FORM 1-K

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 1-K

ANNUAL REPORT PURSUANT TO
REGULATION A OF THE SECURITIES ACT OF 1933

For the fiscal year ended December 31, 2020

Quadrant Biosciences Inc.

(Exact name of issuer as specified in its charter)

Delaware	**47-3417864**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
505 Irving Avenue, Suite 3100AB Syracuse, New York	**13210**
(Address of principal executive offices)	(Zip code)

(315) 614-2325
(Registrant's telephone number, including area code)

Common Stock
(Title of each class of securities issued pursuant to Regulation A)

In this report, the terms "Quadrant", "the company", "we", "us" and "our" refer to Quadrant Biosciences Inc. and its consolidated subsidiaries. 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 semi-annual 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.

Forward-Looking Statements

The following information contains certain forward-looking statements. Forward-looking statements are statements that estimate the happening of future events and are not based on historical fact. Forward-looking statements may be identified by the use of forward-looking terminology, such as "may," "could," "expect," "estimate," "anticipate," "plan," "predict," "probable," "possible," "should," "continue," or similar terms, variations of those terms or the negative of those terms. The forward-looking statements specified in the following information have been compiled by our management on the basis of assumptions made by management and considered by management to be reasonable. Our future operating results, however, are impossible to predict and no representation, guaranty, or warranty is to be inferred from those forward-looking statements.

Item 1. Business

SUMMARY

Overview

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

The company was founded to improve lives through the development of more accurate and timely diagnostics for large-scale health issues; these include Autism Spectrum Disorder ("ASD"), Parkinson's disease ("PD"), mild-Traumatic Brain Injuries ("mTBI" or "concussion injuries"), and most recently SARS-CoV-2 infections ("COVID-19"). In addition to 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 has research relationships with more than 130 academic medical or clinical sites in North America, Central America and Europe; these sites recruit research study participants and collect biological specimens, medical histories, phenotypic characteristics and demographic data.

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

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

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

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

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

To better serve its clients, the company now operates two high-throughput, CLIA high-complexity laboratories located in central and western New York State. The company markets its molecular tests under the brand name "Clarifi".

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

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

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

In addition to sales of its COVID-19 testing products and services, the company has sold Clarifi ASD and the ClearEdge® Brain Health Toolkit ("ClearEdge" or "ClearEdge Toolkit"), both developed and validated in cooperation with the SUNY Upstate Medical University and the Penn State College of Medicine:

- Clarifi ASD is a molecular diagnostic test that provides clinicians with objective support for an earlier diagnosis of Autism Spectrum Disorder, when treatment is most effective. While regulators approved Clarifi ASD as a Laboratory Developed Test ("LDT") pursuant to the Clinical Laboratory Improvement Amendments ("CLIA") in November 2019, many of the company's resources were subsequently diverted toward COVID-19 initiatives; as expected, sales of Clarifi ASD have been limited. During the pandemic, the company continued to pursue several strategic initiatives related to Clarifi ASD, including (i) application to the FDA for "Breakthrough Device" designation (granted in April 2021) and (ii) ongoing implementation of the company's insurance reimbursement strategy. Recent milestones for our insurance reimbursement strategy include: issuance of a unique CPT® PLA code for Clarifi ASD by the American Medical Association, and; establishment of a payment rate of $1,950 for Clarifi ASD by the Centers for Medicare and Medicaid Services ("CMS"). The company is now pursuing state and federal health insurance coverage for Clarifi ASD.
- The ClearEdge Toolkit is a suite of tests and assessments healthcare providers use to measure and track a patient's balance and cognitive reaction time. The ClearEdge Toolkit initially consisted of a cognitive reaction time assessment module, which was a Class II medical device licensed from Anthrotronix and a balance module developed by the company, which was a Class I medical device. An improved version of the balance module was subsequently cleared by the FDA as a Class II medical device in October 2019. Due to limited clinical demand for the product and the company's increased focus on molecular diagnostics, sales of the ClearEdge Toolkit were discontinued in late 2020.

The intellectual property associated with our technology includes:

- potential patent rights in the methods of using the key biomarkers that are associated with a particular condition, such as Autism Spectrum Disorder, Parkinson's Disease, or concussion injuries, together with the associated know-how necessary to implement the methods (patent applications);
- trade secret rights in the specific algorithms that use the human and microbial RNA biomarker transcripts as inputs, and produce the best correlation with the target condition; and
- trade secret rights together with the associated know-how necessary to implement our COVID-19 tests, and how to implement those tests on a high-throughput basis.

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

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

- In 2019, the company was selected as the Technology Business of the Year by the New York State Small Business Development Center and was selected by the National Institutes of Health for inclusion in their Commercialization Accelerator Program ("CAP").
- In 2020, the company was selected as the Small Business of the Year by the CenterState Corporation for Economic Opportunity.
- In 2021, the company's COVID-19 test development and deployment efforts were selected as the Project of the Year by MedTech for its "singular and demonstrable positive impact on public health". Further, the company was selected as the Large Business of the Year by the CenterState Corporation for Economic Opportunity and the company's CEO Richard Uhlig was recognized as one of the top 50 Healthcare Technology CEOs by the Healthcare Technology Report.

The company has seven wholly owned subsidiaries:

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

Principal Products and Services

COVID-19 Testing

Since March 2020, the company has been focusing on ways to utilize its technology to develop a comprehensive approach to assessing COVID-19. The company currently has three COVID-19 products:

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

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

Individual Tests

On September 22, 2020, the company received an EUA for its individual COVID-19 diagnostic test. This is the culmination of work started in March 2020, where the company, in conjunction with SUNY Upstate Medical University and other SUNY researchers, started to develop a diagnostic test for COVID-19. The Clarifi COVID-19 Test kit is a non-invasive and easy to administer saliva swab, and a kit of reagents for extraction of viral RNA and performing qPCR testing to determine the presence or absence of SARS-CoV-2 viral RNA. The Clarifi COVID-19 Test kit contains the saliva collection swab and the reagents needed to run the analysis, together with detailed instructions regarding performing the testing method / procedure. The Clarifi COVID-19 Test kit is available for use by high-complexity clinical laboratories serving patients through physicians' offices, urgent care clinics and hospitals. The company's FDA EUA for this test has been amended to allow for multiple saliva collection devices, self-collection of a saliva specimen and at-home saliva specimen collection. Emergency use authorization for testing asymptomatic individuals is expected in the second quarter of 2021, which will allow us among other things to market the test for that purpose. That company believes that the Clarifi COVID-19 Test is presently the most sensitive saliva test available in the United States (as measured using the FDA SARS-CoV-2 Reference Panel).

Pooling of Specimens

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

Wastewater Surveillance

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

wastewater from county and municipal sewer systems for the presence of the SARS-CoV-2 virus. Results from the wastewater tests are used by local and state authorities to modify public health policies and allocate resources to areas as the virus appears in wastewater several days before infected individuals enter the healthcare system for diagnosis. The company has executed contracts with New York State and other municipalities, colleges, and universities to perform wastewater tests at more than 250 sites throughout New York, Pennsylvania and Vermont.

In addition, the company is actively engaged in the research and development of other COVID-19 tests, including a saliva-based rapid antigen test and a quantitative antibody test (the latter would be used to measure an individual's antibody titer and potential need for future vaccinations).

Clarifi ASD

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

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

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

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

During the pandemic, the company has taken steps in developing a strategy for Clarifi ASD insurance reimbursement. Attaining a unique CPT® PLA code in 2020 was a major step toward reimbursement for Clarifi ASD. On Sept 21, 2020, CMS (Centers for Medicare and Medicaid Services) released a preliminary payment rate determination of $1,950; this rate was finalized and became effective in January 2021. With these now established, the company is pursuing state and federal health insurance coverage for Clarifi ASD.

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

ClearEdge Toolkit

In August 2017, the company began marketing the ClearEdge Toolkit, a data-driven clinical brain health assessment toolkit that is used to manage a number of conditions, including but not limited to general brain health, as measured through an assessment of cognitive processing speed and postural stability. Due to limited clinical demand for the product and the company's increased focus on molecular diagnostics, commercial sale of the ClearEdge Toolkit was discontinued in late 2020, and the product will no longer be operational by the end of 2021. The toolkit consisted of a suite of tests that includes cognitive assessment, balance and symptoms tracking. The toolkit includes three separate tests:

- ClearEdge DANA: an FDA-cleared Class II clinical neurocognitive tool developed by Anthrotronix Inc., measures and monitors subtle changes in cognitive function. ClearEdge DANA is efficient and effective for a wide range of preventive and acute healthcare uses.
- ClearEdge Balance: a Class II medical device that assesses changes in balance using our proprietary Edge™ Sensor. The Edge Sensor is a wireless inertial measurement unit worn on the patient's lower back, at the approximate center of mass. ClearEdge Balance was cleared by the FDA on October 22, 2019. ClearEdge Balance is an improved version of its predecessor ClearEdge Motion, a Class I balance module that also assessed changes in balance using the Edge Sensor. In June, 2020, ClearEdge Motion was discontinued and replaced by ClearEdge Balance in new production of ClearEdge Toolkits, and ClearEdge Toolkits in the market were upgraded with new software to replace ClearEdge Motion with ClearEdge Balance.
- Questionnaires: Questionnaires related to symptoms used for tracking and assessment.

Products Under Development

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

- reduced cost of genetic sequencing technology,
- increasing availability and access to data through cloud computing, and
- ongoing developments in artificial intelligence and machine learning.

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

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

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

Intellectual Property

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

- potential patent rights that may be obtained through the patent applications (together with associated know how) that are jointly invented and owned by the company and the Foundations,
- 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 a combination of provisional patent applications and non-provisional patent applications. The provisional patent applications must be converted into non-provisional applications within one year after filing the provisional application, and the non-provisional applications (current and future converted 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
2020	$ 10,000	$ 5,000	$ 1,000
2021	$ 25,000	$ 10,000	$ 5,000
2022	$ 50,000	$ 25,000	$ 10,000
2023	$ 50,000	$ 25,000	$ 10,000
2024	$ 50,000	$ 25,000	$ 10,000
2025 through expiration (estimated to be 2038)	$ 50,000	$ 25,000	$ 25,000

The total estimated payments, assuming the company pays the minimum royal payment through expiration (estimated to be 2038), for the ASD, Parkinson's and TBI Licenses are $835,000, $415,000 and $361,000, 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.

Quadrant has also entered into a license agreement with the SUNY Research Foundation ("SUNY RF") in relation to its COVID-19 testing technology. The technology embodied in the Clarifi COVID-19 Test was jointly developed by Quadrant and SUNY Upstate Medical University personnel, and is therefore co-owned by Quadrant and SUNY RF. The 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 50% of the net income realized on sales of products or services that embody the COVID-19 Test technology. The term of the license extends for the entire time period during which Quadrant sells any product or service that embodies the COVID-19 Test technology. SUNY RF has the right to terminate the license 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. Quadrant has amended this agreement with SUNY RF to clarify some of the terms, and anticipates formalizing that amendment shortly.

In 2021, the company paid $858,614 in royalty payments with respect to the COVID-19 testing technology.

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 23 pending patent applications, as of April, 2021, grouped in the following 7 patent families:

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

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

- Registered – i.e. the certificate of registration has been issued and is in force: Australia, Canada, China, Brazil, European Union, Great Britain, Hong Kong, Indonesia, India, Japan, Korea, Norway, New Zealand, Philippines, Saudi Arabia, Singapore, Switzerland, Taiwan, Thailand, United Arab Emirates, United States, and Vietnam.
- Filed and pending/allowed – i.e., in this context the term "pending" means the application is in the examination process but has not yet been approved or allowed, and "allowed" means the examiner has approved/allowed the application but it has not yet been registered (it could be waiting for the opposition period to pass or for a Statement of Use to be filed (as in the U.S.): China (1 Registered, 1 Pending), Malaysia (pending).

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

Market-COVID-19

Due to the scope, nature and severity of the current pandemic, there is currently significant need for fast, efficient, non-invasive individual tests. We anticipate the need for these tests will remain at least until there is a widespread, global eradication, either through vaccination or otherwise, of the disease.

Despite current reductions in US cases from peaks experienced in January 2021, the risk of (i) a resurgence of infections, and (ii) an increase in mortality rates, persist. For the next 12-18 months, the company believes that testing will remain a critically important tool for tracking and containing the virus.

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

- Immunity May be Temporal. The percentage of a community with natural immunity from infection (resulting from prior infection) or acquired immunity (resulting from vaccination) is dependent on (i) the durability of each individual's immune response (currently known to persist for at least 6 months for immunity derived from the Pfizer and Moderna vaccines), and (ii) the applicability of derived antibodies to new variations of the virus. The latter of these is believed to be a material risk, particularly given the recent emergence of several SARS-CoV-2 Variants of Concern (as defined by the US Centers for Disease Control and Prevention ("CDC")) in the US and elsewhere. Further, while US vaccination efforts may be successful in reducing infections in the near-term, the virus continues to spread widely in many other countries; for this reason the risk of mutations which enhance transmissibility and allow the virus to evade natural or acquired immunity is high.
- Recently Observed Declines in US Cases may be Predominantly Seasonal. The 7-day moving average of US cases has declined significantly from a peak of approximately 250,000 cases/day (January 2021). While vaccinations and prior infections are believed to play a role in this reduction, a majority of the decline remains unexplained. There is growing evidence that SARS-CoV-2 infections may be seasonal, similar to infections observed from other coronaviruses. A seasonal resurgence of US cases in the Fall of 2021 is possible.

Market - Epigenetics

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

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

Autism Spectrum Disorder

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

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

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

Parkinson's Disease

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

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

Concussion Injuries (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 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.
- Falls and motor vehicle crashes were the first and second leading causes of all TBI-related hospitalizations (52% and 20%, respectively).

Competition

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

Suppliers

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

Research and Development

The amount expensed for research and development for the year ended December 31, 2020 was $521,875 and for the year ended December 31, 2019 was $280,879.

Employees

As of December 31, 2020, the company has 42 full-time employees. All company employees are “at will”; however, the company has employment agreements with basic confidentiality, proprietary rights and non-compete provisions with all employees.

Regulation

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

Unless an exemption applies, each medical device or product we wish to distribute commercially in the United States will require marketing authorization from the FDA prior to distribution, which would be 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.

The ClearEdge Toolkit includes modules that are regulated as medical devices and require premarket notification from the FDA. However, we believe that our epigenetic diagnostic tests are LDTs that are not subject to FDA regulation and do not require this notification. 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) Application

We submitted a 510(k) application for ClearEdge Balance, a new balance sensor, on December 27, 2018. The FDA grants 510(k) clearance when submitted information establishes that the proposed device is “substantially equivalent” to a legally marketed predicate device. We obtained clearance of ClearEdge Balance on October 22, 2019.

