostic Testing:** Through its two CLIA/CLEP laboratories (described below), the company processes saliva specimens to identify individuals infected with the SARS-CoV-2 virus; the company's clients include colleges/universities, K-12 schools, municipal and private employers. For individuals who are symptomatic or otherwise at risk of being infected, the company offers individual diagnostic testing services. For organizations, the company offers clinical screening services, generally utilizing a proprietary specimen pooling technology to reduce costs and minimize in-laboratory processing times. All specimens in a pool which screens "negative" are presumed negative; all specimens in a pool which screens "positive" are further tested on an individual diagnostic basis. Clinical results are available electronically for tested individuals and their respective organizations. To date, the company has processed over 4 million individual clinical specimens for its clients.

The Clarifi COVID-19 tests were all developed and validated in cooperation with SUNY Upstate Medical University, and each of Clarifi ASD and ClearEdge were developed and validated in cooperation with the SUNY Upstate Medical University and the Penn State College of Medicine. In the second quarter of 2021, the company became the sole owners of two laboratories, one located on the SUNY Upstate Syracuse campus and the other on SUNY Buffalo campus. On July 1, 2021, these two laboratories were certified under the Clinical Laboratory Improvement Amendment (Federal) / Clinic Laboratory Evaluation Program (New York State) ("CLIA/CLEP").

The company has received predominantly all of its revenue from COVID-19 products from state and local entities of New York State.

## **Results of Operations**

### ***Year ended December 31, 2021 Compared to Year ended December 31, 2020***

#### *Net Revenues*

The company's revenues consist of revenue derived from product sales, product assembly, testing services, grant revenues and licensing and maintenance services. The company's total revenues for the year ended December 31, 2021 ("Fiscal 2021") were \$60,519,179, an increase of \$48,718,056 from total revenues of \$11,801,123 in the year ended December 31, 2020 ("Fiscal 2020"). This increase is attributable to the company's COVID initiatives, which accounted for \$60,370,952 in Fiscal 2021 compared to \$11,477,679 in Fiscal 2020. The revenues for the COVID initiatives in 2021 included revenues from lab testing in addition to sales from the company's prior COVID products; wastewater testing and Clarifi COVID-19 Test kit sales product assembly services. Cost of products sold increased to \$33,466,238 in Fiscal 2021, an increase of \$24,856,478 from \$8,609,760 in Fiscal 2020, primarily attributable to the sale of the COVID products, including royalty expense of \$7,833,833 in Fiscal 2021 and \$858,614 in Fiscal 2020. Accordingly, the company had gross profit of \$27,052,941 in Fiscal 2021 compared with \$3,191,363 in Fiscal 2020.

#### *Operating Expenses*

Operating expenses consist of sales and marketing expenses, research and development costs, and selling and administrative expenses. Operating expenses in Fiscal 2021 were \$10,398,558, compared to \$7,676,398 in Fiscal 2020, an increase of \$2,722,160. The increase primarily relates to the \$2,111,164 increase in employment related expenses, which includes employee benefits and taxes, salaries and wages and stock option compensation, as well as increases in office expenses of \$563,488 and professional fees of \$553,849. The company had 126 employees at December 31, 2021 compared with 42 employees at December 31, 2020 and in 2021 the company began operations in its two laboratories. The increase in operating expenses was partially offset by a \$394,879 decrease in sales and marketing expense and a \$315,783 decrease in research and development costs due to the company reducing spend on non-COVID-19 related expenses and capitalizing certain research and development expenditures.

#### *Net Income*

The company had other expenses in Fiscal 2021 of \$10,853 compared to other income of \$397,656 in Fiscal 2020. The company's other income/(expense) primarily consists of \$242,746 of noncash grant income related to an equipment use

agreement with The Research Foundation for The State University of New York under which rent payments are forgiven for meeting certain performance milestones, offset by \$309,842 of interest expense accrued related to the company's long-term debt obligations. For Fiscal 2021 the company's other income increased to \$298,989 from other expenses of \$76,402 in Fiscal 2020 due to the equipment use agreement with The Research Foundation for The State University of New York. The total other income in 2020 is primarily attributable to an EIDL advance grant and forgiveness of the company's PPP loan, which totaled \$765,600 in 2020. See "Liquidity and Capital Resources."

The company had deferred income tax and income tax expenses in Fiscal 2021 of \$ 4,395,723 compared with deferred income tax and income tax benefit in Fiscal 2020 of \$5,819,431.

As a result of the foregoing factors, the company's net income was \$12,247,807 in Fiscal 2021 compared with \$1,732,052 in 2020.

### **Liquidity and Capital Resources**

As of December 31, 2021, the company's cash and cash equivalents were \$8,116,233. Historically, we had financed our operations primarily through the issuance of preferred stock, common stock, notes, debt, and research grants. In 2018, we converted our preferred stock into common stock. Beginning in September 2020, we began receiving revenues for our COVID testing and products.

We have devoted substantially all of our financial resources and efforts to (i) developing our molecular diagnostic technologies, identifying potential product candidates and conducting verification and validation testing and (ii) the development of diagnostic testing, screening and surveillance techniques for COVID-19 in individuals and wastewater. On February 18, 2021, the company completed its most recent raise that started in September 2020. The company issued \$416,628 in 6% Convertible Notes that mature on August 25, 2025; as of December 31, 2021 the outstanding balance was \$437,237.

The company has a line of credit with the borrowing capacity of \$1,000,000 from Pathfinder Bank, at an interest rate of the greater of 5.375% or Bank Prime plus 1.125%. The line of credit had a balance of \$0 and \$403,996 at December 31, 2021 and December 31, 2020, respectively. The line is secured by all the business assets of the company. The company also has a loan from VEP Biotech Ltd, with a maturity date of October 2023, an interest rate of 5%, and no required payment of principal or interest until maturity. The outstanding balance as of December 31, 2021 and December 31, 2020 (including principal and interest) were \$5,837,124 and \$5,555,858, respectively. The company also obtained an SBA loan in May 2020, which had an outstanding balance as of December 31, 2021 and December 31, 2020 of \$159,046 and \$153,421, respectively.

### **Trends**

Quadrant started 2020 with sales of Clarifi ASD, having recently achieved regulatory approval for this test in 49 states as an LDT offered through a third-party laboratory. However, not long after the company began to introduce Clarifi ASD to pediatric healthcare providers, the world was besieged by the COVID-19 pandemic. Starting in early 2020, the company's ability to access healthcare providers was greatly restricted by social distancing mandates which, in turn limited its ability to introduce Clarifi ASD to potential customers. In light of these impediments and in deference to the company's concentration in COVID-19 testing products and services, the company temporarily removed the Clarifi ASD test from the market. The company intends to re-validate Clarifi ASD in one of its own laboratories in 2022 and seek regulatory approval from the NYSDOH to re-launch the test as an LDT in all 50 states.

During the pandemic, the company continued to implement its strategy to obtain broad insurance reimbursement for Clarifi ASD. Attaining a unique CPT® PLA code in 2020 was a major step toward this outcome. On Sept 21, 2020, the Centers for Medicare and Medicaid Services ("CMS") released a preliminary payment rate determination of \$1,755 for Clarifi ASD; this rate was finalized and became effective in January 2021. With these now established, the company is pursuing state and federal health insurance coverage for Clarifi ASD.



More recently (April 2021), the FDA designated Clarifi ASD a “Breakthrough Device”; the FDA Breakthrough Device Program is intended to help patients and health care providers receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions.

