

Main Street Software Technology Healthcare Bio Tech

# Quadrant Biosciences Inc.

We develop novel, saliva-based tests for autism. Parkinson's, and COVID-19.

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With respect to the COVID-19 testing, it chose us more than we chose it! Our expertise in saltva-based, RNA testing · as part of our mission to develop diagnostic tests for autism and other neurological conditions - serendipitously placed us in a position to help address this global pandemic. We are now involved in three COVID-19 projects!

Richard Uhlig CEO and Founder @ Quadrant Biosciences Inc.



ABOUT

UPDATES® REVIEWS® ASK A QUESTION®

### Why you may want to support us...

- Quadrant is leading the development of epigenetic diagnostic tools for multiple health conditions.
- 2 Developed & commercialized world's first saliva-based epigenetic test for autism spectrum disorder.
- 3 Applied our expertise in RNA analysis to co-develop COVID-19 saliva test w/SUNY Upstate
- 4 Member of consortium approved by NY State to test municipalities' wastewater for COVID-19.
- 5 Working with SUNY on pooled diagnostic surveillance of returning college students for COVID-19.
- 6 Development of Parkinson's disease, concussion, and Anorexia nervosa, diagnostic tools in progress.
- 7 Led by former Chairman & CEO of Morgan Stanley Bank and a seasoned management team.

## Our team



#### Richard Uhlig CEO and Founder

More than 25 years of business experience focused on the design and development of innovative products across various industries. Former CEO of Morgan Stanley Bank and CIO at Merrill Lynch Bank. Graduate of Cornell University.



# Benjamin Perry

President

Over 10 years of experience in the software development industry, with deep experience in cloud computing architecture, blockchain technology, and agile product management. Graduate of Cornell University.



# Richard Bongo

Chief Financial Officer

Over 30 years of experience in structured finance, Managing Director at one of Europe's largest banks, positions at multiple Wall Street firms such as Lehman Brothers, Credit Suisse, Merrill Lynch and Bank of America. Graduate of Kings College.



#### James Croke

Experienced counsel to underwriters and issuers in the US and global public offerings and private placements as well as a writer and lecturer on legal and regulatory issues. Graduate of University of Kentucky and University of Notre





#### Dave MacLean

Chief Marketing Officer

More than 25 years of business, legal and research experience including film production, entrepreneurship, litigation and research for Cornell University. Graduate of Cornell University and Buffalo Law School.



#### Syed Ameen

Executive Vice President Corporate Strategy Over 25 years of experience as an investment banker, founder and portfolio manager of Tevere Capital. Led multiple trading desks at Bank of America, Lehman Bros, and Morgan Stanley. Graduate of the University of Pennsylvania.



#### Jeremy Williams

Experienced developer and leader spanning complex systems integration, mapping software used by state and municipal governments to manage geo-spatial data, and applications for research data analysis and dissemination. Graduate of Cornell University.



#### Bryan Greene

Chief Operating Officer

More than 10 years of experience in medical device operations, manufacturing, validation, and new product introduction. Graduate of Clarkson University.



Executive Vice President - Sales

Over 39 years of entrepreneurial business experience in leadership, sales, marketing and business development, provided consulting services to a number of startup and growing companies in the orthopedic and medical device industry.



#### Chris Horacek

Deputy General Counsel

Over 30 years' experience working in healthcare arena, and related areas of regulatory compliance and patent protection.



Vice President of Product Management Experienced researcher with a career dedicated to working with children and adolescents with neurodevelopmental disorders in both clinical and research settings. Graduate of Syracuse University.



#### In the news



























# Downloads

Reg CF investor deck - Google Stides.pdf

# From Epigenetic Diagnostics to Comprehensive COVID-19 Testing. How Did We Get Here?

# Leaders in the Development of Epigenetic Diagnostic Tools

Quadrant Biosciences is a life science company working with universities across the US to develop and commercialize epigenetic diagnostic solutions for autism spectrum disorder, Parkinson's disease, and mild traumatic brain injury (concussion). Working closely with medical researchers such as SUNY Upstate Medical University and Penn State College of Medicine, we have developed a novel, saliva-based diagnostic platform called Clarifi\*.

