

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934
Date of Report (Date of earliest event reported): January 5, 2023

HH&L Acquisition Co.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation)

001-40006
(Commission
File Number)

N/A
(I.R.S. Employer
Identification No.)

Suite 2001-2002, 20/F, One Exchange Square
The Landmark, 15 Queen's Road Central
Central, Hong Kong 00000
(Address of principal executive offices, including zip code)

(852) 3752 2870
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A ordinary shares, par value \$0.0001 per share	HHLA	The New York Stock Exchange
Redeemable warrants, each whole warrant exercisable for one Class A ordinary share, each at an exercise price of \$11.50 per share	HHLA WS	The New York Stock Exchange
Units, each consisting of one Class A ordinary share and one-half of one redeemable warrant	HHLA.U	The New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

As previously announced on October 14, 2022, HH&L Acquisition Co., a Cayman Islands exempted company limited by shares (“HH&L”), entered into a Business Combination Agreement (as amended from time to time, the “Business Combination Agreement”), by and among HH&L, Diamond Merger Sub Inc., a Delaware corporation and a direct wholly owned subsidiary of HH&L (“Merger Sub”), and DiaCarta, Ltd., a Cayman Islands exempted company limited by shares (“DiaCarta”).

On January 5, 2022, DiaCarta issued the press release announcing the successful completion of Oncuria® validation study with Nonagen Bioscience.

The information in this Item 8.01 and Exhibits 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liabilities under that section, and shall not be deemed to be incorporated by reference into the filings of CCAC under the Securities Act of 1933, as amended (the “Securities Act”) or the Exchange Act, regardless of any general incorporation language in such filings. This Current Report will not be deemed an admission as to the materiality of any of the information in this Item 8.01, including Exhibit 99.1.

Important Additional Information Will Be Filed with the SEC

This current report relates to the proposed business combination between HH&L and DiaCarta (the “Business Combination”). HH&L has filed a preliminary, and will file a definitive, proxy statement, which will include a prospectus, which will be a part of a registration statement, and other relevant documents with the SEC. This current report does not contain all the information that should be considered concerning the proposed Business Combination and is not intended to form the basis of any investment decision or any other decision in respect of the Business Combination. HH&L’s and DiaCarta’s shareholders and other interested persons are urged to read the proxy statement/prospectus and any other relevant documents filed with the SEC when they become available, and any amendments thereto, because, among other things, they will contain updates to the financial, industry and other information herein as well as important information about HH&L, DiaCarta and the contemplated Business Combination. When available, the definitive proxy statement/prospectus and other relevant materials for the proposed Business Combination will be mailed to shareholders of HH&L as of a record date to be established for voting on the proposed Business Combination. Shareholders will be able to obtain a free copy of the proxy statement/prospectus (when filed), as well as other filings containing information about HH&L, DiaCarta and the proposed Business Combination, without charge, at the SEC’s website located at www.sec.gov or by directing a request to: HH&L Acquisition Co., Suite 2001-2002, 20/F, York House, The Landmark, 15 Queen’s Road Central, Central, Hong Kong. Investment in any securities described herein has not been approved or disapproved by the SEC or any other regulatory authority nor has any authority passed upon or endorsed the merits of the Business Combination or the accuracy or adequacy of the information contained herein. Any representation to the contrary is a criminal offense.