With an aim to grow its domestic sales of Clarifi ASD, the company is refocusing and adapting its sales efforts to new market conditions, continuing to implement its insurance reimbursement strategy, and progressing toward In-Vitro Diagnostic (“IVD”) approval through the FDA’s Breakthrough Device Program.

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In March 2020, Quadrant made a decision to devote a majority of its resources to address the global COVID-19 pandemic in partnership with SUNY Upstate Medical University. We held a strong belief that our combined skills would benefit families and communities in a time of great uncertainty; at the time, the transmissibility, mortality and other health risks posed by the SARS-CoV-2 virus were largely unknown as was the true breadth of the pandemic.

Researchers at Quadrant and SUNY Upstate Medical University leveraged our collective expertise to develop non-invasive, highly accurate and scalable diagnostic solutions for individuals, organizations and policy makers. As a result, today we are involved in three significant COVID-19 projects addressing different ways to assess the presence and prevalence of COVID-19. We anticipate that we will be involved in COVID-19 diagnostics, screening and surveillance activities through 2022, as COVID-19 remains a significant threat to national and worldwide health.

To better serve our clients, in August 2020 Quadrant and SUNY Upstate Medical University built and have continuously operated a CLIA high-complexity laboratory (Syracuse, NY) for high-throughput testing using the Clarifi COVID-19 Test and its pooled-saliva complement. In early 2021, Quadrant built and now operates a second CLIA high-complexity laboratory (Buffalo, NY) for high-throughput COVID-19 testing. Since September 2020, these laboratories have seen significant increases in production volume: in March 2021 alone, these two labs processed saliva specimens for over 380,000 individuals. While a significant portion of the available capacity for each of these labs is expected to be utilized for ongoing COVID-19 testing through 2021 and likely most of 2022, the company is developing plans to add additional molecular tests which best utilize the company’s genetic and epigenetic expertise or which complement our product pipeline.

Quadrant continues to devote significant resources to the ongoing implementation of our COVID-19 business; we anticipate that these products and services will be a significant part of our 2022 revenues.

## **REGULATORY INFORMATION**

### **Disqualification and Compliance Failure**

Neither the company nor any of our officers or managing members is disqualified from relying on Regulation Crowdfunding. The company has not previously failed to comply with the requirements of Regulation Crowdfunding.

### **Regulation A filings**

The company also makes filings under Regulation A under the Securities Act. You can find those filings, including exhibits such as corporate documents and material contracts, at [www.sec.gov](http://www.sec.gov).

**Item 7. Financial Statements**

**QUADRANT BIOSCIENCES INC.  
AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

**Years Ended  
December 31, 2021 and 2020**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
Quadrant Biosciences, Inc. and Subsidiaries

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Quadrant Biosciences, Inc. and Subsidiaries as of December 31, 2021 and 2020, and the related consolidated statements of operations, stockholders' e+quity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Quadrant Biosciences, Inc. and Subsidiaries as of December 31, 2021 and 2020, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These consolidated financial statements are the responsibility of Quadrant Biosciences, Inc. and Subsidiaries' management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to Quadrant Biosciences, Inc. and Subsidiaries in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Quadrant Biosciences, Inc. and Subsidiaries is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.



Member of Geneva Group International, a worldwide alliance of independent professional firms.

## Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

### *Capitalized internal-use software development costs (Software as a Service)*

As discussed in Notes A (22) and E to the consolidated financial statements, Quadrant Biosciences, Inc. and Subsidiaries capitalizes certain internal-use software costs related to new products, as well as existing products when those costs will result in significant additional functionality. Quadrant Biosciences, Inc. and Subsidiaries capitalized internal-use software asset, net of accumulated amortization, was \$7,993,342 and \$6,434,639, as of December 31, 2021 and 2020, respectively.

We identified the determination of capitalized internal-use software development costs as a critical audit matter because of the degree of subjectivity involved in assessing which projects met the capitalization criteria.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of an internal control related to the critical audit matter. This control related to the determination of which software development projects met the capitalization criteria. For a selection of current year capitalized software costs, we evaluated Quadrant Biosciences, Inc. and Subsidiaries' determination to capitalize the costs by reading their analysis and discussing the objective and status of the projects with appropriate members of management. We also assessed consistency with the objectives by testing samples of the most significant categories of capitalized costs.

Dannible & McKee, LLP  
We have served as Quadrant Biosciences, Inc.'s auditor since 2019.  
Syracuse, New York  
April 1, 2022



**QUADRANT BIOSCIENCES INC.  
AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
December 31,**

| <b>ASSETS</b>                             | 2021                 | 2020                 |
|---|----------------------|----------------------|
| <b>Current Assets:</b>                    |                      |                      |
| Cash and cash equivalents                 | \$ 8,116,233         | \$ 9,743,455         |
| Accounts receivable, net                  | 13,651,979           | 1,354,350            |
| Prepaid expenses                          | 3,367,754            | 23,975               |
| Other current assets                      | 1,211,193            | -                    |
| R&D tax credit receivables                | -                    | 188,117              |
| NY tax credit receivable                  | -                    | 34,550               |
| Inventories                               | 472,128              | 1,463,855            |
| <b>Total Current Assets</b>               | <b>26,819,287</b>    | <b>12,808,302</b>    |
| <b>Furniture and Equipment:</b>           |                      |                      |
| Furniture & equipment                     | 1,056,661            | 71,788               |
| Less: accumulated depreciation            | 82,133               | 32,630               |
| <b>Total Furniture and Equipment, net</b> | <b>974,528</b>       | <b>39,158</b>        |
| <b>Other Assets:</b>                      |                      |                      |
| Deferred tax asset                        | 1,564,598            | 5,801,031            |
| Right-of-use lease asset                  | 875,950              | 56,703               |
| Line of credit origination fees           | -                    | 17,099               |
| Software as service                       | 10,187,392           | 8,523,769            |
| Less: accumulated amortization            | 2,194,050            | 2,106,229            |
| <b>Total Other Assets</b>                 | <b>10,433,890</b>    | <b>12,292,373</b>    |
| <b>Total Assets</b>                       | <b>\$ 38,227,705</b> | <b>\$ 25,139,833</b> |

The accompanying notes are an integral part of the consolidated financial statements.

## LIABILITIES AND STOCKHOLDERS' EQUITY

|   | 2021                 | 2020                 |
|---|----------------------|----------------------|
| <b>Current Liabilities:</b>   |                      |                      |
| Accounts payable  | \$ 809,495           | \$ 1,207,732         |
| Royalty payable   | 3,533,378            | 858,614              |
| Contract liabilities  | 1,910,078            | 7,642,227            |
| Pathfinder line of credit   | -                    | 403,996              |
| Current portion lease liability   | 289,756              | 60,918               |
| Accrued payroll and related liabilities   | 229,911              | 789,561              |
| Federal tax payable   | 131,518              | -                    |
| Accrued liabilities   | 483,040              | 21,026               |
| Current portion of long-term debt   | 5,848                | 1,708                |
| <b>Total Current Liabilities</b>  | <b>7,393,024</b>     | <b>10,985,782</b>    |
| <b>Long-Term Liabilities:</b>   |                      |                      |
| Lease liability, net of current portion   | 588,963              | -                    |
| Convertible debt  | 437,237              | -                    |
| Notes payable   | 5,990,322            | 5,707,571            |
| <b>Total Long Term Liabilities</b>  | <b>7,016,522</b>     | <b>5,707,571</b>     |
| <b>Stockholders' Equity:</b>  |                      |                      |
| Common stock, par value \$0.0001 per share, 125,000,000 shares authorized, 88,992,860 and 88,955,194 issued and outstanding, respectively | 8,900                | 8,896                |
| Additional paid in capital  | 29,932,108           | 26,808,240           |
| Accumulated deficit   | (6,122,849)          | (18,370,656)         |
| <b>Total Stockholders' Equity</b>   | <b>23,818,159</b>    | <b>8,446,480</b>     |
| <b>Total Liabilities and Stockholders' Equity</b>   | <b>\$ 38,227,705</b> | <b>\$ 25,139,833</b> |

