

## ANNUAL REPORT

Quadrant Biosciences Inc.



505 Irving Avenue, Suite 3100AB

Syracuse, NY 13210

315-614-2325

[www.quadrantbiosciences.com](http://www.quadrantbiosciences.com)

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, 2022. 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

### SUMMARY

#### Overview

Quadrant Biosciences Inc. is a healthcare company dedicated to improving the lives of children and families by delivering innovative diagnostic, therapeutic, and virtual care solutions for global health priorities.

Quadrant is comprised of five business units:

- Quadrant Laboratories. Quadrant Laboratories (“QLabs”) engages in the research, development and commercialization of molecular diagnostics for certain public health priorities, including Autism Spectrum Disorder (“ASD”), mild-traumatic brain injuries (“mTBI”), Parkinson’s Disease (“PD”) and others. QLABS conducts business through two wholly-owned subsidiaries of Quadrant, Quadrant Laboratories LLC and Quadrant Viral Testing LLC.
- Quadrant Wastewater Solutions. Quadrant Wastewater Solutions (“QWS”) provides communities throughout the northeastern United States and the New York State Department of Health (“NYSDOH”) with weekly wastewater surveillance reporting on the presence and relative abundance of the SARS-CoV-2 virus in wastewater sampled from municipal treatment facilities; additionally, QWS facilitates testing for other human pathogens. QWS conducts business through Quadrant Viral Testing LLC.
- As You Are. As You Are (“AYA”) is a virtual pediatric clinic which provides autism diagnostic evaluations for children 16 months to 10 years of age through telehealth appointments. AYA conducts business through two wholly-owned subsidiaries of Quadrant, Quadrant Medical Staffing LLC and Quadrant Virtual Care Management LLC; Quadrant Virtual Care Management LLC provides management services to As You Are Physicians P.C., which employs physicians and leases those physicians to the billing entities, which along with As You Are Physicians P.C. are variable interest entities.
- Frazier Behavioral Health. Frazier Behavioral Health (“FBH”) delivers individualized therapy for neurodiverse children and adults with behavioral, social, communication, daily living, and educational deficits. FBH conducts business through the wholly-owned subsidiary of Quadrant, Frazier Behavioral Health LLC.
- Autism Analytica. Autism Analytica (“AA”) develops commercial software designed to facilitate the early identification of children on the autism spectrum, predict the type and frequency of services needed, and monitor a child’s progress through treatment over time. AA conducts business through the wholly-owned subsidiary of Quadrant, Autism Analytica LLC.

#### Our Business Units

##### Quadrant Laboratories “QLabs”

QLabs owns and operates a research and development laboratory and a clinical laboratory.

##### *Research and Development Laboratory:*

Quadrant Laboratories strives to improve diagnostic accuracy and patient access through the research, development, and commercial implementation of novel molecular assays for both clinical and public health applications. Our lab has expertise in AI/machine-learning-based discoveries derived from patient phenotypic and genetic/multi-omic next generation sequencing data.

Our current tests include, Clarifi ASD, an easy to administer, non-invasive, molecular test that improves the specificity of tests that are used to screen for Autism Spectrum Disorder (“ASD”). ASD 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. 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. However, during that time 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. In 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. The company is planning to re-validate Clarifi ASD and launch Clarifi ASD as a single lab LDT in all 50 states during the fourth quarter of 2023.

In addition to the Clarifi ASD diagnostic test being developed, the company plans to offer a comprehensive panel of genetic tests built on whole-exome sequencing using saliva samples to increase access to this type of testing. Genetic tests are primarily not to diagnose autism, but to serve as an adjunct after an autism diagnosis to better understand the condition as well as related comorbidities, and create a more targeted treatment. The genetic tests launched via a reference lab in the fourth quarter of 2022 while the company seeks approval for an in-house developed assay through the New York State Department of Health as a Laboratory Developed Test (expected in mid-2023).

Outside of the work focused on autism, the company continues to build its research pipeline. This work includes the exploration of ways to further monetize existing products and processes. The company remains actively engaged in ongoing clinical research to develop a molecular diagnostic aid for mild traumatic brain injuries (mTBI); this work leverages the proprietary methods and intellectual property developed for Clarifi ASD. For mTBI, certain saliva-based biomarkers show promise for identifying the injury while others predict which patients will have persistent post-concussion symptoms. In September of 2020, the company received a \$2.3 million Small Business Technology Transfer ("STTR") grant from the National Institute of Health ("NIH") related to this project, with the second phase of the grant anticipated to begin in 2023. The company anticipates launching a laboratory developed test in mid-2024. We also hope to continue to materially expand our research and development pipeline to include attention deficit/ hyperactivity disorder ("ADD/ADHD"), depression, and diabetes, among other medical conditions.

#### *Clinical Laboratories:*

The company's laboratory located on the SUNY Upstate Syracuse campus is certified under the Clinical Laboratory Improvement Amendment (Federal) / Clinic Laboratory Evaluation Program (New York State) ("CLIA/CLEP"). See "— Regulation -- New York State Department of Health - Clinical Laboratory Evaluation Program and CLIA" below. The processing of COVID-19 tests by the clinical laboratories was the primary revenue generating activity in 2022. The clinical laboratory will expand into additional types of testing as new products are developed; see "Research and Development Laboratory" above.

#### *Specimens:*

Through our laboratory work QLABS has curated and owns one of the world's largest biobanks, including over 615,000 saliva specimens from over 160,000 unique individuals. Specimens included in this biobank are appropriate for genetic and multi-omic discovery. These specimens, along with associated de-identified patient data, will allow QLABS to materially expand its research and development pipeline to include ADHD, Depression and Diabetes, among other medical conditions.

Additionally, the company believes that it will be able to sell some of the specimens in order to help fund the company and its initiatives. The company began marketing its specimens at the end of March 2023 and believes that it will be able to sell them for significantly more than they are currently valued on the balance sheet, which currently is at cost.

#### Quadrant Wastewater Solutions

QWS provides communities throughout the northeastern United States and the New York State Department of Health with weekly wastewater surveillance reporting on the presence and relative abundance of the SARS-CoV-2 virus in wastewater sampled from municipal treatment facilities. 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. As of March 20, 2023, QWS provided these services for approximately 90% of all counties in New York State. Additionally, QWS facilitates additional testing by the NYSDOH (including the phylogenetic classification of SARS-CoV-2 variants and genetic testing for other human pathogens) by providing extracted RNA from wastewater samples. Beginning in August 2023, QWS anticipates beginning in-house testing for additional human pathogens, including Norovirus, Hepatitis A, Flu A/B and RSV; concurrently, QWS will continue to provide extracted RNA to NYSDOH for the detection of Polio and potentially other human pathogens.

#### As You Are

AYA is a virtual pediatric clinic which provides autism diagnostic evaluations for children 16 months to 10 years of age through telehealth appointments; AYA's diagnostic process is facilitated by its proprietary evidence-based medicine platform. As of the date of this Annual Report, AYA serves children and families in 21 states including California, Utah, Maryland, Louisiana, Iowa, Missouri, Montana, Oklahoma, Tennessee, Utah, Vermont, Washington, New York, New Jersey, Texas, Florida, Alabama, Georgia, Kentucky, Ohio, and Pennsylvania; AYA expects to provide services in all 50 states by year-end 2023. AYA began seeing patients in August 2022 and as of April 21, 2023 has provided diagnoses for nearly 1,500 children. Following a diagnosis, families can choose to be paired with a dedicated AYA care coordinator who connects families with resources in their area and provides ongoing support to help children flourish. In each state of operation, AYA accepts nearly all major insurances, including state Medicaid plans.

#### Frazier Behavioral Health

FBH delivers individualized therapy for neurodiverse children and adults with behavioral, social, communication, daily living, and educational deficits; their mission is to assist these individuals in becoming their best selves and create enhanced outcomes at home, at school and in the community. From their clinic in Cleveland, Ohio, and other locations convenient for patients, FBH provides evidence-based therapies and intervention strategies for children and adults with autism, ADD/ADHD, and other developmental conditions. As of March 20, 2023, FBH employs over 30 clinicians providing behavioral health services, including Applied Behavioral Analysis therapy ("ABA"), speech/language therapy ("SLT"), psychological evaluations, education interventions, and other support services.

#### Autism Analytica

AA develops commercial software designed to facilitate the evaluation of cognitive and behavioral functions in children, adolescents, and young adults with a broad range of neurodevelopmental and neurobehavioral challenges, including children without a specific neuropsychiatric diagnosis. One specific focus is to use informant-report and webcam-collected measures to aid in the accurate early identification of children on the autism spectrum, predict the type and frequency of services needed, and monitor a child's progress through treatment over time. Another specific focus is to measure a broad range of neurobehavioral functions that can be used to screen, monitor, and inform intervention strategies for children receiving psychosocial or medical interventions. AA's initial offerings will be comprised of:

- clinical decisions support software, inclusive of ten parent/caregiver-completed, clinically validated, measures of a child's strengths and challenges and the clinical compilation of these results ("Virtual IPM"), and

- an objective, webcam-collected set of measures which utilizes gaze tracking, automated facial expression coding, proprietary stimuli, and AI/machine-learning algorithms to augment clinical decision making relative to ASD (“Neuro IPM”).

AA software is designed for use by clinicians and behavioral health specialists for evaluating and monitoring developmental and intervention progress in children with a range of neurodevelopmental and neuropsychiatric challenges. The first commercial application of Neuro IPM is expected in July 2023. The combination of Virtual IPM and Neuro IPM is scheduled to be the subject of a clinical trial sponsored by Magellan Health, Inc., a subsidiary of the fifth largest health insurance company in the US.

### **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, and one patent issued in Australia in 2023, with claims covering an epigenetic test to aid in the diagnosis of Autism Spectrum Disorder

One patent issued in 2022 in the US with claims covering an epigenetic test to aid in the diagnosis of mild traumatic brain injury

- 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
2022	\$ 50,000	\$ 25,000	\$ 10,000
2023	\$ 50,000	\$ 25,000	\$ 10,000
2024	\$ 50,000	\$ 25,000	\$ 10,000
2025	\$ 50,000	\$ 25,000	\$ 25,000
2026 through expiration (estimated to be 2038)	\$ 50,000	\$ 25,000	\$ 25,000

The total estimated payments going forward, assuming the company pays the minimum royalty payment through expiration (estimated to be 2038), for the ASD, Parkinson's and TBI Licenses are \$800,000, \$400,000 and \$370,000, 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 for Quadrant's payment of a royalty consistent with the terms of the saliva agreement above. 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 2022 and 2021, the company incurred royalty expense due to SUNY RF of \$2,868,377 and \$7,833,833, 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 four granted and 23 pending patent applications. Issued patents are US 11,242,563 B2, issued February 8, 2022, KR 10-2359013, issued January 28, 2022, and AU 2018237366, issued March 23, 2023, each entitled Analysis of Autism Spectrum Disorder, as well as US 11,453,914 B2, issued September 27, 2022, entitled Analysis and Prediction of Traumatic Brain Injury and Concussion Symptoms. The pending patent applications as of April 2023, 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; 4 applications: Japan, 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; 6 national applications: Japan, Australia, European Patent Convention, Canada, Republic of Korea, and New Zealand
- Methods of determining the probability that a patient is affected by Parkinson’s Disease, using RNA biomarkers obtained from saliva, 2 applications: US and European Patent Convention
- 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; 4 applications: US, Japan, Canada, and the European Patent Convention
- Methods of normalizing micro RNA (miRNA) biomarkers to account for circadian variations in any testing process based on differentially expressed miRNAs; 4 national application: 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” and, “filed and pending”) follows:

- Registered – i.e. the certificate of registration has been issued and is in force: Brazil (2 classes), China (2 classes), European Union, Great Britain, Hong Kong, Indonesia, India, Japan, Korea, Malaysia, Norway, New Zealand, Saudi Arabia (3 classes), Singapore, Switzerland, Taiwan (3 classes), United Arab Emirates (3 classes), 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.): Malaysia (pending), Canada (pending).

A filing with the USPTO was made to include the Clarifi word mark, which remains pending.

Quadrant has filed three additional applications following the addition of new business lines. All applications are currently classified as filed and pending/allowed using the definitions above. The details of these efforts follows:

- 1 filed and pending/allowed application for the word mark “Frazier Behavioral Health”
- 1 filed and pending/allowed application for the word mark “As You Are” and 1 filed and pending/allowed application for the design mark relating to “As You Are Pediatric Evaluations”

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

Thomas Frazier, PhD, has three registered US Copyrights relating to Autism Diagnosis, which Quadrant has a right to use in certain instances.

### **Market – Autism Spectrum Disorder**

The target market for our AYA, AA, and certain QLABS products are children who, based on clinical observations, have or are at risk to have Autism Spectrum Disorder. 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.

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

- As of 2020, approximately 1 in 36 children has been identified with Autism Spectrum Disorder according to the most recent estimates from CDC’s Autism and Developmental Disabilities Monitoring (“ADDM”) Network (2023).
- 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; in 2018 the prevalence was 1 in 44; and in 2020 the prevalence was 1 in 36.
- 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%.

See below for further market analysis of each business line.



## **Quadrant Laboratories**

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; see “Market - Autism Spectrum Disorder” above.

### 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.

### 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.

### **Market – Wastewater Solutions**

As individual COVID-19 testing wanes, wastewater testing offers a solution, where large scale testing is performed to monitor community COVID trends as an early-warning system for public health officials. Additionally, the Company has processed samples of Polio, Norovirus, Monkeypox, Hepatitis A, Flu A/B, and RSV. Quadrant has also variant sequenced COVID samples to determine variants and level of each in a community. Our proprietary wastewater surveillance technology is believed to be an order of magnitude more sensitive than our nearest competitor and is estimated to be able to detect 1 COVID case in a population of 10,000. Wastewater Surveillance testing informs policy decisions for Universities, Municipalities, Counties, States Prompts changes in targeted testing frequency and strategies Currently, QWS has provided public health surveillance across the northeastern United States.

### **Market – AYA**

For AYA, 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; see “Market - Autism Spectrum Disorder” above. A commentary released in 2021 in *Autism Research*, written by many world-renowned expert autism clinicians and researchers, urged clinicians to shift the ASD evaluation process to a more adaptable, sustainable and family-centered system of care in order to truly provide families with answers and access to needed intervention services. Telehealth diagnostic models and training pediatricians to better identify children with ASD were two suggested approaches highlighted by this panel of experts to rapidly improve diagnostic practices across the US. A McKinsey study showed that during the COVID-19 pandemic the use of telehealth grew, peaking in April 2020 but has since stabilized with approximately 40% of telemedicine users believing that they will continue to use telehealth at greater or similar levels as during the pandemic.