The ClearEdge Toolkit consists of:

- a software module licensed from Anthrotronix that performs testing of cognitive reaction times, which is a Class II medical device for which Anthrotronix obtained premarket clearance, or 510(k);
- an accelerometer-based sensor for measuring balance which we manufacture, and which is a Class I medical device that does not require premarket clearance or approval from the FDA; and

- an internet-based network system for transmission and storage of the electronic test results generated by the first two sensors, which FDA regulates as a Medical Device Data System that is exempt from most FDA regulatory requirements.

ClearEdge Balance was phased in to replace the predecessor balance module in 2020. Due to limited clinical demand for the product and the company's increased focus on molecular diagnostics, commercial sale of the ClearEdge Toolkit was discontinued in late 2020, and the product will no longer be operational by the end of 2021.

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 and has subsequently filed amendments to this EUA to further expand the product's clinical use.

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).

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. It is unclear at this time when, or if, the FDA will finalize its plans to end enforcement discretion, and how it will implement the directive from HHS. 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. As a result, 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 FDA in August, 2017, 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. However, there is no guarantee that the de novo regulatory pathway can be used, and if it is available, how long it will take to obtain de novo clearance to market the Clarifi ASD test.

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

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

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

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

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

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

The two clinical laboratories operated by the company each hold a NYSDOH clinical laboratory permit, meet CLIA accreditation requirements and have been assigned a CLIA number.

Litigation

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

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

THE COMPANY'S PROPERTY

The company does not currently own real property. We lease office space in (i) Syracuse, New York at SUNY Upstate Medical Center and at a local affiliated biotech accelerator, (ii) Buffalo, New York at the University of Buffalo, and (iii) San Antonio, Texas in a commercial office building. The lease for office space located at SUNY Upstate Medical Center expires in October 2021; the lease for office space located at the biotech accelerator expires in September 2021; the lease for the laboratory and office space at the University of Buffalo expires in February 28, 2022; and the San Antonio commercial office building is leased month-to-month and ended on December 1, 2020. We expect our lease contracts for our office space in Syracuse will be extended on similar terms.

Item 2. 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, 2020.

Overview

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

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

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

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

Due to the pandemic in 2020, the company pivoted from its principal focus on the development and commercialization of epigenetic diagnostic tests and developed COVID-19 diagnostic products, including an individual diagnostic test for which it obtained an FDA EUA in September 2020. The company's 2020 financial revenues primarily relate to its COVID-19 products.

Prior to the commencement of our COVID-19 related work, the company had sold two products, Clarifi ASD and the ClearEdge Toolkit.

- Clarifi ASD is a molecular diagnostic test that provides clinicians with objective support for earlier diagnosis of Autism Spectrum Disorder, when treatment is most effective. While regulators approved Clarifi ASD as a Laboratory Developed Test pursuant to CLIA in November 2019, many of the company's resources were subsequently diverted toward COVID-19 initiatives; as expected, sales of Clarifi ASD have been limited. During the pandemic, the company continued to pursue several strategic initiatives related to Clarifi ASD, including (i) application to the FDA for "Breakthrough Device" designation (granted in April 2021) and (ii) ongoing implementation of the company's insurance reimbursement strategy. Recent milestones for our insurance reimbursement strategy include: issuance of a unique CPT® PLA code for Clarifi ASD by the American Medical Association, and; establishment of a payment rate of $1,950 for Clarifi ASD by the Centers for Medicare and Medicaid Services ("CMS"). The company is now pursuing state and federal health insurance coverage for Clarifi ASD.
- The ClearEdge Toolkit is a suite of tests and assessments healthcare providers use to measure and track a patient's balance and cognitive reaction time. The ClearEdge Toolkit consists of a cognitive reaction time module which is a Class II medical device licensed from Anthrotronix, and a balance module, which initially was sold as a Class I medical device. An improved version of the balance module subsequently was cleared by the FDA as a Class II medical device in October 2019. Due to limited clinical

demand for the product and the company's increased focus on molecular diagnostics, sale of the ClearEdge Toolkit was discontinued in late 2020, and the product will no longer be operational by the end of 2021.

Results of Operations

Year ended December 31, 2020 Compared to Year ended December 31, 2019

Net Revenues

The company's revenues consist of revenue derived from product sales, product assembly, testing services, grant revenues and licensing and maintenance services. The company's total revenues for the year ended December 31, 2020 ("Fiscal 2020") were $11,801,123, an increase of $11,387,312 from total revenues of $413,811 in the year ended December 31, 2019 ("Fiscal 2019"). This increase is attributable to the company's COVID initiatives, which accounted for $11,477,679 (including sales related to wastewater testing, Clarifi COVID-19 Test kit sales product assembly services). Cost of products sold increased to $8,609,760 in Fiscal 2020, an increase of $8,183,248 from $426,512 in Fiscal 2019, primarily attributable to the sale of the COVID products, including royalty payments of $858,614, while there were no corresponding payments in 2019. Accordingly, the company had gross profit of $3,191,363 in Fiscal 2020 compared with a gross loss of $12,701 in Fiscal 2019.

Operating Expenses

Operating expenses in Fiscal 2020 were $6,602,726, compared to $5,968,224 in Fiscal 2019, an increase of $634,502. The increase primarily relates to the increase in employment related expenses, which includes employee benefits and taxes, salaries and wages and stock option compensation, which collectively increased by $1,508,056 to $5,488,259 in Fiscal 2020 from $3,980,203 in Fiscal 2019. The company had 42 employees at December 31, 2020 compared with 39 employees at December 31, 2019. Throughout 2020, the company retrained and reassigned many of its existing employees and hired additional experienced clinical laboratory professionals in order to service the company's COVID-19 testing and products. The increase was partially offset by a $485,180 decrease in professional fees, a decrease in office expenses and travel, which were $216,201 and $216,922, respectively, due to the company cutting spending on any non-COVID-19 related expenses.

Net Income

The company had other income in Fiscal 2020 of $397,656 compared to other expenses of $226,595 in Fiscal 2019. The income in 2020 is primarily attributable to an EIDL advance grant and forgiveness of the company's PPP loan, which totaled $765,600 in 2020. See "—Liquidity and Capital Resources."

The company had an income tax benefit in Fiscal 2020 of $5,819,431, compared with a benefit of $204,267 in Fiscal 2019.

As a result of the foregoing factors, the company's net income was $1,732,052 in Fiscal 2020 compared with a net loss of $7,296,264 in 2019.

Liquidity and Capital Resources

As of December 31, 2020, the company's cash and cash equivalents were $9,743,455. Historically, we had financed our operations primarily through the issuance of preferred stock, common stock, notes, debt, and research grants. In 2018, we converted our preferred stock into common stock. Beginning in September 2020, we began receiving revenues for our COVID testing and products.

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

The company has a line of credit with the borrowing capacity of $500,000 from Pathfinder Bank, at an interest rate of Bank Prime plus 1.125%. The line of credit had a balance of $403,996 and $0 at December 31, 2020 and 2019. The line is secured by all the business assets of the company and certain of the personal assets of the CEO. On February 22, 2021, the company paid down the entire outstanding balance of the line of credit and increased the borrowing limit of the line of credit to $1,000,000. The company also obtained a $160,000 SBA loan

in May 2020, which is secured by all the business assets of the company and a PPP loan of $755,600 which was forgiven in January 2021. The company also has a loan from VEP Biotech Ltd, with a maturity date of October 2023, an interest rate of 5%, and no required payment of principal or interest until maturity. The outstanding balance as of December 31, 2020 and December 31, 2019 (including principal and interest) were $5,555,858 and $5,288,146, respectively.

Trends

Quadrant started 2020 with sales of Clarifi ASD, having recently achieved regulatory approval for this test as an LDT. However, not long after we began to introduce Clarifi ASD to pediatric healthcare providers, the world was besieged by the COVID-19 pandemic. Since that time, our ability to access healthcare providers has been greatly restricted by social distancing mandates which, in turn, has limited our ability to introduce Clarifi ASD to potential customers. As a result of this serious impediment, our sales of the Clarifi ASD test have been well below previous expectations.

During the pandemic, the company continued to implement its strategy to obtain broad insurance reimbursement for Clarifi ASD. Attaining a unique CPT® PLA code in 2020 was a major step toward this outcome. On Sept 21, 2020, the Centers for Medicare and Medicaid Services ("CMS") released a preliminary payment rate determination of $1,950 for Clarifi ASD; this rate was finalized and became effective in January 2021. With these now established, the company is pursuing state and federal health insurance coverage for Clarifi ASD.

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

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

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

Researchers at Quadrant and SUNY Upstate Medical University leveraged our collective expertise to develop non-invasive, highly accurate and scalable diagnostic solutions for individuals, organizations and policy makers. As a result, today we are involved in three significant COVID-19 projects addressing different ways to assess the presence and prevalence of COVID-19. We anticipate that we will be involved in COVID-19 diagnostics, screening and surveillance activities throughout 2021 and likely into 2022, as COVID-19 remains a significant threat to national and worldwide health.

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

Quadrant continues to devote significant resources to the ongoing research, development and implementation of our COVID-19 initiatives; we anticipate that these products and services will be a significant part of our 2021 revenues.

Item 3. Directors and Officers

Directors, Executive Officers and Significant Employees

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

Name	Current Position	Age	Date Appointed to Current Position
Executive Officers			
Richard Uhlig	Chief Executive Officer	55	August 2015
Benjamin Perry, MS	President	30	November 2019
Naved Ameen	Executive Vice President of Corporate Strategy	54	August 2019
Richard Bongo	Chief Financial Officer	59	April 2018
Andrew Brindle	Executive Vice President Research& Development	39	April 2016
James Croke, JD	General Counsel	62	January 2018
Nicholas Gianadda	Chief Technology Officer	39	April 2021
Bryan Greene	Chief Operating Officer	39	October 2015
Chris Horacek, JD	Deputy General Counsel	66	January 2018
David MacLean, JD	Chief Marketing Officer	60	August 2015
Brady Millican	Executive Vice President of Global Sales	60	March 2021
Rita Romano	President - Quadrant Laboratories	55	February 2021
Kayla Wagner, MS	President - ASD Diagnostic Products	28	April 2021
Directors			
Richard Uhlig	Chairman	55	August 2015
Richard Bongo	Director	59	October 2017
James Croke, JD	Director	62	April 2018
Peter Cohen	Director	74	April 2018
Ira Fedder, MD	Director	66	October 2017
Andrew Rock	Director	57	August 2015
Mary Ann Tyzsko	Director	63	August 2015

Biographies of Executive Officers and Directors

Richard Uhlig
Chairman & Chief Executive Officer

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

Benjamin Perry
President

Benjamin's career originates from a technical background, where he spent over ten years in the software development industry. During that time, he both led and contributed to several successful projects in the public, private, and academic sectors. Benjamin's expertise revolves around a wide breadth of disciplines including cloud computing architecture, blockchain technology, and agile project management, where

his experience spans all facets of the product development lifecycle. He strives to build both human and technical systems that are accessible to all, and scale rapidly with demand. Ben has been with Quadrant Biosciences since April 2016. Until his recent promotion to President of the company in November 2019, he served as the Chief Technology Officer for both Quadrant and our subsidiary Motion Intelligence LLC. Prior to 2018, he was the Vice President of Technology at both organizations. Prior to Quadrant Biosciences, Benjamin led projects for the federal statistical system and public opinion domain. More specifically, he was a software developer for the Cornell Institute for Social and Economic Research from June 2013 – April 2016, where his metadata management software was installed within the US Census Bureau as part of an NSF grant. In addition, Benjamin ran a consulting business that provided data management expertise, and software development services. He received his master's degree in Information Science from Cornell University.

Naved Ameen
Executive Vice President of Corporate Strategy

Naved joined Quadrant in August 2019 and has over 25 years' experience working in a variety of financial roles. He started his career in investment banking at Smith Barney, advising institutions ranging from credit card issuers, state housing authorities to the Resolution Trust Corporation. A majority of his career was involved with creating, marketing and trading innovative financial products for investors of every type both domestically and internationally. He also has experience as an investor as a fixed income portfolio manager at Dillon Read and most recently from August 2014 through March 2017 as founder and portfolio manager of Tevere Capital a hedge fund catering to insurance companies. Naved has lead trading desks at Bank of America, Lehman Brothers and Morgan Stanley. He holds a Bachelor's Degree in Economics from The University of Pennsylvania.

Richard Bongo
Chief Financial Officer & Director

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

Andrew Brindle
Executive Vice President - Research and Development

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

James Croke
General Counsel & Director

Jim has been our General Counsel since January 2018. He is currently a principal at the law officers 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.

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 HealtheConnections where he oversaw the technical operations of the organization related to grant work and value based billing products and applications (September 2017 - March 2021) and as CTO at FieldNimble, a software startup focused on the small to medium sized contractor market, where he lead all technical operations for the organization (September 2016 - September 2017). Nick's experience in developing software in the healthcare industry includes applications for single sign-on, patient data access for providers, referral & case management tools, and quality measure calculation. Nick has a long history of building highly performant teams and coordinating successful product launches. He received a BS in Computer Science from Canisius College.

Bryan Greene
Chief Operating Officer

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

Chris Horacek
Deputy General Counsel

Chris has more than 20 years of experience as corporate counsel on matters including transactions, business development, intellectual property, and regulatory compliance. Chris joined Quadrant in January 2018. Previously, he served as Deputy General Counsel and Compliance Officer for Welch Allyn, Inc. for more than 10 years, and in that capacity managed the attorneys in the legal department who worked in the areas of transactions, intellectual property, and compliance, and also served on the executive team that managed the Quality and Regulatory departments. Chris is an adjunct professor at the Syracuse College of Law and teaches a section of the class on technology commercialization. He received a BS in Medicine from the University of Nebraska, and a JD, with distinction, from the University of Nebraska College of Law.

David MacLean
Chief Marketing Officer

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

Brady Millican
Executive Vice President of Global Sales

Brady has more than 30 years of sales, marketing, business development and operations experience in the medical diagnostics/prognostics industry, most recently as Chief Business Officer at Admera Health for the past 7 years. Prior to that, he held senior level sales and marketing positions at Bostwick, Ameripath and Dianon laboratories, he is also the Co-Founder of the Central Florida Autism Institute, Inc., a non-profit organization started by families of children with autism and concerned professionals. Mr. Millican served in the United States Army as an attack and medium-lift helicopter company commander and is airborne and ranger qualified. He holds a Bachelor of Arts Degree from Washington and Lee University.