**QUADRANT BIOSCIENCES INC.  
AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF INCOME  
For the Years Ended December 31,**

|   | 2021          | 2020          |
|---|---------------|---------------|
| <b>Revenues:</b>                                      |               |               |
| Product sales, net                                    | \$ 44,136,077 | \$ 10,602,171 |
| Product assembly                                      | 2,608,994     | 891,574       |
| Testing services, net                                 | 13,641,262    | 48,218        |
| Other revenue   | 132,846       | 259,160       |
| <b>Total Revenues</b>                                 | 60,519,179    | 11,801,123    |
| <b>Cost of Products Sold</b>                          | 33,466,238    | 8,609,760     |
| <b>Gross Profit</b>                                   | 27,052,941    | 3,191,363     |
| <b>Sales and Marketing Expenses</b>                   | 156,918       | 551,797       |
| <b>Research and Development Costs</b>                 | 206,092       | 521,875       |
| <b>Selling and Administrative Expenses:</b>           |               |               |
| Charitable contributions                              | 24,475        | 152,836       |
| Depreciation and amortization                         | 49,504        | 8,336         |
| Employee benefits and taxes                           | 832,622       | 557,420       |
| Office expenses                                       | 760,454       | 196,966       |
| Other expenses  | 653,382       | 361,868       |
| Professional fees                                     | 948,310       | 394,461       |
| Salaries and wages                                    | 3,624,093     | 3,303,932     |
| Stock option compensation                             | 3,142,708     | 1,626,907     |
| <b>Total Selling and Administrative Expenses</b>      | 10,035,548    | 6,602,726     |
| <b>Income (Loss) from Operations</b>                  | 16,654,383    | (4,485,035)   |
| <b>Other (Expenses) Income:</b>                       |               |               |
| Other income (expenses)                               | 298,989       | (76,402)      |
| EIDL advance grant and PPP forgiveness                | -             | 765,600       |
| Interest expense                                      | (309,842)     | (291,542)     |
| <b>Total Other (Expenses) Income</b>                  | (10,853)      | 397,656       |
| <b>Net Income (Loss) Before Income Tax</b>            | 16,643,530    | (4,087,379)   |
| <b>Deferred Income Tax (Expense) Benefit</b>          | (4,236,433)   | 5,801,031     |
| <b>Income Tax (Expense) Benefit</b>                   | (159,290)     | 18,400        |
| <b>Net Income</b>                                     | \$ 12,247,807 | \$ 1,732,052  |
| Per share data:                                       |               |               |
| Basic income, per common share                        | \$ 0.14       | \$ 0.02       |
| Diluted income, per common share                      | 0.12          | 0.02          |
| Shares used in computing net income per common share: |               |               |
| Basic   | 88,974,967    | 88,725,387    |
| Diluted   | 105,832,846   | 105,547,196   |

The accompanying notes are an integral part of the consolidated financial statements.

**QUADRANT BIOSCIENCES INC.  
AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
Years ended December 31, 2021 and 2020**

|   | Common<br>Shares  | Common<br>Stock Par<br>Value | Additional<br>Paid-in<br>Capital | (Accumulated<br>Deficit) | Total                |
|---|-------------------|------------------------------|----------------------------------|--------------------------|----------------------|
| <b>Balance, December 31, 2019</b>             | 87,932,825        | \$ 8,793                     | \$ 22,680,362                    | \$ (20,102,708)          | \$ 2,586,447         |
| Exercised stock options (\$0.003 per share)   | 12,500            | 2                            | 38                               | -                        | 40                   |
| Issuance of common stock, at \$2.50 per share | 702,100           | 70                           | 1,755,180                        | -                        | 1,755,250            |
| Issuance of common stock, at \$3.00 per share | 307,769           | 31                           | 923,276                          | -                        | 923,307              |
| Stock option compensation                     | -                 | -                            | 1,626,907                        | -                        | 1,626,907            |
| Stock issuance costs                          | -                 | -                            | (177,523)                        | -                        | (177,523)            |
| Net income                                    | -                 | -                            | -                                | 1,732,052                | 1,732,052            |
| <b>Balance, December 31, 2020</b>             | 88,955,194        | 8,896                        | 26,808,240                       | (18,370,656)             | 8,446,480            |
| Exercised stock options (\$0.003 per share)   | 37,000            | 4                            | 110                              | -                        | 114                  |
| Exercised stock options (\$3.00 per share)    | 666               | -                            | 1,998                            | -                        | 1,998                |
| Stock option compensation                     | -                 | -                            | 3,142,708                        | -                        | 3,142,708            |
| Stock issuance costs                          | -                 | -                            | (20,948)                         | -                        | (20,948)             |
| Net income                                    | -                 | -                            | -                                | 12,247,807               | 12,247,807           |
| <b>Balance, December 31, 2021</b>             | <u>88,992,860</u> | <u>\$ 8,900</u>              | <u>\$ 29,932,108</u>             | <u>\$ (6,122,849)</u>    | <u>\$ 23,818,159</u> |

The accompanying notes are an integral part of the consolidated financial statements.



**QUADRANT BIOSCIENCES INC.  
AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
Years ended December 31,**

|   | 2021          | 2020         |
|---|---------------|--------------|
| <b>Cash Flows from Operating Activities:</b>                                      |               |              |
| Net income  | \$ 12,247,807 | \$ 1,732,052 |
| Adjustments to reconcile net income to net cash provided by operating activities: |               |              |
| Depreciation and amortization   | 393,060       | 1,494,317    |
| Employee stock option compensation  | 3,142,708     | 1,626,907    |
| Deferred tax expense (benefit)  | 4,236,433     | (5,801,031)  |
| Forgiveness of loan   | (196,345)     | (755,600)    |
| Changes in income tax credit receivable   | 222,667       | 207,324      |
| Changes in accounts receivable  | (12,297,629)  | (1,341,697)  |
| Changes in accounts payable   | (398,237)     | 969,002      |
| Changes in royalty payable  | 2,674,764     | 858,614      |
| Changes in contract liabilities   | (5,732,149)   | 7,572,571    |
| Changes in accrued interest   | 307,500       | 272,814      |
| Changes in inventories  | 991,727       | (1,156,855)  |
| Changes in operating right-of-use lease asset                                     | (833,260)     | 79,163       |
| Changes in income taxes payable   | 131,518       | -            |
| Changes in pledges payable  | -             | (225,000)    |
| Changes in operating lease liability  | 830,347       | (80,567)     |
| Changes in prepaid expenses and other current assets                              | (4,554,972)   | 15,572       |
| Changes in accrued payroll and related liabilities                                | (559,650)     | 743,231      |
| Changes in accrued liabilities  | 166,239       | (55,413)     |
| <b>Cash Provided by Operating Activities</b>                                      | 772,528       | 6,155,404    |
| <b>Cash Flows from Investing Activities:</b>                                      |               |              |
| Cash paid for purchases of fixed assets   | (492,753)     | (33,496)     |
| Payments of software development costs  | (1,888,247)   | (1,476,916)  |
| <b>Cash Used in Investing Activities</b>  | (2,381,000)   | (1,510,412)  |
| <b>Cash Flows from Financing Activities:</b>                                      |               |              |
| Payments on financing lease   | (12,546)      | -            |
| Proceeds from SBA EIDL loan   | -             | 150,000      |
| Proceeds from PPP loan  | -             | 755,600      |
| Proceeds from line of credit  | -             | 500,000      |
| Repayment of line of credit   | (403,996)     | (97,685)     |
| Proceeds from convertible debt  | 416,628       | -            |
| Proceeds from sale of stock and exercise of options, net of issuance costs        | (18,836)      | 2,501,074    |
| <b>Cash (Used in) Provided by Financing Activities</b>                            | (18,750)      | 3,808,989    |
| <b>Net Change in Cash</b>   | (1,627,222)   | 8,453,981    |

The accompanying notes are an integral part of the consolidated financial statements.