### **Market – AA**

For AA, we believe our target market is a combination of (i) clinicians and healthcare organizations engaged in providing behavioral health services to children and (ii) health insurance companies. In both cases, AA software products are intended to improve patient outcomes, streamline clinical workflows and reduce overall costs. The market for behavioral health services related to neurodevelopmental challenges is estimated below (see “Market - Behavioral Health Services for neurodevelopmental challenges”); the market for software related to the behavioral health services business is a fraction of the overall behavioral health services market.

### **Market – Behavioral Health Services for Neurodevelopmental Challenges**

The global neurodevelopmental challenges treatment market is projected to grow from \$1.93 billion in 2022 to \$3.17 billion by 2029, at a compound annual growth rate of 7.4%.

### **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, traumatic brain injury, and Parkinson’s Disease. As evidenced by the wait times for ASD evaluations there is a need for additional autism diagnostic opportunities and the Company believes that a telemedicine model geared specifically towards ASD will fill this void. 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.

The Company's biobank is believed to be the fourth largest in the world with over 615,000 samples. The Company expects competition from primarily commercial biobanks, of which 23andME and Regeneron are the largest commercial biobanks in the world.

FBH competes with other local therapy providers.

### **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 and testing for state and local entities of New York State. Revenue derived from AYA and FBH are from providing services to individuals and are predominantly reimbursed via commercial insurance, including Medicaid.

### **Research and Development**

The amount expensed for research and development for the year ended December 31, 2022 was \$1,018,519 and for the year ended December 31, 2021 was \$206,092.

### **Employees**

As of December 31, 2022, 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***

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.

#### 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 healthcare 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.

Our Syracuse Lab currently holds a NYSDOH clinical laboratory permit, meets CLIA accreditation requirements and has been assigned a CLIA number. The laboratory has demonstrated 100% scores in proficiency testing performance over the last four required testing cycles. The laboratory also conducts periodic internal audits to further review and refine processes consistent with applicable standards. The laboratory is permitted to accept clinical specimens for testing in all 50 states.

### *Specimens*

Specifically related to our biobank, we are engaged in ongoing privacy compliance and oversight efforts, including in connection with the requirements of numerous local, state, and federal laws, rules, and regulations relating to the privacy and security of directly or indirectly identifiable personal information (collectively, "Data Protection Laws"). Such Data Protection Laws address the collection, storage, sharing, use, disclosure, processing, transferring, and protection of personal information, including genetic information, and evolve frequently in scope and enforcement. There can also be uncertainty, differing interpretations, and contradictory requirements across the privacy and security legal and regulatory landscape. The Company also expects new Data Protection Laws to be proposed and enacted in the future and current Data Protection Laws to evolve frequently through new legislation and amendments to existing legislation

and changes in enforcement. The effects of such changes may be inconsistent from one jurisdiction to another, and potentially far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses.

### ***Medical and Behavioral Health Practices***

#### *Provider Licensing and Related Laws and Guidelines*

The practice of medicine is subject to various federal, state and local certification and licensing laws, regulations, approvals and standards, relating to, among other things, the adequacy of medical care, the practice of medicine (including the provision of remote care), equipment, personnel, operating policies and procedures and the prerequisites for the prescription of medication and ordering of tests. In particular for FBH, we are subject to the rules of Ohio and for AYA we are subject to all the areas in which patients are located and further, since AYA is digital care application of some of these laws to digital care is unclear and subject to differing interpretations.

Specifically for AYA, Physicians who provide professional medical services to a patient via digital care must, in most instances, hold a valid license to practice medicine in the state in which the patient is located. We have established systems for ensuring that our affiliated physicians and other clinicians are appropriately licensed under applicable state law and, to the extent applicable, that their provision of digital care to patients occurs in each instance in compliance with applicable rules governing the practice of medicine/digital care. Failure to comply with these laws and regulations could result in licensure actions against the physicians, our services being found to be non-reimbursable, or prior payments being subject to recoupments and can give rise to civil, criminal or administrative penalties.

#### *Telehealth*

As AYA is a virtual medical practice, our operations are subject to comprehensive United States federal, state and local regulations in the jurisdictions in which we do business. Our ability to operate profitably will depend, in part, upon our ability to maintain all necessary licenses and to operate in compliance with applicable laws and rules. Because the widespread use of telemedicine is a relatively new development in the field of medicine, those laws and rules continue to evolve, and we therefore devote significant resources to monitoring developments in healthcare and medical practice regulation. As the applicable laws and rules change, we are likely to make conforming modifications in our business processes from time to time. In some jurisdictions where we operate, neither our current nor our anticipated business model has been the subject of formal judicial or administrative interpretation. We cannot be assured that a review of our business by courts or regulatory authorities will not result in determinations that could adversely affect our operations or that the healthcare regulatory environment will not change in a way that impacts our operations.

In response to the COVID-19 pandemic, state and federal regulatory authorities loosened or removed a number of regulatory requirements in order to increase the availability of digital care services. For example, many state governors issued executive orders permitting physicians and other healthcare professionals to practice in their state without any additional licensure or by using a temporary, expedited or abbreviated licensure process so long as they hold a valid license in another state. In addition, changes were made to the Medicare and Medicaid programs (through waivers and other regulatory authority) to increase access to digital care services by, among other things, increasing reimbursement, permitting the enrollment of out of state providers and eliminating prior authorization requirements. Legislation that passed at the end of 2022 will extend most Medicare reimbursement flexibilities through December 31, 2024 and we anticipate many Medicaid agencies will follow suit. This extension includes a waiver for geographic site restrictions (patients may be located at home).

We believe that a return to the status quo would not have a material negative impact on any commercial agreements we have entered into.

#### *Corporate Practice of Medicine Laws in the U.S.; Fee Splitting*

We contract with physicians or physician-owned professional associations and professional corporations to provide access to the platform and management services. We have entered into management services contracts with Quadrant-

affiliated entities pursuant to which we provide them with billing, scheduling and a wide range of other administrative and management services, and they pay us for those services via management and other service fees. These contractual relationships are subject to various state laws, including those of New Jersey, Pennsylvania, New York, Texas, Michigan and California, that prohibit fee splitting or the practice of medicine by lay entities or persons and that are intended to prevent unlicensed persons from interfering with or influencing a physician's professional judgment. Activities other than those directly related to the delivery of healthcare may be considered an element of the practice of medicine in many states. Under the corporate practice of medicine restrictions of certain states, decisions and activities such as scheduling, contracting, setting rates and the hiring and management of non-clinical personnel may implicate the restrictions on the corporate practice of medicine.

State corporate practice of medicine and fee splitting laws and rules vary from state to state and are not always consistent among states. In addition, these requirements are subject to broad interpretation and enforcement by state regulators. Some of these requirements may apply to us even if we do not have a physical presence in the state, based solely on our engagement of a provider licensed in the state or the provision of digital care to a resident of the state. Thus, regulatory authorities or other parties, including our providers, may assert that, despite these arrangements, we are engaged in the corporate practice of medicine or that our contractual arrangements with affiliated physician groups constitute unlawful fee splitting. In such event, failure to comply could lead to adverse judicial or administrative action against us and/or our affiliated providers, civil, criminal or administrative penalties, receipt of cease-and-desist orders from state regulators, loss of provider licenses, the need to make changes to the terms of engagement of our providers that interfere with our business, and other materially adverse consequences.

#### *U.S. Federal and State Fraud and Abuse Laws*

##### *Federal Stark Law*

We are subject to the federal self-referral prohibitions, commonly known as the Stark Law. Where applicable, this law prohibits a physician from referring Medicare patients for "designated health services" such as laboratory and radiology services that are furnished at an entity if the physician or a member of such physician's immediate family has a "financial relationship" with the entity, unless an exception applies. Sanctions for violating the Stark Law include treble damages (three times the amount of the claim submitted), denial of payment, civil monetary penalties, and exclusion from the federal health care programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the False Claims Act ("FCA"). The FCA also provides for an additional penalty of \$13,508 to \$27,018 per claim submitted in violation of the Act for 2023. The Stark Law is a strict liability statute, which means proof of specific intent to violate the law is not required. In addition, the government and some courts have taken the position that claims presented in violation of the various statutes, including the Stark Law, can be considered a violation of the federal False Claims Act (described below) based on the contention that a provider impliedly certifies compliance with all applicable laws, regulations and other rules when submitting claims for reimbursement. A determination of liability under the Stark Law could have a material adverse effect on our business, financial condition and results of operations.



### *Federal Anti-Kickback Statute*

We are also subject to the federal Anti-Kickback Statute. The Anti-Kickback Statute is broadly worded and prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person covered by Medicare, Medicaid or other governmental programs, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs or (iii) the purchasing, leasing or ordering or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other governmental programs. Certain federal courts have held that the Anti-Kickback Statute can be violated if “one purpose” of a payment is to induce referrals. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation, making it easier for the government to prove that a defendant had the requisite state of mind or “scienter” required for a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act, as discussed below. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations of the Federal Anti-Kickback Statute can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. Imposition of any of these remedies could have a material adverse effect on our business, financial condition and results of operations. In addition to a few statutory exceptions, the HHS Office of Inspector General (“OIG”) has published safe-harbor regulations that outline categories of activities that are deemed protected from prosecution under the Anti-Kickback Statute provided all applicable criteria are met. The failure of a financial relationship to meet all of the applicable safe harbor criteria does not necessarily mean that the particular arrangement violates the Anti-Kickback Statute. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

Although we believe that our arrangements with physicians and other referral sources comply with current law and available interpretative guidance, as a practical matter, it is not always possible to structure our arrangements so as to fall squarely within an available safe harbor. Where that is the case, we cannot guarantee that applicable regulatory authorities will determine these financial arrangements do not violate the Anti-Kickback Statute or other applicable laws, including state anti-kickback laws.

### *False Claims Act*

Both federal and state government agencies have continued civil and criminal enforcement efforts as part of numerous ongoing investigations of healthcare companies and their executives and managers. Although there are a number of civil and criminal statutes that can be applied to healthcare providers, a significant number of these investigations involve the federal False Claims Act. These investigations can be initiated not only by the government but also by a private party asserting direct knowledge of fraud. These “qui tam” whistleblower lawsuits may be initiated against any person or entity alleging such person or entity has knowingly or recklessly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or has made a false statement or used a false record to get a claim approved. In addition, the improper retention of an overpayment for 60 days or more is also a basis for a False Claim Act action, even if the claim was originally submitted appropriately. Penalties for False Claims Act violations include fines ranging from \$11,803 to \$23,607 for each false claim, plus up to three times the amount of damages sustained by the federal government. A False Claims Act violation may provide the basis for exclusion from the federally funded healthcare programs.

### *State Fraud and Abuse Laws*

Several states in which we operate, or plan to operate in, have also adopted or may adopt similar fraud, whistleblower and false claims laws as described above. The scope of these laws and the interpretations of them vary by jurisdiction

and are enforced by local courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by Medicaid programs and any third party payer, including commercial insurers or to any payer, including to funds paid out of pocket by a patient. A determination of liability under such state fraud and abuse laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

#### *Other Healthcare Laws*

HIPAA established several separate criminal penalties for making false or fraudulent claims to insurance companies and other non-governmental payers of healthcare services. Under HIPAA, these two additional federal crimes are: "Healthcare Fraud" and "False Statements Relating to Healthcare Matters". The Healthcare Fraud statute prohibits knowingly and recklessly executing a scheme or artifice to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from government sponsored programs. The False Statements Relating to Healthcare Matters statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact by any trick, scheme or device or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and may result in fines or imprisonment. This statute could be used by the government to assert criminal liability if a healthcare provider knowingly fails to refund an overpayment. These provisions are intended to punish some of the same conduct in the submission of claims to private payers as the federal False Claims Act covers in connection with governmental health programs.

In addition, the Civil Monetary Penalties Law imposes civil administrative sanctions for, among other violations, inappropriate billing of services to federally funded healthcare programs and employing or contracting with individuals or entities who are excluded from participation in federally funded healthcare programs. Moreover, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration, including waivers of copayments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties of up to \$10,000 for each wrongful act. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Anti-Kickback Statute and civil False Claims Act, which can impose additional penalties associated with the wrongful act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payers may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts, and statutory or common law fraud.

#### *U.S. State and Federal Health Information Privacy and Security Laws*

There are numerous U.S. federal and state laws and regulations related to the privacy and security of Personal Identifiable Health Information, including health information. In particular, The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") establishes privacy and security standards that limit the use and disclosure of protected health information ("PHI"), and require the implementation of administrative, physical, and technical safeguards to ensure the confidentiality, integrity and availability of PHI in electronic form. AYA, QLABS and FBH are all regulated as covered entities under HIPAA. Quadrant and AA are business associates of our covered entity clients (and subsidiaries) when working on behalf of covered entity clients, including but not limited to our affiliated medical groups and also when we are providing technology services to those clients via our platform. As a business associate, we are also directly regulated by HIPAA and are required to provide satisfactory written assurances to our covered entity clients through written business associate agreements that we will provide our services in accordance with HIPAA. Failure to comply with these contractual agreements could lead to loss of clients, contractual liability to our clients, and direct action by HHS, including monetary penalties.

Violations of HIPAA may result in significant civil and criminal penalties. Our management responsibilities to Quadrant include assisting it with its obligations under HIPAA's breach notification rule. Under the breach notification rule, covered entities must notify affected individuals without unreasonable delay in the case of a breach of unsecured PHI, which may compromise the privacy, security or integrity of the PHI. In addition, notification must be provided to HHS and the local media in cases where a breach affects more than 500 individuals. Breaches affecting fewer than 500 individuals must be reported to HHS on an annual basis. HIPAA also requires a business associate to notify its covered entity clients of breaches by the business associate.

State attorneys general also have the right to prosecute HIPAA violations committed against residents of their states. While HIPAA does not create a private right of action that would allow individuals to sue in civil court for a HIPAA violation, its standards have been used as the basis for the duty of care in state civil suits, such as those for negligence or recklessness in misusing personal information. In addition, HIPAA mandates that HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the Civil Monetary Penalty fine paid by the violator. In light of the HIPAA Omnibus Final Rule, recent enforcement activity, and statements from HHS, we expect increased federal and state HIPAA privacy and security enforcement efforts.