Rita Romano
President - Laboratory Services

Rita has more than 30 years of clinical laboratory experience. Prior to joining Quadrant in February 2021, she was Director of the Operations Center for Laboratory Alliance of CNY, a locally owned, independent reference laboratory, a position she held since 2011. In

this role, she had technical and regulatory oversight of clinical laboratory services performing over 10 million tests/year. She developed strategic partnerships with both larger and smaller institutions to improve the delivery of laboratory testing for a clinically integrated network of health care providers in a cost-effective manner.Rita earned her Bachelor of Science in Medical Technology and her Masters of Arts in Strategic Leadership from St. Bonaventure University. She is certified by the American Society of Clinical Pathologists. Rita serves as the President of the Central New York Chapter of Clinical Laboratory Management Association and chair of the membership committee.

Kayla Wagner
President - ASD Diagnostic Products

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

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.

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.

Ira Fedder, MD
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.

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.

Compensation of Directors and Executive Officers

For the fiscal year ended December 31, 2020, we compensated our three highest-paid directors and executive officers as follows:

Name	Capacities in which compensation was received	Cash compensation ($)	Other compensation ($) (1)	Total compensation ($) (2)
Richard Uhlig	Chairman and CEO	$ 196,154	$ 452,500	$ 684,654
Richard Bongo	CFO	$ 167,308	$ 452,500	$ 619,808
Benjamin Perry	President	$ 167,308	$ 452,500	$ 619,808

(1) Other compensation is limited to stock options; the Black-Scholes formula was used to determine the value of the options at the date of grant.

(2) Total compensation is the sum of cash compensation and other compensation.

(3) 250,000 stock options were granted to each of Richard Uhlig, Richard Bongo and Ben Perry for their services as Chairman and CEO, CFO and President, respectively.

Item 4. 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 par value $0.0001 per share. As of December 31, 2020, there were 88,955,194 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, 2020, 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	32,779,154	6,764,016	41.31%
Research Foundation for the State University of New York	5,959,241	--	6.70%
James Croke, General Counsel and Director	2,020,398	3,336,442	5.80%
Richard Bongo, CFO and Director	1,184,263	3,409,380	4.97%
All Directors and Executive Officers (14 total)	46,002,500	19,387,101	60.35%
All Directors (8 total)	39,197,772	16,676,547	52.90%

(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, 2021.

(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%.

Item 5. Interest of Management and Others in Certain Transactions

In 2019, the company entered into a month-to-month lease agreement for the use of 1,500 square feet of commercial office space at 619 W. Rhapsody Drive, San Antonio, Texas 78216. Monthly rent for this lease was $2,250. This lease agreement was terminated as of December, 2020. The beneficial owner of this property was Wade West; during the time of this lease, Mr. West was the company's Executive Vice President of Sales and a member of the Board of Directors. Rental expense paid to this former Board member amounted to $18,000 and $7,500 for the years ended December 31, 2020 and 2019, respectively. This lease ended on December 1, 2020

Item 6. Other Information

None.

Item 7. Financial Statements

QUADRANT BIOSCIENCES INC.
AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Years Ended
December 31, 2020 and 2019

DANNIBLE & McKEE, LLP
Certified Public Accountants and Consultants
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. and Subsidiaries

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Quadrant Biosciences, Inc. and Subsidiaries ("the Company") as of December 31, 2020 and 2019, 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, 2020 and 2019, 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 the 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 audit 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.

Critical Audit Matter

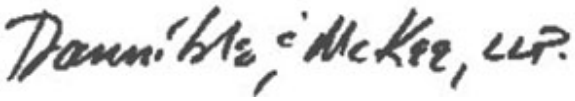
The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial 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 (21) and E to the consolidated financial statements, the Company capitalizes certain internal-use software costs related to new products as well as existing products when those costs will result in significant additional functionality. The Company's capitalized internal-use software asset, net of accumulated amortization, was $6,434,639 as of December 31, 2020. The Company capitalized $1,849,840 of internal-use software costs during the year ended December 31, 2020.

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

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



Dannible & McKee, LLP
We have served as Quadrant Biosciences, Inc.'s auditor since 2019.
Syracuse, New York
April 1, 2021

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

ASSETS

	2020	2019
Current Assets:		
Cash and cash equivalents	$ 9,743,455	$ 1,289,474
Accounts receivable, net of allowance for doubtful accounts of $0 in 2020 and 2019.	1,354,350	12,653
Prepaid expenses and other current assets	23,975	39,547
R&D tax credit receivables	188,117	413,841
NY tax credit receivable	34,550	16,150

Inventories	1,463,855	307,000
Total Current Assets	12,808,302	2,078,665
Furniture and Equipment:		
Furniture & equipment	71,788	38,292
Less: accumulated depreciation	32,630	24,294
Total Furniture and Equipment	39,158	13,998
Other Assets:		
Deferred tax asset	5,801,031	-
Right-of-use lease asset	56,703	135,866
Line of credit origination fees	17,099	17,099
Software as service	8,523,769	7,046,853
Less: accumulated amortization	2,106,229	620,248
Total Other Assets	12,292,373	6,579,570
Total Assets	$ 25,139,833	$ 8,672,233

LIABILITIES AND STOCKHOLDERS' EQUITY

	2020	2019
Current Liabilities:		
Accounts payable	$ 1,207,732	$ 238,730
Royalty payable	858,614	-
Contract liabilities	7,642,227	69,656
Pathfinder line of credit	403,996	-
Current portion lease liability	60,918	80,567
Accrued payroll and related liabilities	789,561	46,330
Accrued liabilities	21,026	76,439
Current portion of long-term debt	1,708	-
Pledges payable	-	225,000
Total Current Liabilities	10,985,782	736,722
Long-Term Liabilities:		
Lease liability, net of current portion	-	60,918
Notes payable	5,707,571	5,288,146
Total Long Term Liabilities	5,707,571	5,349,064
Stockholders' Equity:		
Common stock, par value $0.0001 per share, 125,000,000 shares authorized, 88,955,194 and 87,932,825 issued and outstanding, respectively	8,896	8,793
Additional paid in capital	26,808,240	22,680,362
Accumulated deficit	(18,370,656)	(20,102,708)
Total Stockholders' Equity	8,446,480	2,586,447
Total Liabilities and Stockholders' Equity	$ 25,139,833	$ 8,672,233

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

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

	2020	2019

Revenues:		
Product sales, net	$ 10,602,171	$ 3,454
Product assembly	891,574	-
Testing services	48,218	51,283
Grant revenue	241,646	316,299
Licensing and maintenance services	17,514	42,775
Total Revenues	11,801,123	413,811
Cost of Products Sold	8,609,760	426,512
Gross Profit	3,191,363	(12,701)
Sales and Marketing Expenses	551,797	1,012,132
Research and Development Costs	521,875	280,879
Selling and Administrative Expenses:		
Depreciation and amortization	8,336	6,407
Employee benefits and taxes	557,420	365,595
Office expenses	196,966	413,167
Other expenses	293,400	280,900
Professional fees	394,461	879,641
Rent & lease expense	130,888	100,568
Salaries and wages	3,303,932	2,724,030
Stock option compensation	1,626,907	890,578
Travel	90,416	307,338
Total Selling and Administrative Expenses	6,602,726	5,968,224
Loss from Operations	(4,485,035)	(7,273,936)
Other (Expenses) Income:		
Toolkit rental income	20,333	5,460
Loss on software impairment	(98,646)	-
EIDL advance grant and PPP forgiveness	765,600	-
Interest income	1,911	22,787
Interest expense	(291,542)	(254,842)
Total Other Income (Expenses)	397,656	(226,595)
Net Loss Before Income Tax	(4,087,379)	(7,500,531)
Income Tax Benefit	5,819,431	204,267
Net Income (loss)	$ 1,732,052	$ (7,296,264)
Per share data:		
Basic income (loss), per common share	$ 0.02	$ (0.09)
Diluted income (loss), per common share	0.02	(0.09)
Shares used in computing net income (loss) per common share:		
Basic	88,725,387	84,183,139
Diluted	105,547,196	84,183,139

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, 2020 and 2019

	Common Shares	Treasury Stock Common Shares	Common Stock Par Value	Treasury Stock (Common)	Additional Paid-in Capital	(Accumulated Deficit)	Total
Balance, December 31, 2018	82,481,721	-	$ 8,248	$ -	$ 15,841,089	$ (12,806,444)	$ 3,042,893
Exercised stock options ($0.003 per share)	40,000	-	4	-	116	-	120
Purchase of treasury stock, at $1.25 per share	(40,000)	40,000	(4)	(4)	(49,996)	-	(50,000)
Retired treasury stock	-	(40,000)	-	4	-	-	-

Issuance of common stock, at $1.25 per share	4,042,000	-	404	-	5,052,096	-	5,052,500
Exercised stock options ($0.003 per share)	652,288	-	65	-	1,893	-	1,958
Exercised stock options ($0.39 per share)	434,816	-	44	-	169,618	-	169,662
Issuance of common stock, at $2.50 per share	322,000	-	32	-	804,968	-	805,000
Stock option compensation	-	-	-	-	890,578	-	890,578
Stock issuance costs	-	-	-	-	(30,000)	-	(30,000)
Net loss	-	-	-	-	-	(7,296,264)	(7,296,264)
Balance, December 31, 2019	87,932,825	-	8,793	-	22,680,362	(20,102,708)	2,586,447
Exercised stock options ($0.003 per share)	12,500	-	2	-	38	-	40
Issuance of common stock, at $2.50 per share	702,100	-	70	-	1,755,180	-	1,755,250
Issuance of common stock, at $3.00 per share	307,769	-	31	-	923,276	-	923,307
Stock option compensation	-	-	-	-	1,626,907	-	1,626,907
Stock issuance costs	-	-	-	-	(177,523)	-	(177,523)
Net income	-	-	-	-	-	1,732,052	1,732,052
Balance, December 31, 2020	88,955,194	-	$ 8,896	$ -	$ 26,808,240	$ (18,370,656)	$ 8,446,480

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,

	2020	2019
Cash Flows from Operating Activities:		
Net income (loss)	$ 1,732,052	$ (7,296,264)
Adjustments to reconcile net income (loss) to net cash provided by (used in) by operating activities:		
Depreciation and amortization	1,494,317	396,773
Employee stock option compensation	1,626,907	890,578
Deferred tax benefit	(5,801,031)	-
Forgiveness of PPP loan	(755,600)	-
Changes in income tax credit receivable	207,324	(192,475)
Changes in accounts receivable	(1,341,697)	11,424
Changes in accounts payable	969,002	75,742
Changes in royalty payable	858,614	-
Changes in contract liabilities	7,572,571	(11,711)
Changes in accrued interest	272,814	254,813
Changes in inventories	(1,156,855)	(14,309)
Changes in right-of-use lease asset	79,163	83,032
Changes in pledges payable	(225,000)	(75,000)
Changes in lease liability	(80,567)	(78,818)
Changes in prepaid expenses and other current assets	15,572	25,316
Changes in accrued payroll and related liabilities	743,231	(139,894)
Changes in accrued liabilities	(55,413)	11,556
Cash Provided by (Used in) Operating Activities	6,155,404	(6,059,237)
Cash Flows from Investing Activities:		
Cash paid for purchases of fixed assets	(33,496)	-
Payments of software development costs	(1,476,916)	(3,546,255)
Cash Used in Investing Activities	(1,510,412)	(3,546,255)
Cash Flows from Financing Activities:		
Proceeds from SBA EIDL loan	150,000	-
Proceeds from PPP loan	755,600	-
Proceeds from line of credit	500,000	-

Repayment of line of credit	(97,685)	-
Proceeds from sale of stock and exercise of options, net of issuance costs	2,501,074	5,999,240
Purchase of treasury stock	-	(50,000)
Cash Provided by Financing Activities	3,808,989	5,949,240
Net Change in Cash	8,453,981	(3,656,252)
Cash, beginning of year	1,289,474	4,945,726
Cash, end of year	$ 9,743,455	$ 1,289,474
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	$ 20,409	$ 29
Income taxes	1,143	12,845

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, 2020 and 2019

A. Summary of Significant Accounting Policies:

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

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

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

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

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

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

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

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

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

Quadrant Laboratories LLC is a wholly owned, which, plans to operate and administer clinical laboratories in which diagnostic medical testing and related commercial activities are conducted.

2. Principles of Consolidation – The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Motion Intelligence LLC, Quadrant Epigenetics LLC, Quadrant IP Holdings LLC, Quadrant Vision

Technologies LLC, Quadrant Viral Testing LLC, Quadrant Biosciences Canada Ltd, and Quadrant Laboratories LLC. All intercompany balances and transactions have been eliminated in consolidation.

3. Cash – For the purposes of cash flow disclosures, cash is defined as cash deposited in financial institutions and any investments that mature within three months or less from the initial purchase date.

4. Furniture and Equipment – Furniture and equipment acquisitions are recorded at cost. Depreciation is computed using the straight-line method based on the expected useful lives of the assets, which range from 5 to 7 years. 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, 2020 and 2019 was $8,336 and $6,407, respectively.

5. Inventories – Inventories 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 80 hours paid vacation time after one year of service, after three years of service eligible employees will receive 120 hours paid vacation. 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 for a COVID-19 Saliva Diagnostic. The Company shall pay to the Foundation a royalty of 50% of all net income as defined in the agreement. Net income is defined as 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. As of December 31, 2020, and 2019 the amount owed for royalty payments was $858,614 and $0, respectively. Royalty expense is included in cost of products sold. For the year ended December 31, 2020 and 2019 the expense was $858,614 and $0, 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 ASB 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.

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 $521,875 and $280,079 for the years ended December 31, 2020 and 2019, respectively, were expensed as incurred.

10. Accounts Receivable – Accounts receivable are recorded at the invoiced amount and do not bear interest. 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 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. Presently no allowance has been established for potential losses. The Company does not have any off-balance-sheet credit exposure related to its customers.

11. Other Assets – Line of credit origination fees of $17,099 in 2020 and 2019, net of accumulated amortization of $17,099 at December 31, 2020 and 2019, respectively, were being amortized on a straight-line basis over the expected term of the loan, which was 24 months. Amortization expense for the line of credit origination fees for the years ended December 31, 2020 and 2019 was $0 and $7,528, respectively.

12. Concentration of Business Risk – In 2020 and 2019, all of the Company's Clarifi ASD inventory was purchased from two vendors and held by another two vendors. 78% of inventory purchases were from a single vendor for Clarifi Covid-19 and Wastewater. In 2020 95% of test kit sales and 100% of product assembly were to one customer.

13. Advertising – The Company expenses all advertising costs. Advertising expenses totaled $535,567 and $965,412 for the years ended December 31, 2020 and 2019, respectively.

14. 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.

15. Stock-Based Compensation – The Company accounts for stock options under the provisions of ASC 718 Stock Compensation. For options granted in 2020 and 2019, 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.

