UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of September 2020

Commission File Number: 001-39328

Genetron Holdings Limited
(Exact Name of Registrant as Specified in Its Charter)

1-2/F, Building 11, Zone 1
No.8 Life Science Parkway
Changping District, Beijing, 102206
People's Republic of China
+86 10 5090-7500
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F x Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

SIGNATURES

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, thereunto duly authorized.

Genetron Holdings Limited

By: /s/ Sizhen Wang
Name: Sizhen Wang
Title: Director and Chief Executive Officer

Date: September 30, 2020

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release titled "Genetron Health Receives U.S. FDA Breakthrough Device Designation for its Blood-based NGS Test for Early Detection of Hepatocellular Carcinoma"

Genetron Health Receives U.S. FDA Breakthrough Device Designation for its Blood-based NGS Test for Early Detection of Hepatocellular Carcinoma

Designation represents Genetron Health's first step to potentially expand the geographical reach of HCCscreen™

BEIJING, CHINA and GAITHERSBURG, MARYLAND, September 30, 2020 (GLOBE NEWSWIRE) — Genetron Holdings Limited ("Genetron Health" or the "Company", Nasdaq: GTH), a leading precision oncology platform company in China that specializes in offering molecular profiling tests, early cancer screening products and companion diagnostics development, today announced that its blood-based next-generation sequencing (NGS) test, HCCscreen™, has been granted Breakthrough Device designation by the U.S. Food and Drug Administration (FDA). Based on the correspondence with Center for Devices and Radiological Health (CDRH) of the FDA, HCCscreen™ is intended for early detection of hepatocellular carcinoma in individuals who are designated to be at high-risk for HCC due to chronic HBV infection and/or liver cirrhosis.

Under the FDA's Breakthrough Devices Program, the Breakthrough Device designation is granted for products that have the potential to offer more effective diagnosis of life-threatening diseases with an unmet medical need. The program is designed to speed up development, assessment and review processes, in order to provide patients with quicker access to those devices. Genetron Health's HCCscreen™ was granted based on its superior clinical performance over the current standard of care (i.e., ultrasound plus alpha-fetoprotein (AFP)) in a prospective clinical study. With this designation, the Company will have an opportunity to interact with the FDA's experts to efficiently address topics through the pre-submission process, so as to receive feedback from the FDA and identify areas of agreement in a timely way. It also allows priority review upon premarket approval (PMA) submission, and Medicare coverage by the CMS (Center for Medicare and Medicaid Services) upon formal approval.

Genetron Health intends to develop HCCscreen™ as an NGS-based product in the US. The company is also building a lab in Maryland, which it intends to seek CLIA certification, to serve global pharmaceutical companies on R&D and commercialization. In China, HCCscreen™ has recently been commercialized as a lab developed test (LDT). The Company has five laboratories in China, of which the Beijing lab is one of the few domestic labs that are both CAP and CLIA certified.

HCCscreen™ is powered by Genetron Health's innovative and proprietary Mutation Capsule™ technology, which enables detection of multiple methylation alterations in parallel with mutations in cell-free DNA from peripheral blood specimens. Currently, HCCscreen™ is being tested in its ongoing prospective study with 4,500 HBsAg+ individuals. As of the date of this announcement, 2,000 patients have already completed the study, and preliminary data from 297 patients at one center has demonstrated over 92% sensitivity and 93% specificity, compared to 67% and 99%, respectively in the ultrasound + AFP arm. HCCscreen™ also achieved a 35% positive predictive value and 99.6% negative predictive value. Furthermore, stratifying by tumor sizes, of the 12 patients identified with HCC in the preliminary dataset, ten patients had tumor sizes of less than five centimeters, indicating HCCscreen™'s detection ability in early-stage HCCs. The company expects to announce the full data set from all 2,000 patients in the first half of 2021.