In December 2019 we launched Clarifi ASD\*, the world's first saliva test for autism spectrum disorder. The test, intended for children 18 months through six years of age, provides a probability of an autism diagnosis based on epigenetic markers in the saliva. Then the COVID-19 Pandemic happened

Not long after we began to introduce Clarifi ASD to pediatric health care providers, the world was besieged by the COVID-19 pandemic. Our ability to access healthcare providers and share the scientific and practical utility Clarifi ASD provides to parents and physicians was greatly restricted by social distancing mandates and virus concerns which, in turn, limited our sales team's ability to affect sales and increased commercial demand for Clarifi ASD. As a result, our sales of the Clarifi ASD test have been below expectations.

#### So, we adapted!

In response to the COVID pandemic, we immediately reduced our operating costs and, given our existing experience with RNA analysis - and the fact that COVID-19 is an RNA virus - we made the decision to pivot and work with our university partners to develop diagnostic tools for COVID-19. As a result, today we are involved in three significant, complementary COVID-19 projects to aid in the detection of COVID-19 in individuals and communities across the U.S.

Watch this brief overview video of our company projects:



# Three Levels of Testing: A Comprehensive Approach to Assessing COVID-19



# 1. Individual Testing - Clarifi COVID-19 Test Kit

The development of an individual saliva test for COVID-19 was a natural extension of our earlier work with Clarifi ASD\*, which used a similar saliva collection methodology. Working in partnership with SUNY Upstate Medical University, we developed the "Clarifi COVID-19 Test Kit by SUNY Upstate Medical and Quadrant Biosciences," a non-invasive and easy to administer swab that collects saliva which is then analyzed to determine the presence or absence of the SARS-CoV-2 virus. On September 23rd, we received Emergency Use Authorization (EUA) for the Clarifi COVID-19 Test Kit!



The Clarifi COVID-19 Test Kit contains the saliva collection swab and the reagents needed to run the analysis and is available for use by high-complexity clinical laboratories serving patients through physicians' offices, urgent care clinics, and hospitals.



# Wastewater Surveillance Community Screening

#### 2. Community/Municipal Screening: Wastewater Surveillance

This project, funded by New York State, involves our collaboration with SUNY ESF, Upstate Medical University, Syracuse University, and global civil engineering firm Arcadis, to collect and analyze wastewater from the county and municipal sewer systems for the presence of the COVID-19 virus. Our analysis of wastewater samples provides local health officials and policymakers with early indications and information regarding the presence and preponderance of COVID-19 infections in these communities.



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"This can be a real game-changer in the detection and monitoring of COVID-19.

Information from this testing will allow municipalities to estimate COVID-19 transmission in real time, provide instant feedback on social distancing and reopening phases, help predict hospitalizations and provide confidence for locations with zero transmission to resume normal activity."

Richard Uhlig, Founder and CEO of Quadrant Biosciences

Because this allows for large regions to be effectively tested for the presence of the COVID-19 virus, it provides a cost-effective and efficient way to screen residents in towns, cities, states, and universities, even in the absence of individual testing.



# 3. Group/College Testing: Pooled Testing

Finally, in response to an overwhelming need to efficiently test university students prior to attending classes, we have partnered with the Upstate Medical University to conduct pooled testing services for over 450,000 students preparing to begin the fall semester at SUNY schools.

Each of these pooled tests for COVID-19 involves a single test of saliva samples collected from a group of 12 students. A negative test result means that all 12 students are presumed to be coronavirus-free. A positive test for the pool would mean every student in that group would need to be individually tested. Performing single tests of groups of students greatly reduces the cost of supplies, staffing, and time required to perform and interpret tests.



"SUNY Upstate Medical University's work with Quadrant Biosciences, a Start-Up New York company, has led to important breakthroughs in the development of saliva-based diagnostic solutions for neurological conditions such as autism spectrum disorder, Parkinson's disease and concussion injuries. The ability to transfer this innovative approach to assist colleges and universities with the unprecedented and complex work of preparing for the return of students to campuses across the state is an important part of New York's response to the COVID pandemic."

