



NEWS RELEASE

Castle Biosciences to Acquire Cernostics

10/19/2021

Fuels mid- and long-term growth with TissueCypher® platform enabling GI franchise

Acquisition will expand Castle's estimated U.S. TAM by approximately \$1 billion

Castle executive management to host conference call and webcast today at 7:30 a.m. ET

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), applying innovative diagnostics to transform disease management and improve patient outcomes, today announced it has signed a definitive agreement to acquire Cernostics, Inc. (Cernostics), an Illumina Ventures company. Cernostics specializes in spatial biology and artificial intelligence-driven image analysis of tissue biopsies. Its TissueCypher® Barrett's Esophagus Assay is the first precision medicine test designed to predict future development of high-grade dysplasia (HGD) and/or esophageal cancer in patients with Barrett's esophagus (BE).

"We are pleased to welcome Cernostics into the Castle family," said Derek Maetzold, president and CEO of Castle Biosciences. "Acquiring the TissueCypher platform is aligned with our commitment to utilizing innovative technology to provide clinically actionable information that guides disease management and improves patient outcomes. The TissueCypher Barrett's Esophagus Assay addresses an unmet need in BE, as it is designed to objectively and accurately predict progression from non-dysplastic, indefinite for dysplasia and low-grade dysplasia BE to HGD or esophageal adenocarcinoma (EAC). This is critical, as EAC is highly lethal, with five-year survival rates under 20%¹, and intervention (ablation) in patients with BE has been proven to reduce progression to EAC. Unfortunately, the incidence of esophageal cancer is increasing at one of the fastest rates of all cancers in the U.S., so we need new clinical tools to reverse this growth trend in the diagnosis of EAC.



“We believe the combined strengths of Castle and Cernostics will position us for continued growth and success as a leader in the diagnostics space, complementing our first-to-market dermatologic franchise. Beginning with a common patient-centric mind-set, our companies are strategically aligned with compatible company cultures and business models that include a strong, ongoing emphasis on growing the body of clinical evidence backing our tests. Together, we have the opportunity to accelerate our impact on patient care and thus drive value creation for shareholders.”

“We are excited about joining forces with Castle, a leader in the precision diagnostics space with a strong history of commercial success,” said Mike Hoerres, chief executive officer of Cernostics. “We believe the TissueCypher Barrett’s Esophagus Assay is a valuable tool for improving prevention of esophageal cancer, particularly, to help physicians and patients make more informed management decisions based on the unique biology of an individual patient’s esophageal biopsy.”

There are approximately 4 million patients in the U.S. diagnosed with BE, and annually, approximately 400,000 endoscopies are performed on BE patients. TissueCypher Barrett’s Esophagus Assay is listed in Group 1 of Novitas’ Billing and Coding Article “Molecular Pathology and Genetic Testing” (A58917). The article becomes effective on November 8, 2021.

Transaction Terms and Other Information

Under the terms of the definitive agreement, Cernostics will become a wholly owned subsidiary of Castle Biosciences. At closing, Castle will pay \$30 million in initial consideration to Cernostics security holders, which may consist entirely of cash or \$20 million in cash and \$10 million in common stock of Castle, at Castle’s sole discretion. The purchase price is subject to customary working capital and other adjustments. Further, up to an additional \$50 million in cash and/or common stock, at Castle’s sole discretion, is payable in connection with the achievement of certain milestones based on 2022 performance. The transaction is expected to close prior to year-end 2021, subject to the delivery of certain financial statements to the Company, continued employment of certain Cernostics personnel and satisfaction of other customary conditions to closing.

Upon finalization of the transaction, Hoerres and Cernostics’ executive management team and other staff based in Pittsburgh are expected to stay with the Company. Cernostics’ laboratory and operations will remain in Pittsburgh.

Company management will host a conference call and webcast to discuss this transaction at 7:30 a.m. Eastern time today.