HIPAA also required HHS to adopt national standards for electronic transactions that all healthcare providers must use when submitting or receiving certain healthcare transactions electronically. On January 16, 2009, HHS released the final rule mandating that everyone covered by HIPAA must implement ICD-10 for medical coding on October 1, 2013, which was subsequently extended to October 1, 2015, and is now in effect.

Many states in which we operate and in which our patients reside also have laws that protect the privacy and security of sensitive and personal information, including health information. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, the laws of the State of California, in which we operate, are more restrictive than HIPAA. Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Not only may some of these state laws impose fines and penalties upon violators, but, unlike HIPAA, some may afford private rights of action to individuals who believe their personal information has been misused. In addition, state laws are changing rapidly, and there is discussion of a new federal privacy law or federal breach notification law, to which we may be subject.

In addition to HIPAA and state health information privacy laws, we may be subject to other state and federal privacy laws, including laws that prohibit unfair privacy and security acts or practices and deceptive statements about privacy and security and laws that place specific requirements on certain types of activities, such as data security and texting. The FTC and states' attorneys general have brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and similar state laws.

In recent years, there have been a number of well publicized data breaches involving the improper use and disclosure of personal identifiable information and PHI. Many states have responded to these incidents by enacting laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach, such as providing prompt notification of the breach to affected individuals and state officials and provide credit monitoring services and/or other relevant services to impacted individuals. In addition, under HIPAA and pursuant to the related contracts that we enter into with our clients who are covered entities, we must report breaches of unsecured PHI to our clients following discovery of the breach. Notification must also be made in certain circumstances to affected individuals, federal authorities and others.

## **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 numerous office and lab spaces, the material leases including spaces 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), (iii) San Antonio, Texas in a commercial office building, (iv) Mayfield Heights, Ohio in a commercial office building. The lease for laboratory and office space at the University of Buffalo expired in February 2022. All other office and laboratory space rentals are on a month-to-month basis. Additionally, the Company has entered into two finance leases for laboratory equipment in Syracuse, New York, with payments through October 2025. The Company is in process of negotiating lease extensions and the Company expects our month-to-month lease contracts for our office space in Syracuse and Buffalo to continue with similar terms. During the years ended December 31, 2022 and 2021, rent expenses were recognized associated with operating and finance leases as fixed rent expense of \$425,350 and \$147,797 respectively.

## DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES

### Directors, Executive Officers and Significant Employees

The company's executive officers, directors and significant employees as of April 1, 2023 are listed below.

Name	Current Position	Age	Date Appointed to Current Position	Approximate hours per week for part-time employees
<b>Executive Officers</b>				
Richard Uhlig	Chief Executive Officer	57	August 2015	Full time
Richard Bongo	Chief Financial Officer	61	April 2018	Full time
Bryan Greene	Chief Operating Officer	41	July 2019	Full time
Erica Ash	Executive Vice President - General Counsel	33	November 2022	Full time
Nicholas Gianadda	Chief Technology Officer	41	April 2021	Full time
<b>Directors</b>				
Richard Uhlig	Chairman	57	August 2015	
Richard Bongo	Director	61	October 2017	
Peter Cohen	Director	77	April 2018	
James Croke, JD	Director	64	April 2018	
Ira Fedder, MD	Director	68	October 2017	
Andrew Rock	Director	59	August 2015	
Mary Ann Tyzsko	Director	65	August 2015	
<b>Significant Employees</b>				
Kayla Wagner, MS	Executive Vice President - Virtual Care	30	April 2022	Full time
Benjamin Perry, MS	Executive Vice President - Molecular Diagnostics	32	November 2019	Full time
Andrew Brindle	Executive Vice President Research & Development	41	April 2016	Full time
Rita Marble	Executive Vice President - Human Resources	52	June 2021	Full time
Erin Echelmeyer	Executive Vice President - Marketing and Communications	35	May 2022	Full time
Ira Fedder, MD	Executive Vice President Corporate Strategy	68	December 2021	Full time
Thomas Frazier, PhD	Executive Vice President Virtual and Clinical Care	47	May 2020	8 hours/week
Funda Suer, PhD	Executive Vice President - Clinical Diagnostics & Clinical Lab	49	September 2022	Full time
Steven Hicks, MD PhD	Chief Medical Officer	39	October 2022	10 hours/week
Karen Canestrare	Treasurer	56	May 2022	Full time
Allison Frazier	CEO Frazier Behavioral Health	44	April 2022	Full time

## **Biographies of Directors, Executive Officers and Significant Employees**

*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.

*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.

*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 and co-CEO of QLABS since August 2022. 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.

*Erica Ash*

*Executive Vice President - General Counsel*

Prior to joining Quadrant in December 2021 and being promoted to General Counsel in November 2022, Erica practiced at Husch Blackwell LLP, an AmLaw 100 law firm. Upon completion of law school at the University of Kansas, Erica joined Husch Blackwell LLP in 2019 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 hospitals and laboratories. She was also a part of various firm leadership activities, including associate recruiting and associate business development. Throughout her career, Erica has focused on healthcare. Prior to law school, from 2015-2017,

Erica worked at Taro Pharmaceuticals, interacting directly with providers. Erica obtained her J.D. from the University of Kansas.

*Kayla Wagner*

*Executive Vice President - Virtual Care*

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. Prior to her promotion to Executive Vice President - Virtual Care and CEO of As You Are, Kayla was previously the President of ASD Diagnostic Products and the VP of Product Management where Kayla led the development and commercialization of Clarifi ASD. 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*

*Executive Vice President - Molecular Diagnostics*

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 and became co-CEO of Q Labs in August 2022. Until his 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.

*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.

*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.

*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 at Pinnacle Employee Services, a high growth PEO, from July 2016-June 2021. 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 in 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.

*Erin Echelmeyer*

*Executive Vice President - Marketing and Communications*

Erin is a senior level marketing and communications strategist. Erin joined Quadrant in May 2022 with over 15 years of experience in marketing and communications. Erin has spent the majority of her career, over a decade, supporting large healthcare systems. Most recently prior to joining Quadrant, Erin worked at Hospital Corporation of America (HCA) beginning in March 2019 and left in May 2022 as the Interim VP of Marketing. Prior to HCA, Erin was the Public relations and Marketing Manager for Reston Hospital Center from January 2016-March 2019. Focused on driving growth initiatives Erin worked with hospitals and clinicians in the acute care space, leveraging expertise in marketing, digital, content, reputation and branding strategy. She has her Masters of Business Administration and Management from Webster University and a Bachelor's of Marketing, Retail Merchandising and Business Administration from Lindenwood 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, PhD*

*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.

*Funda Suer, PhD*

*Executive Vice President - Clinical Diagnostics & Clinical Lab Director*

Dr. Suer has an extensive background in genetics and genomics. Prior to joining Quadrant in March 2022, she served as the Senior Director of Reproductive and Diagnostic Genomics, Division Head of Diagnostic testing at SEMA4 Inc (June 2017-March 2022), and Clinical laboratory Director at Mount Sinai Genomics Sciences. Dr. Suer received her PhD in Medical Genetics at Gulhane Medical Academy in Turkey and completed her postdoctoral residency/fellowship training program in clinical molecular genetics at the National Institute of Health Genomic Research Institute (NIHGRI). Additionally, she is a diplomate of the American Board of Medical Genetics and Genomics (ABMGG), a fellow of the American College of Medical Genetics and Genomics (ACMG), is certified by the NYS DOH as a clinical director in molecular genetic testing and a member of the American Association of Molecular Pathology (AMP). She has overseen multiple commercial laboratories as Senior Clinical Laboratory Director and corporate brand transformations, as well as academic laboratories including Quest Diagnostics, Athena Diagnostics Laboratories, Mount Sinai Genomics Testing Laboratories. Dr. Suer previously established genetics training programs as training laboratory site director at Quest Diagnostics, and served as a program director of the ABMGG Laboratory Genetics Training Program at Mount Sinai Icahn School of Medicine, and served as Associate Professor at Mount Sinai Icahn School of Medicine, Department of Genetics and Genomics Sciences.

*Steven Hicks, MD, PhD*

*Chief Medical Officer*

Dr. Hicks is on the Clinical Advisory Board and the Chief Medical Officer of As You Are, and an Associate Professor of Academic General Pediatrics at Pennsylvania State College of Medicine in Hershey, PA. In addition to his work at As You Are and Penn State, he is a physician scientist who has served the Central Pennsylvania community as a general pediatrician at Penn State since August 2015, performing well-child check-ups, sick visits, and developmental evaluations. His clinical focus is on the early, and accurate diagnosis of autism. Dr. Hicks' interest in autism stems from his PhD training in neurogenetics. As a physician scientist, he studies the influence of genetics and the environment on pediatric diseases involving growth and neurodevelopment. Dr. Hicks has also been awarded the Outstanding Early Faculty Career Development Award from the National Association for Clinical and Translational Science, and the Distinguished Early Stage Investigator Award from the Penn State College of Medicine. Dr. Hicks has published over 50 articles in peer reviewed journals, including JAMA Pediatrics and Clinical and Translational Medicine. He completed his undergraduate degree from Marist College and completed his MD, PhD and residency at the State University of New York Upstate Medical University.

*Karen Canestrare*

*Treasurer*

Karen has 30 years of leadership experience in corporate and operations level finance and accounting in publicly and privately held organizations, as well as start-ups. Prior to joining Quadrant in June 2021, Karen's experience spans various industries including telecommunications/wireless/media, manufacturing, financial services and quick service restaurants. Karen's experience most recently prior to joining Quadrant includes serving as Director of Accounting and Treasury at JMA Wireless (March 2020-March 2021) and Corporate Manager Financial Planning & Analysis at Carrols Corporation (2018-March 2020). Throughout the span of her career, Karen's experience includes financial planning & analysis, financial reporting, merger and acquisitions, audit, treasury, key stakeholder in ERP implementations, process improvement and change management, where she has championed several change initiatives of various sizes and complexities. She has earned a certification of Leadership for Success from Dale Carnegie and has participated in various mentorship programs for Women in Technology. Karen earned her Bachelor of Science in Accounting and her Masters in Business from the Madden School of Business at Le Moyne College.

*Allison Frazier, MA, BCBA*

*CEO Frazier Behavioral Health*

Allison Frazier is a Board Certified Behavior Analyst with over 12 years experience in behavioral health. Her areas of expertise include direct behavior therapy with clients 18 months to 36 years old; private and public school consultation; parent and teacher training; community education; and clinical supervision. She previously directed the Cleveland Clinic Center for Autism (CCCA) Outreach Department and was the assistant director of their summer program. Prior to founding FBH in 2019, Allison was a school administrator and behavior specialist at the Julie Billiart Schools (JB) from August 2014-August 2019. During her tenure at JB, she founded and directed a national award winning camp. Throughout her career, she worked as an adjunct professor at John Carroll University, Ursuline College, and Lakeland Community College. Allison currently serves on the board at the Cuyahoga County Board of Developmental Disabilities.

*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*

*Director*

Jim was our General Counsel from January 2018 through November 2021. Jim continues to serve the company 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.***

In Fiscal year 2022, we once again incurred losses from operations which were approximately \$2.9 million; as of December 31, 2022, we had an accumulated deficit of approximately \$8.4 million. As anticipated, revenues related to our COVID-19 initiatives have been reduced significantly, and we anticipate these revenues may continue to decline if transmissibility or virulence of the SARS-CoV-2 virus changes or public health policy relative to the SARS-CoV-2 virus changes. As we refocus on our core mission, we have dedicated significant resources to prior initiatives (e.g., Clarifi ASD) as well as newer initiatives including telehealth and individual therapies as well as analytical tools; However, work related to AYA and FBH have only produced limited revenues. To date, our significant revenue has come from COVID-19 testing, and we expect to continue to incur significant expenses for the foreseeable future. We expect that our expenses may increase 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 and Clarifi mTBI, expand the clinical utility of the Clarifi COVID-19 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 LDT submission for additional COVID-19 products and of our other saliva-based epigenetic diagnostics in 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;
- continue to build a sales and marketing infrastructure and scale up diagnostic clinical capabilities, either through offices or through telehealth for our FBH and AYA units; 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 2022 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.

***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 overall and in its new business lines 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 a telehealth platform, 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 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 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. In addition, other companies may compete with our diagnostic, therapeutic, and virtual care solutions. 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 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 material 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 or personal health information, as defined by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) 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. The Note is due in October of 2023 and Quadrant is looking to settle any outstanding debt with the lender. Should we not be able to do so, it may have a negative impact on our financials.

***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 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 laboratory 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 facility. 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 and other intangible assets, 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.

***We may enter new business areas, such as additional primary, pediatric care services. If we were to enter new business areas, we would likely face competition from entities more familiar with those businesses, and our efforts may not succeed.***

In the future, we may expand our operations into business areas, such as additional primary, pediatric care services, additional diagnostics, and behavior modification, where we do not have any experience. These areas would be new to our product development and marketing personnel, and we cannot be assured that the markets for these products and services will develop or that we will be able to compete effectively or will generate significant revenues in these new areas making our success in this area difficult to predict. Many companies of all sizes, including major pharmaceutical companies, specialized biotechnology companies and traditional healthcare providers, are engaged in redesigning approaches to medical care and diagnostic medicine. Competitors operating in these potential new business areas may have substantially greater financial and other resources, larger research and development staff, and more experience in these business areas. There can be no assurances that if we undertake new business areas, that the market will accept our offerings, or that such offerings will generate.

***The value of our products (e.g., our specimen banks) as well as the sizes of the markets and forecasts of market growth for the demand of our products and services, including our analytical products and need for diagnostics and therapeutic services and other key potential success factors are based on a number of complex assumptions and estimates, and may be inaccurate.***

We have also developed a standard set of key performance indicators in order to enable us to value our specimen bank as well as assess the performance of our business in and across multiple markets, and to forecast future revenue. These estimates, forecasts and key performance indicators are based on a number of complex assumptions, internal and third-party estimates and other business data, including assumptions and estimates relating to our ability to

generate revenue from the development of new workflows. While we believe our assumptions and the data underlying our estimates and key performance indicators are reasonable, there are inherent challenges in measuring or forecasting such information. As a result, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors and indicators. For example, if the annual total addressable market or the potential market growth for our products and services is smaller than we have estimated or if the key business metrics we utilize to forecast revenue are inaccurate, it may impair our sales growth and have an adverse impact on our business, financial condition, results of operations and prospects.