Forward-Looking Statements

This current report contains certain statements, estimates, targets, forecasts, and projections with respect to HH&L or DiaCarta. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements include, without limitation, statements regarding the estimated future financial performance and financial position of DiaCarta. Future results are not possible to predict. Opinions and estimates offered in this current report constitute DiaCarta’s judgment and are subject to change without notice, as are statements about market trends, which are based on current market conditions. You can identify these forward looking statements through the use of words such as “may,” “will,” “can,” “anticipate,” “assume,” “should,” “indicate,” “would,” “believe,” “contemplate,” “expect,” “seek,” “estimate,” “continue,” “plan,” “point to,” “project,” “predict,” “could,” “intend,” “target,” “potential” and other similar words and expressions of the future, but the absence of these words does not necessarily mean that a statement is not forward-looking. Such forward-looking statements are based on estimates, assumptions and factors that are inherently uncertain, that are beyond DiaCarta’s control or ability to predict and that could cause actual results to differ materially from expected results. As a result, they are subject to significant risks and uncertainties and actual events or results may differ materially from these forward-looking statements. No reliance should be placed on, any forward-looking statements, including any projections, targets, estimates or forecasts contained in this current report. Any forward-looking statement speaks only as of the date on which it was made, based on information available as of the date of this current report, and such information may be inaccurate or incomplete. Products described by DiaCarta in its pipeline are under investigation and have not been proven to be safe or effective, and there is no guarantee any such product will be approved in the sought-after indication or will meet the developmental milestones set forth herein, including within the timeline set forth herein. Neither DiaCarta, nor HH&L undertakes any obligation to release any revisions to such forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. Information regarding performance by, or businesses associated with, our management team or businesses associated with them is presented for informational purposes only. Past performance by DiaCarta’s management team and its affiliates is not a guarantee of future performance. Therefore, you should not rely on the historical record of the performance of DiaCarta’s management team or businesses associated with them as indicative of DiaCarta’s future performance of an investment or the returns DiaCarta will, or is likely to, generate going forward.

Participants in the Solicitation

HH&L and its directors and executive officers may be deemed to be participants in the solicitation of proxies from HH&L’s shareholders in connection with the proposed Business Combination. A list of the names of HH&L’s directors and executive officers and information regarding their interests in HH&L is contained in HH&L’s Annual Report on Form 10-K, which was filed with the SEC on March 30, 2022, and is available free of charge at the SEC’s website at www.sec.gov, or by directing a request to HH&L Acquisition Co., Suite 2001-2002, 20/F, York House, The Landmark, 15 Queen’s Road Central, Central, Hong Kong. Additional information regarding the interests of any such participants will be contained in the proxy statement/prospectus for the proposed Business Combination when available.

DiaCarta and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the shareholders of HH&L in connection with the proposed Business Combination. A list of the names of such directors and executive officers and information regarding their interests in the proposed Business Combination will be included in the proxy statement/prospectus for the proposed Business Combination when available.

The definitive proxy statement/prospectus will be mailed to shareholders as of a record date to be established for voting on the proposed Business Combination when it becomes available. Shareholders, potential investors and other interested persons should read the proxy statement/prospectus carefully when it becomes available before making any voting or investment decisions.

No Offer or Solicitation

This current report is for informational purposes only and does not constitute (i) a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Business Combination, (ii) an offer or invitation for the sale or purchase of the securities, assets or business described herein or a commitment of HH&L, DiaCarta or any of their respective subsidiaries, stockholders, affiliates, representatives, partners, directors, officers, employees, advisers or agents, with respect to any of the foregoing, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction, and this press release shall not form the basis of any contract, commitment or investment decision and does not constitute either advice or recommendation regarding any securities.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated as of January 5, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HH&L ACQUISITION CO.

By: /s/ Richard Qi Li
Name: Richard Qi Li
Title: Chief Executive Officer and Director

Date: January 5, 2023

PRESS RELEASE



DiaCarta Announces Successful Completion of Oncuria® Validation Study with Nonagen Bioscience

DiaCarta Starts to Receive Samples for Oncuria® Bladder Cancer Test at its CLIA Lab

PLEASANTON, CA and LOS ANGELES, CA—January 5, 2023—DiaCarta, Ltd. (“DiaCarta”), a precision molecular diagnostics company, and Nonagen Bioscience Corporation (“Nonagen”), a cancer diagnostics company, today announced the successful completion of the validation study of Oncuria® multiplex bladder cancer immunoassay as a laboratory developed test (“LDT”). DiaCarta also announced that it has begun receiving patient urine samples for testing in its CLIA certified lab in Pleasanton, California.