**QUADRANT BIOSCIENCES INC.  
AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)  
Years ended December 31,**

|   | <u>2021</u>                | <u>2020</u>                |
|---|----------------------------|----------------------------|
| <b>Net Change in Cash</b>                                 | (1,627,222)                | 8,453,981                  |
| Cash, beginning of year                                   | <u>9,743,455</u>           | <u>1,289,474</u>           |
| Cash, end of year   | <u><u>\$ 8,116,233</u></u> | <u><u>\$ 9,743,455</u></u> |
| <b>Supplemental Disclosures of Cash Flow Information:</b> |                            |                            |
| Cash paid during the year for:                            |                            |                            |
| Interest  | \$ 2,342                   | \$ 20,409                  |
| Income taxes  | 14,345                     | 1,143                      |

The accompanying notes are an integral part of the consolidated financial statements.

**QUADRANT BIOSCIENCES INC.  
AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
Years ended December 31, 2021 and 2020**

**A. Summary of Significant Accounting Policies:**

1. Quadrant Biosciences Inc. (“the Company,” “Quadrant”) is an epigenetic diagnostic company with a focus on the early detection of neurological disorders and other large-scale health issues. The Company operates primarily in the United States. Markets served include the healthcare, educational institution, and sports management fields.

The Company’s commercial technology results from the translation of basic science developed by the company and in conjunction with academic partners.

Quadrant Biosciences Inc. is the parent company and owns 100% of its subsidiaries, Motion Intelligence LLC, Quadrant Epigenetics LLC, Quadrant IP Holdings LLC, Quadrant Vision Technologies LLC, Quadrant Viral Testing LLC, Quadrant Biosciences Canada Ltd, and Quadrant Laboratories LLC.

Motion Intelligence LLC is a wholly owned subsidiary which sold ClearEdge toolkits to end users utilizing distributors and agents.

Quadrant Epigenetics LLC is a wholly owned subsidiary which will record revenue from epigenetic activities.

Quadrant IP Holdings LLC is a wholly owned subsidiary which houses the Company’s patents.

Quadrant Vision Technologies LLC is a wholly owned subsidiary created to partner with a health provider.

Quadrant Viral Testing LLC is a wholly owned subsidiary created to sell the wastewater testing services and the Clarifi COVID-19 individual test kit to CLIA approved laboratories.

Quadrant Biosciences Canada Ltd is a wholly owned subsidiary created to pay an employee residing in Canada.

Quadrant Laboratories LLC is a wholly owned subsidiary, which, operates and administers clinical laboratories in which diagnostic medical testing and related commercial activities are conducted. On July 1, 2021, Quadrant Laboratories, LLC received CLIA Accreditation and NY State Department of Health CLEP permits for its two laboratories located in Syracuse and Buffalo, New York. These laboratories will be performing all of the Company’s COVID-19 testing going forward along with any future tests that the Company develops or other third-party tests it decides to perform.

2. Principles of Consolidation – The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Motion Intelligence LLC, Quadrant Epigenetics LLC, Quadrant IP Holdings LLC, Quadrant Vision Technologies LLC, Quadrant Viral Testing LLC, Quadrant Biosciences Canada Ltd, and Quadrant Laboratories LLC. All intercompany balances and transactions have been eliminated in consolidation.

3. Cash – For the purposes of cash flow disclosures, cash is defined as cash deposited in financial institutions and any investments that mature within three months or less from the initial purchase date.
4. Furniture and Equipment – Furniture and equipment acquisitions are recorded at cost. Depreciation is computed using the straight-line method based on the expected useful lives of the assets, which range from 5 to 7 years. The Company has \$538,475 in laboratory equipment received, but not in service as of December 31, 2021. Expenditures for repairs and maintenance are charged to expense as incurred, whereas major betterments are capitalized. Depreciation expense is included in selling and administrative expenses. Depreciation expense for the years ended December 31, 2021 and 2020 was \$49,503 and \$8,336, respectively.
5. Inventories – Inventories consist of raw materials and supplies, and are stated at the lower of cost or market using the average cost method or net realizable value. Net realizable value is determined as the estimated selling price in the normal course of business minus the cost of completion, disposal and transportation.
6. Accrued Vacation – Employees are eligible to receive paid vacation time based on years of service. The vacation policy is a use it or lose it policy.
7. Royalty Payable – The Company has an exclusive license with The Research Foundation for The State University of New York (the Foundation) for a COVID-19 Saliva Diagnostic. The Company paid to the Foundation a royalty of 50% of all net income as defined in the agreement through June 30, 2021. Under this agreement income is defined as COVID-19 related gross revenue received by the Company and its affiliates from third party customers, less, sales tax or duties actually paid, transportation costs actually paid, amounts credited or returned, cost of goods sold, commissions paid to sales representatives, patent costs paid by the Company, and product liability insurance premiums covering the licensed product. Effective July 1, 2021, the Company shall pay to the Foundation a royalty on COVID-19 related net sales at 10% for the quarter beginning July 1, 2021, through December 31, 2021 and decreasing by 2% each quarter until it reaches 6% for the period beginning July 1, 2022 through termination of the agreement, with certain specific exclusions. As of December 31, 2021, and 2020 the amount owed for royalty payments was \$3,533,378 and \$858,614, respectively. Royalty expense is included in cost of products sold. For the year ended December 31, 2021 and 2020 the expense was \$7,833,833 and \$858,614, respectively.
8. Income Taxes – The Company accounts for income taxes under FASB ASC 740-10. Deferred tax assets and liabilities are based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates which are anticipated to be in effect when these differences reverse. The deferred tax provision is the result of the net change in the deferred tax assets and liabilities. A valuation allowance is established when it is necessary to reduce deferred tax assets to amounts expected to be realized. See Note G.

The Company follows FASB ASC 740-10, which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Additionally, it provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company will include interest on income tax liabilities in interest expense and penalties in operations if such amounts arise. The Company determined it has no uncertain tax positions and therefore no amounts are recorded.

Commencing on July 24, 2015, the Company is a certified Start-Up New York business. As such the Company is exempt from New York franchise tax for 10 years due to their Start-Up New York locations.

9. Research and Development Expenditures – Research and development expenditures of \$206,092 and \$521,875 for the years ended December 31, 2021 and 2020, respectively, were expensed as incurred.
10. Accounts Receivable – Accounts receivable are recorded at the invoiced amount less certain price concessions and do not bear interest. The Company's accounts receivable is bifurcated between direct customers and third-party payers.