Conference Call and Webcast Details

A live webcast of the conference call can be accessed here:

<https://event.on24.com/wcc/r/3461313/A7A42B75D3B07FF06436E80CF28C7EE6> or via the webcast link on the Investor Relations page of the Company's website: <https://ir.castlebiosciences.com/overview/default.aspx>. Please access the webcast at least 10 minutes before the conference call start time. An archive of the webcast will be available on the Company's website until Nov. 8, 2021.

To access the live conference call via phone, please dial 1 844 200 6205 from the United States and Canada, or +1 929 526 1599 internationally, at least 10 minutes prior to the start of the call, using the conference ID 781408.

There will be a brief Question & Answer session following management commentary.

About Cernostics and TissueCypher[®] Barrett's Esophagus Assay

Cernostics applies spatial biology and biologically-aware AI and machine learning to tissue diagnostics, delivering precision diagnostic testing to patients and gastroenterologists. This technology and platform are the core of the TissueCypher[®] Barrett's Esophagus Assay, the world's first precision medicine test designed to predict future development of high-grade dysplasia (HGD) and/or esophageal cancer in patients with Barrett's esophagus (BE). The TissueCypher Barrett's Esophagus Assay is indicated for patients with endoscopic biopsy confirmed BE that is graded non-dysplastic, indefinite for dysplasia or low-grade dysplasia. The TissueCypher Barrett's Esophagus Assay is a proprietary Laboratory Developed Test (LDT) with its own unique CPT PLA code (0108U), available only from Cernostics' CLIA-certified pathology laboratory. The TissueCypher Barrett's Esophagus Assay has been on the Medicare Clinical Laboratory Fee Schedule since January 2021.

About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a commercial-stage dermatologic diagnostics company focused on providing physicians and their patients with personalized, clinically actionable genomic information to make more accurate treatment decisions. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx[®]-Melanoma, DecisionDx[®]-CMSeq), cutaneous squamous cell carcinoma (DecisionDx[®]-SCC), suspicious pigmented lesions (myPath[®] Melanoma, DecisionDx[®] DiffDx[™]-Melanoma,) and uveal melanoma (DecisionDx[®]-UM, DecisionDx[®]-PRAME and DecisionDx[®]-UMSeq). For more information about Castle's gene expression profile tests, visit www.CastleTestInfo.com.

Castle also has active research and development programs for tests in other dermatologic diseases with high clinical need, including its test in development to predict systemic therapy response in patients with moderate to severe psoriasis, atopic dermatitis and related conditions. Castle Biosciences is based in Friendswood, Texas (Houston), and has laboratory operations in Phoenix.

For more information, visit www.CastleBiosciences.com.

DecisionDx-Melanoma, DecisionDx-CMSeq, DecisionDx-SCC, myPath Melanoma, DecisionDx DiffDx-Melanoma, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UMSeq are trademarks of Castle Biosciences, Inc.

Forward-Looking Statements

The information in this press release contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created by those sections. These forward-looking statements include, but are not limited to, statements concerning the expected timing and actual closing of the transaction, Castle’s estimated U.S. TAM following the consummation of the transaction, Castle’s ability to integrate the TissueCypher Barrett’s Esophagus Assay into its commercial offerings, the ability of the Cernostics and Castle teams to complement each other and to accelerate our impact on patient care and drive value creation for shareholders, the ability of the TissueCypher Barrett’s Esophagus Assay to predict future development of HGD and/or esophageal cancer in patients with BE, objectively and accurately predict progression from BE to HGD or EAC, improve the prevention of esophageal cancer and help physicians and patients make more informed management decisions based on the unique biology of individual patients’ esophageal biopsies. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the conditions to closing may not be satisfied and the transaction may be delayed or not close at all, the effects of the COVID-19 pandemic on our business and our efforts to address its impact on our business, the TissueCypher Barrett’s Esophagus Assay’s ability to provide the aforementioned benefits to patients, physicians and Castle and the risks set forth in our Quarterly Report on Form 10-Q for the quarter June 30, 2021, and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, except as may be required by law.

¹ Esophageal Cancer Action Network, <https://ecan.org/facts/>

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