16. Treasury Stock – The Company repurchased common stock shares of 40,000 in the year ending December 31, 2019 at $1.25 per share. During 2020 and 2019, 0 and 40,000 shares of treasury stock were retired, respectively.

17. Estimates and Assumptions – Management of the Company uses estimates and assumptions in preparing consolidated financial statements in accordance with generally accepted accounting principles. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could vary from the estimates that management uses.

18. Shipping Costs – Shipping costs are included in cost of goods sold.

19. Grant Revenue – The Company evaluates terms and conditions of individual grants to determine whether they meet the characteristics of an exchange transaction or a nonexchange transaction. Revenue from grants that are determined to be exchange transactions are recognized according to ASC 606. Revenue from grants that are nonexchange transactions are recognized over the period of performance, to match the revenue with the related expenses in a systematic manner. In 2020 and 2019, the Company recognized revenue on a grant from National Institute of Mental Health (NIH), which was classified as a nonexchange transaction, of $241,646 and $316,299, respectively.

20. Earnings Per Share – The Company presents basic earnings per share ("EPS"), computed based on the weighted average number of common shares outstanding for the period, and when applicable diluted EPS, which gives the effect to all dilutive potential shares outstanding (i.e. options) 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 for the year ended December 31, 2020 of 16,821,443. The dilutive options for 2020 have been included in the EPS calculation and have not been included for 2019 due to being antidilutive.

21. 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.

An impairment charge related to capitalized software development costs for ClearEdge were taken of $98,646 for the year ending December 31, 2020. No impairment has been recorded for the year ended December 31, 2019.

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

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

23. Leases – The Company has recognized right-of-use assets and lease liabilities resulting from operating 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.

24. Revenue from Contracts with Customers – All of the Company's revenue from contracts with customers are in the scope of ASC 606 and are included in revenues on the Consolidated Statement of Operations. Revenue is measured based on consideration specified in a contract with a customer and excludes any sales discounts. 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.

25. Related Party Transactions – The Company rents certain operating premises from a related party, as explained in Note C.

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:

Credits provided as incentives on ClearEdge toolkit sales – At times, the Company provided credits to certain customers who purchased ClearEdge toolkits to be redeemed for future testing services. The Company allocated a portion of the consideration received from the toolkit sales to these credits based on the observable stand-alone selling price of $1 per credit and allocated the remaining consideration to the toolkit using the residual approach as an estimate of the toolkit's stand-alone selling price. The amount allocated to the credits was deferred in contract liabilities on the Consolidated Balance Sheet and was recognized as revenue when the credits were redeemed for testing services. Revenue was recognized in net product sales. All credits were redeemed as of December 31, 2020.

Testing services – Testing services consist of diagnostic tests and assessments performed by the Company using its ClearEdge technology. The Company recognizes revenue at the time the service is provided. Customers typically prepay for testing services by purchasing credits to be redeemed for future testing services. The credits are deferred in contract liabilities on the Consolidated Balance Sheet and recognized as testing services revenue at the time of performance.

Licensing services – Licensing services consist of a license granted to end users in order to access the ClearEdge network, including its database of test results, via the communications interface incorporated into the toolkit. Revenue is recognized on a monthly basis after the month of licensing services are complete. The Company stopped performing licensing services in October 2020.

Maintenance services – Maintenance services consist of an agreement to replace a customer's toolkit with a replacement unit if the equipment fails to operate in accordance with its performance specifications during the term of the agreement due to ordinary wear and tear or accidental damage. The plan is limited to one replacement unit in any 12-month period and a new unit after 5 years. Revenue is recognized on a monthly basis after the month of maintenance services are complete. The Company stopped performing maintenance services in October 2020.

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.

Wastewater testing – In 2020, the Company began offering testing services to analyze wastewater across NYS 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 prepay 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.

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

Disaggregation of Revenues

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

Major products/service lines	2020	2019
ClearEdge toolkit sales	$ -	$ 3,454
Testing services run on ClearEdge platform	48,218	51,283
Licensing and maintenance services	17,514	42,775
Clarifi ASD tests	16,066	-
Wastewater testing	769,440	-
Clarifi COVID-19 test kit sales	9,816,665	-
Product assembly services	891,574	-
	$ 11,559,477	$ 97,512

Timing of revenue recognition	2020	2019
Transferred at a point in time	$ 11,541,963	$ 54,737
Transferred over time	17,514	42,775
	$ 11,559,477	$ 97,512

Contract Balances

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

	2020	2019
Receivables, which are included in "Accounts receivable"	$ 1,354,350	$ 3,373
Contract liabilities	7,642,227	69,656

Full payment on toolkits is due at the time of shipment, 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 for ClearEdge test runs, Clarifi ASD tests, and Clarifi COVID-19 test kit sales. Customers typically prepay for test runs, ASD tests, and COVID-19 test kit sales. At the time of payment for ClearEdge test runs, such customers receive credits to use at their discretion.

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

	2020	2019
Revenue recognized that was included in the contract liability balance at the beginning of the period	$ 66,656	$ 54,737
Increases due to cash received, excluding amounts recognized as revenue during the period	(7,639,227)	(43,026)

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, 2020 and 2019 are $7,642,227 and $69,656, respectively. Unsatisfied (or partially satisfied) performance obligations mainly consist of prepayments for Clarifi COVID-19 test kits. The Company recognized $69,656 of the revenue from remaining performance obligations as of December 31, 2019 in 2020, and expects to recognize all revenue from remaining performance obligations as of December 31, 2020 in 2021.

C. Operating Lease Commitments:

The Company has entered into a number of lease arrangements. Specifically, operating leases for office space have been entered into in Ithaca and Syracuse, NY and San Antonio, TX during the periods. The Company leases its San Antonio premises from a Board member and officer of the Company through December 31, 2020. Rental expense paid to this Board member amounted to $18,000 and $7,500 for the years ended December 31, 2020 and 2019, respectively.

In addition, the Company has elected the short-term lease practical expedient related to office space rentals. Two of the Company's office space leases include optional renewal periods. The Company does not consider these additional renewal periods to be reasonably certain of being exercised, as comparable locations could be identified within the same trade areas for comparable lease rates.

The provisions of the Company's leases include both fixed rental payments and lease payments that increase at pre-determined dates. While the majority of the Company's leases are gross leases, there is a lease where separate payments are made to the lessor based on the pro-rata share of operating expenses including real property taxes, insurance and common area maintenance expenses. The Company has elected the practical expedient not to separate lease and non-lease components for all office space leases.

During the years ended December 31, 2020 and 2019, rent expenses were recognized associated with operating leases as fixed rent expense of $87,583 and $89,369 respectively.

Amounts recognized as right-of-use assets related to operating leases are included in other assets, while related lease liabilities are shown as current liabilities and long-term liabilities. As of December 31, 2020 and 2019, right-of-use assets and lease liabilities relating to operating leases were as follows:

	2020	2019
Operating lease right-of-use assets	$ 56,703	$ 135,866
Operating lease liabilities		
Current portion of lease liability	60,918	80,567
Lease liability, net of current portion	-	60,918

During the years ended December 31, 2020 and 2019, the Company had the following cash and non-cash activities associated with operating leases:

	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 88,987	$ 83,369

No non-cash activity during the period

The future minimum annual payments due under operating leases as of December 31, 2020 are as follows:

2021	$	60,918

As of December 31, 2020, and 2019, the weighted-average remaining lease term for all operating leases is .75 and 1.75 years, respectively.

Because 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, 2020 and 2019 is 4.51% and 4.44%, respectively.

D. Inventories:

Inventories consisted of the following:

	2020	2019
Clarifi ASD		
Testing supplies	$ 124,985	$ 144,809
Clarifi COVID-19		
Testing supplies	925,448	-
Inventory in transit	302,368	-
Wastewater		
Testing supplies	111,054	-
ClearEdge		
Raw materials	-	95,851
Finished goods	-	66,340
	$ 1,463,855	$ 307,000

E. Software as Service:

The Company capitalized software costs of $1,849,840 and $3,546,255 for the years ended December 31, 2020 and 2019, respectively. The Company expensed $274,280 as research and development costs for software that was capitalized that was discontinued.

The Company amortized $1,485,981 and $382,838 of capitalized costs for the years ended December 31, 2020 and 2019, respectively. The Company has software development costs of $3,999,241 for which amortization has not started as the software has not yet been placed in service for the year ended December 31, 2020. Amortization expense is included in cost of goods sold. Future amortization for assets placed in service will be $1,277,179, and $1,158,220 for 2021 and 2022, respectively.

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 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:

	2020	2019
Dividend yield	0%	0%
Volatility	50.00%	50.00%
Discount rate	1.64%	3.03%
Expected life	5.77	5.77
Fair value of common stock per share	$ 3.00	$ 1.25
Expected rate of forfeitures	0.00%	0.00%

Management's policy is to account for forfeitures as they occur. Total compensation cost related to nonvested awards not yet recognized is $6,256,981 as of December 31, 2020. It is expected to be recognized over the weighted-average period of 2.193 years. Stock option compensation of $1,626,907 and $890,578 was recognized for the years ending December 31, 2020 and 2019, respectively.

A summary of the status of the Company's stock option plan as of December 31, 2020 and 2019 is presented below:

Fixed Options	Shares	Weighted Average Exercise Price
January 1, 2019	25,856,511	$ 0.277
Granted	6,332,930	1.250
Forfeited	(4,739,647)	0.368
Exercised	(1,127,104)	0.152
December 31, 2019	26,322,690	0.456
Granted	4,210,568	3.00
Forfeited	(1,431,158)	0.466
Exercised	(12,500)	0.003
December 31, 2020	29,089,600	0.824
Exerciseable:		
December 31, 2020	21,907,699	
Weighted average fair value of options granted in 2020	$ 1.43	

G. Income Taxes:

The components of the benefit for income taxes in the accompanying Consolidated Statements of Operations are as follows:

	2020	2019

Current:		
Federal	$ -	$ 188,117
State	18,400	16,150
	18,400	204,267
Deferred:		
Federal	4,363,047	-
State	1,437,984	-
	5,801,031	-
Tax benefit	$ 5,819,431	$ 204,267

The components of the benefit for income taxes differs from the amount that would result from applying the federal statutory rate for the years ended December 31, 2020 and 2019 as follows:

	2020		2019	
	Amount	%	Amount	%
Statutory tax rate	$ (1,034,107)	25.3%	$ (1,897,634)	25.3%
Valuation allowance change	(5,016,348)	122.7%	1,705,054	-22.7%
Permanent differences	231,024	-5.7%	(11,687)	0.2%
	$ (5,819,431)	142.4%	$ (204,267)	2.7%

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

	2020	2019
Accelerated depreciation	$ (2,694)	$ (1,604)
Other assets	(1,802,164)	(1,803,818)
Charitable contribution carryovers	168,464	91,638
Stock option compensation	550,146	500,686
Research and development tax credit carryforward	243,367	52,882
NOL carryforward	6,643,912	6,176,564
Valuation allowance	-	(5,016,348)
Net deferred tax position	$ 5,801,031	$ -

The (decrease) and increase in the valuation allowance was approximately ($5,016,000) and $1,705,000 for the years ended December 31, 2020 and 2019, respectively.

As required by FASB ASC 740 the Company has evaluated the positive and negative evidence bearing upon the realization of its net deferred tax assets. The Company has determined that, at this time, it is more likely than not that the Company will realize all of the benefits of federal and state net deferred tax assets, and, as a result, the established valuation allowance was removed. The research and development tax credit carryforwards and NOL carryforwards generated through December 31, 2020, of approximately $243,000 and $24,718,000, respectively, expire at various time through 2038. The Company has recorded income tax credit receivable amounts of $18,400 and $204,267 for the years ending December 31, 2020 and 2019, respectively. These credits consist of $0 and $188,117 of federal research and development credits which the Company as a qualified small business elected as a payroll tax credit, and $18,400 and $16,150 from New York State QETC employment credit. 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 is currently open to audit under the statute of limitations by the Internal Revenue Service for the years ended December 31, 2017 through December 31, 2020. The Company has no uncertain tax positions. As of December 31, 2020, and 2019 there is no accrual for interest or penalties related to uncertain tax positions.

H. Pension Plan:

The Company utilizes the Pinnacle Employee Services, LLC 401(k) and Profit Sharing Plan, as all employees of Quadrant Biosciences Inc. are provided through Pinnacle Employee Services, LLC. All employees are eligible to participate. Employees receive a 3% non-elective company contribution after 90 days of employment. Company contributions totaled $110,258 and $90,870 for the years ended December 31, 2020 and 2019, respectively.

I. Line of Credit:

In November 2017, the Company obtained a line of credit with a borrowing capacity of $500,000 and $1,250,000 as of December 31, 2020 and December 31, 2019, respectively, at an interest rate of Bank Prime plus 1.125%. The interest rate at December 31, 2020 and 2019 was 5.375% and 5.875%, respectively. The line of credit had a balance of $403,996 and $0 at December 31, 2020 and 2019.

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

J. Long-Term Debt:

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

	2020	2019
Loan from VEP Biotech Ltd, with a maturity date of October 2023, an interest rate of 5%, and no required payment of principal or interest until maturity.	$ 5,555,858	$ 5,288,146
SBA Economic Injury Disaster loan, with a maturity date of May 2050, an interest rate of 3.75%, and payments of $731 beginning in May 2021	153,421	-
	5,709,279	5,288,146
Less: current portion	1,708	-
	$ 5,707,571	$ 5,288,146

Future maturities of long-term debt subsequent to 2021 are $3,077 in 2022, $5,559,053 in 2023, $3,317 in 2024, $3,443 in 2025 and $138,681 in 2026 and thereafter.

Accrued interest included in the outstanding loan balance due to VEP Biotech, Ltd. was $555,858 and $288,146 for the years ending December 31, 2020 and 2019, respectively.

Accrued interest included in the outstanding loan balance due to the SBA was $3,421 for the year ended December 31, 2020.

K. Pledges Payable:

The Company pledged contributions to Autism Speaks, a 501(c)(3) not-for-profit corporation dedicated to promoting solutions, across the spectrum and throughout the life span, for the needs of individuals with autism and their families. The total pledged contribution was $350,000. The balance at the end of 2019 of $225,000 was paid in 2020.

L. Paycheck Protection Plan Loan:

During April 2020, the Company applied for and received a Paycheck Protection Program Loan of $755,600 as created by the C.A.R.E.S Act and a EIDL advance grant of $10,000. The loan has an interest rate of 1%, a maturity date of 2 years, and loan payments are deferred for six months. The loan is eligible for forgiveness based on the employer maintaining or quickly rehiring employees and maintaining salary levels. Forgiveness will be reduced if full-time headcount declines, or if salaries and wages decrease.

