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): November 24, 2020

F-STAR THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001- 37718**	**52-2386345**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Eddeva B920 Baraham Research Campus
Cambridge, United Kingdom CB22 3AT
(Address of principal executive offices)

+44-1223-497400
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)**
Common Stock, $0.0001 par value	**FSTX**	**The Nasdaq Stock Market (Nasdaq Capital Market)**

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 7.01 Regulation FD Disclosure

On November 24, 2020, the Company announced the the authorization of the Clinical Trial Application (CTA) in Spain for the initiation of a Phase 1, open label, first-in-human clinical study of FS222. The press release is attached hereto as Exhibit 99.1 and incorporated by reference herein. The information in this paragraph (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and is not incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Act.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated November 24, 2020.
104	Cover Page Interactive File (the cover page tags are embedded within the Inline XBRL document)

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 hereunto duly authorized.

F-STAR THERAPEUTICS, INC.

Date: November 25, 2020

/s/ Darlene Deptula-Hicks
Darlene Deptula-Hicks
Chief Financial Officer and Treasurer

F-star Therapeutics Announces Clearance of

Clinical Trial Application for FS222

CD137/PD-L1 Bispecific Antibody for Patients with Advanced Malignancies to Enter the Clinic

First-in-Human Adaptive Trial to Evaluate Safety, Pharmacology and Anti-tumor Activity

Cambridge, UK and Cambridge, MA, November 25, 2020 – F-star Therapeutics, a clinical-stage biopharmaceutical company dedicated to developing next generation immunotherapies to transform the lives of patients with cancer, today announces the authorization of the Clinical Trial Application (CTA) in Spain for the initiation of a Phase 1, open label, first-in-human clinical study of FS222. FS222 is a potentially best-in-class bispecific antibody targeting CD137 (4-1BB) and PD-L1.

FS222 has a natural antibody structure and a unique tetravalent bispecific mechanism of action. It has the potential to overcome cancer resistance by combining PD-L1 blockade with tumor-targeted, potent CD137 agonism. Most patients do not respond or have a short duration of response to currently approved immune checkpoint inhibitors such as PD-1 or PD-L1 antibodies. In preclinical studies, FS222-mediated PD-L1 blockade that synergized with conditional CD137 agonism stimulated lymphocyte activation and showed antitumor responses beyond that achieved with PD-L1 inhibition alone. FS222 is Fcg receptor null and was well tolerated in preclinical toxicology studies using animal models.

Dr. Louis Kayitalire, CMO of F-star said: "*With this CTA authorization we are excited to bring this novel immunotherapy into the clinic for patients with cancer. We are eager to investigate its safety and potential differentiated benefit in partnership with immuno-oncology leaders in Spain. As our third wholly-owned bispecific to enter the clinic, we believe that F-star's novel platform technology can be the answer that so many patients have been waiting for.*"

- END-

About F-star Therapeutics Inc

F-star is a clinical-stage biopharmaceutical company dedicated to developing next generation immunotherapies to transform the lives of patients with cancer. By developing medicines that seek to block tumor immune evasion, the Company's goal is to offer patients greater and more durable benefits than current immuno-oncology treatments. Through its proprietary tetravalent, bispecific natural antibody (mAb²™) format, F-star generates highly differentiated drug candidates that are expected to be best-in-class, using monoclonal antibody-like manufacturability. For more information visit www.f-star.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). Forward-looking statements include statements, other than statements of historical fact, regarding, among other things statements relating to F-star's approach to bispecifics; potential benefits of the IgG1 antibody format; the timing of the initiation of F-star's clinical trial in Spain and anticipated therapeutic benefits. These include statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. We use words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. Such forward-looking statements are based on F-star's expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to F-star's status as a clinical stage immuno-oncology company and its need for substantial additional funding in order to complete the development and commercialization of its product candidates, that it may experience delays in completing, or ultimately be unable to complete, the development and commercialization of its product candidates, that its clinical trials may fail to adequately demonstrate the safety and efficacy of its product candidates, that preclinical drug development is uncertain, and some of F-star's product candidates may never advance to clinical trials, that results of preclinical studies and early stage clinical trials may not be predictive of the results of later state clinical trials, that F-star relies on patents and other intellectual property rights to protect our product candidates, and the enforcement, defense and maintenance of such rights may be challenging and costly, that we face significant competition in our drug discovery and development efforts, risks from global pandemics including COVID-19, and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in the F-star's filings with the SEC. New factors emerge from time to time and it is not possible for F-star to predict all such factors, nor can it assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements included in this press release are based on information available to us as of the date of this press release. F-star does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release.

For further information, please contact:

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