Progenity Announces Successful Achievement of its Preeclampsia Test Analytical Verification Milestone

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Announces Expansion of its COVID-19 Testing Offering

Provides Preliminary Third Quarter 2020 Financial Update

SAN DIEGO, Oct. 29, 2020 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), a biotechnology company with an established track record of success in developing and commercializing molecular testing products, today announced a key achievement in the verification of its preeclampsia rule-out test, a significant milestone demonstrating the robustness of the underlying assays and the clinical performance of the Laboratory Developed Test in its CLIA laboratory in Ann Arbor.

Preeclampsia Rule-out Test Analytical Verification Milestone Achieved

The company confirmed it had validated all its key operational methods, including analytical accuracy, analytical precision, analytical sensitivity, analytical specificity, linearity, and stability of the assays. “We’re very excited to report the achievement of this key milestone in the development of our preeclampsia rule out test and are confident the underlying assays are robust and will assess the true biological responses associated with preeclampsia. The clinical verification cohort continues to be analyzed but headline performance was consistent with prior observations with our feasibility and optimization clinical cohorts. Moreover, we observed a longevity of the rule-out result we believe should enable effective integration into existing clinical care paths. We are looking forward to the initiation of the key clinical validation phase, for which samples have already been collected,” said Matthew Cooper, PhD, MBA, Chief Scientific Officer of Progenity.

Harry Stylli, PhD, CEO, chairman of the board and co-founder of Progenity added, “We are also continuing to engage with the FDA regarding the IVD version of the test and recently had a productive pre-submission meeting with the Agency on our development path and we are happy with their guidance. We’re looking forward to sharing more information, including an FDA update and data from the verification studies, during an upcoming preeclampsia R&D day scheduled for November 20, 2020. At the R&D day, we and our advisors will review and discuss our program and illustrate how we intend to fulfill the current clinical unmet need and help healthcare providers and patients better manage this debilitating syndrome. This significant opportunity represents a potential $3 billion US total market that we intend to access with our innovative test.”

Expansion of COVID-19 PCR Test Offering

The company announced it has secured a substantial increase in its COVID-19 PCR testing capacity to more than 750,000 tests per annum and supply chain access through its existing relationship with ThermoFisher, in order to meet the high demand for the test ahead of the winter season, and expects to begin a gradual expansion of its commercial testing offering nationally beginning mid-November.

“Presently, 97% of our COVID-19 tests are resulted within 24 hours from receiving samples, which meets the new government mandate for higher reimbursement rates,” Dr. Stylli continued, “While this test offering is complementary to Progenity’s core women’s health business, it fulfills an important unmet need as demand currently outpaces supply for COVID testing within the turnaround window, and this service is designed to satisfy both our higher risk OBGYN/MFM patients as well as broader national demand for COVID-19, flu and respiratory virus testing.”

Preliminary Third Quarter 2020 Revenue and Test Volume

Based on preliminary financial information, Progenity expects to report revenue for the third quarter of 2020 in a range of approximately $25 to $26 million, compared to reported revenue of $17.1 million in the second quarter of 2020. Progenity’s reported test volume for the third quarter of 2020 was more than 84 thousand tests compared to approximately 75 thousand tests in the second quarter of 2020, representing a 12% quarter over quarter increase.

“We’re still very much in the early phase of benefitting from improvement to our revenue cycle management processes but anticipate these initiatives will begin to contribute more evidently to revenue in the fourth quarter of 2020 and explicitly in 2021,” said Dr. Stylli. “We are making significant progress with our innovation pipeline as illustrated by this week’s ACG PILDx and preeclampsia rule-out test announcements, and we expect to provide further updates with regard to our Innatal4 program as well as our GI Precision Medicine pipeline in the near future.”

About Progenity

Progenity, Inc. is a biotechnology company with an established track record of success in developing and commercializing molecular testing products, as well as innovating in the field of precision medicine. Progenity provides in vitro molecular tests designed to improve lives by providing actionable information that helps guide patients and physicians in making medical decisions during key life stages. The company applies a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics to its molecular testing products and to the development of a suite of investigational ingestible devices designed to provide precise diagnostic sampling and drug delivery solutions. Progenity’s vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies. For additional information about Progenity, please visit the company’s website at www.progenity.com.

COVID-19 Update

Public health measures related to the novel coronavirus are greatly impacting healthcare practices. We have responded to the COVID-19 pandemic by

implementing and maintaining robust response plans, seamlessly continuing laboratory operations and maintaining pre-pandemic turnaround times. We enhanced our digital sales and support capabilities, increased proactive test reporting and remote genetic counseling capabilities, and expanded our mobile phlebotomy services, assisting our customers to continue serving their patients with the same quality care.

Preliminary Financial Information

The preliminary revenue estimate presented above is the responsibility of management and has been prepared in good faith on a consistent basis with prior periods. This preliminary estimate is based solely upon information available to management as of the date of this press release. However, the Company has not completed its financial closing procedures for the three months ended September 30, 2020, and its actual results could vary materially from this preliminary revenue estimate. In addition, the Company's independent registered public accounting firm has not reviewed this information or completed its review procedures for the quarter ended September 30, 2020 and does not express an opinion or any other form of assurance with respect to this preliminary revenue estimate or its achievability. During the course of the preparation of the Company's consolidated financial statements and related notes as of and for the three months ended September 30, 2020, the Company and its auditors may identify items that would require the Company to make material adjustments to the preliminary estimates presented above. As a result, investors should exercise caution in relying on this information and should not draw any inferences from this information regarding financial or operating data not provided. This preliminary revenue estimate should not be viewed as a substitute for full financial statements prepared in accordance with GAAP. In addition, this preliminary revenue estimate is not necessarily indicative of the results to be achieved in any future period. Investors are cautioned not to place undue reliance on such preliminary estimates. Investors should read the Company's unaudited consolidated financial statements and the notes thereto for the three months ended September 30, 2020 once they become available.

Safe Harbor Statement or Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, including statements concerning the preliminary results for the quarter ended September 30, 2020, the impact of the COVID-19 pandemic on our business, operations, financial results, and future performance, the impact of the improvements in our revenue cycle management process, the progress of our in-network transition, the development progress of our preeclampsia rule-out test, increases in our COVID-19 testing capacity, plans for future test offerings, the sufficiency of our capital, the resiliency of our business, and the progress of our research and development efforts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "preliminary," "expect," "expected," "estimate," or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Such risks, uncertainties, and other factors include, among others, the ongoing COVID-19 pandemic and associated shelter-in-place orders, our ability to develop and commercialize our testing products as well as innovate in the field of precision medicine, the size and growth potential of the markets for our products, and our ability to serve those markets, the rate and degree of market acceptance and clinical utility of our products and coverage and rates of reimbursement for our products, the performance of third parties in connection with the commercialization and development of our products, including third-party suppliers for COVID-19 assays, regulatory developments in the United States and foreign countries, our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines or at all, our ability to improve and enhance our products, our plans to research, develop, and commercialize new products, the development, regulatory approval, efficacy, and commercialization of competing products, the outcome of pending and future investigations and legal proceedings, the loss or retirement of key scientific or management personnel, our ability to develop and maintain our corporate infrastructure, including maintaining effective internal controls, our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others, our compliance with the terms and conditions of our corporate integrity agreement, potential overpayment obligations and those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Progenity's Registration Statement on Form S-1 (File No. 333-238738), as amended, filed with the U.S. Securities and Exchange Commission, Progenity's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 14, 2020, and other subsequent documents we file with the SEC.

Progenity expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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