The AICPA has issued TQA 3200.18 outlining treatment options of the PPP loan by non-governmental entities, and the Staff of the Office of the Chief Accountant of the SEC have indicated they would not object to an SEC registrant accounting for a PPP loan under either option. These options include treating the amount as a loan in accordance with FASB ASC 470 and accruing

interest in accordance with FASB ASC 835-30, or as a government grant by analogy to International Accounting Standard (IAS) 20, Accounting for Government Grants and Disclosure of Government Assistance.

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

The Company applied for and received forgiveness of the entire loan in January 2021.

M. Concentration of Credit Risk:

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

N. Reclassification:

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

O. Industry Segment Data:

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

certified laboratories and sells and operates wastewater detection services for coronavirus disease.

P. Legal Matters:

None.

Q. Coronavirus (COVID-19):

Due to the uncertainties created by COVID-19, including the mandated temporary work stoppage in many sectors and imposing limitations on travel and size and duration of grouping meetings, the Company took actions to limit and mitigate the financial impact. Based on these uncertainties, the Company reduced salaries ranging from 10-75% during 2020. The salary reductions will be accrued to employees and paid out when and in a manner determined appropriate by management.

The Company also applied for and received relief from Federal stimulus programs, including the Paycheck Protection Program, and the Economic Injury Disaster Loan program.

R. Subsequent Events:

On February 18, 2021, the Company completed its most recent raise that started in September 2020. The Company raised $384,363 via the issuance of a 6% Convertible Note that matures on August 25, 2025.

On February 22, 2021, the Company paid down the entire outstanding balance of the Line of Credit in the amount of $403,996.

On March 18, 2021, the Line of Credit mentioned in Footnote I was increased to a borrowing limit of $1,000,000.

In March 2021, Quadrant Laboratories LLC has (itself and/or in association with the State University of New York) established clinical laboratories in Syracuse and Buffalo, New York.

The Company has evaluated subsequent events through April 1, 2021, the date which the financial statements were available for issue.

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 (2)

4 Form of subscription agreement (3)

6.1 2016 Equity Incentive Plan (4)

6.2 Amended and Restated Stockholders' Agreement (5)

6.3 Laboratory Services Agreement between Admera Health LLC and the company dated July 13, 2018 (6)

6.4 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 (7)

6.5 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 (8)

6.6 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 (9)

6.7 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

(1) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920000350/filename4.htm)

(2) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920000350/filename5.htm)

(3) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920021527/tm1928372d2_ex4.htm)

(4) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920000350/filename7.htm)

(5) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920000350/filename8.htm)

(6) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920021527/tm1928372d2_ex6-3.htm)

(7) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920021527/tm1928372d2_ex6-4.htm)

(8) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920021527/tm1928372d2_ex6-5.htm)

(9) Filed as an exhibit to the Quadrant Biosciences Inc. Regulation A Offering Statement on Form 1-A (Commission File No. 024-11155 and incorporated herein by reference. Available at, https://www.sec.gov/Archives/edgar/data/1651239/000110465920021527/tm1928372d2_ex6-6.htm)

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 29, 2021.

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 29, 2021
Richard Uhlig
Chief Executive Officer, Chairman

/s/ Richard Bongo — Date: April 29, 2021
Richard Bongo
Chief Financial Officer, Principal Accounting Officer, Director

/s/ James Croke — Date: April 29, 2021
James Croke
General Counsel, Director

/s/ Peter Cohen — Date: April 29, 2021
Peter Cohen
Director

/s/ Ira Fedder — Date: April 29, 2021
Ira Fedder MD
Director

/s/ Andrew Rock — Date: April 29, 2021

Andrew Rock
Director

/s/ Mary Ann Tyszko — Date: April 29, 2021

Mary Ann Tyszko
Director

Exhibit 6.7

Exclusive License Agreement Between
The Research Foundation for The State University of New York
and
Quadrant Biosciences Inc.
(COVID-19 Saliva Diagnostic)

This Exclusive License Agreement (hereinafter, "**Agreement**") is made and is effective as of the date of the last signature below (hereinafter, "**Effective Date**") by and between The Research Foundation for The State University of New York ("**SUNY**"), on behalf of Upstate Medical University ("**Upstate**"), a non-profit educational corporation, organized and existing under the laws of the State of New York, having offices at 750 East Adams St., WH 1109C, Syracuse, NY 13210 (hereinafter, "**Foundation**" or **"Licensor**") and Quadrant Biosciences Inc., a Delaware corporation, having a primary address at 505 Irving Ave., Suite 3100AB, Syracuse, NY 13210 (hereinafter, "**Licensee**", and together with Foundation, the "**Parties**", and each individually a "**Party**").

RECITALS

WHEREAS, Foundation and Licensee have an ongoing research collaboration and as a result jointly created and own certain Technology (as defined below).

WHEREAS, Foundation desires to have the Technology developed and used to the fullest extent in the Field (as defined below) for the benefit of the public and is therefore willing to grant Licensee exclusive rights in the Technology; and

WHEREAS, Licensee desires to obtain certain exclusive rights to Technology for the purpose of developing and commercializing Licensed Products (as defined below) in the Field;

NOW, THEREFORE, subject to the terms and conditions contained herein, and in consideration of the premises and other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

All capitalized terms used in this Agreement will have the meanings stated below or defined elsewhere in the Agreement, whether in singular or plural form (provided that the parties acknowledge and agree that, as a matter of construction of this contract, the singular shall include the plural and the plural shall include the singular, as the context so requires).

1.1. **"Affiliate"** means any corporation or other business entity that controls, is controlled by, or is under common control with another corporation or business entity or person. A person, corporation or other business entity will be regarded as in control of another corporation or other business entity if he, she or (i) owns, or directly or indirectly controls at least fifty percent (50%) of the outstanding shares or other voting rights of the subject corporation or business entity or such lesser percentage that is the maximum permitted to be owned by a foreign entity in those jurisdictions where majority ownership by foreign entities is prohibited; (ii) has the right to elect a controlling number of the directors, officers or managers of the subject corporation or other business entity; (iii) has the power

to direct or cause the direction of the management and policies of the subject corporation or other business entity.

1.2. **"Business Development Program"** means an implemented and sufficiently resourced program of Licensee or Affiliates of any of the foregoing, for, consistent with Commercially Reasonable Efforts: (i) developing Licensed Product, (ii) obtaining all regulatory approvals necessary for the sale of such Licensed Product in a given market (geographic and/or application-specific); and (iii) fulfilling demand for such Licensed Product in such market, once approvals in such market are received.

1.3. **"Commercially Reasonable Efforts"** shall mean a level of effort consistent with the commercially reasonable practices of small and mid-sized, professionally-managed, investor-backed companies striving in good faith to expeditiously develop, obtain regulatory approval for, and commercialize, in multiple national markets, products based on or incorporating new medical technology, including obtaining sufficient funding therefor.

1.4. **"Confidential Information"** has the meaning assigned and ascribed in Section 16.1.

1.5. "**Cost of Goods Sold**" means all reasonable costs that are directly related to Licensee's direct production of Licensed Products, as calculated in accordance with GAAP and including the following costs: (i) materials costs, which means the price paid for raw material components and finished goods which are purchased from outside vendors as well as any freight and duty where applicable; (ii) direct labor costs, which means the employment costs, including salary and benefits, within the relevant manufacturing operating unit; (iii) contract manufacturing, fill and finish, packaging, labeling and storage; and (iv) routine quality compliance and quality assurance programs.

1.6. "**Cover**" or "**Covered By**" means (i) infringes, in the case of a claim in an issued patent, or (ii) would infringe the claim if it existed in an issued patent, in the case of a claim in a pending application.

1.7. **"Diagnostic Kit(s)"** means an In Vitro Diagnostic Product for which pre-market regulatory clearance is required by the FDA in the United States, or the equivalent agency responsible for regulating such products in another market. Review of analytical and clinical validity of a Diagnostic Kit is done prior to the marketing of the test system, and therefore, prior to the use of the test system on patient specimens in the clinical diagnosis/treatment context (clinical validity refers to the accuracy with which the Diagnostic Kit identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient). In the

United States, pre-market regulatory clearance is obtained via one of four paths: (a) 510(k) (the new test can be shown to be substantially equivalent to an existing predicate test on the market), (b) premarket approval (PMA) (the new diagnostic technology cannot be considered substantially equivalent to an existing technology), (c) de novo reclassification (no predicate device exists and the test is of low or moderate risk) or (d) through FDA emergency use authorization.

1.8. **"FD&C Act"** means the Federal Food Drug & Cosmetics Act (Title 21, Code of the United States Code of Federal Regulations (CFR) [21 U.S.C.]).

1.9. **"FDA"** means the Food and Drug Administration.

1.10. "**Field**" means the manufacture and distribution of kits, tests, and other materials for pooled and individual COVID-19 diagnosis.

1.11. **"GAAP"** means generally accepted accounting principles in the United States of America as in effect at the time in question.

1.12. **"In Vitro Diagnostic Product" or "IVD"** means a medical device as defined in section 210(h) of the FD&C Act, and may also be a biological product subject to section 351 of the Public Health Service Act. Like other medical devices, IVDs are subject to premarket clearance or approval by FDA, as well as, postmarket controls. Premarket clearance pursuant to the 510(k) process applies to IVDs that are substantially equivalent to an predicate device and the premarket approval process applies to IVDs for which no predicate device exists. IVDs are also subject to the Clinical Laboratory Improvement Amendments of 1988. In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. [21 CFR 809.3]

1.13. **"Indemnified Parties"** has the meaning assigned and ascribed in Section 8.1(a).

1.14. **"Inventions"** means any and all patentable or not patentable inventions described in NTD 110-2124 or in any patent application identified on Exhibit A.

1.15. **"Know-How"** means all know-how, technical information and data developed by Foundation under the direction of Dr. Frank Middleton related to Inventions or disclosed in NTD 110-2024 and provided to or received by Licensee from Foundation before the Effective Date, whether or not confidential in nature, and which are necessary or useful to commercialize Licensed Products or Patented Products.

1.16. **"Laboratory Developed Test" or "LDT"** means a laboratory developed test as defined by the FDA. The FDA defines a laboratory developed test as an In Vitro Diagnostic Product that is manufactured by and used within a single laboratory (i.e. a laboratory with a single CLIA certificate). Laboratory Developed Tests are considered "devices," as defined by the FD&C Act, and are therefore subject to regulatory oversight by FDA, and are regulated by the CMC under CLIA. CLIA does not address the clinical validity of any LDT (clinical validity refers to the accuracy with which the LDT identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient).

1.17. **"Licensed Patent(s)"** means any patent application filed claiming Inventions, including the patent applications listed in Exhibit A, and continuing applications thereof including divisions, substitutions, and continuations-in-part (but only to extent a claim thereof is enabled by disclosure of the parent application), and any patents issuing on said applications including reissues, reexaminations and extensions, and any corresponding foreign applications and issued patents.

1.18. **"Licensed Product(s)"** means any product or service (or component thereof), the discovery, development, manufacture, use, sale, offering for sale, importation, exportation, distribution, rental or lease of which involves the use or incorporation, in whole or in part, of Know-How, Inventions, Technology, or Patented Products.

1.19. **"Material Obligations"** has the meaning assigned and ascribed in Section 9.2(a).

1.20. **"Net Income"** means gross revenues received by Licensee and its Affiliates from Third Party customers for the import, export, manufacture, use, sale, lease, or other transfer of any Licensed Product, less (i) sales and/or use taxes and import or export duties actually paid, (ii) outbound and inbound transportation costs actually paid, (iii) amounts allowed or credited, and actually refunded, due to returns (as reflected on the invoice, and not to exceed the original billing amount), (iv) Cost of Goods Sold, (v) Selling and Administrative Expenses, (vi) Patent Costs paid by Licensee, and (vii) premiums for product liability insurance premiums covering the Licensed Product, provided that, in the event that Licensee carries product liability insurance on the total of its operations and no separately identifiable premium is charged for the coverage of the Licensed Product, the portion of such premiums which Licensee shall be entitled to deduct shall be calculated by multiplying said annual premium by a fraction the numerator of which is the total gross receipts for sales of Licensed Product by Licensee during the prior year and the denominator of which is the total gross receipts for sales of all products or services by Licensee during such period.

In this context, gross revenues will also include the fair market value of any non-cash consideration received from Third Party customers for the import, export manufacture, use, sale, lease, or other transfer of Licensed Product. The intent of this definition of Net Income is to allow Foundation to derive a Royalty on the end sale of a Licensed Product to the first Third Party.

In the case of transfers of Licensed Product between any of Licensee and its Affiliates for subsequent sale, rental, lease or other transfer of such Licensed Product to Third Parties, gross revenue shall be the greater of (i) the actual amount charged for the transfer of the Licensed Product between any of Licensee and its Affiliates , and (ii) the gross invoice or contract price charged to the Third Party customer for that License Product in an arms-length transaction.

In the case of transfers of Licensed Product between any of Licensee its Affiliates for use by Licensee and its Affiliates such that the Licensed Product is consumed or used, and is not incorporated into a product or service subsequently sold to a Third Party customer, gross revenue shall mean the greater of: (1) the actual amount charged for the transfer of the Licensed Product between any of Licensee and its Affiliates , and (2) what the fair market value of the Licensed Product would be in an arm's length transaction.

1.21. **"NTD 110-2124"** means Foundation New Technology Disclosure 110-2124, entitled "Methods of Quantifying SARS-CoV-2 from Individual and Pooled Saliva"

1.22. **"Patent Costs"** means all out-of-pocket expenses incurred by Licensors or Licensee in preparing, filing, prosecuting, and maintaining Licensed Patents, and all reasonable out-of-pocket expenses costs incurred in consequence of any re-examinations or reissue thereof, or incurred in consequence of any pre- or post-grant proceedings or oppositions or challenges related thereto, including but not limited to supplemental examination, inter partes review, ex partes reexamination and post-grant review, or incurred for patentability opinions and inventorship review and determination related to Licensed Patents.

1.23. **"Patent Rights"** means Licensors' rights to any subject matter that is claimed in, could be claimed in, or is otherwise Covered By one or more Valid Claims in any Licensed Patent.

1.24. **"Patented Product"** means any products or service (or component thereof) that: (i) if made, manufactured, used, offered for sale, sold, imported, leased or otherwise transferred within the Territory, but for the license granted herein, would infringe Patent Rights.

1.25. **"Payments Due"** means, individually or collectively, all Royalties, Minimum Royalties, milestone payments, annual fees, late payment fees, Patent Cost reimbursements, and any other amounts due to Licensor under this Agreement.