Dr Mantosh Dewan, Interim President, SUNY Upstate Medical University

#### Disclaimers:

\*On September 22, 2020, The Clarifi COVID-19 Test Kit obtained Emergency User Authorization (EUA) by the Food and Drug Administration (FDA) to be used for the diagnosis fo SARS-CoV-2. The Clarifi COVID-19 test Letter of Authorization, along with the authorization Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website.

The Clarifi COVID-19 Test Kit has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories. Clarifi COVID-19 has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b) (1), unless the authorization is terminated or revoked sooner.

Despite the fact that we have the expertise, capability, and customer demand for these COVID-19 tests, the supplies needed to perform quantitative PCR are becoming increasingly difficult to obtain. This, and supply chain disruptions generally throughout the industry, could impair our ability to successfully commercialize one or all of these tests.

#### But, we are still very much an Epigenetics Diagnostic Company!

#### The Clarifi ASD\* Test - A Game-Changer for Autism Diagnostics

We continue to maintain a focus on our core mission to develop epigenetic diagnostic tools, such as Clarifi ASD\*, the world's first saliva test for autism spectrum disorder.



# What is it?

Clarifi ASD $^{\rm o}$  is a saliva test that indicates the probability that a child has autism spectrum disorder.

### Who is it for?

Clarifi ASD\* is being used primarily by pediatricians and family physicians with patients (18 months through 6 years of age) with a positive autism screening test or a clinical suspicion to aid in a formal diagnosis.

#### Why is it needed?

With 1 in 54 children being diagnosed with autism in the US according to the CDC, it is one of the most commonly diagnosed developmental disabilities in the country. Unfortunately, the current diagnostic process involves long wait times, largely the result of a small number of trained clinicians to administer behavioral tests. This, in turn, leads to delays in children receiving critical intervention services. If autism is identified and treatment is initiated early, the trajectory of a child's life can be positively changed.

# How Clarifi ASD Can Make a Difference

For the first time, clinicians have an accurate biological tool to aid in the early diagnosis of

- ~ Help start services earlier when treatment is most effective
- ~ Provide specialists biological data to support their behavioral assessments
- $\sim$  Facilitate cost savings through improving the diagnostic process

"What we've been able to do over the last 7 years, working together with a very dedicated team, is develop a test that utilizes saliva and can accurately distinguish whether a child has autism spectrum disorder or does not. This relies on a new type of molecular analysis that wasn't even possible until recently."

Frank Middleton, Ph.D. Associate Professor of Neuroscience and Physiology, Biochemistry and Molecular Biology, Pediatrics, and Psychiatry and Behavioral Sciences.

#### When was it launched?

Clarifi ASD was launched commercially in the US in 49 states (excluding New York), in December 2019.

#### Watch a short video about Clarifi ASD here:



# Who we are

Quadrant Biosciences Inc was started in 2015 by Founder and CEO Rich Uhlig, and we have since grown to over 40 employees. Our team has a shared passion in being a part of positive changes in healthcare.

"As a company, we are committed to looking outside ourselves, and deploying our resources to assist other organizations and research efforts dedicated to improving the lives of people with autism and their families."

Richard Uhlig, Founder and CEO, Quadrant Biosciences





#### Capital Raised to Date

As of August 2020, we have raised over \$30 million in previous financing rounds from private investors who have recognized the value in how we intend to change the landscape of diagnostics in the future.

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Series A Preferred funding	Established bank credit line	Converted Series A Preferred to common equity; sold 10% equity interest	A 5-year convertible note (convertible to common equity)	Common Equity	Common Equity	Reg A Crowd Funding
\$6.1 M	\$1.25 M	\$12.5 M	\$5.0 M	\$5.0 M	\$2.5 M	\$1.0 M

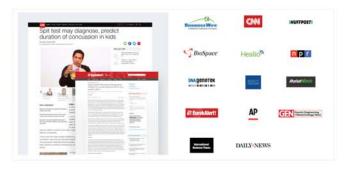
We have received numerous grants to support our research efforts."



("The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.)

