CAREPOINT SOLUTIONS

Accelerating Coronavirus Testing Solutions (ACTS)

Funding Proposal from CarePoint Solutions

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Covid testing: A Perfect Storm for Diagnostic Error

Problem:

Hundreds of new commercial COVID-19 diagnostic tests are being rushed to market in response to the global coronavirus pandemic. Under FDA Emergency Use Authorizations, millions of minimally validated tests are now flooding the marketplace. Hundreds of thousands of new sample collection facilities and point-of-care testing locations are now conducting COVID-19 testing for the first time, oftentimes under challenging conditions (e.g., outdoor drive-thru collection centers). While scientists continue to characterize the behavior of this lethal pathogen, many new diagnostic technologies are being advanced to help out, and the actual performance characteristics of these new technology platforms are being determined in clinics across the US – on real patients, in real time.

Yet the need to ensure the accuracy of COVID-19 testing is especially great. Misdiagnoses, such as false positive and false negative results pose significant harm and potential fatality to healthcare workers, patients, coworkers, patient families, and society at large.

Solution:

Pro-QCP™ is a first-of-its-kind web app being developed by CarePoint Solutions that:

- Guides clinicians through a comprehensive risk assessment of their COVID-19 test process, through each phase of testing and at each location where testing is conducted
- Generates an effective Individualized Quality Control Plan (IQCP) to satisfy federal regulatory compliance
- Drives efficiencies and improves clinical outcomes by identifying sources of error at each test location and suggesting proven measures to mitigate those errors
- Provides inter-laboratory comparisons, allowing users to compare their procedures and test performance to other labs
- Offers surveillance of major COVID-19 diagnostic platforms, in real-time as used in real-world conditions

To date, CarePoint Solutions has invested over 3 years and $1.5M into the design and creation of Pro-QCP. More than 150 modules of the program are now in the development pipeline, each module specific to a major point-of-care diagnostic test platform. The development effort has

William Donohue, President/CEO
CarePoint Solutions, Inc. 100 Cummings Center Suite 434-E Beverly, MA 01915
bill.donohue@carepointsolutions.com 508-517-6849

included the input from over 30 clinical lab experts, healthcare institutions from across the country, major healthcare accreditation agencies, the Clinical & Laboratory Standards Institute, and hundreds of diagnostic test manufacturers

CarePoint is now seeking funding to: **1.)** expedite the final development and completion of the Pro-QCP platform in time for a Q4 2020 launch – to maximize its utility in the containment of the pandemic, **2.)** build 100 or more program modules, each specific to a major COVID-19 test platform on the market, **3.)** commercially launch and promote Pro-QCP into the US market, and **4.)** develop Pro-QCP Version 2 that will expand program capabilities, interface and share data with users' laboratory information systems, and aggregate data to produce real-time industry-wide performance summary reports that evaluate the performance of each major COVID-19 test platform.

Background:

CarePoint Solutions, Inc. founded in 2012 and headquartered in Beverly Massachusetts, is a diagnostics company on the front lines of the battle against preventable medical error – the #3 cause of death in the US.

CarePoint has participated in, and benefitted from the MLSC Internship Program for many years.

CarePoint's QC Division formulates and manufactures blood-like quality control solutions used to verify the performance and improve the accuracy of diagnostic analyzers. These products are supplied on an OEM basis to in vitro diagnostic analyzer manufacturers and federally-approved proficiency test organizations. The company's focus and areas of expertise include coagulation, blood chemistry, blood gases, blood oximetry, blood lead, and blood glucose.

CarePoint's QA Division develops and markets data-driven, outcomes-oriented quality management software that improve the accuracy of diagnostic testing and help ensure regulatory compliance. Pro-QCP, CarePoint's initial software offering, will be the first quality management system for point-of-care testing. The program is the product of a nation-wide collaboration of industry and subject matter experts and has been endorsed by clinical leaders and top clinical laboratory accreditation organizations. As an industry first, and filling an essential role in diagnostic testing, Pro-QCP is poised to become an industry standard.