#### **Risks Related to our clinical work at FBH and AYA**

***If we are unable to attract and retain high quality healthcare providers for our patients, our business, financial condition, and results of operations may be materially and adversely affected.***

Our success is dependent upon our continued ability to maintain a network of qualified healthcare providers, including telehealth providers for AYA. If we are unable to recruit and retain board-certified physicians and other healthcare professionals, it would adversely affect our business, financial condition, and results of operations and ability to grow. In any particular market, providers could demand higher payments or take other actions that could result in higher medical costs, less attractive service for our patients, or difficulty meeting regulatory or accreditation requirements. The failure to maintain or to secure new cost-effective provider contracts may result in a loss of or inability to grow our patient base, higher costs, less attractive service for our patients, and/or difficulty in meeting regulatory or accreditation requirements, any of which could have a material adverse effect on our business, financial condition, and results of operations.

***The telehealth market is immature and volatile, and if it does not develop, if it encounters negative publicity, or if the increased use of telehealth solutions as a result of the COVID-19 pandemic does not continue after the pandemic, then the growth of our business and our results of operation will be harmed.***

The telehealth market is relatively new and unproven, and it is uncertain whether it will achieve and sustain high levels of demand, consumer acceptance, and market adoption. The outbreak of the COVID-19 pandemic has increased utilization of telehealth services, but it is uncertain whether such increase in demand will continue. The success of our telehealth business will depend to a substantial extent on the willingness of our patients to use, and to increase the frequency and extent of their utilization of our solution, as well as on our ability to demonstrate the value of telehealth to patients. Negative publicity concerning our telehealth services, or the telehealth market as a whole, could limit market acceptance of our solution. If our telehealth patients do not perceive the benefits of our services, then our market may develop more slowly than we expect or not at all. Similarly, individual and healthcare industry concerns or negative publicity regarding patient confidentiality and privacy in the context of telehealth could limit market acceptance of our healthcare services. If any of these events occurs, it could have a material adverse effect on our business, financial condition, and results of operations.

***We depend on our relationships with physician practices, which we have through management services agreements, to provide certain administrative services, and our business could be adversely affected if those relationships were disrupted.***

In certain jurisdictions, the corporate practice of medicine doctrine generally prohibits non-physicians from practicing medicine, including by employing physicians to provide clinical services, directing the clinical practice of physicians, or holding an ownership interest in an entity that employs or contracts with physicians. Some states have similar doctrines with respect to other professional licensure categories, including behavioral health services and providers. Other practices, such as professionals splitting their professional fees with a non-professional, are also prohibited in some jurisdictions. Many states also limit the extent to which nurse practitioners can practice independently and require that they practice under the supervision of or in collaboration with a supervising physician.

Through AYA, our patients gain access to one or more licensed healthcare providers for telehealth consultations. These providers are employed by a professional entity, owned by a physician, which in turn contracts the other with professional entities owned by licensed physicians to provide telehealth consultations and related services. We enter into certain contractual arrangements with the professional entities and their provider owners, including a management services agreement with each professional entity for the exclusive provision by us of non-clinical services and support. While we expect that these relationships with each professional entity will continue, we cannot guarantee that they will. We believe that our arrangements with the professional entities have been structured to comply with applicable law and allow the healthcare providers the ability to maintain exclusive authority regarding the provision of clinical

healthcare services, but there can be no assurance that government entities or courts would find our approach to be consistent with their interpretation of, and enforcement activities or initiatives related to, these laws and the corporate practice of medicine doctrine or similar prohibitions. If our arrangements are deemed to be inconsistent with any applicable government entity's interpretation of a law or regulation prohibiting the corporate practice of medicine, a fee-splitting law, or similar regulatory prohibitions, we would need to restructure the arrangements with the professional entities to create a compliant arrangement or terminate the arrangement, and we could face fines or other penalties in connection with such arrangements. A material change in our relationships with the professional entities, whether resulting from a dispute, a change in government regulation, or enforcement patterns, a determination of non-compliance, or the loss of these agreements or business relationships, could impair our ability to provide services to our patients and could have a material adverse effect on our business, financial condition, and results of operations. Violations of the prohibition on corporate practice of medicine doctrine, fee-splitting, or similar laws may impose penalties (e.g., fines or license suspension) on healthcare providers, which could discourage professionals from entering into arrangements with the professional entities and using our management services and could result in lawsuits by providers against the professional entities and us. These laws and regulations are subject to change and enforcement based upon political, regulatory, and other influences. More restrictive treatment of healthcare professionals' relationships with non-professionals, such as our Company, in the healthcare services delivery context could have a material adverse effect on our business, financial condition, and results of operations. In addition, pending legislation in certain states (like California) could affect the structure of the arrangements.

***Any interruptions or delays in services from third parties, including our telehealth platform providers and other hardware and software vendors, or our inability to adequately plan for and manage service interruptions or infrastructure capacity requirements, could impair the delivery of our services and harm our business.***

We currently serve our telehealth customers by using an electronic health record system, with a telehealth platform built in, that is located in the United States. We also rely on computer hardware purchased or leased from, software licensed from, and cloud computing platforms provided by third parties to offer our services, including database software, hardware and data from a variety of vendors. Any damage to, or failure of our systems generally, including the systems of our third-party platform providers, could result in interruptions in our services. Interruptions in our services may cause us to lose customers, harm our ability to attract new customers, all of which would reduce our revenue. Our business would also be harmed if our customers and potential customers believe our services are unreliable.

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

***Though to date we have been able to commercialize our COVID-19 individual saliva Test Kit and our COVID-19 work in relation to pooled screening for COVID-19, the need for these tests has already been significantly reduced and may be limited in the future particularly with the ending of the Public Health Emergency in May 2023 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 when insurers are not required to pay the laboratory's cash-pay price, listed on its website, for out-of-network tests under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which sunsets with the end of the federally declared public health emergency in May 2023. 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 payers, 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, and the end of the nationally declared public health emergency, the need for some of our products in the future may be limited. Additionally, the widespread availability and free provision of rapid, home testing kits could continue to diminish the demand for laboratory testing.

***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, convenience, and speed. This includes the use of rapid antigen testing, proliferated through government subsidies to provide households with no-cost test kits. 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. Further, when the EUA declaration is no longer in effect these EUAs will be required to either obtain clearance as a laboratory designed test ("LDT") or to seek FDA approval as an in-vitro diagnostic. This process could limit our ability to market and sell our COVID-19 diagnostics.

#### **Risks Related to Government Regulation for all Businesses**

***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.

Additionally some of the software offerings being developed by Autism Analytica may require similar FDA or other regulatory clearance. In which case, the risks above would also apply.

***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.

***AA software, Neuro IPM and Virtual IPM is designed for use by clinicians and behavioral health specialists for evaluating and monitoring developmental and intervention progress in children with a range of neurodevelopmental and neuropsychiatric challenge 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.***

If the service offerings require 501(k) clearance or the FDA regulates one or more of the AA offerings 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 products 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 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 products. 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 products, we



cannot assure you that our products will be cleared or approved on a timely basis, if at all. There is also no assurance that FDA will permit marketing of our products for the clinical uses that we desire, and such limitations on marketing claims may adversely affect the adoption of and reimbursement for our products. If the FDA regulates our products, 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 laboratory 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, information related to the company's biobank, 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.

***We will face legal, reputational, and financial risks if we fail to protect our customer data from security breaches or cyberattacks. Changes in laws or regulations relating to privacy or the protection or transfer of data relating to individuals, or any actual or perceived failure by us to comply with such laws and regulations or any other obligations relating to privacy or the protection or transfer of data relating to individuals, could adversely affect our business.***

We receive and store a large volume of personally identifiable information (“PII”), genetic and protected health information (“PHI”), and other data relating to our customers and patients, as well as other PII and other data relating to individuals such as our employees. Security breaches, employee malfeasance, or human or technological error could lead to potential unauthorized disclosure of our customers’ and patients’ personal information. Even the perception that the privacy of personal information is not satisfactorily protected or does not meet regulatory requirements could inhibit sales of our solutions and any failure to comply with such laws and regulations could lead to significant fines, penalties or other liabilities. Further for our telehealth and some of our other services we rely on third party vendors and their actions and/or inactions may be attributed to us. These service providers include AWS - Amazon Web Services (hosting and database services across all business lines), Athena (EMR system & Telehealth for AYA), ReThink (EMR system for FBH), Lab Collector (LIS system for QL), Salesforce (Marketing and Notification services across all business lines), WordPress (Hosting for all marketing sites), Google Cloud Services (Email/User management), QuickBooks online (billing and accounting system) and RingCentral (Phone and Fax services across all business lines).

Increased global IT security threats and more sophisticated and targeted computer crime pose a risk to the security of our systems and networks and the confidentiality, availability, and integrity of our data. There have been several recent, highly publicized cases in which organizations of various types and sizes have reported the unauthorized disclosure of customer or other confidential information, as well as cyberattacks involving the dissemination, theft, and destruction of corporate information, intellectual property, cash, or other valuable assets. There have also been several highly publicized cases in which hackers have requested “ransom” payments in exchange for not disclosing customer or other confidential information or for not disabling the target company’s computer or other systems. A security breach or privacy violation that leads to disclosure or unauthorized use or modification of, or that prevents access to or otherwise impacts the confidentiality, security, or integrity of, sensitive, confidential, or proprietary information we or our third-party service providers maintain or otherwise process, could compel us to comply with breach notification laws, and cause us to incur significant costs for remediation, fines, penalties, notification to individuals and governmental authorities, implementation of measures intended to repair or replace systems or technology, and to prevent future occurrences, potential increases in insurance premiums, and forensic security audits or investigations. Additionally, a security compromise of our information systems or of those of businesses with whom we interact that results in confidential information being accessed by unauthorized or improper persons could harm our reputation and expose us to customer and patient attrition, and claims brought by our customers, patients, or others for breaching contractual confidentiality and security provisions or data protection laws. Monetary damages imposed on us could be significant and not covered by our liability insurance. As a result, a security breach or privacy violation could result in increased costs or loss of revenue.

Techniques used by bad actors to obtain unauthorized access, disable or degrade service, or sabotage systems evolve frequently and may not immediately produce signs of intrusion, and we may be unable to anticipate these techniques or to implement adequate preventative measures.

We have developed and maintain policies and procedures with respect to PHI and PII that we use or disclose in connection with our operations, including the adoption of administrative, physical, and technical safeguards to protect the privacy and security of such information. As our business operations continue to develop, including through the launch of new product offerings or the development of new services, we may collect additional sensitive health and personal information from our customers and patients that could create additional compliance obligations and may increase our exposure to compliance and regulatory risks regarding the protection and dissemination of such information.

In addition to HIPAA, numerous other local, municipal, state, federal, and international laws and regulations address privacy and the collection, storing, sharing, use, disclosure, and protection of certain types of data, including the California Online Privacy Protection Act, the Personal Information Protection and Electronic Documents Act, the Telephone Consumer Protection Act of 1991, or the TCPA, Section 5 of the Federal Trade Commission Act, and effective as of January 1, 2020, the CCPA. These laws, rules, and regulations evolve frequently, and their scope may continually change, through new legislation, amendments to existing legislation, and changes in enforcement, and may be inconsistent from one jurisdiction to another. For example, the CCPA, which went into effect on January 1, 2020, among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of

certain sales of personal information. The CCPA provides for fines of up to \$7,500 per violation. Aspects of the CCPA and its interpretation and enforcement remain uncertain. The effects of this legislation potentially are far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. The CCPA has been amended on multiple occasions. For example, in November 2020, the CPRA was approved by California voters and significantly modifies the CCPA, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CPRA does not become operative until January 1, 2023 (and then applies only to consumer data collected on or after January 1, 2022, (the “lookback period”), with enforcement beginning July 1, 2023. While the CCPA will remain operative and enforceable from now until July 1, 2023, we will continue to monitor developments related to the CPRA. The effects of this legislation potentially are far-reaching, however, and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. Additionally, many laws and regulations relating to privacy and the collection, storing, sharing, use, disclosure, and protection of certain types of data are subject to varying degrees of enforcement and new and changing interpretations by courts. The CCPA and other changes in laws or regulations relating to privacy, data protection, breach notifications, and information security, particularly any new or modified laws or regulations, or changes to the interpretation or enforcement of such laws or regulations, that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer, or disclosure, could greatly increase the cost of providing our platform, require significant changes to our operations, or even prevent us from providing our platform in jurisdictions in which we currently operate and in which we may operate in the future.

In the U.S., there have been proposals for federal privacy legislation and many new state privacy laws proposed. Since 2021, laws specific to genetic testing companies have passed in California, Utah, Arizona, Maryland, Kentucky and Wyoming and legislation has been proposed in other states. Other countries have enacted or are considering enacting data localization laws that require certain data to stay within their borders. We may also face audits or investigations by one or more domestic or foreign government agencies or our customers or patients pursuant to our contractual obligations relating to our compliance with these regulations. Complying with changing regulatory requirements requires us to incur substantial costs, exposes us to potential regulatory action or litigation, and may require changes to our business practices in certain jurisdictions, any of which could materially adversely affect our business operations and operating results.

Despite our efforts to comply with applicable laws, regulations, and other obligations relating to privacy, data protection, and information security, it is possible that our interpretations of the law, practices, or platform could be inconsistent with, or fail or be alleged to fail to meet all requirements of, such laws, regulations, or obligations. Our failure, or the failure by our third-party providers on our platform, to comply with applicable laws or regulations or any other obligations relating to privacy, data protection, or information security, or any compromise of security that results in unauthorized access to, or use or release of PII or other data relating to our customers and patients, or other individuals, or the perception that any of the foregoing types of failure or compromise have occurred, could damage our reputation, discourage new and existing customers and patients from using our platform, or result in fines, investigations, or proceedings by governmental agencies and private claims and litigation, any of which could adversely affect our business, financial condition, and results of operations. Even if not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition, and results of operations.

***Government regulation of healthcare creates risks and challenges with respect to our compliance efforts and our business strategies, and if we fail to comply with applicable healthcare and other governmental regulations, we could face substantial penalties, our business, financial condition, and results of operations could be adversely affected, and we may be required to restructure our operations.***

The healthcare industry is subject to changing political, economic, and regulatory influences that may affect our telehealth business. During the past several years, the healthcare industry has been subject to an increase in governmental regulation and subject to potential disruption due to legislative initiatives and government regulation, as well as judicial interpretations thereof. While these regulations may not directly impact us or our offerings in every instance, they will affect the healthcare industry as a whole and may impact patient use of our services. Failure to comply with any applicable federal, state, and local laws and regulations could have a material adverse effect on our business, financial condition, and results of operations.