#### Quadrant Biosciences in the Media

Our company has been featured many times in national news and scientific media outlets regarding our research and technology accomplishments in the areas of autism, COVID-19, concussion, and Parkinson's disease.



#### Clarifi ASD is just the beginning! Future products in the works.

One of the most exciting things that we've discovered is that our Clarifi\* epigenetic diagnostic platform has applications for many other health issues. Diagnostic solutions for early-stage Parkinson's disease, mTBI/concussion, anorexia, and schizophrenia are currently in development. Several peer-reviewed research papers have already been published on the application of this approach to these worldwide neurological health concerns.



# We have numerous peer-reviewed publications supporting our science

To date, there have been 19 peer-reviewed papers published supporting our development of epigenetic biomarkers for autism, mild traumatic brain jury, Parkinson's disease, anorexia nervosa, and Pantothenate kinase-associated neurodegeneration disease (PKAN). These have been published in a variety of scientific journals including JAMA Pediatrics, Frontiers in Genetics, Journal of Neurotrauma, Journal of Oral Microbiology, Journal of Experimental Neuroscience, and Autism Research.



#### Research Partnerships

We are honored to partner with a number of outstanding research universities and organizations to help further the understanding of epigenetics.



#### International Research Partnerships

We also actively partnered with several international research organizations:

European Autism Interventions, A Multicentre Study for Developing New Medications (EU-AIMS) - first Europe-wide collaboration between organizations with the goal of identifying markers of autism that would help in earlier and more accurate diagnosis, prognosis, and the development with new therapies

Comprehensive Care Center for Disability (CAID) - centers in Santiago, San Juan, Higuey, and Santo Domingo, the Dominican Republic dedicated to the evaluation, diagnosis, and rehabilitation of children from zero to ten years with Autism Spectrum Disorder.

#### Our Clinical Advisory Board

Our clinical advisory board comprises some of the leading autism and epigenetic researchers and clinicians. It is our privilege to work alongside these luminaries in the field to help families and children with autism.



# Want to learn more?

For more information about the company, download the investor deck and visit Quadrant Biosciences www.quadrantbiosciences.com; for more information about the Clarifi ASD visit www.clarifiasd.com.

# Investor Q&A

#### What does your company do? ~

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We develop epigenetic saliva biomarkers including the world's first saliva test for autism. We recently received FDA emergency use authorization for a COVID-19 saliva test, and are currently working on developing tests for Parkinson's disease, concussion, and Anorexia nervosa.

# Where will your company be in 5 years? ~

Our goal is to have the Clarifi epigenetic diagnostic tests become the standard of care, positively impacting millions of people across the globe. We also want to be on the forefront of RNA analysis and continue to contribute to the fight against RNA viruses such as COVID-19.

#### Why did you choose this idea? ~

With respect to the COVID-19 testing, it chose us more than we chose it! Our expertise in saliva-based, RNA testing - as part of our mission to develop diagnostic tests for autism and other neurological conditions - serendipitously placed us in a position to help address this global pandemic. We are now involved in three COVID-19 projects!

# Why is this a good idea, right now? What changed in the world? Why wasn't this done a few years ago? $\,^{\vee}$

The short answer is a global pandemic. Just nine months ago we were solely focused on the release of our new Clarifi ASD autism diagnostic test, and developing epigenetic saliva biomarkers for Parkinson's disease, concussion and other neurological disorders. Then the pandemic hit and we found ourselves in the unique position to leverage our understanding of RNA analysis to join the fight against the virus. Since March, we have been involved in three distinct, but complementary, approaches to COVID-19 testing: 1) individual testing using our FDA EUA authorized Clarifi COVID-19 Test Kit developed in partnership with SUNY Upstate Medical, 2) group pooled surveillance testing of colleges

#### How far along are you? What's your biggest obstacle?

We just commercially launched the first of these epigenetic tests, Clarifi ASD, in December 2019. Clarifi ASD is the world's first epigenetic diagnostic tool for autism spectrum disorder. Our COVID-19 diagnostic work consists of three mechanisms of testing: municipal wastewater surveillance, pooled surveillance testing of NYS college students, and an individual COVID-19 diagnostic saliva test that recently received FDA emergency use authorization (EUA). Our biggest obstacle is having sufficient resources to continue to work with our university partners to research, develop, and commercialize diagnostic tools to the market as quickly as we have to date.