Pro-QCP for COVID testing represents a unique and essential resource that clinical lab directors can use to effectively evaluate their unique testing processes and circumstances for sources of error. The program allows new users of COVID tests to get up to speed quickly and establishes a continuous quality improvement process that suggests proven measures that can further reduce errors. Key performance indicators are monitored over time for each lab and inter-laboratory

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comparison reports establish realistic performance targets. Pro-QCP's monitoring and reporting on the performance of each major diagnostic platform helps inform laboratory buying decisions and helps lab directors ensure that the tests they employ are the most appropriate for their particular patient populations.

Monitoring and improving COVID-19 testing accuracy is essential to containing the current coronavirus pandemic. Greater test accuracy ensures downstream healthcare decisions are more effective, allows healthcare organizations to channel essential resources most appropriately, measurably improves clinical outcomes, and allows screening and contact tracing efforts to be more effective at reducing community spread.

As a novel post-market surveillance system, Pro-QCP for COVID testing will establish industry-wide performance standards and flag poorly performing diagnostics that pose the greatest threat of harm to society.

Pro-QCP for COVID testing is a software as a service (SaaS) platform and will be available on an annual subscription basis with a target price of $795 per module, per year. A scalable version of the program is currently under development by an outsourced software development team and, with proper funding, the program will be launched before the end of the year as 250 modules that cover 150 point-of-care tests and 100 COVID-19 tests.

CarePoint has lined up a host of channel partners that are interested in promoting and co-marketing the product once it is available. These include proficiency test organizations such as the American Association of BioAnalysts, subject matter experts such as Westgard QC, national distributors such as Thermo Fisher Scientific, and major diagnostic suppliers such as Abbott Diagnostics. CarePoint is optimistic that, once it is available, Pro-QCP will be eligible to be featured on the CDC COVID Resource website and perhaps coverage on the bi-weekly CDC COVID resource update calls, and other industry COVID resource boards. CarePoint has conducted an ongoing content marketing campaign that has generated a database of over 6000 pre-qualified clinical prospects for Pro-QCP, and the company hosts a key clinical lab forum, the POCT Listserv, that provides immediate access to over 1500 laboratory directors and point-of-care test coordinators, most of whom are actively involved with and oversee COVID-19 testing within their institutions and integrated delivery networks.

CarePoint was on track to self-fund the original launch of Pro-QCP, but COVID's impact on ongoing clinical trials for several of our clients has impacted the revenue stream for our QC Division. In response, we have sought BARDA COVID funding, but because we are technically not a COVID diagnostic test, we were deemed ineligible. CarePoint is also pursuing SBIR funding, but the application process and funding timeline would delay the launch of this urgently needed lab utility. With critical and timely funding from the MLSC, CarePoint can keep our development schedule on track for a Q4 2020 commercial launch and maximize our contribution to the country's pandemic response.

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CarePoint is seeking $355,000 in grant funding for the following purpose:

1.) Content development of 100 new COVID test modules ($75k)
2.) Completion of the Pro-QCP commercial platform ($80k)
3.) Development of Pro-QCP 2.0 that provides LIS integration and nation-wide IVD test surveillance ($100k)
4.) Promotion of Pro-QCP for COVID testing to the US market ($100k)

The completion of the commercial Pro-QCP platform is active and ongoing, and with adequate and immediate funding, CarePoint is targeting launch of Pro-QCP with 100 modules to cover the most popular COVID tests by the end of November 2020. Development will then continue on the platform to expand capabilities, including the integration with end user laboratory information systems (LIMs) to passively capture real-time performance data and leveraging those data to produce nation-wide IVD test platform performance reports. Launch of the version 2.0, if we can hold to our current schedule, is targeted for Q1 2021.

CarePoint management anticipates that, given the strong value proposition that Pro-QCP has for diagnostic testing in general, combined with the urgent need to monitor and improve the accuracy of COVID testing, Pro-QCP annual subscription revenues could top $20M in 2021 and grow to $100M revenue per year within five years. This forecast assumes uptake by 25,000 testing locations in the first year (8% of the 300,000+ locations that will likely conduct COVID testing). With these revenues, the company will re-invest in infrastructure to create a dedicated in-house IT development team, expand marketing and sales efforts, and build a customer service team to support product uptake. Based on these projections, CarePoint anticipates adding 10-12 new employees in 2021.

William R. Donohue, President/CEO

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