Oncuria is a multiplex protein-based urine test aiming to provide early and accurate detection, therapy choice, and disease monitoring of bladder cancer. Oncuria detects concentrations of 10 proteins associated with bladder cancer in urine samples. In clinical studies, Oncuria was shown to have 93% sensitivity and 93% specificity for detecting bladder cancer. Additionally, Oncuria has demonstrated consistent sensitivity and specificity across bladder cancer tumor grades and stages. Oncuria’s accuracy is especially meaningful for detecting low-grade tumors, which is an area of high unmet need in bladder cancer management. Oncuria is intended for use, in conjunction with, and not in lieu of, current standard diagnostic procedures.

The American Medical Association has issued dedicated Current Procedural Terminology (CPT®) Proprietary Laboratory Analyses (PLA) codes—Oncuria Detect 0365U, Oncuria Monitor 0366U, and Oncuria Predict 0367U—which are effective as of January 1, 2023.

Oncuria received Breakthrough Device Designation from the US Food and Drug Administration (FDA) in September 2021 for predicting responses to Bacillus Calmette-Guérin (BCG) therapy, a first-line treatment for bladder cancer. Oncuria’s predictive capability is noteworthy given the current shortage of BCG.

Oncuria was developed and patented in the U.S. and China by Nonagen. DiaCarta has licensed the exclusive right to offer Oncuria as a LDT testing service in the U.S. and plans to work with Nonagen to pursue regulatory approvals in the U.S. and China.

“The results of our collaborative validation study with Nonagen Bioscience are exciting and showcase Oncuria as a truly novel test with potential as an aid for the early diagnosis of bladder cancer, monitoring of tumor recurrence, and predicting responses to therapy,” said Aiguo (Adam) Zhang PhD, President & CEO of DiaCarta. “This product complements DiaCarta’s existing suite of novel liquid biopsy tests, including the RadTox™ cfDNA test to monitor tumor response, and the ColoScape™ Colorectal Cancer test, further strengthening our robust LDT portfolio,” concluded Dr. Zhang.

PRESS RELEASE



“DiaCarta’s expertise in developing oncology tests using liquid biopsy makes them an ideal lab services partner for making Oncuria available as a laboratory developed test,” said Charles Joel Rosser, MD, MBA, chief executive officer at Nonagen Bioscience. “We are thrilled to be collaborating with DiaCarta to give doctors a new, highly accurate, and versatile diagnostic tool to manage bladder cancer.”

About DiaCarta

DiaCarta is a molecular diagnostics company that has developed innovative technologies that transform patient care by providing effective precision diagnostics using liquid biopsy. Its novel XNA technology provides a high level of sensitivity as it binds to the wild-type sequence, which enables only the mutant target sequence to be amplified. Using this technology, DiaCarta has developed its ColoScape™ colorectal cancer mutation test. Powered by its SuperbDNA™ technology that amplifies the signal and requires no RNA/DNA extraction or amplification, DiaCarta has developed its RadTox™ test which personalizes radiation and chemotherapy, mitigates adverse events and enhances patient care. Based in Pleasanton, California, DiaCarta is ISO certified, GMP-compliant, and offers CLIA certified laboratory services to its customers. www.diacarta.com

On October 14, 2022, DiaCarta and HH&L Acquisition Co. (NYSE: HHLA), a special purpose acquisition corporation, entered into a definitive business combination [agreement](#) that would result in DiaCarta becoming a public company.

About Nonagen Bioscience

Nonagen Bioscience is a privately-held biotechnology company that is focused on globally reducing the burden of cancer with innovative diagnostics. As a physician-led company, Nonagen Bioscience is committed to bringing to market the best-in-class, noninvasive diagnostics for cancer detection, therapy choice, and disease monitoring, so patients can live better, longer lives. The Los Angeles-based company was founded in 2011 and is currently developing diagnostics for bladder, breast, and prostate cancers. Pending FDA approval, Nonagen Bioscience intends to make its bladder cancer test, Oncuria, available as an in vitro diagnostic. www.nonagen.com

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