#### Who competes with you? What do you understand that they don't? ~

Though we believe we do not currently have any direct competitors for our Clarifi ASD product, we believe that a number of organizations are, or may be, working to develop human health and disease diagnostic and preventative mechanisms, and or other novel technologies that may be competitive with our technology. We have numerous capable competitors in the area of detection and diagnosis of COVID-19, many of which are further along and better funded than we are.

#### How will you make money? ~

By selling our epigenetic products commercially to pediatricians and clinicians; first in the United States and then globally; and by selling our COVID-19 diagnostic tools and services.

# What are the biggest risks? If you fail, what would be the reason? What has to go right for you to succeed?

The following are only some of the risks associated with this offering. Please refer to our offering document which contains a comprehensive list of risk factors that could adversely affect our business and prospects.

- 1. We are an early stage revenue producing company and have incurred losses since our inception. We have recently begun to generate some significant revenues but there can be no assurance that we will continue to do so, or that we will not incur annual losses for the foreseeable future as we further expand our product offerings, and may never achieve or maintain annual profitability. Any valuation of the company at this stage is difficult to assess.
- There is currently no public market for our Common Stock or our convertible notes, and a public market for our Common Stock or our convertible notes may never develop.
- 3. Even if any of our product candidates receives marketing clearance or approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- 4. We have limited experience with the manufacturing and delivery processes and systems needed for us to commercialize our products on a large scale.
- If the company loses certain senior management and key personnel or are unable to attract and retain skilled employees when needed, it may not be able to operate successfully.

For more risks, see the Offering Document.

# What is your proudest accomplishment?

With a relatively small team of highly dedicated individuals, we were able to accelerate the transformation of what we believe is a revolutionary scientific finding into a viable commercial product accessible to the public - Clarifi ASD. More recently, post-COVID we quickly applied our experience in RNA detection and analysis to develop commercial products and services for the detection and analysis of COVID-19.

#### What do you understand that your competitors don't?

That we are the first company to develop an epigenetic saliva test for autism speaks volumes about the current approach being taken to identify biological markers for autism. Significant time and money has been spent by many in the pursuit of a genetic biomarker for autism, however to date it has failed to yield a biomarker with any practical utility. On the other hand, we believe our novel approach, developed in research labs at SUNY Upstate Medical University and Penn State College of Medicine, and backed by peer-reviewed research, provides accurate diagnostic biomarkers for autism, and appears to hold promise as well for other neurological conditions such as Parkinson's disease, concussion and Anorexia nervosa.

## What do you need the most help with?

Achieving sufficient funding to permit us to remain liquid and to grow and advance our concurrent development and regulatory approval of our suite of epigenetic and COVID-19 diagnostics and services.

### What would you do with the money you raise?

- 1. Use the money for working capital purposes.
- Continue to grow and expand the development and regulatory approval of our epigenetic diagnostic tests and our COVID-19 diagnostics and services.

It began almost a decade ago in a cold ice rink in upstate New York. There, Quadrant Biosciences' founder and CEO Rich Uhlig, was watching a youth hockey game when his son suffered a severe concussion. Frustrated with the diagnosis and management of his son's concussion, he was determined to do something about it, and thus Quadrant Biosciences was born. In the process of developing and launching a technology to objectively test balance and cognitive function called ClearEdge, Rich moved the company to the SUNY Upstate Medical University in Syracuse to leverage its highly regarded concussion clinic and motion analysis lab. That move changed everything.

It just so happened that our office was in the same building that housed the Neuroscience departments and molecular core facility—and its director Dr. Frank Middleton. Rich learned that Frank, and his then grad student Steve Hicks, MD/Ph.D., had stumbled upon an exciting discovery that certain molecules in the saliva of children were different in kids with autism. Unfortunately, the funding had run out and the research was at risk of being shelved indefinitely. Recognizing the groundbreaking nature of their findings, we entered into a relationship with SUNY Upstate to support the research and work on turning this amazing discovery into a viable commercial product.