Direct customers represent the portion of the Company's revenue and accounts receivable related to employers, schools and other entities where payment is received directly from the entity ordering the product or service. Accounts receivable for customers are recorded at the invoiced amount. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing accounts receivable. The Company reviews its allowance for doubtful accounts on an ongoing basis. Past due balances for client payers are reviewed individually for collectability. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. There has been no allowance established for potential losses on direct customer accounts receivable.

Third-party payers represent the portion of the Company's revenue and accounts receivable related to Medicare, Medicaid, and commercial insurance companies. Third-party payer revenue and accounts receivable is recorded net of explicit and implicit price concessions which are based on healthcare industry trends and regulations, current economic conditions, and aging of accounts. The Company reviews its allowances for the explicit and implicit price concessions on an ongoing basis. The Company has contracted with a medical billing company that provides billing services for the laboratories.

The Company does not have any off-balance-sheet credit exposure related to its customers.

11. Prepaid Expenses – Prepaid expenses primarily consist of prepaid expenses related to various insurances and agreements over a period of time. In 2021 the Company entered into a research support agreement under which the contracting entity will use its best efforts to recruit and coordinate participation in a study for the Company. In exchange the Company provided prepaid research funding of \$3,100,000 during the fourth quarter of 2021 and will provide up to an additional \$3,097,000 through October 31, 2023, based on certain participation milestones being met.
12. Other Current Assets – Other current assets represent the capitalization of potentially useful scrap materials.
13. Concentration of Business Risk – In 2021 and 2020, all of the Company’s Clarifi ASD inventory was purchased by two vendors. There is no Clarifi ASD inventory recorded at December 31, 2021. For the year ended December 31, 2021 and 2020 94% and 78%, respectively, of inventory related to the Clarifi COVID-19 and wastewater services were purchases from a single vendor.  
  
For the year ended December 31, 2021 80% of test kit sales, 100% of product assembly services and 100% of lab testing revenue were to one customer. For the year ended December 31, 2020 95% of test kit sales and 100% of product assembly services were to one customer.
14. Advertising and Promotion – The Company expenses all advertising costs. Advertising expenses totaled \$95,946 and \$535,567 for the years ended December 31, 2021 and 2020, respectively.
15. Sales Tax – Certain states impose a sales tax on the Company’s sales to nonexempt customers. The Company collects the required sales tax from customers and remits the entire amount to the respective states. The Company’s policy is to exclude the tax collected and remitted from revenues and expenses and record a liability for the tax at the time of invoicing.
16. Stock-Based Compensation – The Company accounts for stock options under the provisions of ASC 718 Stock Compensation. For options granted in 2021 and 2020, compensation expense is recognized over the requisite service periods of the option agreements based on their fair value computed under Black-Scholes option-pricing model. See Note F.
17. Estimates and Assumptions – Management of the Company uses estimates and assumptions in preparing consolidated financial statements in accordance with generally accepted accounting principles. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could vary from the estimates that management uses.
18. Shipping Costs – Shipping costs that are non-reimbursable are included in cost of goods sold.

19. Grant Revenue – The Company evaluates terms and conditions of individual grants to determine whether they meet the characteristics of an exchange transaction or a nonexchange transaction. Revenue from grants that are determined to be exchange transactions are recognized according to ASC 606. Revenue from grants that are nonexchange transactions are recognized over the period of performance, to match the revenue with the related expenses in a systematic manner. In 2021 and 2020, the Company recognized revenue within other revenue on a grant from National Institute of Mental Health (NIH), which was classified as a nonexchange transaction, of \$132,846 and \$241,646, respectively.

During 2021, the Company entered an equipment use agreement with The Foundation, acting on behalf of the University at Buffalo. This equipment use agreement provides that the Foundation will contribute resources to the Company valued at up to \$500,000 by way of a grant with ownership of the equipment transferring to the Company at the end of the agreement period, provided the Company meets certain performance milestones. The monthly payments due under the agreement will be deferred and forgiven annually for meeting performance milestones. Under the agreement, \$492,120 of equipment was recorded in furniture and equipment at December 31, 2021. \$196,345 pro-rata forgiveness of the accrued liability was recorded in other income (expenses) for the year ended December 31, 2021, with the remaining liability of \$295,775 recorded in accrued liabilities in the consolidated balance sheet at December 31, 2021. As neither the acquisition of the equipment nor the corresponding liability represented a source or use of cash, these activities have been excluded from the consolidated statements of cash flows.

20. Earnings Per Share – The Company presents basic earnings per share (“EPS”), computed based on the weighted average number of common shares outstanding for the period, and when applicable diluted EPS, which gives the effect to all dilutive potential shares outstanding (i.e. options, convertible debt) during the period after restatement for any stock dividends. Income or loss used in the EPS calculation is net income or loss for each year. There are outstanding dilutive stock options and convertible debt for the year ended December 31, 2021 and 2020, of 16,857,879 and 16,821,809, respectively.





22. Software – In accordance with authoritative accounting guidance, costs related to the development of internal use software are evaluated based upon the development stage of the software and expensed or capitalized based upon this evaluation.

Expenses are reviewed on a quarterly basis for inclusion in the software as service capitalization and include but are not limited to software, software subscriptions, consultants, testing materials, sponsored research, legal fees, and salaries for employees based on estimations of time spent in development, design, testing, or otherwise supporting the software as service projects. The capitalized costs are amortized over the estimated lives of the products, which is generally three years. See Note E.

23. Leases – The Company has recognized right-of-use assets and lease liabilities resulting from operating and finance leases where the Company is the lessee, as described in Note C. The Company has made an accounting policy election to not recognize lease assets and lease liabilities for leases with a term of 12 months or less unless the company has the ability and intent to extend the lease beyond a 12-month term.

24. Revenue from Contracts with Customers – All of the Company’s revenue from contracts with customers are in the scope of ASC 606 and are included in revenues on the Consolidated Statements of Income. Revenue is measured based on consideration specified in a contract with a customer, less any explicit or implicit price concessions. The Company recognizes revenue when it satisfies a performance obligation by transferring control of a product or service to a customer. No incremental contract costs are incurred in obtaining contracts.

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transactions, that are collected by the Company from a customer, are excluded from revenue. See Note B.

25. Related Party Transactions – The Company did not have any significant related party transactions for the years ended December 31, 2021 and 2020.

**B. Revenue from Contracts with Customers:**

**Performance Obligations and Significant Judgments**

The following is a description of the Company’s performance obligations from contracts with customers accounted for under ASC 606:

Testing services – Testing services consist of diagnostic tests and assessments performed by the Company using its Clarifi COVID-19 Saliva Test in its CLIA and CLEP laboratories and its ClearEdge technology. The Company recognizes revenue at the time the service is provided. Third-party payers being billed for certain COVID-19 tests are billed once the testing service is complete. Other customers at times prepay for testing services. ClearEdge customers prepay for testing services by purchasing credits to be redeemed for future testing services. The revenues are deferred in contract liabilities on the Consolidated Balance Sheet and recognized as testing services revenue at the time of performance.

Clarifi ASD tests – In 2019, the Company launched Clarifi, a new clinically-validated saliva test aiding in the diagnosis of autism spectrum disorder. The Company recognizes revenue at the time the test results are delivered to the customer. Customers prepay for the test upon submitting the saliva sample. The payments are deferred in contract liabilities on the Consolidated Balance Sheet and recognized in net product sales at the time of performance. In 2021, Clarifi ASD tests were temporarily removed from the market due to the Company’s concentration in COVID-19 testing products and services.