Even within the narrowed band of applicable healthcare laws and regulations, because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our activities could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or

regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Although we have adopted policies and procedures designed to comply with these laws and regulations and conduct internal reviews of our compliance with these laws, our compliance is also subject to governmental review. The growth of our business and organization and our future continued expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state, and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages and fines, disgorgement, additional reporting requirements and oversight, and imprisonment for individuals, as well as contractual damages and reputational harm. We could also be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Our ability to offer access to telehealth services is subject to the applicable laws governing remote care and the practice of medicine in the applicable state jurisdiction. Interpretation and enforcement of these laws is evolving and could vary significantly. We cannot provide assurance that we have accurately interpreted each such law and regulation. Moreover, these laws and regulations may change significantly as this manner of providing products and services evolves. New or revised laws and regulations (or interpretations thereof) could have a material adverse effect on our business, financial condition, and results of operations.

***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; Stark Law; 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.

***We could be subject to the federal self-referral prohibitions, commonly known as the Stark Law.***

Where applicable, this law prohibits a physician from referring Medicare (and possibly Medicaid patients, as decided by certain jurisdictions like Florida) patients to an entity providing "designated health services" if the physician or a member of such physician's immediate family has a "financial relationship" with the entity, unless an exception applies. Included in "designated health services" are laboratory services and also speech language pathology. The penalties for

violating the Stark Law include the denial of payment for services ordered in violation of the statute, mandatory refunds of any sums paid for such services, large civil penalties for each violation, and twice the dollar value of each such service and possible exclusion from future participation in the federally funded healthcare programs. The Stark Law is a strict liability statute, which means proof of specific intent to violate the law is not required. In addition, the government and some courts have taken the position that claims presented in violation of the various statutes, including the Stark Law can be considered a violation of the federal False Claims Act based on the contention that a provider impliedly certifies compliance with all applicable laws, regulations and other rules when submitting claims for reimbursement. A determination of liability under the Stark Law could have a material adverse effect on our business, financial condition, and results of operations. In addition, many states have adopted analogous statutes that apply more broadly.

***We are also subject to the federal Anti-Kickback Statute and False Claims Act.***

The Anti-Kickback Statute is broadly worded and prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person covered by Medicare, Medicaid or other governmental programs, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs, or (iii) the purchasing, leasing, or ordering or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other governmental programs. Certain federal courts have held that the Anti-Kickback Statute can be violated if “one purpose” of a payment is to induce referrals. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation, making it easier for the government to prove that a defendant had the requisite state of mind or “scienter” required for a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act, as discussed below. Violations of the Anti-Kickback Statute can result in exclusion from Medicare, Medicaid or other governmental programs as well as civil and criminal penalties, including civil monetary penalties and criminal fines of \$100,000 per violation, and three times the amount of the unlawful remuneration, and imprisonment of up to ten years. Imposition of any of these remedies could have a material adverse effect on our business, financial condition, and results of operations. In addition to a few statutory exceptions, the HHS Office of Inspector General (“OIG”) has published safe-harbor regulations that outline categories of activities that are deemed protected from prosecution under the Anti-Kickback Statute provided all applicable criteria are met. The failure of a financial relationship to meet all of the applicable safe harbor criteria does not necessarily mean that the particular arrangement violates the Anti-Kickback Statute. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

Although there are a number of civil and criminal statutes that can be applied to healthcare providers, a significant number of these investigations involve the federal False Claims Act. These investigations can be initiated not only by the government but also by a private party asserting direct knowledge of fraud. These “qui tam” whistleblower lawsuits may be initiated against any person or entity alleging such person or entity has knowingly or recklessly presented, or caused to be presented, a false or fraudulent request for payment from the federal government or has made a false statement or used a false record to get a claim approved. In addition, the improper retention of an overpayment for 60 days or more is also a basis for a False Claim Act action, even if the claim was originally submitted appropriately. Furthermore, violations of the Stark Law and Anti-Kickback Statute can both be predicates for False Claims Act liability. Penalties for False Claims Act violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government. A False Claims Act violation may provide the basis for exclusion from the federally funded healthcare programs. In addition, some states have adopted similar fraud, whistleblower, and false claims provisions.

***Several states and foreign jurisdictions in which we operate have also adopted or may adopt similar fraud and abuse laws as described above.***

The scope of these laws and the interpretations of them vary by jurisdiction and are enforced by local courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any payor, including patients and commercial insurers, not just those reimbursed by a federally funded healthcare program. A determination of liability under such state fraud and abuse laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

***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 "Description of Capital Stock – 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, 2022, there were 89,009,360 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, 2022, 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):

Name and address of beneficial owner (1)	Number of Common Shares Owned	Number of Common Shares Acquirable (2)	Percent of ownership (3)
Richard Uhlig, Chairman and CEO	32,975,977	6,977,639	41.62%
Research Foundation for the State University of New York	5,959,241	--	6.70%
James Croke, Secretary and Director	2,020,398	3,547,491	6.02%
Richard Bongo, CFO and Director	1,204,266	3,689,669	5.28%
All Directors and Executive Officers (10 total)	40,214,466	17,401,129	54.14%
All Directors (7 total)	39,214,595	16,397,067	52.76%

(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, 2023.

(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 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**

Holders 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 traveling 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 2022 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 2023 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, 2022.

### **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 healthcare company dedicated to improving the lives of children and families by delivering innovative diagnostic, therapeutic, and virtual care solutions for global health priorities. Quadrant is comprised of five business units: Quadrant Laboratories, Quadrant Wastewater Solutions, As You Are, Frazier Behavioral Health and Autism Analytica.

The company was founded to improve the lives of children and families through the development of more accurate and timely clinical solutions for certain global health priorities; these include Autism Spectrum Disorder, mild traumatic brain injuries (or concussion injuries), Parkinson’s disease, and 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 healthcare, educational institutions, and laboratory services. In some cases, 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 Clarifi COVID-19 tests were all developed and validated in cooperation with SUNY Upstate Medical University. The company’s 2021 and 2022 financial revenues are primarily derived from its COVID-19 products and services.

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.

- 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 individuals, 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 sold over 4 million saliva based COVID-19 tests.
- Community/Municipal Wastewater Surveillance: Performing tests on municipal wastewater samples for SARS-CoV-2, principally in New York State.

In the second quarter of 2021, the company became the sole owner of two laboratories, one located on the SUNY Upstate Syracuse campus and the other on the SUNY Buffalo campus. On July 1, 2021, these two laboratories were certified under CLIA/CLEP. The acquisition and certification of the labs allowed the company to begin performing certain COVID-19 laboratory testing services that facilitated a new testing model under which the company began administering tests directly to individuals by operating testing sites beginning in the fourth quarter of 2021. During the COVID-19 surge in the first quarter of 2022 the company opened 45 community test sites in conjunction with schools and counties in New York State. There were over 100,000 tests collected at these testing sites. In accordance with the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) these tests were billed to third-party insurers. Under the CARES Act if an individual is uninsured Quadrant billed and received reimbursement as administered through Health Resources and Services Administration ("HRSA"). HRSA stopped accepting claims for testing on March 22, 2022. In-line with the national trajectory of the COVID-19 pandemic and public appetite for testing, volumes at the community test sites declined during the second quarter of 2022 and substantially all of the community test sites were closed. Additionally, due to the decline in COVID-19 testing volumes, the company closed the lab located in Buffalo, New York in July 2022.

For the cost of products sold the company not only includes the materials and shipping costs related to the products but also royalty expenses related to its products. For 2021 and 2022 the royalty payments predominantly relate to the company's exclusive license with The Research Foundation for The State University of New York for its COVID-19 products. Under the agreement through June 30, 2021, the company pays a royalty of 50% of all net income (as defined in the license). Effective July 1, 2021, the company began paying 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% until it reaches 6% for the period beginning July 1, 2022, through termination of the agreement, with certain specific exclusions.

In conjunction with the existing laboratory services, in 2022, the company began dedicating resources to improving the lives of children and families by developing a plan to deliver innovative diagnostic, therapeutic and virtual care solutions for the diagnosis and treatment of autism, attention deficit/ hyperactivity disorder ("ADD/ADHD"), and other developmental conditions. In April 2022, through the acquisition of Frazier Behavioral Health LLC ("FBH") the company began providing behavioral health services including therapies, consultation services and training in social behavior techniques and intervention strategies for children and adults with autism, ADD/ADHD, and other developmental conditions (see "Trends" below).

Additionally, during 2022, Quadrant started building a virtual telemedicine clinic focused on diagnosing autism spectrum disorder in children. The virtual care clinic launched in August 2022, under the branding “As You Are” and provides autism diagnostic evaluations for children 16 months to 10 years of age through telehealth appointments; AYA’s diagnostic process is facilitated by its proprietary evidence-based medicine platform. At the time of the launch, the virtual clinic was able to serve patients in five states and as of the date of this Annual Report serves families in 21 states including California, Utah, Maryland, Louisiana, Iowa, Missouri, Montana, Oklahoma, Tennessee, Utah, Vermont, Washington, New York, New Jersey, Texas, Florida, Alabama, Georgia, Kentucky, Ohio, and Pennsylvania. AYA conducts business through two wholly-owned subsidiaries of Quadrant, Quadrant Medical Staffing LLC and Quadrant Virtual Care Management LLC; Quadrant Virtual Care Management LLC provides management services to As You Are Physicians P.C., which employs physicians and leases those physicians to the billing entities. Those billing entities include Quadrant CA Virtual Pediatric Medical Care, PC, Quadrant MI Virtual Care PC, Quadrant NJ Virtual Care PC, Quadrant PA Virtual Care PC, and Quadrant TX Virtual Care PA. These entities are consolidated in the company’s financial statements.

## **Results of Operations**

### ***Year ended December 31, 2022 Compared to Year ended December 31, 2021***

#### *Net Revenues*

The company’s revenues consist of revenue derived from product sales, behavioral health services, product assembly, testing services, and grant revenues. The company’s total revenues for the year ended December 31, 2022 (“Fiscal 2022”) were \$36,395,155, a decrease of \$24,124,024 from total revenues of \$60,519,179 in the year ended December 31, 2021 (“Fiscal 2021”). This decrease is primarily attributable to:

- decreases in product sales (net) and product assembly of \$36,314,961 and 2,608,994, respectively, due in part to the company’s new testing model and the trajectory of the public response to the COVID-19 pandemic (see “Overview” above).
- an increase of \$14,421,305 related to testing services, which includes COVID-19 testing performed outside of the initial pooled testing included with product sales and wastewater testing. Specifically, in the fourth quarter of 2021, the company launched a new model of testing delivery (see “Overview” above).
- an increase in revenue related to behavioral health services as FBH began receiving revenue in April 2022 (see “Overview” above).
- an increase in revenue related to virtual care diagnostic services as AYA began receiving revenue in August 2022 (see “Overview” above).

Cost of products sold decreased to \$14,340,093 in Fiscal 2022, a decrease of \$19,126,145 from \$33,466,238 in Fiscal 2021, due primarily to improvements related to scaling and efficiency resulting from the acquisition of the two labs allowing for a shift from a focus on product sales to more of a focus on testing services. Accordingly, the company had gross profit of \$22,055,062 in Fiscal 2022 compared with \$27,052,941 in Fiscal 2021.

#### *Operating Expenses*

Selling and administrative expenses in Fiscal 2022 were \$22,179,592, compared to \$10,035,548 in Fiscal 2021, an increase of \$12,144,044. The increase primarily relates to the increase in employment related expenses, which includes salaries and wages, employee benefits and taxes, and stock option compensation, which collectively increased by \$8,764,369 to \$16,363,792 in Fiscal 2022 from \$7,599,423 in Fiscal 2021. The company began independently operating the clinical labs in July 2021 and from then through the first quarter of 2022, the company hired additional employees, including clinical laboratory professionals, to service the company’s COVID-19 testing and products. Additionally, the company hired a wide range of research scientists, clinicians, and support staff to facilitate the company’s new initiatives; see “Overview” above. Professional fees increased by \$1,528,828 to \$2,477,138 in Fiscal 2022 from \$948,310

in Fiscal 2021, due to services used in conjunction with the company's third-party insurance billing for COVID-19 testing services. Sales and marketing expense increased in this period by \$1,588,198 related primarily to marketing for the COVID-19 testing sites opened in the first quarter of 2022 and marketing efforts for the launch of AYA. There was also an increase in research and development expense of \$812,427 driven by the company refocusing on its research pipeline once the COVID-19 business line was established; see "Trends" below.

### Net (Loss) Income

The company had other income in Fiscal 2022 of \$237,020 compared to other expense of \$10,853 in Fiscal 2021. The company's other income/(expense) consists of \$294,775 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 and other miscellaneous income items, offset by \$325,338 of interest expense related to the company's long-term debt obligations.

The company had deferred income tax benefit and income tax expense in Fiscal 2022 of \$206,388 compared with deferred income tax expense and income tax expense in Fiscal 2021 of \$4,395,723.

As a result of the foregoing factors, the company's net loss was \$2,444,757 in Fiscal 2022 compared with a net income of \$12,247,807 in Fiscal 2021.

### **Liquidity and Capital Resources**

As of December 31, 2022, the company's cash and cash equivalents were \$13,882,387. 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 and through the first half of calendar year 2021, the company's revenues related to COVID-19 testing and products. Beginning in July 2021, with the acquisition of two labs, the company began receiving revenues for testing services. Under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") testing services are primarily billed to third-party insurers. With the company's shift in testing model during the fourth quarter of 2021, there was a delay in collections while the appropriate billing practices were established; accordingly, during 2022 between the billing delay and the decline in COVID-19 testing in the fourth quarter of 2022 compared to the fourth quarter of 2021, the company's accounts receivable (net) decreased by \$12,240,046 to \$1,411,933 as of December 31, 2022, from \$13,651,979 as of December 31, 2021, and cash and cash equivalents increased by \$5,766,154 to \$13,882,387 as of December 31, 2022, from \$8,116,233 as of December 31, 2021.