1.26. **"Reporting Period"** means a calendar quarter. The first calendar year is the year in which the Effective Date occurs.

1.27. **"Royalty"** means the share of all Net Income of Licensee and its Affiliates that is due Foundation on all Net Income pursuant to this Agreement (see Section 3.1 and Section 3.5), which is calculated by multiplying Net Income by the Royalty Rate specified. The Royalty due Foundation is [Royalty Rate * Net Income].

1.28. **"Royalty Rate"** means any royalty rate specified in Section 3 of this Agreement for use in calculating Royalties due to Foundation on Net Income.

1.29. **"Selling and Administrative Expenses"** means costs the operating expenses of Licensee directly and solely related to the sale and manufacture of Licensed Product that are not included in Cost of Goods Sold.

1.30. **"Technology"** means Inventions, Know-How, the information and data provided in NTD 110-2124, and anything claimed or described in Licensed Patent(s).

1.31. **"Term"** has the meaning assigned and ascribed in Section 10.1.

1.32. **"Territory"** means the world.

1.33. **"Third Party"** means entity or person other than Licensee or its Affiliates.

1.34. **"Valid Claim(s)"** means any unexpired claim in an issued unexpired patent, or any claim of a pending patent application or supplementary protection certificate that has not been revoked, abandoned, disclaimed or withdrawn, or held unenforceable, unpatentable, or invalid by a court of competent jurisdiction in a final judgment that has not been appealed within the time allowed by law or from which there is no further appeal.

2. GRANT OF RIGHTS AND RETAINED RIGHTS

2.1. **Licenses.** Subject to the terms of this Agreement, including without limitation the rights retained by Licensor under Section 2.2, and the timely payment of all Payments Due, Licensee shall, in the Field, in the Territory and during the Term, have an EXCLUSIVE license to use Technology to make, manufacture, use, sell, have sold, lease, have leased, and offer for sale Licensed Products.

This license may be subject to the overriding obligations to the U.S. Government set forth in 35 U.S.C. §§ 200-212 and any future amendments thereto, and applicable governmental implementing regulations, including but not limited to those described in Section 12.2 herein.

2.2 **License to Affiliates.** Licensee may exercise its rights and perform its obligations under this Agreement either directly or through one or more of its Affiliates which have executed a counterpart signature page to this Agreement (see Exhibit B) evidencing said Affiliate's agreement to be bound by the terms and conditions hereof, with such counterpart signature page provided to Foundation for its records. All such Affiliates of Licensee who have countersigned this Agreement will have all rights and obligations (including all licenses) of Licensee under this Agreement, and shall be jointly and severally liable with Licensee and all other Affiliates of Licensee for the performance of the terms hereof, including without limitation the obligation to make all Payments timely when due. In the event that any such Affiliates of Licensee countersign this Agreement, (i) as used in this Agreement, "Licensee" will be interpreted to mean "Licensee and/or its Affiliates" where necessary to give Licensee's Affiliates the benefit of the rights and obligations provided to Licensee in this Agreement, and (ii) in any event Licensee will remain responsible for the acts and omissions, including financial liabilities, of its Affiliates, as if such action or omission were taken by Licensee itself.

2.3. **Importance of Know-How.** Licensee has requested, and Licensor has agreed, to grant certain rights to Know-How. Licensee requires these rights in order to develop and commercialize the technology licensed hereunder. Because of the importance of Know-How, Licensee has agreed to pay a Royalty to Foundation on Net Income from Licensed Products, fully acknowledging and understanding that such Licensed Products are not presently Covered By Patent Rights, in order to obtain exclusive commercial rights to Know-How. Licensee has agreed to these payments because of the commercial value of the Know-How, separate and distinct from the commercial value of the Patent Rights. Licensee acknowledges that it would not have entered into this Agreement without receiving the rights to the Know-How specified in this Section 2.4. Licensee further acknowledges that licenses to Know-How and each patent and application within the definition of Patent Rights were not separately available from a license to the Patent Rights, and that for convenience and because of the preference of Licensee, the parties executed a combined license to the Patents Rights and Know-How.

2.4. **Retained Rights.**

Licensor reserves the right to:

(a) Use the Technology for academic, educational, and research purposes, including, without limitation, sponsored research and other collaborations that may utilize Technology for pooled COVID-19 testing methods and scenarios;

(b) Subject to the confidentiality terms of Section 16, publish or otherwise disseminate any information about the Technology at any time; and

(c) Allow, at Licensor's sole discretion, other educational and nonprofit institutions to use the Licensed Subject Matter for non-commercial academic, educational, and research purposes.

3. CONSIDERATION AND PAYMENT TERMS

The Parties understand that the fees and royalties payable by Licensee to Licensor under this Agreement are partial consideration for the license granted under this Agreement. Licensor acknowledges and agrees that all payments to be made under or in connection with this Agreement shall be made to Foundation.

3.1. **Royalties on Net Income.**

(a) **Royalties.** Notwithstanding anything to the contrary in this Agreement, Licensee shall pay to Foundation a Royalty of fifty percent (50%) of all Net Income of Licenseeand its Affiliates.

(b) **Duration of Royalties.** Royalties on Licensed Products will be payable, on a country-by-country and product-by-product basis for as long as Licensee is generating Net Income from Licensed Products.

3.2. **Payment Terms**. All dollar amounts for Payments Due referenced herein will refer to U.S. Dollars. Payments with designated payment dates are due and payable on or before those dates. Royalties due Foundation on Net Income of Licensee its Affiliates will be due and payable as specified in Section 6.3. All invoiced amounts, including, but not limited to, the reimbursement of Patent Costs, will be due and payable within thirty (30) days of the respective invoice date. When Licensed Products are sold for currencies other than U.S. Dollars, Royalties will first be determined in such foreign currency and then converted into equivalent U.S. Dollars per the exchange rate quoted in the Wall Street Journal on the last business day of the applicable Reporting Period. For the avoidance of doubt, Licensee is solely responsible for bank transfer charges, including but not limited to, wire transfer fees.

3.3. **Miscellaneous.** Without Foundation's prior written consent, not to be unreasonably withheld, delayed or conditioned, Licensee and its Affiliates of the foregoing shall not solicit or accept any consideration for the sale of any Licensed Product other than as will be accurately reflected in the calculation of Net Income. Furthermore, Licensee shall not enter into any transaction with any Affiliate that would circumvent its monetary or other obligations under this Agreement. Licensee agrees not to pay Royalties into escrow or any other similar account, nor

allow an Affiliate to do so. Non-US taxes paid by Licensee and its Affiliates of any of the foregoing related to Royalties are not deductible from any payments due Foundation.

3.4. **Payment Address.** All payments for Payments Due will be made payable to "The Research Foundation for The State University of New York" and will be sent to the following address:

The Research Foundation for The State University of New York
Office of Industry & External Affairs
35 State Street
Albany, NY 12207
Attn: Director, Innovation & Partnerships

For Wire Transfers:
Bank: Key Bank of New York
66 South Pearl Street
Albany, NY 12207
Account Number: 10970107
Routing Number: ABA 0213-00077
Swift Code: KEYBUS33
Please include the notation: "Office of Industry & External Affairs, SUNY Upstate Medical University: COVID-19 Saliva Diagnostic/Quadrant Biosciences (110-2124)"

3.5. **Late Payment.** In the event that any Payments Due are not timely received by Foundation when due, Licensee will pay to Foundation, in addition to such Payments Due, interest on such Payments Due computed using the lesser rate of: (i) twelve percent (12%) per annum; or (ii) the maximum rate allowable under the applicable law (such rate, the **"Default Interest Rate"**). Interest will be calculated from the date payment was due until actually received by Foundation, inclusive.

3.6. **Foreign Sales.** Royalties due for sales that occur in any country may not be reduced by any deduction of withholding, value-added taxes, fees, or other charges imposed by the government of such country, except as permitted in the definition of Net Income. If at any time legal restrictions prevent the acquisition or prompt remittance of U.S. dollars by Licensee and its Affiliates of any of the foregoing with respect to any country where a Licensed Product is sold, Licensee shall either (i) pay any Royalties or (ii) cease sales by Licensee and its Affiliates of Licensed Product in such country and require the cessation of sales of Licensed Product by Licensee and its Affiliates in such country.

4. DUE DILIGENCE AND COMMERCIALIZATION ACTIVITIES

4.1. **Commercially Reasonable Efforts.** Licensee shall using Commercially Reasonable Efforts, diligently proceed with the development, manufacture and sale of Licensed Products.

4.2. **Regulatory and Market Diligence.** Licensee shall using Commercially Reasonable Efforts, obtain, in a logical, sequential and expeditious manner, all necessary governmental approvals and/or clearances for the manufacture, use, and sale or provision of Licensed Products in each national market,; and upon receiving all applicable approvals in each market beyond all appeal periods, reasonably fulfill normal market demand for such Licensed Products in such market.

4.3. **First Sale of Licensed Product.** Licensee shall use Commercially Reasonable Efforts to achieve a first sale in the United States of a Licensed Product as soon as possible after the Effective Date, but in no event later than September 30, 2020.

4.4. **Diagnostic Kits and LDTs.** Licensee will have discretion to commercialize Licensed Products as either Diagnostic Kits or LDTs in each national market.

4.5. **Markets Not Served by Licensee.** If by the end of calendar year 2021 Licensee has failed to implement and/or sufficiently resource a Business Development Program in any country in the Territory, then within twelve (12) months after written notification from Foundation about such failure in such country, Licensee shall make good faith, Commercially Reasonable Efforts, to establish a Business Development Program in such country. If Foundation notifies Licensee that Foundation has received a bona fide offer to license the Technology to commercialize Licensed Product in such country from an offeror which has already established a Business Development Program in such country or can show that it can imminently establish a Business Development Program in such country, then if within twelve (12) months Licensee fails to establish a Business Development Program in such country, then Foundation can exclude such country from the Territory and license the Patent Rights or Know-How to the offeror in such country.

4.6. **Fundamental Purpose of Agreement.** Licensee acknowledges and agrees that a fundamental purpose of this Agreement is to achieve development and commercialization of Licensed Products in the Field in the Territory, and the terms in this Section 4 constitute material terms of this Agreement.

5. PATENT PROSECUTION AND PATENT COSTS

5.1. **Patent Rights Management.**

(a) Licensee has the option to undertake the preparation, filing, prosecution, and maintenance of Licensed Patents, and for paying all Patent Costs. Licensor agrees to cooperate with Licensee in a timely manner in the preparation, filing, prosecution, and maintenance of Licensed Patents by disclosing such information as may be requested from time to time by Licensee and by promptly executing such documents as Licensee may reasonably request in connection therewith. Licensor will bear their own costs in connection with their cooperation with Licensee under this Section 5.1. If Licensee does not wish to file a patent application, continue prosecution of a pending patent application, or maintain a patent through its full term, Licensee will notify Foundation in writing no less than thirty (30) days in advance of the relevant patent deadline and Foundation shall have the option, but not the obligation, to take over control of the prosecution and maintenance of the patent or application. If Licensor obtains Patent Rights as a result of prosecution paid for by Licensor, upon Licensor's request, the Parties will negotiate an amendment to this Agreement to enable Licensor to realize the value of the Patent Rights, for example by narrowing the Field to exclude the Valid Claims or converting the Agreement to nonexclusive status.

(b) In the event Foundation takes over control and maintenance of a patent or application pursuant to Section 5.1(a), Foundation will be solely responsible for the preparation, filing, prosecution, and maintenance of such patent or application, and for paying all Patent Costs for such patent or application. In the case where Licensee is an owner of such patent or application, Licensee agrees to cooperate, and to cause its Affiliates to cooperate, with Foundation in a timely manner in the preparation, filing, prosecution, and maintenance of such patent or application by disclosing such information as may be requested from time to time by Foundation and by promptly executing such documents as Foundation may reasonably request in connection therewith. Licensee will bear its own costs in connection with their cooperation with Foundation under this Section 5.1

(c) For the preparation, filing, prosecution, and maintenance of Licensed Patents, Licensee shall use a patent attorney acceptable to Foundation whose firm has no conflicts of interest with any of Foundation, Upstate or SUNY.

5.2. **Payment of Future Patent Costs.** If Licensee undertakes prosecution of Patent Rights, Licensee will pay all Patent Costs incurred on or after the Effective Date directly to the firm selected by Licensee in accordance with Section 5.1 above.

5.3. **Discontinuing Payment of Patent Costs.** If Licensee decides to discontinue its support of Patent Costs for a Licensed Patent, Licensee will notify Foundation in writing ninety (90) days prior to any such discontinuation. Licensee will be responsible for reimbursing Foundation for any Patent Costs associated with such Licensed Patent incurred up to ninety (90) days after the date of the receipt of such notice. Foundation will make good faith efforts to minimize costs during such 90-day period. Upon such discontinuation, Foundation, at its sole discretion, will have the rights to: (i) abandon such Licensed Patent or (ii) continue prosecution of the Licensed Patent, and any other Licensed Patent that claims priority to such Licensed Patent, at its expense, and (iii) discontinue any license of Licensed Patent granted under this Agreement.

6. BOOKS, RECORDS, AND REPORTS

6.1. **Full and Accurate Records.** Licensee will keep full and accurate books and records in sufficient detail so that Licensee's compliance with its obligations under this Agreement can be properly determined without undue delay or difficulty. Such books and records will be maintained for at least five (5) years after the Reporting Period(s) to which they relate. Books and records will include but not be limited to: accounting general ledgers; invoice/sales registers; original invoice and shipping documents; federal and state business tax returns; itemized calculations for all Cost of Goods Sold; itemized calculations for all Selling and Administrative Expenses; and itemized calculations for all other deductions captured in the calculation of Net Income; company financial statements; sales analysis reports; inventory and manufacturing records; distributor agreements; price lists, product catalogs, and other marketing materials; agreements with third parties (including Affiliates of Licensee and customers); and laboratory notebooks.

6.2. **Inspection of Records**.

(a) Foundation may, from time to time and at any reasonable time, not exceeding once every twelve (12) months, through such individuals and auditors as Foundation may designate, inspect the books and records of Licensee and its Affiliates in order to verify the accuracy of any reported statement by Licensee of Payments Due or amounts paid, or to determine compliance with any other obligation or obligations of Licensee under this Agreement.

(b) After completion of any such inspection, Foundation will notify Licensee, as appropriate, in writing of any discrepancies in the Payments Due or amounts paid to Licensor. Such inspection will be made at the expense of Foundation, unless such inspection discloses a discrepancy of at least five percent (5%) or more than $5,000 in the Payments Due or amounts paid to Licensor. In such case, Licensee will be responsible for reimbursing Foundation for the inspection fee and expenses associated with such inspection. Licensee agrees to pay past due amounts for any deficiency error in Payments Due as determined by the auditor, including without limitation any payment deficiency since the Effective Date of the Agreement.