Wastewater testing – In 2020, the Company began offering testing services to analyze wastewater across New York State for the COVID-19 virus. The Company recognizes revenue in net product sales at the time the test results are delivered to the customer. Customers are invoiced for these services upon delivery of test results and recorded in accounts receivable until payment is received.

Clarifi COVID-19 test kit sales – In 2020, the Company, along with SUNY Upstate, developed a saliva test to detect the COVID-19 virus. The Company recognizes revenue at the time the test kits are shipped to the customer. Customers pay for the test kits at the time of order. The payments are deferred in contract liabilities on the Consolidated Balance Sheet and recognized in net product sales at the time of performance. For test kits sold to camps, counties, and private businesses a portion of revenue is recognized when the swabs are shipped with the remaining revenue being recognized as test results are delivered.

Third-party COVID testing revenue - In 2021, the Company began performing certain COVID-19 laboratory testing services that in accordance with the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) are billed to third party insurers. Under the CARES Act if an individual is uninsured Quadrant will bill and receive reimbursement as administered through Health Resources and Services Administration (HRSA). The third-party payers are billed at the Company's established list price and revenue is recorded net of contractual discounts. The Company’s sales are recorded based upon reimbursement amounts as required under the CARES Act and historical reimbursement experience. In addition to contractual discounts, other adjustments including anticipated payer denials are considered when determining revenue. Any remaining adjustments to revenue are recorded at the time of final collection and settlement. These adjustments are not material to the Company’s results of operations in the year ending December 31, 2021.

Product assembly services – At times, the Company provides assembly services for Clarifi COVID-19 test kits for a separate fee. The Company recognizes revenue in product assembly revenue at the time the test kits are shipped to the customer. Customers are invoiced for these services upon shipment of test kits and recorded in accounts receivable until payment is received.

### **Disaggregation of Revenues**

The following table presents the Company's sources of net revenues, disaggregated by major product and service lines, and timing of revenue recognition for the year ended December 31,

| Major products/service lines       | 2021                 | 2020                 |
|------------------------------------|----------------------|----------------------|
| Lab testing revenue                | \$ 2,625,456         | \$ -                 |
| ClearEdge and ASD                  | 15,381               | 64,284               |
| Licensing and maintenance services | -                    | 17,514               |
| Third-party COVID testing revenue  | 11,001,414           | -                    |
| Wastewater testing                 | 698,784              | 769,440              |
| Clarifi COVID-19 test kit sales    | 43,436,304           | 9,816,665            |
| Product assembly services          | 2,608,994            | 891,574              |
|                                    | <u>\$ 60,386,333</u> | <u>\$ 11,559,477</u> |

Other than licensing and maintenance services, revenue is recognized at a point in time.

### **Contract Balances**

The following table provides information about receivables and contract liabilities from contracts with customers as of December 31,

|  | 2021          | 2020         |
|--|---------------|--------------|
| Receivables, which are included in "Accounts receivable" | \$ 13,651,979 | \$ 1,354,350 |
| Contract liabilities                                     | 1,910,078     | 7,642,227    |

Full payment on test kits is due at the time of shipment, unless specified within the contract, full payment on wastewater tests is due at the time of delivery of test results, and full payment on product assembly services is due at the time of shipment of test kits. Receivables represent the Company's unconditional rights to such consideration.

Contract liabilities represent advance consideration received from customers related to Clarifi COVID-19 test kit sales. Certain lab testing is typically included with the sale of COVID-19 test kits and the revenue allocated to the lab testing performance obligation is recognized by the Company when the testing is completed. Additionally, at times customers prepay for return shipping of the Clarifi COVID-19 tests and the Company recognizes the related revenue when shipping occurs.

Significant changes in the contract liabilities balances during the period are as follows:

|   | <u>2021</u>    | <u>2020</u> |
|---|----------------|-------------|
| Revenue recognized that was included in the contract liability balance at the beginning of the period | \$ (7,642,227) | \$ (66,656) |
| Increases due to cash received, excluded amounts recognized as revenue during the period              | 1,910,078      | 7,639,227   |

**Allocation of Transaction Price to Remaining Performance Obligations**

Estimated revenues expected to be recognized in the future relating to performance obligations that are unsatisfied (or partially satisfied) as of December 31, 2021 and 2020 are \$1,910,078 and \$7,642,227, respectively. Unsatisfied (or partially satisfied) performance obligations mainly consist of prepayments for Clarifi COVID-19 test kits. The Company recognized all the revenue from the remaining performance obligations as of December 31, 2020 in 2021, and expects to recognize all revenue from remaining performance obligations as of December 31, 2021 in 2022.

**C. Lease Commitments:**

The Company has entered into a number of lease arrangements. Specifically, operating leases for office space have been entered into in Syracuse and Buffalo, NY and San Antonio, TX during the periods. A finance lease has been entered into for equipment in Syracuse, NY.

The Company has elected the practical expedient related to short term leases for office space rentals. One of the Company's office space leases include optional renewal periods. The Company considers the renewal reasonably certain of being exercised.

The provisions of the Company's leases include both fixed rental payments and lease payments that increase at pre-determined dates. The Company has elected the practical expedient not to separate lease and non-lease components for all leases.

During the years ended December 31, 2021 and 2020, rent expenses were recognized associated with operating and finance leases as fixed rent expense of \$147,797 and \$87,583 respectively.

Amounts recognized as right-of-use assets related to operating and finance leases are included in other assets, while related lease liabilities are shown as current liabilities and long-term liabilities. As of December 31, 2021 and 2020, right-of-use assets and lease liabilities relating to leases were as follows:

|   | <u>2021</u> | <u>2020</u> |
|---|-------------|-------------|
| Operating lease right-of-use assets       | \$ 560,667  | \$ 56,703   |
| Finance lease right-of-use assets         | 315,283     | -           |
| Operating and finance lease liabilities:  |             |             |
| Current portion of operating lease        | 211,944     | 60,918      |
| Current portion of finance lease          | 77,812      | -           |
| Operating lease liability, net of current | 343,019     | -           |
| Finance lease liability, net of current   | 245,944     | -           |

During the years ended December 31, 2021 and 2020, the Company had the following cash and non-cash activities associated with operating and finance leases:

|   | <u>2021</u> | <u>2020</u> |
|---|-------------|-------------|
| Cash paid for amounts included in the measurement of lease liabilities- |             |             |
| Operating cash flows:   |             |             |
| from operating leases   | \$ 141,811  | \$ 88,987   |
| from finance leases   | 15,694      | -           |
| Additions to right-of-use assets obtained from:                         |             |             |
| New operating lease liabilities   | 630,742     | -           |
| New finance lease liabilities   | 336,302     | -           |

The future minimum annual payments due under operating and finance leases as of December 31, 2021 are as follows:

|      | <u>Operating</u>  | <u>Financing</u>  |
|------|-------------------|-------------------|
| 2022 | \$ 225,579        | \$ 94,164         |
| 2023 | 150,589           | 94,164            |
| 2024 | 135,591           | 94,164            |
| 2025 | 79,094            | 78,470            |
|      | <u>\$ 590,853</u> | <u>\$ 360,962</u> |

Amortization of finance lease right-of-use assets was \$14,013 and \$0 for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, and 2020, the weighted-average remaining lease term for all operating leases is 3.39 and .75 years, respectively.