Globally, liver cancer is the fourth most common cause of cancer-related death and the sixth in terms of incidence[1]. China represents the largest market, accounting for almost half of the global incidences. New incidence in China was estimated to be around 393,000 per year, with 369,000 deaths[2]. Market data by Frost and Sullivan estimated that as of 2019, among the 120 million high risk liver cancer population in China, around 74 million were HBV carriers. In the US, liver cancer is the fifth leading cause of cancer death in all ages, and it is increasing by 2% to 3% annually. New liver cancer cases in US was estimated to be 42,810 in 2020, with 30,160 deaths[3]. HCC represents the major histological type of liver cancer, accounting for 85—90% of cases[4]. Moreover, there is no effective therapy for advanced stage HCC. Previous estimates showed that the one-year survival for HCC in the United States is less than 50%, while the five-year survival is 10%[5]. Early detection of HCC is an unmet medical need. Current guidelines recommend at-risk patients undergo testing every six months using ultrasound with or without the AFP blood test[6].

“We are very pleased with the FDA’s recognition of HCCscreen™’s potential as a more effective test for early detection of hepatocellular carcinoma. This designation also represents a significant milestone for our plan to expand HCCscreen™’s geographical reach. Hepatocellular carcinoma is one of the leading causes of cancer deaths globally, and an accurate, easy to use, blood-based early screening test would offer tremendous clinical value,” commented Sizhen Wang, Genetron Health’s co-founder and CEO. “Our HCCscreen™ asset has shown promising preliminary data in all key metrics including sensitivity, specificity, and positive predictive value. Notably, most of the confirmed HCC patients in the study had tumor sizes below five centimeters. This level of performance is highly encouraging as detecting tumor presence while they are small allows effective early interventions, which could lead to better outcomes. Our goal is to continue to make clinical progress in order to potentially bring HCCscreen™ to more patients globally. This FDA designation represents the first, yet an important step, in our effort to achieve that goal.”

Notes:

1. Villanueva, A. Hepatocellular Carcinoma. N. Engl. J. Med. 2019, 380, 1450—1462.
2. Globocan 2018. https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf
3. National Institute of Health. https://seer.cancer.gov/statfacts/html/livibd.html
4. Wong MCS, et al. (2018) The changing epidemiology of liver diseases in the Asia-Pacific region. Nature reviews. Gastroenterology & hepatology
5. Altekruse SF, McGlynn KA, Reichman ME. Hepatocellular carcinoma incidence, mortality, and survival trends in the United States from 1975 to 2005. J Clin Oncol 2009;27:1485—91
6. Harris PS, Hansen RM, Gray ME, et al. Hepatocellular carcinoma surveillance: An evidence-based approach. World J Gastroenterol. 2019:25(13):1550-1559

About Genetron Holdings Limited

Genetron Holdings Limited ("Genetron Health" or the "Company") (Nasdaq: GTH) is a leading precision oncology platform company in China that specializes in cancer molecular profiling and harnesses advanced technologies in molecular biology and data science to transform cancer treatment. The Company has developed a comprehensive oncology portfolio that covers the entire spectrum of cancer management, addressing needs and challenges from early screening, diagnosis and treatment recommendations, as well as continuous disease monitoring and care. Genetron Health also partners with global biopharmaceutical companies and offers customized services and products. For more information, please visit ir.genetronhealth.com.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of federal securities laws, including the HCCscreen™ study results and statements regarding the prospects and plans for commercializing HCCscreen™ in the United States, which involve risks and uncertainties that could cause the actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Statements that are not historical facts, including statements about the Company's beliefs and expectations, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and a number of factors could cause actual results to differ materially from those contained in any forward-looking statement. In some cases, forward-looking statements can be identified by words or phrases such as "may", "will," "expect," "anticipate," "target," "aim," "estimate," "intend," "plan," "believe," "potential," "continue," "is/are likely to" or other similar expressions. Further information regarding these and other risks, uncertainties or factors is included in the Company's filings with the SEC. All information provided in this press release is as of the date of this press release, and the Company does not undertake any duty to update such information, except as required under applicable law.

Investor Relations Contacts
US:
Hoki Luk
Head of Investor Relations
Email: hoki.luk@genetronhealth.com
Phone: +1 (408) 891-9255

Stephanie Carrington
Westwicke, an ICR Company
Email: Stephanie.Carrington@westwicke.com
Phone: +1 (646) 277-1282

Asia:
Bill Zima
ICR, Inc.
Email: bill.zima@icrinc.com
GenetronIR@icrinc.com

Media Relations Contact
Edmond Lococo
ICR
Edmond.Lococo@icrinc.com
Mobile: +86 138-1079-1408
genetron.pr@icrinc.com