(c) Any underpayment as determined by the auditor will bear interest at the Default Interest Rate from the date the original payment was due.

(d) The Licensor and the auditor will maintain in confidence such inspection and the resulting report. The auditor may from time to time consult the Licensor and any of their employees or third party counsel on questions as they relate to this Agreement. The auditor may not disclose financial or proprietary information except as required to conduct the audit, to report the results of the audit, or as otherwise permitted by this Agreement or if the information already exists in the public domain. No other confidentiality agreement will be required to conduct the audit of the Licensee's books and records.

6.3. **Reporting Period Reports and Payment of Payments Due.** On or before each September 1, December 1, March 1 and June 1 following the first commercial sale of Licensed Product by Licensee or its Affiliates Licensee will provide to Foundation written reports containing the following information for the immediately preceding Reporting Period: (i) the number and type of Licensed Products made by or for Licensee and its Affiliates; (ii) the number and type of Licensed Products sold by Licensee and its Affiliates; (iii) the Net Income (and the calculation of Net Income) received by Licensee or its their Affiliates; (iv) the Royalties due under Section 3.1 (and the itemized calculation thereof, including without limitation any deductions for Cost of Goods Sold and/or Selling and Administrative Expenses);(v) the total amount of Payments Due; and (vi) projection of the Royalties due under Section 3.1 for the next Reporting Period (and calculation thereof). Licensee will submit these reports to Foundation even if there are no Payments Due for a particular Reporting Period. The foregoing will be provided on a country-by-country basis. The items in this Section 6.3(i)-(vi) will be reported separately for Licensee and for each Affiliate of Licensee. Each report will provide year-to-date totals. Licensee shall remit Payments Due for the

applicable Reporting Period to Foundation together with its submission of the subject report.

6.4. **Due Diligence Reports.** On or before September 1 of each year, Licensee will provide a report containing the following information relating to the preceding year: progress on the commercialization and development of Licensed Products (*i.e.*, new product development, product evaluation and testing, marketing plans, sales forecasts, and significant commercialization events), including resources expended. These reports will include any relevant information provided to investors or potential investors. Licensee shall, within thirty (30) days after each deadline for achieving a first sale of a Licensed Product specified in Section 4.3, report to Foundation, in writing, whether such first sale has occurred.

6.5. **Licensee Responsible for Payments Due.** Licensee shall be responsible for making sure that Foundation receives all Payments Due and that all reports due to Licensor are delivered, whether such Payments Due are owed by Licensee, or its Affiliates. Licensee shall be responsible for paying to Foundation any Payments Due owed to Licensor by its Affiliates, unless such Payments Due are paid directly to Foundation by the subject Affiliate in a manner that is in accordance with this Agreement.

6.6. **Report Certification.** An officer of Licensee will sign and certify each report, and all reports will be prepared in accordance with GAAP.

7. ENFORCEMENT OF PATENT RIGHTS

7.1. The Licensor and Licensee will promptly inform the other in writing of any actual, alleged, or suspected infringement of a Licensed Patent or violation of any Patent Right by a third party, of which it is aware, and provide available evidence of infringement.

7.2. With respect to any Patent Rights licensed exclusively by Licensor to Licensee under this Agreement, Licensee shall have, for an initial period of ninety (90) days following notice under the provisions of Section 7.1, the first right, but not the obligation, to institute and control the prosecution of a suit or to take any other action for infringement of the Patent Rights. Licensee will notify Foundation of its intent to institute such action, in writing. Licensor will have thirty (30) days from receipt of such notice to notify Licensee that it will join Licensee in such action under the provisions of Section 7.4.

7.3. Subsequent to Licensee's initial ninety day period and subject to Licensee's reasonable consent, the Licensor shall have the right, but not the obligation, to institute and control the prosecution of a suit or to take any other action for

infringement of any of the Patent Rights, provided that withholding of consent shall not be reasonable unless the benefit of foregoing a suit or any action for infringement of the Patent Rights has a benefit of like magnitude for both Licensee and Licensor. If such Licensor decides to initiate a lawsuit to enforce Patent Rights pursuant to this Section 7.3, Foundation will notify Licensee in writing. Licensee will have thirty (30) days from receipt of such notice to notify Foundation that Licensee will join Licensor in such lawsuit under the provisions of Section 7.4.

7.4. The Licensee and Licensor may agree to enforce patent rights jointly, including by filing a lawsuit jointly or by one Party joining a lawsuit initiated by another Party. If a lawsuit is brought jointly in the names of Licensor and Licensee, then the out-of-pocket costs of each Party shall be borne by such Party any recovery or settlement shall be shared equally. Licensor and Licensee shall agree to the manner in which they shall exercise control over such lawsuit. Each Party may, at its own option and expense, be represented by separate counsel of its own selection.

7.5. If any suit is brought involving the enforcement or defense of the Patent Rights by one of the Parties, the other Party hereto agrees, at the request and expense of the Party initiating such suit, to reasonably cooperate and to make available relevant records, papers, information, samples, specimens and the like.

7.6. No settlement or consent judgment or other voluntary final disposition of an enforcement or defense suit initiated by any Party to this Agreement may be entered into without the consent of Licensee and Licensor, which consent will not be unreasonably withheld.

7.7. The party paying Patent Costs shall control any declaratory judgment litigation brought to challenge the validity, enforceability, and/or infringement of the Patent Rights, including the selection of litigation counsel. All other parties to this Agreement having an ownership interest in the Patent Rights shall cooperate fully in connection with such litigation. The party controlling declaratory judgment litigation shall bear any and all costs of the action and shall be solely responsible for any and all damages, awards or settlements, including any award of costs to the prevailing party.

7.8. The cost of any action commenced or defended by Licensee which Licensor declines to join under Section 7.4 of this Agreement will be borne by Licensee. Licensor agrees to be named as plaintiff and participate in the lawsuit and take further steps (at Licensee's expense, including any award of costs to the prevailing party) to the extent necessary for legal standing purposes. Licensor agrees, at the request and expense of Licensee, to reasonably cooperate and to make available relevant records and information, execute required documents, and do other acts

as the Licensee may reasonably request from time to time. Any recovery or damages resulting from such an action will first be applied to Licensee's out-of-pocket expenses and legal fees, and second will be applied to Licensor's out-of-pocket expenses, including legal fees and other costs associated with cooperation as described above. Any excess recovery or damages for past sales will be deemed Net Income, and Licensee will pay Foundation Royalties at the rates specified in Section 3 above. The Parties will negotiate in good faith appropriate compensation to Licensor for any non-cash settlement or non-cash cross-license.

8. INDEMNIFICATION AND INSURANCE

8.1. **Indemnification.**

(a) Licensee shall indemnify, defend, and hold harmless the Foundation, and their respective trustees, officers, staff, employees, students, and agents, and their respective successors, heirs, and assigns (together, the "**Indemnified Parties**"), against any liability, damage, loss, or expense associated with such liability, damage, or loss (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Indemnified Parties or any one of them in connection with any third party claims, suits, actions, demands, or judgments: (i) arising out of the design, production, manufacture, sale, use in commerce or in human clinical trials, lease, or promotion, by Licensee and its Affiliates, of any Licensed Product, process or service relating to, or developed pursuant to, this Agreement; or (ii) arising out of any other activities to be carried out by or on behalf of Licensee pursuant to this Agreement.

(b) With respect to an Indemnified Party, Licensee's indemnification under subsection 8.1(a)(i) shall apply to any liability, damage, loss, or expense whether or not it is attributable to the negligent activities of such Indemnified Party. Licensee's indemnification obligation under subsection 8.1(a)(ii) shall not apply to any liability, damage, loss, or expense to the extent that it is attributable to the negligent activities of any such Indemnified Party.

(c) Licensee agrees, at its own expense, to provide attorneys reasonably acceptable to Foundation, as the case may be, to defend against any actions brought or filed against any Indemnified Parties of Foundation, as the case may be, with respect to the subject of indemnity to which such Indemnified Parties are entitled hereunder, whether or not such actions are rightfully brought. Foundation, as the case may be, will cooperate in the defense thereof, provided, however, that Foundation, as the case may be, will have

the right, but not the obligation, to control the defense, at its expense, of any such actions. Foundation and its respective Indemnified Parties may, at their option and expense, have their own counsel participate in any proceeding which is under direction of Licensee and will cooperate with Licensee and its insurer in the disposition of any such matter; provided, however, that if Licensee shall not defend such actions, Foundation, and its respective Indemnified Parties shall have the right to defend such actions themselves and recover from Licensee all reasonable attorneys' fees and expenses incurred by it during the course of such defense.

(d) Neither Foundation, the Indemnified Parties, nor Licensee shall enter into, or permit, any settlement of any such actions without the express written consent of the other parties named in such action, which shall not unreasonably be withheld.

8.2. **Security for Indemnification.**

(a) At such time as any product, process, or service relating to, or developed pursuant to, this Agreement, including Licensed Products, is commercially distributed or sold, or tested in clinical trials by or on behalf of Licensee or its Affiliates, Licensee shall at its sole cost and expense, procure and maintain policies of comprehensive general liability insurance in amounts not less than (i) $2,000,000 per incident and $4,000,000 annual aggregate during the period that such Licensed Product, process, or service is being tested in clinical trials prior to commercial sale, and (ii) $2,000,000 per incident and $4,000,000 annual aggregate during the period that such Licensed Product, process, or service is being commercially distributed or sold, and in each case naming the Indemnified Parties as additional insureds. Such comprehensive general liability insurance shall provide: (i) product liability coverage; and (ii) broad form contractual liability coverage for Licensee's indemnification obligations under Section 6.1 of this Agreement. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of $250,000 annual aggregate) such self-insurance program shall include assets or reserves which have been actuarially determined for the liabilities associated with this Agreement and must be acceptable to the Licensor.

(b) The minimum amounts of insurance coverage required under this Section 8.2 shall not be construed to create a limit of Licensee's liability with respect to its indemnification obligations under Section 8.1 of this Agreement.

(c) Licensee shall provide Foundation with written evidence of such insurance upon request of Foundation. Licensee shall provide Foundation with written

notice at least sixty (60) days prior to the cancellation, non-renewal, or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage by the end of such sixty (60) day period, Foundation shall have the right to immediately terminate this Agreement period without notice or any additional waiting periods.

(d) Licensee shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during: (i) the period that any Licensed Product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold or tested in clinical trials by or for Licensee or its Affiliates; and (ii) a reasonable period after the period referred to in (i) above which in no event shall be less than fifteen (15) years.

9. TERM AND TERMINATION

9.1. **Term.** This Agreement shall be effective as of the Effective Date and shall continue in full force and effect until its expiration or termination in accordance with this Section 9. Unless terminated earlier under any provision of this Agreement, the term of the licenses granted hereunder shall extend, on a country-by-country and product-by-product basis, until Licensee or its Affiliate's final sale of Licensed Product.

9.2. **Termination by Foundation.**

(a) Licensee acknowledges and agrees that Licensee's obligations under the following provisions are material terms of this Agreement, and Licensee's failure to meet its obligations under these provisions will be treated as a material breach of this Agreement ("**Material Obligations**"): (i) obligations under this Agreement to make Payments Due to Foundation according to the schedules set forth herein; (ii) obligations under Article 4 to diligently pursue and achieve commercialization activities; and (iii) obligations under Article 8 related to indemnification and insurance.

(b) Should Licensee: (i) fail to perform any covenant, condition, or undertaking of the Material Obligations of this Agreement or (ii) materially breach any other provision of this Agreement; then Foundation may give written notice of such default to Licensee. If Licensee should fail to cure a default of its diligence milestones under Article 4 within sixty (60) days of notice of such default, then Foundation will have the unilateral right and option to terminate this Agreement or to modify the terms of this Agreement from an exclusive license to a non-exclusive license, a right to modify the terms which supersedes the rights granted in Section 2.1 of this Agreement. If Licensee

should fail to cure any other default within ninety (90) days of notice of such default, then this Agreement may, at Foundation's option, be terminated by written notice to Licensee.

(c) The licenses granted under this Agreement may be terminated by Foundation or, at Foundation's option, Foundation has the right to convert any or all of such exclusive licenses granted under this Agreement to nonexclusive licenses, and no right by Licensee to initiate legal proceedings pursuant to Section 7 in the event: (i) Licensee becomes insolvent or is generally not paying its debts as such debts become due; (ii) Licensee ceases to conduct business as a going concern (a sale or change of control does not constitute the cessation of conducting business); or (iii) Licensee, or any entity or person acting on its behalf, initiates any proceeding or otherwise asserts any claim challenging the validity or enforceability of any Licensed Patent in any court, administrative agency or other forum. Termination under subsections (i) – (iii) of this Section 9.2(c) shall be effective upon date of notice sent pursuant to Section 17.6.

9.3. **Termination by Licensee.** Licensee may notify Foundation of its decision to terminate this Agreement at any time by giving Foundation one-hundred eighty (180) days prior written notice. The termination will take effect at the end of the first Reporting Period after the ninetieth day has elapsed.

9.4. **Accrued Obligations.** Termination of this Agreement will not relieve Licensee and Licensor of any obligation or liability accrued hereunder prior to such termination, or rescind or give rise to any right to rescind any payments made or other consideration given to the Licensor hereunder prior to the time such termination becomes effective. Such termination will not affect in any manner any rights of Licensor arising under this Agreement prior to the date of such termination. Licensee will pay any and all attorneys' fees and costs incurred by the Licensor in successfully enforcing any obligation of Licensee or accrued right of the Licensor.

9.5. **Disposition of Licensed Products.** Upon expiration or termination of this Agreement by Licensee or Foundation, Licensee will provide Foundation with a written inventory of all Licensed Products in process of manufacture, in use, or in stock by or at Licensee or its Affiliates. Licensee may dispose of any such Licensed Products within the ninety (90) day period following such expiration or termination, or such longer period as the Parties may reasonably agree, provided, however, that Licensee will pay Royalties and render reports to Foundation thereon in the manner specified herein.

9.6. **Survival.** The provisions of Section 1 (Definitions), Section 3 (Consideration and Payment Terms), Section 5 (Patent Prosecution and Patent Costs), Section 6 (Books, Records and Reports), Section 8 (Indemnification and Insurance), Section 9.5 (Accrued Obligations), Section 9.6 (Disposition of Licensed Products), Section 9.7 (Survival), Section 10 (Warranty and Liability), Section 12 (Obligations to Federal Government), Section 13 (Non-Use of Names), Section 16 (Confidentiality), and Section 17 (Miscellaneous) will survive expiration or termination of this Agreement.