When the Company does not have access to the rate implicit in the lease, the incremental borrowing rate is utilized as the discount rate. The weighted average discount rate associated with operating leases as of December 31, 2021 and 2020 is 4.14% and 4.51%, respectively.

**D. Inventories:**

Inventories consisted of the following:

|                      | <u>2021</u>       | <u>2020</u>         |
|----------------------|-------------------|---------------------|
| Clarifi ASD          |                   |                     |
| Testing supplies     | \$ -              | \$ 124,985          |
| Clarifi COVID-19     |                   |                     |
| Testing supplies     | 457,441           | 925,448             |
| Inventory in transit | -                 | 302,368             |
| Wastewater           |                   |                     |
| Testing supplies     | 14,687            | 111,054             |
|                      | <u>\$ 472,128</u> | <u>\$ 1,463,855</u> |

**E. Software as Service:**

The Company capitalized software costs of \$1,888,247 and \$1,849,840 for the years ended December 31, 2021 and 2020, respectively.

The Company amortized \$329,544 and \$1,485,981 of capitalized costs for the years ended December 31, 2021 and 2020, respectively. The Company has software development costs of \$5,887,489 for which amortization has not started as the software has not yet been placed in service for the year ended December 31, 2021. Amortization expense is included in cost of goods sold. Future amortization for assets placed in service will be \$0 for 2022, and in subsequent years, until software is placed into service or back into service.

**F. Stock Option Plan:**

Under the Company's 2016 Equity Incentive Plan (the Plan), the Company, at the discretion of the board of directors, may issue stock awards for shares of the Company's common stock. The board may, in its discretion, determine restrictions and conditions on the exercisability of the stock options and stock purchase rights. No option shall be exercisable after expiration of ten years from the date it was granted. Shares issued for exercised options are newly-issued from shares authorized. 34,000,000 common stock options have been authorized for the Plan.

The price of common stock covered by any option granted under the Plan shall be determined by the board at the time such option is granted, provided, however, that in the case of incentive stock options the option price shall not be less than the fair market value of the common stock on the date granted. No options have been granted for less than 100% of the fair market value of common shares at the date of option grant. Vesting periods for these awards generally range from under one year to three years. The fair value of the awards is determined and fixed on the grant date based on the Company's most recent stock valuation report. The stock valuation report is a IRS Code Section 409A estimation of fair value report prepared by a qualified outside party. The traditional valuation techniques and methodologies used in determining the fair market value include market, income and cost valuation approaches. Changes in the assumptions made in the valuation may contribute to significant changes in the fair market value of the underlying stock during the period. This estimation of fair value is considered highly complex and subjective.

The Company's calculation for the stock awards under its stock-based compensation arrangements was made using the Black-Scholes model with the following assumptions:

|                                      | 2021    | 2020    |
|--------------------------------------|---------|---------|
| Dividend yield                       | 0%      | 0%      |
| Volatility                           | 60.00%  | 50.00%  |
| Discount rate                        | 0.27%   | 1.64%   |
| Expected life                        | 5.77    | 5.77    |
| Fair value of common stock per share | \$ 3.00 | \$ 3.00 |
| Expected rate of forfeitures         | 0.00%   | 0.00%   |

Management's policy is to account for forfeitures as they occur.

A summary of the status of the Company's stock option plan as of December 31, 2021 and 2020 is presented below:

| Fixed Options     | Shares            | Weighted<br>Average<br>Exercise Price |
|-------------------|-------------------|---------------------------------------|
| January 1, 2020   | 26,322,690        | \$ 0.456                              |
| Granted           | 4,210,568         | 3.000                                 |
| Forfeited         | (1,431,158)       | 0.466                                 |
| Exercised         | (12,500)          | 0.003                                 |
| December 31, 2020 | 29,089,600        | 0.824                                 |
| Granted           | 1,665,000         | 3.000                                 |
| Forfeited         | (3,329,883)       | 1.520                                 |
| Exercised         | (37,666)          | 0.056                                 |
| December 31, 2021 | <u>27,387,051</u> | 0.873                                 |
| Exercisable:      |                   |                                       |
| December 31, 2021 | 22,469,673        |                                       |

The weighted-average grant-date fair value of options granted during the years ended December 31, 2021 and 2020, was \$1.60 and \$1.43.

A summary of the status of the Company's nonvested shares as of December 31, 2021 and the changes during the year then ended is presented below.

| Nonvested shares               | Shares      | Weighted<br>Average Grant-<br>Date Fair Value |
|--------------------------------|-------------|---|
| Nonvested at January 1, 2021   | 7,181,901   | \$ 1.09                                       |
| Granted                        | 1,665,000   | 1.60  |
| Vested                         | (2,755,188) | 1.00  |
| Forfeited                      | (1,174,334) | 1.25  |
| Nonvested at December 31, 2021 | 4,917,379   | \$ 1.26                                       |

Total compensation cost related to nonvested awards not yet recognized is \$4,299,548 as of December 31, 2021. It is expected to be recognized over the weighted-average period of .91 years. Stock option compensation of \$3,142,708 and \$1,626,907 was recognized for the years ending December 31, 2021 and 2020, respectively.

**G. Income Taxes:**

The components of the (expense)/benefit for income taxes in the accompanying Consolidated Statements of Income are as follows:

|                       | 2021           | 2020         |
|-----------------------|----------------|--------------|
| Current:              |                |              |
| Federal               | \$ (128,795)   | \$ -         |
| State                 | (30,495)       | 18,400       |
|                       | (159,290)      | 18,400       |
| Deferred:             |                |              |
| Federal               | (3,186,135)    | 4,363,049    |
| State                 | (1,050,298)    | 1,437,982    |
|                       | (4,236,433)    | 5,801,031    |
| Tax (expense) benefit | \$ (4,395,723) | \$ 5,819,431 |

The components of the expense (benefit) for income taxes differs from the amount that would result from applying the federal statutory rate for the years ended December 31, 2021 and 2020 as follows:

|                            | 2021         |       | 2020           |        |
|----------------------------|--------------|-------|----------------|--------|
|                            | Amount       | %     | Amount         | %      |
| Statutory tax rate         | \$ 4,210,813 | 25.3% | \$ (1,034,107) | 25.3%  |
| Valuation allowance change | -            | 0.0%  | (5,016,348)    | 122.7% |
| Permanent differences      | 184,910      | 1.1%  | 231,024        | -5.7%  |
|                            | \$ 4,395,723 | 26.4% | \$ (5,819,431) | 142.4% |



The temporary differences which give rise to deferred tax assets and (liabilities) at December 31 are as follows:

|  | <u>2021</u>         | <u>2020</u>         |
|--|---------------------|---------------------|
| Accelerated depreciation                         | \$ (112,353)        | \$ (2,694)          |
| Other assets                                     | (2,241,065)         | (1,802,164)         |
| Charitable contribution carryovers               | 91,556              | 168,464             |
| Stock option compensation                        | 895,468             | 550,146             |
| Research and development tax credit carryforward | 20,103              | 243,367             |
| NOL carryforward                                 | 2,910,889           | 6,643,912           |
| Net deferred tax asset                           | <u>\$ 1,564,598</u> | <u>\$ 5,801,031</u> |

The decrease in the valuation allowance was approximately \$0 and \$5,016,000 for the years ended December 31, 2021 and 2020, respectively.