The company's current liabilities have increased by \$1,440,106, primarily attributed to the VEP Biotech Ltd loan being due within the year. The loan from VEP Biotech Ltd, has a maturity date of October of 2023, with an interest rate of 5%, and no required payment of principal or interest until maturity. The outstanding balance as of December 31, 2022, and December 31, 2021 (including principal and interest) were \$6,132,628 and \$5,837,124, respectively. The company is currently in discussions with VEP Biotech Ltd regarding final payment terms. This increase in current liabilities was offset by decreases, specifically royalties payable decreased by \$3,306,783 from \$3,533,378 as of December 31, 2021, to \$226,595 as of December 31, 2022, due to payments made to the Research Foundation throughout the year and a decline in COVID-19 related revenue from the fourth quarter of 2021 compared to the fourth quarter of 2022. Additionally, contract liabilities decreased by \$1,763,133 from \$1,910,078 as of December 31, 2021 to \$146,945 due to recognition of deferred revenue for lab testing completed in 2022 related to COVID-19 test kits sold in 2021.

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, which had an outstanding balance as of December 31, 2022, and December 31, 2021 (including principal and interest) of \$462,235 and \$437,237, respectively.

The company also obtained an SBA loan in May 2020, with a maturity date of May 2050, an interest rate of 3.75% and payments of \$731 which began in December 2022, which had an outstanding balance as of December 31, 2022, and December 31, 2021 (including principal and interest) of \$162,947 and \$159,046, respectively.

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 interest rate was 8.375% and 5.375% at December 31, 2022 and 2021, respectively. The line of credit did not have a balance outstanding at December 31, 2022, and December 31, 2021. The line is secured by all the business assets of the company.

## **Trends**

The company anticipates that COVID-19 saliva testing revenues will continue to wane and that the majority of its revenue in 2023 and going forward will be autism diagnostic revenues generated via lab testing, the As You Are virtual platform, and commercial software through the Autism Analytica platform.

Below describes the company's current and planned initiatives and our thoughts on them over the next couple of years:

### *COVID-19 Saliva Testing and Wastewater Surveillance*

Beginning in 2020 and continuing into 2022 the company derived predominately all its revenue from COVID-19 related products and services. At the peak of the COVID-19 pandemic, the company operated two CLIA/CLEP laboratories and opened 45 community test sites in conjunction with schools and counties in New York State. Through the second quarter of 2022, the lab continues to process a lower volume of saliva based COVID-19 tests. Due to the reduced volumes, the company closed the lab located in Buffalo, New York in July 2022. It is expected that the remaining lab will continue to perform saliva based COVID-19 testing at reduced volumes through at least the second quarter of 2023. The area of testing that continues to be strong into 2023 and likely beyond is wastewater surveillance testing which the company performs for many college campuses and in communities across the northeastern United States. In addition to the COVID-19 testing, the company has expanded surveillance testing to include additional viruses, including Polio, Norovirus, Monkeypox, Hepatitis A, Flu A/B, and RSV. The company plans to continue to expand the types and quantity of wastewater surveillance performed in 2023.

As the testing appetite for the COVID-19 pandemic wanes, the company has shifted its focus back to research, development and commercialization of molecular diagnostics, therapeutics and related products and services.

### *Autism Spectrum Disorder*

Through its work on autism spectrum disorder, the company intends to fill a gap in care existing in the United States as it currently takes on average three years from the time of a parent's first concern to clinical diagnosis. Early clinical diagnosis is critical: with early diagnosis, children have access to evidence-based therapeutic interventions when they are most effective and with the best likelihood of achieving substantial cognitive gains. To begin to fill this need, during 2022 and into 2023, the company has implemented a multi-pronged approach to provide an array of diagnostic (e.g., Clarifi ASD and genetic testing) and therapeutic solutions (e.g., As You Are, Autism Analytica) to children with autism and their families.

#### *Clarifi ASD*

Quadrant Laboratories strives to improve diagnostic accuracy and patient access through the research, development, and commercial implementation of novel molecular assays for both clinical and public health applications. 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. However, during that time 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. The company is planning to re-validate Clarifi ASD and launch Clarifi ASD as a single lab LDT in all 50 states during the fourth quarter of 2023.

#### *Genetic Testing*

In addition to the Clarifi ASD diagnostic test being developed, the company plans to offer a comprehensive panel of genetic tests built on whole-exome sequencing using saliva samples to increase access to this type of testing. Genetic tests are primarily not to diagnose autism, but to serve as an adjunct after an autism diagnosis to better understand the condition and create a more targeted treatment. The genetic tests launched via a reference lab while the company seeks approval for an in-house developed assay through the New York State Department of Health as a Laboratory Developed Test (expected in the second quarter of 2023).

#### *As You Are*

During August 2022, the company launched a pediatric virtual clinic branded “As You Are” which specializes in autism diagnosis. The mission of As You Are is to establish a world-class virtual pediatric clinic that dramatically increases access to early autism diagnostic services. The company’s team of specialized pediatricians are providing an evaluation to diagnose in under 4 weeks. Currently, diagnostic services are offered in 21 states with expansion anticipated into all 50 states by the end of 2023.

#### *Autism Analytica*

In August 2022, the company founded Autism Analytica LLC (“Autism Analytica”). Autism Analytica (“AA”) develops commercial software designed to facilitate the early identification and monitoring of children with neurodevelopmental challenges including those with autism spectrum disorder and related conditions and those without a specific neuropsychiatric disorder, predict the type and frequency of services needed, and monitor a child’s progress through treatment over time. AA’s software is comprised of (i) clinical decisions support software, inclusive of ten parent/caregiver-completed, clinically validated, measures of a child’s strengths and challenges and the clinical compilation of these results (“Virtual IPM”), and an objective, webcam-collected set of measures which utilizes gaze tracking, automated facial expression coding, proprietary stimuli, and AI/machine-learning algorithms to augment clinical decision making relative to ASD (“Neuro IPM”). AA software is designed for use by clinicians evaluating and monitoring developmental and intervention progress in children with a broad range of neurobehavioral challenges and behavioral health specialists.

#### *Behavioral Health Services*

To complement the work of Quadrant Laboratories and As You Are, Quadrant Biosciences acquired Frazier Behavioral Health effective April 1, 2022. FBH is a behavioral health clinic providing evidence-based therapies, consultation services and training in social behavior techniques and intervention strategies for children and adults with autism, ADD/ADHD, and other developmental conditions. To best meet each child’s needs, wraparound clinical care is provided in the following areas: psychological services, behavioral services (i.e., Applied Behavioral Analysis therapy), speech and language therapy, sensory and daily living skills services and medication management. These disciplines are supplemented by FBH with school educational services and community inclusion. Currently, FBH is located in Cleveland, Ohio. The global neurodevelopmental challenges market is projected to grow from \$1.93 billion in 2022 to \$3.17 billion by 2029, at a compound annual growth rate of 7.4%. As such, beginning in 2024 it is anticipated that FBH will expand to other major cities in Ohio including Columbus, Cincinnati, Dayton and Akron.

#### *Other Initiatives*

Outside of the work focused on autism the company continues to build its research pipeline. This work includes the exploration of ways to further monetize existing products and processes. The company remains actively engaged in ongoing clinical research to develop a molecular diagnostic aid for mild traumatic brain injuries (mTBI); this work leverages the proprietary methods and intellectual property developed for Clarifi ASD. For mTBI certain saliva-based biomarkers show promise for identifying the injury while others predict which patients will have persistent post-concussion symptoms. In September of 2020, the company received a \$2.3 million Small Business Technology Transfer

("STTR") grant from the National Institute of Health ("NIH") related to this project, with the second phase of the grant anticipated to begin in 2023. The company anticipates launching a laboratory developed test in mid-2024.

## **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, 2022 and 2021**

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Financial Plaza, 221 S. Warren St., Syracuse, New York 13202-1628  
(315) 472-9127 Fax (315) 472-0026

### Report of Independent Registered Public Accounting Firm

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

#### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Quadrant Biosciences, Inc., its Subsidiaries and its Affiliates (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, stockholders' equity, 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 the Company as of December 31, 2022 and 2021, 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 the Company's 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 the Company 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. The Company 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 (23) and E to the consolidated financial statements, the Company capitalizes certain development costs that relates to internal use software incurred during the application development stage. The Company capitalized internal-use software assets, net of accumulated amortization, was \$11,189,946 and \$7,993,342, as of December 31, 2022 and 2021, respectively.

Auditing the Company's capitalization of software costs was especially challenging because management's determination of which projects and development activities qualify for capitalization requires significant judgment, as only those costs incurred in certain stages of software development can be capitalized in accordance with the applicable accounting standards.

We obtained an understanding and evaluated the design of internal controls over the Company's internal use software costs processes. This includes the controls over management's determination of which projects and costs qualify for capitalization in accordance with the applicable accounting standards.

To test the Company's capitalization of software costs, we performed audit procedures that included, among others, inspecting underlying documentation to evaluate whether the costs were capitalizable under the applicable accounting standards. We also inquired of project managers for significant projects to assess the nature of the costs, the time devoted to capitalizable activities and the underlying documentation.

/s/ Dannible & McKee, LLP

Dannible & McKee, LLP

We have served as Quadrant Biosciences, Inc.'s auditor since 2019.

Syracuse, New York

April 3, 2023



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

**ASSETS**

	2022	2021
<b>Current Assets:</b>		
Cash and cash equivalents (amounts related to VIEs of \$12,629 and \$0, respectively)	\$ 13,882,387	\$ 8,116,233
Accounts receivable, net (amounts related to VIEs of \$42,719 and \$0, respectively)	1,411,933	13,651,979
Prepaid expenses	2,782,317	3,367,754
Other current assets	137,257	1,211,193
Inventories	1,554,754	472,128
<b>Total Current Assets</b>	<b>19,768,648</b>	<b>26,819,287</b>
<b>Property and Equipment:</b>		
Property & equipment	1,949,648	1,056,661
Less: accumulated depreciation	283,278	82,133
<b>Total Property and Equipment, net</b>	<b>1,666,370</b>	<b>974,528</b>
<b>Other Assets:</b>		
Deferred tax asset	1,812,777	1,564,598
Right-of-use lease asset	1,713,488	875,950
Goodwill	150,000	-
Software as service	13,383,996	10,187,392
Less: accumulated amortization	2,194,050	2,194,050
<b>Total Other Assets</b>	<b>14,866,211</b>	<b>10,433,890</b>
<b>Total Assets</b>	<b>\$ 36,301,229</b>	<b>\$ 38,227,705</b>

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

## LIABILITIES AND STOCKHOLDERS' EQUITY

	2022	2021
<b>Current Liabilities:</b>		
Accounts payable	\$ 926,151	\$ 809,495
Royalty payable	226,595	3,533,378
Contract liabilities	146,945	1,910,078
Current portion lease liability	492,712	289,756
Accrued payroll and related liabilities (amounts related to VIEs of \$39,612 and \$0, respectively)	328,905	229,911
Federal tax payable	-	131,518
Accrued liabilities	570,422	483,040
Current portion of long-term debt	6,141,400	5,848
<b>Total Current Liabilities</b>	<u>8,833,130</u>	<u>7,393,024</u>
<b>Long-Term Liabilities:</b>		
Lease liability, net of current portion	1,284,026	588,963
Convertible debt	462,235	437,237
Notes payable	154,175	5,990,322
<b>Total Long Term Liabilities</b>	<u>1,900,436</u>	<u>7,016,522</u>
<b>Stockholders' Equity:</b>		
Common stock, par value \$0.0001 per share, 125,000,000 shares authorized, 89,009,360 and 88,992,860 issued and outstanding, respectively	8,901	8,900
Additional paid in capital	34,126,368	29,932,108
Accumulated deficit	(8,385,254)	(6,122,849)
Non-controlling interests	(182,352)	-
<b>Total Stockholders' Equity</b>	<u>25,567,663</u>	<u>23,818,159</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 36,301,229</u>	<u>\$ 38,227,705</u>

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

	2022	2021
<b>Revenues:</b>		
Testing services, net (amounts relating to VIEs of \$55,577 and \$0, respectively)	\$ 28,062,567	\$ 13,641,262
Product sales, net	7,821,116	44,136,077
Behavioral health services	306,546	-
Product assembly	-	2,608,994
Other revenue	204,926	132,846
<b>Total Revenues</b>	<b>36,395,155</b>	<b>60,519,179</b>
<b>Cost of Products Sold</b>	<b>14,340,093</b>	<b>33,466,238</b>
<b>Gross Profit</b>	<b>22,055,062</b>	<b>27,052,941</b>
<b>Sales and Marketing Expenses</b>	<b>1,745,116</b>	<b>156,918</b>
<b>Research and Development Costs</b>	<b>1,018,519</b>	<b>206,092</b>
<b>Selling and Administrative Expenses:</b>		
Charitable contributions	33,922	24,475
Depreciation and amortization	201,145	49,504
Employee benefits and taxes (amounts relating to VIEs of \$69,604 and \$0, respectively)	2,223,051	832,622
Office expenses	1,550,745	760,454
Other expenses (amounts related to VIEs of \$229 and \$0, respectively)	1,552,850	653,382
Professional fees	2,477,138	948,310
Salaries and wages (amounts relating to VIEs of \$562,712 and \$0, respectively)	9,910,023	3,624,093
Stock option compensation	4,230,718	3,142,708
<b>Total Selling and Administrative Expenses</b>	<b>22,179,592</b>	<b>10,035,548</b>
<b>(Loss) Income from Operations</b>	<b>(2,888,165)</b>	<b>16,654,383</b>
<b>Other Income (Expenses):</b>		
Other income	562,358	298,989
Interest expense	(325,338)	(309,842)
<b>Total Other Income (Expenses)</b>	<b>237,020</b>	<b>(10,853)</b>
<b>Net (Loss) Income Before Income Tax</b>	<b>(2,651,145)</b>	<b>16,643,530</b>
<b>Deferred Income Tax Expense</b>	<b>264,247</b>	<b>(4,236,433)</b>
<b>Income Tax Expense</b>	<b>(57,859)</b>	<b>(159,290)</b>
<b>Net (Loss) Income</b>	<b>(2,444,757)</b>	<b>12,247,807</b>

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

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

	2022	2021
<b>Less: Net Loss Attributable to Non-Controlling Interests</b>	(182,352)	-
<b>Net (Loss) Income Attributable to Common Stockholders</b>	<u>\$ (2,262,405)</u>	<u>\$ 12,247,807</u>
Per share data:		
Basic (loss) income, per common share	\$ (0.03)	\$ 0.14
Diluted (loss) income, per common share	(0.03)	0.12
Shares used in computing net income per common share:		
Basic	89,002,878	88,974,967
Diluted	89,002,878	105,832,846