10. WARRANTY AND LIABILITY

10.1. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, LICENSOR AND SUNY, AND EACH OF THEIR TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES, MAKE NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF PATENT RIGHTS. ALL MATERIALS PROVIDED BY LICENSOR AND SUNY, AND EACH OF THEIR TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES, UNDER THIS AGREEMENT ARE PROVIDED "AS-IS".

10.2. NO WARRANTY OR REPRESENTATION IS MADE THAT ANYTHING MADE, USED, SOLD, OR COMMERCIALLY TRANSFERRED, UNDER THE TERMS OF THIS AGREEMENT, WILL BE FREE FROM INFRINGEMENT OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

10.3. NOTHING IN THIS AGREEMENT, EITHER EXPRESS OR IMPLIED, OBLIGATES LICENSOR EITHER TO BRING OR TO PROSECUTE ACTIONS OR SUITS AGAINST THIRD PARTIES FOR PATENT INFRINGEMENT OR ENFORCEMENT OR TO FURNISH ANY INTELLECTUAL PROPERTY, INFORMATION OR MATERIALS NOT PROVIDED IN THE TECHNOLOGY.

10.4. IN NO EVENT WILL LICENSOR BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE EXERCISE OF THIS AGREEMENT OR THE USE OF THE TECHNOLOGY, OR LICENSED PRODUCTS, INCLUDING, WITHOUT LIMITATION, FOR LOST PROFITS, LOST DATA, OR DOWNTIME, WHETHER OR NOT LICENSOR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10.5. IN NO EVENT WILL LICENSOR'S AGGREGATE LIABILITY TO LICENSEE OR ANY THIRD PARTY FOR ANY CLAIMS, LOSSES, INJURIES, SUITS, DEMANDS, JUDGMENTS, LIABILITIES, COSTS, EXPENSES, OR DAMAGES, FOR ANY CAUSE WHATSOEVER (INCLUDING, BUT NOT LIMITED TO, THOSE ARISING OUT OF OR RELATED TO THIS AGREEMENT), AND REGARDLESS OF THE FORM OF ACTION

OR LEGAL THEORY, EXCEED THE FEES RECEIVED BY LICENSOR FROM LICENSEE PURSUANT TO THIS AGREEMENT. LIMITATIONS OF LIABILITY REFLECT THE ALLOCATION OF RISK BETWEEN THE PARTIES. THE LIMITATIONS SPECIFIED IN THIS ARTICLE 10 WILL SURVIVE AND APPLY EVEN IF ANY LIMITED REMEDY SPECIFIED IN THIS AGREEMENT IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE.

10.6. THIS AGREEMENT DOES NOT CONFER BY IMPLICATION, ESTOPPEL, OR OTHERWISE ANY LICENSE OR RIGHTS TO ANY OTHER PROPERTY OF LICENSOR OR SUNY OTHER THAN THOSE RIGHTS EXPRESSLY STATED HEREIN.

11. ASSIGNMENT

11.1. This Agreement and the license granted hereunder may not be assigned or transferred by Licensee without Licensor's prior written consent except in connection with the sale or other non-bankruptcy transfer of Licensee's business to which the license granted hereunder relates, or the merger of Licensee's business with another legal entity. Licensee will give Foundation at least thirty (30) days prior written notice of any assignment, transfer, or merger of Licensee's business to which the license granted hereunder relates, and will provide Foundation with documentation executed by the assignee or transferee that confirms their agreement to be bound by the terms and provisions of this Agreement.

11.2. In the event of a bankruptcy of Licensee, assignment is permitted only to a party that can provide adequate assurance of future performance, including diligent development and sales of Licensed Product.

12. OBLIGATIONS TO FEDERAL GOVERNMENT AND OTHER SPONSORS

12.1. The Agreement may be subject to the rights of the United States Government, if any, resulting from any funding of the Inventions by the United States Government. This Agreement will also be subject to the rights of any other entities that may have contributed funding to development of the Inventions, if any. Licensee acknowledges that such rights, if applicable to Inventions, may reserve to the United States Government, a royalty-free, non-exclusive, non-transferable license to practice or have practiced on its behalf any government-funded Invention claimed within any associated patents or patent applications as well as other rights.

12.2. Licensee agrees that any Patented Products leased or sold in the United States which are subject to the rights of the United States Government will be manufactured substantially in the United States, pursuant to 35 U.S.C. § 204.

13. NON-USE OF NAMES

Except as required by law, Licensee agrees that it will not use Foundation's name or State University of New York, or Upstate Medical University, or any adaptation thereof (including trademarks, logos, and symbols associated therewith), or the names of the scientists, researchers, or others employed there at or therewith in any advertising, promotional, or sales literature without first obtaining Foundation's prior written consent, or in the case of the names of such researchers, scientists, or employees, the prior written consent of the individuals, except that Licensee may state that it is a licensee of Foundation.

14. FOREIGN LAWS

When required by local or national law, Licensee will register this Agreement, pay all costs and legal fees connected therewith, and otherwise insure that the local and national laws affecting this Agreement are fully satisfied.

15. COMPLIANCE WITH LAWS

15.1. **General Compliance.** Licensee will ensure compliance with all applicable county, state, federal or foreign laws, rules, and regulations governing the production, use, marketing, sale, and distribution of Licensed Products, including by all Affiliates of Licensee.

15.2. **Export Control Laws.** Licensee will, and Licensee will ensure that all of its Affiliates will, comply with all U.S. laws and regulations controlling the export of certain commodities and technical data, including, without limitation, all export control regulations of the U.S. Department of Commerce and the International Traffic In Arms Regulations of the U.S. Department of State, subject to all exemptions and exclusions thereto. Among other things, these laws and regulations prohibit the export, or require a license for the export, of certain types of commodities and technical data to specified countries.

(a) **Licensee Export.** Licensee will not knowingly, and Licensee will ensure that its Affiliates do not knowingly, unless prior, written authorization is obtained from Licensor and in full compliance with all U.S. laws and regulations, export, directly or indirectly, to any restricted country: (i) any technical data received from Licensor under this Agreement; and (ii) any Licensed Product or technical data. Licensee shall be solely responsible for obtaining all licenses, permits, or authorizations as required from time to time by the U.S. and any other government for any such export or re-export. Licensor makes no representation that an export license is or is not required,

nor does Licensor make a representation that, if required, a license will be issued by the U.S. Department of Commerce or other appropriate governmental entity.

(b) **Licensee Disclosure to Licensor.** Licensee will not disclose or transfer any export controlled technology or technical data identified on any US export control list, including, but not limited to, the Commerce Control List (CCL) at 15 C.F.R. § 774 and the U.S. Munitions List (USML) at 22 C.F.R. § 121. In the event Licensee intends to provide either Licensor with export controlled information, Licensee will inform such Licensor, in writing, thirty (30) days prior to the release of export controlled technology or technical data. Licensee agrees not to provide any export controlled information to a Licensor without the written authorization of that Licensor.

16. CONFIDENTIALITY

16.1. **Confidential Information.** As used in this Agreement, "**Confidential Information**" will mean confidential or proprietary information exchanged between the Parties hereunder and relating to the Technology or the performance of the obligations set forth herein, including without limitation: (i) written or other tangible information marked as confidential or proprietary; (ii) orally disclosed information that is identified as confidential and summarized in a notice delivered within thirty (30) days of the disclosure; and (iii) information that should reasonably be considered confidential under the context in which the disclosure is made (*i.e.*, nonpublic patenting information and nonpublic infringement information).

16.2. **Confidentiality Obligations.** Each Party agrees to: (i) maintain the other Parties' Confidential Information with the same level of care as it does its own valuable and sensitive information of a similar nature and, in any event, with not less than a reasonable degree of care; and (ii) not disclose another Party's Confidential Information to any other party, without the prior written consent of the disclosing Party. Each Party agrees to limit its use of the other Parties' Confidential Information to the purposes permitted by this Agreement. The obligation of confidentiality under this Section 16.2 shall continue for five (5) years from the expiration or termination of this Agreement.

16.3. **Exceptions.** The obligations of a receiving Party under Section 16.2 will not apply to information that the receiving Party can demonstrate by appropriate documentation: (i) was in its possession at the time of disclosure and without restriction as to confidentiality; (ii) at the time of disclosure is generally available to the public or after disclosure becomes generally available to the public through

no breach of agreement or other wrongful act by the receiving Party; (iii) has been received from a third party without restriction on disclosure and without breach of agreement or other wrongful act by the receiving Party unless the receiving Party should reasonably conclude that the information is Confidential Information; (iv) is independently developed by the receiving Party without regard to the Confidential Information of another Party; or (v) is required to be disclosed by law or order of a court of competent jurisdiction or regulatory authority; provided, however, the receiving Party shall: (a) give the disclosing Party, to the extent possible, advance notice prior to disclosure so the disclosing Party may contest the disclosure or seek a protective order; and (b) limit the disclosure to the minimum Confidential Information that is legally required to be disclosed. Notwithstanding any other provision of this Agreement to the contrary, Licensee hereby acknowledges that Foundation complies with the New York Freedom of Information Law, N.Y. Pub. Off. Law §84, et seq., as the same may be amended from time to time, and may be required to make disclosures of information which it receives in compliance therewith.

16.4. **Injunctive Relief.** The Parties agree that the breach, or threatened breach, of any of the confidentiality provisions of this Article 16 may cause irreparable harm without adequate remedy at law. Upon any such breach or threatened breach, Licensee or Licensor will be entitled to injunctive relief to prevent any other Party from commencing or continuing any action constituting such breach, without having to post a bond or other security and without having to prove the inadequacy of other available remedies. Nothing in this Section will limit any other remedy available to any Party.

17. MISCELLANEOUS

17.1. **Governing Law.** This Agreement will be construed, governed, interpreted and applied in accordance with the laws of the State of New York. The Parties consent to the exclusive personal jurisdiction of the state and federal courts of the State of New York and irrevocably waive any and all rights any such Party may now or hereafter have to object to such jurisdiction or the convenience of the forum.

17.2. **Entire Agreement.** This Agreement, including any recitals, Exhibits or attachments hereto (all of which are hereby deemed incorporated into the body of this Agreement as if the same had been restated herein in their entirety), embodies the entire agreement and understanding among the Parties to this Agreement and supersedes all prior agreements and understandings relating to the subject matter of this Agreement. None of the terms or provisions of this

Agreement may be altered, modified, or amended except by the execution of a written instrument signed by the Parties hereto.

17.3. **Severability.** The provisions of this Agreement are severable, and in the event that any provisions of this Agreement are determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability will not in any way affect the validity or unenforceability of the remaining provisions hereof.

17.4. **No Third-Party Beneficiaries.** Except as expressly set forth herein, the Parties hereto agree that there are no third-party beneficiaries of any kind to this Agreement.

17.5. **Construction.** All Parties contributed equally to the drafting of all parts of this Agreement and agree to all of the terms herein. All Parties reviewed this Agreement thoroughly prior to execution.

17.6. **Notices**. All notices, requests, consents, and other communications to be provided under this Agreement must be in writing and will be delivered electronically (e.g., email or facsimile), in person or sent overnight delivery by a nationally recognized courier or by certified or registered mail, return receipt requested, to the addresses provided below, and will be deemed to have been given when hand delivered, one (1) day after mailing when mailed by overnight courier, five (5) days after mailing by registered or certified mail, or upon confirmation of receipt of an electronic delivery by recipient.

If to Licensee, to:

Quadrant Biosciences Inc.
505 Irving Avenue, Suite 3100AB
Syracuse, NY 13210
Email: Richard.Uhlig@QuadrantBiosciences.com

If to Foundation, to:

The Research Foundation for The State University of New York
Office of Industry & External Affairs
35 State St.
Albany, NY 12207
Attn: Director, Innovation & Partnerships
Email: commercialization@rfsuny.org

17.7. **No Waiver.** No waiver by any Party hereto of any breach or default of any of the covenants or agreements herein set forth will be deemed a waiver as to any subsequent or similar breach or default. The pursuit by any Party of any remedy to which it is entitled at any time or continuation of the Agreement despite a breach by any other Party shall not be deemed an election of remedies or waiver of the right to pursue any other remedies to which it may be entitled.

17.8. **Patent Marking.** As required by law, Licensee will mark, and will cause all of its Affiliates to mark, all Patented Products that are manufactured or sold under this Agreement with: (i) the number of each issued patent under the Patent Rights that applies to such Patented Product; or (ii) the word 'patent' or the abbreviation 'pat.' together with an address of a posting on the Internet, accessible to the public without charge for accessing such address, that associates such Patented Product with the number of the issued patent under the Patent Rights.

17.9. **Independent Parties.** This Agreement will not be construed as creating a relationship of employment, agency, partnership, joint venture, or any other form of legal association between Licensee and either Licensor. The relationship between the Parties shall never be construed to be that of employer-employee. No Party has any power to bind another Party or to assume or to create any obligation or responsibility on behalf of another Party or in another Party's name.

17.10. **Force Majeure.** No Party will be liable for failure or delay of fulfillment of all or part of this Agreement, directly or indirectly owing to acts of nature, governmental orders or restriction, war, warlike conditions, revolution, riot, looting, strike, lockout, fire, flood, or any other cause or circumstances beyond the Party's control.

17.11. **Headings.** The headings of the articles and sections are inserted for convenience of reference only, and are not intended to influence the interpretation of this Agreement.

17.12. **Counterparts and Signatures.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Further, any Party's signature to a copy of this Agreement will be deemed a signature to, and may be attached to, any other identical copy of the Agreement. Facsimile or electronic signatures will be as binding and effective as original signatures, and the Parties hereby waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature. This Agreement is not binding on the Parties until it has been signed below on behalf of each Party.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

QUADRANT BIOSCIENCES INC.

By: 
Name: Richard Uhlig
Title: Founder and CEO

Date: 8/7/2020

THE RESEARCH FOUNDATION FOR THE STATE UNIVERSITY OF NEW YORK

By: 
Name: David Amberg
Title: RF Operations Manager, Vice President for Research

Date: 8/7/2020

EXHIBIT A

Inventions and Licensed Patents

Inventions

RF Disclosure #	Title	Inventors
110-2124	*Methods of quantifying SARS-CoV-2 from individual and pooled saliva*	Dr. Qian Du Dr. Frank Middleton

Licensed Patents

Application #	Application Status	Status	Title
TBD	Drafting	Unfiled	*Methods of Quantifying SARS-CoV-2 from Individual and Pooled Saliva*

EXHIBIT B

Affiliates of Licensee

Pursuant to Section 2.2 of this Agreement, the Affiliates identified below shall be jointly and severally liable with Licensee and all other Affiliates of Licensee for the performance of the terms hereof.

QUADRANT VIRAL TESTING, LLC.

By: 
Name: Richard Uhlig
Title: CEO