Fast forward seven years and lots of research, development, peer-reviewed publications, and hard work, the Clarifi ASD test is now available to the public. Moreover, we have been able to leverage our expertise in RNA analysis to co-develop an FDA EUA authorized COVID-19 test with SUNY Upstate Medical University, as well as provide pooled surveillance testing and wastewater monitoring for COVID-19.

#### What does your product pipeline look like? ~

One of the most exciting things about our epigenetic approach to autism diagnoses is that it has proven to have similar diagnostic utility to many other neurological conditions. In fact, we have published peer-reviewed research papers on epigenetic tests for Parkinson's disease, mild traumatic brain injury (concussion), and Anorexia nervosa. Commercial development of the Parkinson's disease product is currently slated for Q3 2021. Our COVID-19 work as part of a consortium selected by NY State to perform wastewater testing for communities around NY is ongoing, and subject to supply chain availability of materials needed to conduct the tests, looks promising. Our partnership with SUNY Upstate in conducting pooled surveillance testing of students returning to school looks very promising - we are currently contracted to provide test materials and services in relation to the testing of 450,000 students. Our partnership with SUNY Upstate in developing a saliva test for COVID-19 in individuals has resulted in FDA emergency use authorization for this test in September, 2020.

#### How much capital have you raised to date? ~

As of August 2020, we have raised over \$30 million from private investors who have recognized the value in how we intend to change the landscape of diagnostics in the future.

## Why is a Test Like Clarifi™ ASD So Critical Today? ~

1) Autism Prevalence is increasing at a rapid rate

The prevalence of Autism has increased from 1 in 150 in 2000, to 1 in 54 according to estimates from the CDC. There are several theories related to this rise in prevalence, but answers remain unknown.

2) Early diagnosis and intervention can change the trajectory of a child's life

Decades of scientific research continuously show that children make greater improvements when intervention is started early in development. With early intensive behavioral intervention, initiated in the second or third year of life, approximately 50% of children with autism become functionally indistinguishable from their peers by the time they get to first grade. However, in the absence of such early intervention, only about 2% achieve average educational and intellectual equivalency.

3) Children need to be diagnosed before they can begin intervention services. Unfortunately, many aren't being diagnosed until after age 4, even though autism can be diagnosed as early as 18 months. This is due to several reasons but chief among them is the relatively small number of specialists trained to administer behavioral-based diagnostic assessments. In fact, the wait time for a child to be evaluated by a specialist is up to 1.5 years in some areas of the U.S.!

This means that children in the United States, and many other countries, are not receiving a timely diagnosis or access to critical services until well after the point where they are most effective.

4) There are other challenges with the current diagnostic process

Before Clarifi ASD, there were no other accurate biological tests to aid in diagnosing autism. Diagnostics rely heavily on direct observation of a child's behavior by a trained clinician and parent report of behaviors in other settings, leading to a process that has approximately 69% inter-rater reliability. This means that sometimes, even with several hours of comprehensive evaluation, a traditional autism diagnosis is missed or incorrectly provided.

# Can Clarifi play a role in reducing the societal costs associated with autism?

Although the costs associated with autism treatment and care are substantial, early diagnosis and intervention can help significantly reduce these costs. In fact, if interventional services are initiated earlier in life, annual cost savings in education are estimated to exceed \$13 billion, and annual cost savings in medical and residential care approach \$24 billion. These are the quantifiable cost saving benefits based on excenditures. The value of reduction in opportunity costs, indeed the benefit of

opportunities open to patients and their families of early diagnosis and treatment are incalculable as is the potential improvement in quality of life.

### Where is your office located? ~

We are strategically headquartered in the Institute for Human Performance on the SUNY Upstate Medical University campus to rapidly translate cutting edge scientific advancements into commercial products. Our business is co-located with the University Hospital's:

Neuroscience Department Molecular Analysis Core Facility Concussion Management Clinic Concussion Research and Motion Laboratory

We also recently opened an office in San Antonio, Texas.



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