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, 2022 and 2021**

	Common Shares	Common Stock Par Value	Additional Paid-in Capital	(Accumulated Deficit)	Non-Controlling Interests	Total
<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>	88,992,860	8,900	29,932,108	(6,122,849)	-	23,818,159
Exercised stock options (\$0.003 per share)	16,500	1	51	-	-	52
Stock option compensation	-	-	4,230,718	-	-	4,230,718
Stock issuance costs	-	-	(36,509)	-	-	(36,509)
Net income	-	-	-	(2,262,405)	(182,352)	(2,444,757)
<b>Balance, December 31, 2022</b>	89,009,360	\$ 8,901	\$ 34,126,368	\$ (8,385,254)	\$ (182,352)	\$ 25,567,663

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,**

	2022	2021
<b>Cash Flows from Operating Activities:</b>		
Net (loss) income	\$ (2,444,757)	\$ 12,247,807
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	311,621	393,060
Employee stock option compensation	4,230,718	3,142,708
Deferred tax expense	(250,745)	4,236,433
Forgiveness of loan	(295,775)	(196,345)
Changes in income tax credit receivable	-	222,667
Changes in accounts receivable	12,240,046	(12,297,629)
Changes in accounts payable	116,656	(398,237)
Changes in royalty payable	(3,306,783)	2,674,764
Changes in contract liabilities	(1,763,133)	(5,732,149)
Changes in accrued interest	324,403	307,500
Changes in inventories	(289,858)	991,727
Changes in right-of-use lease assets	(948,014)	(833,260)
Changes in income taxes payable	(131,518)	131,518
Changes in lease liabilities	1,001,358	830,347
Changes in prepaid expenses and other current assets	509,314	(4,554,972)
Changes in accrued payroll and related liabilities	98,994	(559,650)
Changes in accrued liabilities	339,804	166,239
<b>Cash Provided by Operating Activities</b>	<b>9,742,331</b>	<b>772,528</b>
<b>Cash Flows from Investing Activities:</b>		
Cash paid for purchases of fixed assets	(489,777)	(492,753)
Purchase of goodwill	(150,000)	-
Payments of software development costs	(3,196,604)	(1,888,247)
<b>Cash Used in Investing Activities</b>	<b>(3,836,381)</b>	<b>(2,381,000)</b>
<b>Cash Flows from Financing Activities:</b>		
Payments on financing lease	(103,339)	(12,546)
Repayment of line of credit	-	(403,996)
Proceeds from convertible debt	-	416,628
Proceeds from sale of stock and exercise of options, net of issuance costs	(36,457)	(18,836)
<b>Cash Used in Financing Activities</b>	<b>(139,796)</b>	<b>(18,750)</b>
<b>Net Change in Cash</b>	<b>5,766,154</b>	<b>(1,627,222)</b>

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,**

	2022	2021
<b>Net Change in Cash</b>	5,766,154	(1,627,222)
<b>Cash, beginning of year</b>	8,116,233	9,743,455
<b>Cash, end of year</b>	<u>\$ 13,882,387</u>	<u>\$ 8,116,233</u>
<b>Supplemental Disclosures of Cash Flow Information:</b>		
Cash paid during the year for:		
Interest	\$ 935	\$ 2,342
Income taxes	201,729	14,345
Non-Cash Operating and Investing Activities:		
During 2022, \$792,768 of other current assets were reclassified to inventory and \$359,857 of other current assets were reclassified to fixed assets.		

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, 2022 and 2021**

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

1. Quadrant Biosciences Inc. (the “Company”, “Quadrant”) is a healthcare company dedicated to improving the lives of children and families by delivering innovative diagnostic, therapeutic, and virtual care solutions for global health priorities. Quadrant is comprised of five business units: Quadrant Laboratories, Quadrant Wastewater Solutions, As You Are, Frazier Behavioral Health and Autism Analytica.

Quadrant Laboratories (“QLabs”) performs COVID-19 testing and engages in the research, development and commercialization of molecular diagnostics for certain public health priorities, including Autism Spectrum Disorder (“ASD”), mild-traumatic brain injuries (“mTBI”), Parkinson’s Disease (“PD”) and others. Quadrant Laboratories has curated and owns a biobank, including over 610,000 saliva specimens from over 160,000 unique individuals; specimens included in this biobank are appropriate for genetic and multi-omic discovery. QLABs operates through Quadrant Laboratories LLC.

Quadrant Wastewater Solutions (“QWS”) provides communities throughout New York State and the New York State Department of Health (“NYSDOH”) with weekly wastewater surveillance reporting on the presence and relative abundance of the SARS-CoV-2 virus in wastewater sampled from municipal treatment facilities. As of March 20, 2023, QWS provided these services for approximately 90% of all counties in New York State. Additionally, QWS facilitates additional testing by the NYSDOH (including the phylogenetic classification of SARS-CoV-2 variants and genetic testing for other human pathogens) by providing extracted RNA from wastewater samples. QWS conducts business through Quadrant Viral Testing LLC.

As You Are (“AYA”) is a virtual pediatric clinic which launched in August 2022 and provides autism diagnostic evaluations for children 16 months to 10 years of age through telehealth appointments; AYA’s diagnostic process is facilitated by its proprietary evidence-based medicine platform. Currently, AYA serves families in ten States, including Texas, Florida, New York, New Jersey, Pennsylvania, Ohio, Virginia, Georgia, Kentucky, and Alabama. AYA conducts business through two wholly-owned subsidiaries of Quadrant, Quadrant Medical Staffing LLC and Quadrant Virtual Care Management LLC; Quadrant Virtual Care Management LLC provides management services to As You Are Physicians PC, which employs physicians and leases those physicians to the billing entities. Those billing entities include Quadrant CA Virtual Pediatric Medical Care PC, Quadrant MI Virtual Care PC, Quadrant NJ Virtual Care PC, Quadrant PA Virtual Care PC, and Quadrant TX Virtual Care PA.

Frazier Behavioral Health LLC (“FBH”) delivers individualized therapy for neurodiverse children and adults with behavioral, social, communication, daily living, and educational deficits; their mission is to assist these individuals in becoming their best selves and create enhanced outcomes at home, at school and in the community. From their clinic in Cleveland, OH, and other locations convenient for patients, FBH provides evidence-based therapies and intervention strategies for children and adults with autism, ADD/ADHD, and other developmental conditions. Quadrant Biosciences Inc. purchased Frazier Behavioral Health LLC through a Membership Interest and Purchase Agreement effective April 1, 2022. Quadrant Behavioral Staffing LLC and Quadrant Behavioral Care Management LLC were created to operate in conjunction with Frazier Behavioral Health LLC. Operations of Quadrant Behavioral Staffing LLC and Quadrant Behavioral Care Management LLC have not yet commenced.

Autism Analytica (“AA”) develops commercial software designed to facilitate the early identification of children on the autism spectrum, predict the type and frequency of services needed, and monitor a child’s progress through treatment over time. AA’s software is comprised of (i) clinical decisions support software, inclusive of ten parent/caregiver-completed, clinically validated, measures of a child’s strengths and challenges and the clinical compilation of these results (“Virtual IPM”), and (ii) an objective, clinical diagnostic aid which utilizes vision-tracking technology, proprietary stimuli, and AI/machine-learning algorithms to augment clinical decision making relative to ASD (“Neural IPM”). AA software is designed for use by clinicians diagnosing children with ASD and behavioral health specialists serving children with ASD. AA conducts business through the wholly-owned subsidiary of Quadrant, Autism Analytica LLC.

Motion Intelligence LLC is a wholly owned subsidiary which sold ClearEdge toolkits to end users utilizing distributors and agents. Effective September 7, 2022, Motion Intelligence LLC was dissolved in Delaware and effective January 11, 2023 was dissolved in New York.

Quadrant Epigenetics LLC is a wholly owned subsidiary which will record revenue from epigenetic activities. Effective September 7, 2022, Quadrant Epigenetics LLC was dissolved in Delaware and effective January 11, 2023 was dissolved in New York.

Quadrant IP Holdings LLC is a wholly owned subsidiary which houses the Company’s patents. Effective September 7, 2022, Quadrant IP Holdings LLC was dissolved.

Quadrant Vision Technologies is a wholly owned subsidiary created to partner with a health provider. Effective September 9, 2022, Quadrant Vision Technologies LLC was dissolved.

Quadrant Biosciences Canada Ltd is a wholly owned subsidiary created to pay an employee residing in Canada. Effective October 12, 2022, Quadrant Biosciences Canada Ltd was dissolved.

Quadrant Biosciences Inc. is the sole owner of its subsidiaries Quadrant Laboratories LLC, Quadrant Viral Testing LLC, Quadrant Virtual Care Management LLC, Quadrant Medical Staffing LLC, Frazier Behavioral Health LLC, Quadrant Behavioral Staffing LLC, Quadrant Behavioral Care Management LLC, Autism Analytica LLC, Motion Intelligence LLC, Quadrant Epigenetics LLC, Quadrant IP Holdings LLC, Quadrant Vision Technologies LLC, and Quadrant Biosciences Canada Ltd.

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, Quadrant Laboratories LLC, Autism Analytica LLC, Frazier Behavioral Health LLC, Quadrant Behavioral Staffing LLC, Quadrant Behavioral Care Management LLC, Quadrant Virtual Care Management LLC, and Quadrant Medical Staffing LLC.

In addition to the Company and its wholly owned subsidiaries, As You Are Physicians PC, Quadrant CA Virtual Pediatric Medical Care PC, Quadrant MI Virtual Care PC, Quadrant NJ Virtual Care PC, Quadrant PA Virtual Care PC and Quadrant TX Virtual Care TX Virtual Care PA are consolidated in the consolidated financial statements as variable interest entities (“VIE”). The Company evaluates its ownership, contractual, and other interests in entities to determine if an entity qualifies as a VIE. These evaluations are complex and involve judgment. The Company has consolidated VIE’s which the Company has concluded it holds a contractual or ownership interest in and that the Company is the primary beneficiary of in the consolidated financial statements. The primary beneficiary of a VIE is the party that meets both of the following criteria: (i) has the power to make decisions that most significantly affect the economic performance of the VIE, and (ii) has the obligation to absorb losses or the right to receive benefits that in either case could potentially be significant to the VIE. The Company has determined that based on the substance of various agreements, including management agreements, physician shareholder agreements, and stock transfer restriction agreements that the aforementioned physician practices qualify as VIE’s. The Company regularly reassess whether changes in the facts and circumstances regarding the Company’s involvement with a VIE will cause the consolidation conclusion to change. Changes in consolidation status are applied prospectively.

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. Property 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 10 years. The Company had \$538,475 in laboratory equipment received, but not in service as of December 31, 2021, all equipment received as of December 31, 2022 has been placed in service. 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, 2022 and 2021 was \$201,145 and \$49,504, 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, 2022, and 2021 the amounts owed for royalty payments were \$226,595 and \$3,533,378, respectively. Royalty expense is included in cost of products sold. For the year ended December 31, 2022 and 2021 the expense was \$2,868,377 and \$7,833,833, 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 \$1,018,519 and \$206,092 for the years ended December 31, 2022 and 2021, 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 and another medical billing company that provides billing services for behavioral health services.

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. During the year ended December 31, 2022, the Company capitalized as software \$822,951 of the prepaid research funding recorded based on the number of participants enrolled in the study.

12. Other Current Assets – In late 2021 the Company began a project to build a legally compliant large-scale biodepository and initiated the systematic curation of its “Project Silver Linings” Biobank and data repository. At December 31, 2021, other current assets represent the capitalization of the biobank samples and the related costs of storage. During 2022, it was determined that the biobanking project was viable and ready to be sold and marketed. Therefore, during 2022 \$792,768 and \$359,857 of the capitalized costs were reclassified as inventory and property and equipment, respectively.
13. Concentration of Business Risk – In 2021, all of the Company’s Clarifi ASD inventory was purchased from two vendors. There is no Clarifi ASD inventory recorded as December 31, 2022. For the year ended December 31, 2022 and 2021 17% and 94%, respectively, of inventory related to the Clarifi COVID-19 and wastewater services were purchases from a single vendor.  
  
For the year ended December 31, 2022 100% of lab testing revenue of \$1,595,798 was to one customer. For the year ended December 31, 2021 80% of test kit sales of \$43,436,304, 100% of lab testing revenue of \$2,625,450, and 100% of product assembly services of \$2,608,994 were to one customer.
14. Cost of Goods Sold – During 2021 and 2022 the cost of goods sold includes costs and expenses directly related to the operations of the clinical and environmental labs.
15. Advertising and Promotion – The Company expenses all advertising costs. Advertising expenses totaled \$1,745,116 and \$156,918 for the years ended December 31, 2022 and 2021, respectively.
16. 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.
17. Stock-Based Compensation – The Company accounts for stock options under the provisions of ASC 718 Stock Compensation. For options granted in 2022 and 2021, 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.
18. 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.
19. Shipping Costs – Shipping costs that are non-reimbursable are included in cost of goods sold.

20. 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 2022 and 2021, 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 \$204,926 and \$132,846, 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. As of December 31, 2022 the performance milestones have been met and forgiveness of the liability has been recorded as other income. 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

21. 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, 2022 and 2021, of 21,660,677 and 16,857,879, respectively. The dilutive stock options and convertible debt for the year ended December 31, 2022 have not been included for 2022 due to being antidilutive.



The following table illustrates the computation of basic and diluted EPS for the year ended December 31, 2022, and 2021.

	<b>For the Year Ended December 31, 2021</b>		
	<b>Income (Numerator)</b>	<b>Shares (Denominator)</b>	<b>Per-Share Amount</b>
Income from continuing operations	\$ 12,247,807		
<b>Basic EPS</b>			
Income available to common stockholders	<u>12,247,807</u>	<u>88,974,967</u>	<u>\$ 0.14</u>
<b>Effect of Dilutive Securities</b>			
Common Stock Options		16,821,443	
Convertible Debt		<u>36,436</u>	
<b>Diluted EPS</b>			
Income available to common stockholders and assumed conversions	<u>\$ 12,247,807</u>	<u>105,832,846</u>	<u>\$ 0.12</u>
	<b>For the Year Ended December 31, 2022</b>		
	<b>Income (Numerator)</b>	<b>Shares (Denominator)</b>	<b>Per-Share Amount</b>
Income from continuing operations	\$ (2,262,405)		
<b>Basic EPS</b>			
Income available to common stockholders	<u>(2,262,405)</u>	<u>89,002,878</u>	<u>\$ (0.03)</u>
<b>Effect of Dilutive Securities</b>			
Common Stock Options		21,634,532	
Convertible Debt		<u>26,145</u>	
<b>Diluted EPS</b>			
Income available to common stockholders and assumed conversions	<u>\$ (2,262,405)</u>	<u>110,663,555</u>	<u>\$ (0.02)</u>

22. Impairment of Long-Lived Assets – The carrying values of long-lived assets other than goodwill are generally evaluated for impairment only if events or changes in facts and circumstances indicate that carrying values may not be recoverable. Any impairment determined would be recorded in the current period and would be measured by comparing the fair value of the related asset to its carrying value. Fair value is generally determined by identifying estimated undiscounted cash flows to be generated by those assets. No impairment was recorded for the years ended December 31, 2022 and 2021, respectively.