As required by FASB ASC 740 the Company has evaluated the positive and negative evidence bearing upon the realization of its net deferred tax assets. The Company has determined that, at this time, it is more likely than not that the Company will realize all of the benefits of federal and state net deferred tax assets, and, as a result, the established valuation allowance was removed in 2020. The research and development tax credit carryforwards and NOL carryforwards generated through December 31, 2021, of approximately \$20,000 and \$10,650,000, respectively, expire at various time through 2038. Pursuant to the Tax Cuts and Jobs Act, any of the Company's newly generated Federal NOL carryforwards can be carried forward indefinitely, while being limited to 80% of taxable income (determined without regard to the deduction). The Company had a change of control during 2015, which limits the amount of Federal NOL that can be used per year going forward from the NOLs created prior to the change in control. The Company is currently open to audit under the statute of limitations by the Internal Revenue Service for the years ended December 31, 2018 through December 31, 2021. The Company has no uncertain tax positions. As of December 31, 2021, and 2020 there is no accrual for interest or penalties related to uncertain tax positions.

#### **H. Pension Plan:**

The Company partners with a professional employer organization to offer a defined contribution retirement plan. All employees are eligible to participate and receive a 3% non-elective company contribution beginning after 90 days of employment on the first day of the subsequent quarter. Company contributions totaled \$120,377 and \$110,258 for the years ended December 31, 2021 and 2020, respectively.

#### **I. Line of Credit:**

The Company has a line of credit with a borrowing capacity of \$1,000,000 at an interest rate of greater of 5.375% or Bank Prime plus 1.125%. The interest rate at December 31, 2021 and 2020 was 5.375%. The line of credit had a balance of \$0 and \$403,996 at December 31, 2021 and 2020.

This line of credit was secured by all the business assets of the Company and certain of the personal assets of Richard Uhlig, the Company's Chairman and CEO. As compensation, Richard Uhlig received 6,480,683 stock options in 2018 with a value of \$1,555,364 based on the Black-Scholes model calculation.

**J. Paycheck Protection Plan Loan:**

During April 2020, the Company applied for and received a Paycheck Protection Program Loan of \$755,600 as created by the C.A.R.E.S Act and a EIDL advance grant of \$10,000. The loan is eligible for forgiveness which the company applied for and received in January 2021.

The AICPA has issued TQA 3200.18 outlining treatment options of the PPP loan by non-governmental entities, and the Staff of the Office of the Chief Accountant of the SEC have indicated they would not object to an SEC registrant accounting for a PPP loan under either option. These options include treating the amount as a loan in accordance with FASB ASC 470 and accruing interest in accordance with FASB ASC 835-30, or as a government grant by analogy to International Accounting Standard (IAS) 20, Accounting for Government Grants and Disclosure of Government Assistance.

The Company has elected to treat the PPP loan as a government grant under IAS 20 utilizing the option provided by AICPA TQA 3200.18. Under this treatment, income is recognized as the funds are spent. All funds from the PPP loan were spent as of June 30, 2020.

**K. Long-Term Debt:**

Long-term debt including accrued interest consists of the following as of December 31:

|   | <u>2021</u>         | <u>2020</u>         |
|---|---------------------|---------------------|
| Loan from VEP Biotech Ltd, with a maturity date of October 2023, an interest rate of 5%, and no required payment of principal or interest until maturity. | \$ 5,837,124        | \$ 5,555,858        |
| Convertible debt, with a maturity of August 2025, an interest rate of 6% and no required payment of principal or interest until maturity or conversion.   | 437,237             | -                   |
| SBA Economic Injury Disaster loan, with a maturity date of May 2050, an interest rate of 3.75%, and payments of \$731 beginning in May 2022               | <u>159,046</u>      | <u>153,421</u>      |
|   | 6,433,407           | 5,709,279           |
| Less: current portion   | <u>5,848</u>        | <u>1,708</u>        |
|   | <u>\$ 6,427,559</u> | <u>\$ 5,707,571</u> |

Future minimum annual debt payments subsequent to 2022 are as follows:

|                |           |                  |
|----------------|-----------|------------------|
| 2023           | \$        | 5,845,896        |
| 2024           |           | 8,772            |
| 2025           |           | 446,009          |
| 2026           |           | 8,772            |
| 2027 and after |           | <u>118,110</u>   |
|                | <u>\$</u> | <u>6,427,559</u> |

Accrued interest included in the outstanding loan balance due to VEP Biotech, Ltd. was \$837,124 and \$555,858 for the years ending December 31, 2021 and 2020, respectively.

Accrued interest included in the outstanding loan balance due to the SBA was \$9,046 and \$3,421 for the years ending December 31, 2021 and 2020, respectively.

Accrued interest included in the outstanding loan balance due convertible debt holders was \$20,609 for the year ended December 31, 2021.

Convertible debt is convertible to common stock upon qualified financing, maturity or change in control the conversion is based upon the most recent price per share multiplied by 0.8.

**L. Concentration of Credit Risk:**

The Company may, at times, have cash on deposit in financial institutions in excess of FDIC or NCUA insured amounts.

**M. Reclassification:**

Certain accounts in the prior-year financial statements have been reclassified for comparative purposes in order to conform with the presentation in the current year consolidated financial statements.

**N. Industry Segment Data:**

The Company's primary business segments involve the operation of Quadrant Biosciences Inc, Quadrant Laboratories LLC, and Quadrant Viral Testing LLC. Quadrant Biosciences Inc researches, designs, and develops technological tools to identify epigenetic and functional disorders resulting from neurodegeneration and brain trauma, and pooled saliva detection services for the coronavirus disease. Quadrant Laboratories LLC operates and administers clinical laboratories which process COVID-19 testing kits. Quadrant Viral Testing LLC sells COVID-19 testing kits to certified laboratories and sells and operates wastewater detection services for coronavirus disease.

**O. Legal Matters:**

None.

**P. Coronavirus (COVID-19):**

During 2020 due to the onset of the COVID-19 pandemic, the Company took actions to limit and mitigate any potential negative financial impact. Additionally, during 2020 the Company applied for and received relief from Federal stimulus programs, including the Paycheck Protection Program and the Economic Injury Disaster Loan Program.

Throughout 2021 and into 2022 there continues to be uncertainty related to COVID-19 for the Company, particularly as it relates to the Company's Clarifi COVID-19 business line. Globally, the continued uncertainty is caused by new COVID-19 variants, public health policy and regulations, and supply chain constraints.

**Q. Subsequent Events:**

The Company has evaluated subsequent events through April 1, 2022, the date which the financial statements were available for issue.

## SIGNATURES

Pursuant to the requirements of Regulation Crowdfunding, the issuer has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Registrant

*Quadrant Biosciences Inc.*

Date: May 2, 2022

By: /s/ Richard Uhlig

Richard Uhlig

Chief Executive Officer

Pursuant to the requirements of Regulation Crowdfunding, this report has been signed below by the following persons on behalf of the issuer and in the capacities and on the dates indicated.

/s/ Richard Uhlig

Richard Uhlig

Chief Executive Officer, Chairman

Date: May 2, 2022

/s/ Richard Bongo

Richard Bongo

Chief Financial Officer, Principal Accounting Officer, Director

Date: May 2, 2022

/s/ James Croke

James Croke

Director

Date: May 2, 2022

/s/ Peter Cohen

Peter Cohen

Director

Date: May 2, 2022

/s/ Ira Fedder

Ira Fedder MD

Director

Date: May 2, 2022

/s/ Andrew Rock

Andrew Rock

Director

Date: May 2, 2022

/s/ Mary Ann Tyszko

Mary Ann Tyszko

Director

Date: May 2, 2022