23. 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.
24. 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.
25. 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.
26. Related Party Transactions – The Company did not have any significant related party transactions for the years ended December 31, 2022 and 2021.

**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). HRSA stopped accepting claims for testing on March 22, 2022. 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, 2022 and 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.

Behavioral Health Services – In 2022, through the acquisition of Frazier Behavioral Health LLC the Company began providing behavioral health services including therapies, consultation services and training in social behavior techniques and intervention strategies for children and adults with autism, ADD/ADHD, and other developmental conditions. The Company's behavioral health service revenues are recorded based upon 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, 2022.

Diagnostic Services – The Company launched a virtual care clinic on August 1, 2022 under the branding “As You Are” to provide autism diagnostic services. The Company’s diagnostic service revenues are recorded based upon the established Medicaid fee schedule in the state that the visit occurred as well as 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, 2022.

#### 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	2022	2021
Third-party COVID testing revenue	\$ 26,336,566	\$ 11,001,414
Clarifi COVID-19 test kit sales	6,112,886	43,436,304
Lab testing revenue	1,595,798	2,625,456
Wastewater testing	1,708,230	698,784
Behavioral health services	306,546	-
Diagnostic services	130,203	-
Product assembly services	-	2,608,994
Other	-	15,381
	<u>\$ 36,190,229</u>	<u>\$ 60,386,333</u>

All 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,

	2022	2021
Receivables, which are included in "Accounts receivable"	\$ 1,411,933	\$ 13,651,979
Contract liabilities	146,945	1,910,078

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:

	2022	2021
Revenue recognized that was included in the contract liability balance at the beginning of the period	\$ (1,910,078)	\$ (7,642,227)
Increases due to cash received, excluded amounts recognized as revenue during the period	146,945	1,910,078

#### **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, 2022 and 2021 are \$146,945 and \$1,910,078, 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, 2021 in 2022, and expects to recognize all revenue from remaining performance obligations as of December 31, 2022 in 2023.

#### **C. Lease Commitments:**

The Company has entered into several lease arrangements. Specifically, the Company has operating leases for lab space, warehouse space, and office space in Syracuse, NY, Buffalo, NY, Mayfield Heights, OH and San Antonio, TX during the periods. Two finance leases have 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 includes 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, 2022 and 2021, rent expenses were recognized associated with operating and finance leases as fixed rent expense of \$425,350 and \$147,797 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, 2022 and 2021, right-of-use assets and lease liabilities relating to leases were as follows:

	2022	2021
Operating lease right-of-use assets	\$ 1,212,500	\$ 560,667
Finance lease right-of-use assets	500,988	315,283
<b>Operating and finance lease liabilities:</b>		
Current portion of operating lease	303,140	211,944
Current portion of finance lease	189,572	77,812
Operating lease liability, net of current	940,648	343,019
Finance lease liability, net of current	343,378	245,944

During the years ended December 31, 2022 and 2021, the Company had the following cash and non-cash activities associated with operating and finance leases:

	2022	2021
<b>Cash paid for amounts included in the measurement of lease liabilities-</b>		
<b>Operating cash flows:</b>		
from operating leases	\$ 292,379	\$ 141,811
from finance leases	103,339	15,694
<b>Additions to right-of-use assets obtained from:</b>		
New operating lease liabilities	846,156	630,742
New finance lease liabilities	294,306	336,302

The future minimum annual payments due under operating and finance leases as of December 31, 2022 are as follows:

	Operating	Financing
2023	\$ 374,791	\$ 204,227
2024	357,226	204,227
2025	282,691	161,017
2026	204,303	-
2027	193,893	-
Total future minimum lease payments	1,412,904	569,471
Less: Amount representing interest	169,115	36,524
Present value of future net minimum lease payments	1,243,789	532,947
Less: Current portion	303,140	189,571
Long-term obligations under finance leases	\$ 940,649	\$ 343,376

Amortization of finance lease right-of-use assets was \$110,476 and \$14,013 for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, and 2021, the weighted-average remaining lease term for all operating leases is 3.91 and 3.39 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, 2022 and 2021 is 5.67% and 4.14%, respectively.

**D. Inventories:**

Inventories consisted of the following:

	2022	2021
Clarifi COVID-19		
Testing supplies	\$ 224,837	\$ 457,441
Project Silver Lining		
Biobank Samples	1,291,649	-
Wastewater		
Testing supplies	38,268	14,687
	<u>\$ 1,554,754</u>	<u>\$ 472,128</u>

**E. Software as Service:**

The Company capitalized software costs of \$3,196,604 and \$1,888,247 for the years ended December 31, 2022 and 2021, respectively.

The Company amortized \$0 and \$329,544 of capitalized costs for the years ended December 31, 2022 and 2021, respectively. The Company has software development costs of \$9,084,093 for which amortization has not started as the software has not yet been placed in service for the year ended December 31, 2022. Amortization expense is included in cost of goods sold. Future amortization for assets placed in service will be \$0 for 2023, 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:

	2022	2021
Dividend yield	0%	0%
Volatility	60.00%	60.00%
Discount rate	1.51%	0.27%
Expected life	5.77	5.77
Fair value of common stock per share	\$ 4.42	\$ 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, 2022 and 2021 is presented below:

Fixed Options	Shares	Weighted Average Exercise Price
January 1, 2021	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	27,387,051	0.873
Granted	3,092,629	4.420
Forfeited	(1,172,149)	3.177
Exercised	(16,500)	0.003
December 31, 2022	<u>29,291,031</u>	1.155
Exercisable:		
December 31, 2022	24,733,696	

The weighted-average grant-date fair value of options granted during the years ended December 31, 2022 and 2021, was \$2.43 and \$1.60.



A summary of the status of the Company's nonvested shares as of December 31, 2022 and the changes during the year then ended is presented below:

Nonvested shares	Shares	Weighted Average Grant- Date Fair Value
Nonvested at January 1, 2022	4,917,379	\$ 1.26
Granted	3,092,629	2.43
Vested	(2,630,522)	1.05
Forfeited	(822,151)	1.96
Nonvested at December 31, 2022	<u>4,557,335</u>	<u>\$ 2.05</u>

Total compensation cost related to nonvested awards not yet recognized is \$6,056,101 as of December 31, 2022. It is expected to be recognized over the weighted-average period of 1.11 years. Stock option compensation of \$4,230,718 and \$3,142,708 was recognized for the years ending December 31, 2022 and 2021, respectively.

#### G. Income Taxes:

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

	2022	2021
Current:		
Federal	\$ (20,630)	\$ (128,795)
State	(37,229)	(30,495)
	<u>(57,859)</u>	<u>(159,290)</u>
Deferred:		
Federal	275,662	(3,186,135)
State	(11,415)	(1,050,298)
	<u>264,247</u>	<u>(4,236,433)</u>
Tax expense	<u>\$ 206,388</u>	<u>\$ (4,395,723)</u>

The components of the expense for income taxes differs from the amount that would result from applying the federal statutory rate for the years ended December 31, 2022 and 2021 as follows:

	2022		2021	
	Amount	%	Amount	%
Statutory tax rate	\$ (670,740)	25.3%	\$ 4,210,813	25.3%
Valuation allowance change	-	0.0%	-	0.0%
Permanent differences	464,352	-17.5%	184,910	1.1%
	<u>\$ (206,388)</u>	<u>7.8%</u>	<u>\$ 4,395,723</u>	<u>26.4%</u>

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

	2022	2021
Accelerated depreciation	\$ (141,683)	\$ (112,353)
Other assets	(2,057,325)	(2,241,065)
Charitable contribution carryovers	8,761	91,556
Stock option compensation	1,280,880	895,468
Research and development tax credit carryforward	393,858	20,103
NOL carryforward	2,328,286	2,910,889
Net deferred tax asset	<u>\$ 1,812,777</u>	<u>\$ 1,564,598</u>

There was no adjustment to the valuation allowance for the Company for the years ended December 31, 2022 and 2021, respectively.

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

	2022	2021
NOL carryforward	\$ 48,522	\$ -
Valuation allowance	(48,522)	-
Net deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

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, there is no established allowance valuation. The VIEs have determined that, at this time, it is more likely than not that the VIEs will not realize all of the benefits of federal and state net deferred taxes, and, as a result, there is a full valuation allowance recorded. The research and development tax credit carryforwards and NOL carryforwards generated through December 31, 2022 for the Company, of approximately \$390,000 and \$8,560,000, 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, 2019 through December 31, 2022. The Company has no uncertain tax positions. As of December 31, 2022, and 2021 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 \$325,567 and \$120,377 for the years ended December 31, 2022 and 2021, 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 was 8.375% and 5.375% at December 31, 2022 and 2021, respectively. The line of credit did not have a balance outstanding at December 31, 2022 and 2021.

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. The personal Guarantee of the CEO was released on November 17, 2022.

**J. Long-Term Debt:**

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

	2022	2021
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.	\$ 6,132,628	\$ 5,837,124
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.	462,235	437,237
SBA Economic Injury Disaster loan, with a maturity date of May 2050, an interest rate of 3.75%, and monthly payments of \$731 beginning in December 2022	162,947	159,046
	6,757,810	6,433,407
Less: current portion	6,141,400	5,848
	<u>\$ 616,410</u>	<u>\$ 6,427,559</u>

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

2023	\$ 6,141,400
2024	3,147
2025	465,122
2026	3,231
2027 and after	144,910
	<u>\$ 6,757,810</u>

Accrued interest included in the outstanding loan balance due to VEP Biotech, Ltd. was \$1,132,628 and \$837,124 for the periods ending December 31, 2022 and 2021, respectively.

Accrued interest included in the outstanding loan balance due convertible debt holders was \$45,607 and \$20,609 for the periods ending December 31, 2022 and 2021, respectively.

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.

Accrued interest included in the outstanding loan balance due to the SBA was \$12,948 and \$9,046 for the periods ending December 31, 2022 and 2021, respectively.

**K. Concentration of Credit Risk:**

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

**L. Legal Matters:**

None.

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

Throughout 2021, 2022 and into 2023 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.

**N. Subsequent Events:**

The Company has evaluated subsequent events through April 3, 2023, the date which the financial statements were available for issue, and no events required disclosure.

**Item 8. Exhibits**

The documents listed in the Exhibit Index of this report are incorporated by reference or are filed with this report, in each case as indicated below.

- [2.1 Second Amended and Restated Certificate of Incorporation, as amended \(1\)](#)
- [2.2 Bylaws \(1\)](#)
- [4 Form of subscription agreement \(1\)](#)
- [6.1 2016 Equity Incentive Plan \(1\)](#)
- [6.2 Amended and Restated Stockholders' Agreement \(1\)](#)
- [6.3 Exclusive License Agreement between the Research Foundation for the State University of New York, the Penn State Research Foundation, and the company \(Autism Spectrum Disorder\) dated April 5, 2018 \(1\)](#)
- [6.4 Exclusive License Agreement between the Research Foundation for the State University of New York, the Penn State Research Foundation, and the company \(Traumatic Brain Injury\) dated April 5, 2018 \(1\)](#)
- [6.5 Exclusive License Agreement between the Research Foundation for the State University of New York, the Penn State Research Foundation, and the company \(Parkinson's Disease\) dated April 5, 2018 \(1\)](#)
- [6.6 Exclusive License Agreement between the Research Foundation for The State University of New York and Quadrant Biosciences Inc. \(COVID-19 Saliva Diagnostic\) dated August 7, 2020 \(2\)](#)
- [6.7 First Amendment to the Exclusive License Agreement between the Research Foundation for The State University of New York and Quadrant Biosciences Inc. \(COVID-19 Saliva Diagnostic\) \(3\)](#)
- [6.8 Research Support Agreement between Autism Speaks Inc. and the company dated November 12, 2021 \(3\)](#)
  - (1) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155)
  - (2) Filed as an exhibit to the Quadrant Biosciences Inc. Annual Report on Form 1-K filed on April 29, 2021
  - (3) Filed as an exhibit to the Quadrant Biosciences Inc. Annual Report on Form 1-K filed on April 29, 2022

SIGNATURE

Pursuant to the requirements of Regulation A, the issuer has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Syracuse, New York, on April 28, 2023.

QUADRANT BIOSCIENCES INC.

By /s/ Richard Uhlig

Name: Richard Uhlig

Title: Chief Executive Officer

Pursuant to the requirements of Regulation A, 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

Date: April 28, 2023

Richard Uhlig

Chief Executive Officer, Chairman

/s/ Richard Bongo

Date: April 28, 2023

Richard Bongo

Chief Financial Officer, Principal Accounting Officer, Director

/s/ James Croke

Date: April 28, 2023

James Croke

General Counsel, Director

/s/ Peter Cohen

Date: April 28, 2023

Peter Cohen

Director

/s/ Ira Fedder

Date: April [X], 2023

Ira Fedder MD

Director

/s/ Andrew Rock

Date: April 28, 2023

Andrew Rock

Director

/s/ Mary Ann Tyszko

Date: April 28, 2023

Mary Ann Tyszko

Director

## 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: April 28, 2023

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: April 28, 2023

/s/ Richard Bongo

Richard Bongo

Chief Financial Officer, Principal Accounting Officer, Director

Date: April 28, 2023

/s/ James Croke

James Croke

Director

Date: April 28, 2023

/s/ Peter Cohen

Peter Cohen

Director

Date: April 28, 2023

/s/ Ira Fedder

Ira Fedder MD

Director

Date: April 28, 2023

/s/ Andrew Rock

Andrew Rock

Director

Date: April 28, 2023

/s/ Mary Ann Tyszko

Mary Ann Tyszko

Director

Date: April 28, 2023