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): June 3, 2024

Structure Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Cayman Islands	**001-41608**	**98-1480821**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

601 Gateway Blvd., Suite 900 **South San Francisco, California** **(Address of principal executive offices)**	**94080** **(Zip Code)**

(Registrant's telephone number, including area code): (628) 229-9277

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 (see General Instruction A.2. below):

☐ 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	**Name Of Each Exchange Trading Symbol(s)**	**On Which Registered**
American Depositary Shares (ADSs), each representing three ordinary shares, par value $0.0001 per ordinary share	GPCR	Nasdaq Global Market
Ordinary shares, par value $0.0001 per share*		Nasdaq Global Market*

* Not for trading, but only in connection with the registration of the American Depositary Shares

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.

Structure Therapeutics Inc. (the "Company") is filing this Current Report on Form 8-K to update the following disclosures previously provided in its filings with the Securities and Exchange Commission ("SEC"):

(a) The Company is updating the disclosure in its Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 8, 2024 (the "Annual Report") under "Item 1. Business – Overview – Our Lead GPCR Programs – Overview of GLP-1R Signaling Pathway and Target Biology" as follows:

> "The six marketed GLP-1R and GLP-1R/GIPR agonists are synthetic peptides and include liraglutide and semaglutide marketed by Novo Nordisk; dulaglutide and tirzepatide marketed by Eli Lilly; exenatide marketed primarily by AstraZeneca plc ("AstraZeneca"); and lixisenatide marketed by Sanofi. According to Global Data, these six GLP-1R and GLP-1R/GIPR peptides approved for type 2 diabetes mellitus ("T2DM") and obesity collectively generated approximately $35.9 billion in worldwide sales in 2023, which is projected to reach $85.9 billion by 2027."

(b) The Company is updating and supplementing the Company's risk factors in its Annual Report and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 filed with the SEC on May 9, 2024 (the "Quarterly Report") with the risk factors set forth in Exhibit 99.1 to this report and incorporated herein by reference.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements about the Company and its industry that involve substantial risks and uncertainties. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including, without limitation, statements concerning the projected worldwide sales for peptides approved for T2DM and obesity, the Company's future plans and prospects, any expectations regarding the safety, efficacy, tolerability of GSBR-1290, including based on the clinical update from the Company's Phase 2a obesity study, and other candidates under development, the ability of GSBR-1290 to treat T2DM, obesity or related indications, the planned IND submission and initiation s, potential difficulties or delays in the commencement or completion, or termination or suspension, of the Company's planned clinical trials and its impact on the Company's commercial prospects, the impact of any regulations on the Company's reliance on third parties for the manufacture of its product candidates, and the Company's ability to obtain alternative sources for supplies. In addition, when or if used in this Current Report on Form 8-K, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to the Company may identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Although the Company believes the expectations reflected in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. Readers are cautioned that actual results, levels of activity, safety, performance or events and circumstances could differ materially from those expressed or implied in the Company's forward-looking statements due to a variety of risks and uncertainties, which include, without limitation, risks and uncertainties related to topline results that the Company reports is based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial, the preliminary nature of the results due to length of the study and sample size and results from earlier clinical trials not necessarily being predictive of future results, including the results using the least square means and mixed model for repeated measures which uses all available data, including data from patients who did not follow-up at 12 weeks, and estimates how patients with missing data would have responded based on patients who continued the study and had similar baseline characteristics (implicit imputation), potential delays in the IND submission or commencement, enrollment and completion of the Company's planned Phase 2 trials, including that the Company will need to receive allowance from the FDA to proceed before initiating the planned Phase 2b trial, the Company's ability to advance GSBR-1290, LTSE-2578, ANPA-0073 and its other therapeutic candidates, obtain regulatory approval of and ultimately commercialize the Company's therapeutic candidates, competitive products or approaches limiting the commercial value of the Company's product candidates, the timing and results of preclinical and clinical trials, the Company's ability to fund development activities and achieve development goals, the impact of any global pandemics, inflation, supply chain issues, rising interest rates and future bank failures on the Company's business, its ability to protect its intellectual property and other risks and uncertainties described in the Company's filings with the SEC, including its Quarterly Report, and future reports the Company may file with the SEC from time to time. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Updated Risk Factors
104	Cover Page Interactive Data File (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.

Structure Therapeutics Inc.

Date: June 3, 2024

By: /s/ Raymond Stevens
Raymond Stevens, Ph.D.
Chief Executive Officer

Exhibit 99.1

As of the date of this Current Report, Structure Therapeutics Inc. (the "Company") updates and supplements the risk factors disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on March 8, 2024 ("Annual Report"), as supplemented and updated by the risk factors disclosed in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024 filed with the SEC on May 9, 2024 ("Quarterly Report"), with the following risk factors. If any of the risk factors disclosed in the Company's Annual Report or Quarterly Report actually occurs, its business, prospects, operating results and financial condition could suffer materially, the trading price of its American Depositary Shares could decline, and you could lose all or part of your investment. The risks and uncertainties described in the Company's Annual Report and Quarterly Report are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially and adversely affect our business, prospects, operating results and financial condition. Capitalized terms used below which are not defined have the definitions as provided in the Annual Report and Quarterly Report.

Risks Related to the Discovery, Development and Regulatory Approval of Product Candidates

Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes. The results of prior clinical trials and preclinical studies are not necessarily predictive of future results, and may not be favorable, or receive regulatory approval on a timely basis, if at all.

Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. For example, we depend on the availability of non-human primates ("NHP") to conduct certain preclinical studies that we are required to complete prior to submitting an investigational new drug application ("IND") and initiating clinical development. There is currently a global shortage of NHPs available for drug development. This has caused the cost of obtaining NHPs for our preclinical studies to increase dramatically and, if the shortage continues, could also result in delays to our development timelines. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. Furthermore, the results from clinical trials or preclinical studies of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. For example, in December 2023, we reported topline and interim data from our 12-week Phase 2a clinical trial, which focused on safety and tolerability of GSBR-1290 in a total of 94 participants, including 60 participants randomized to GSBR-1290. The results showed GSBR-1290 was generally well-tolerated with no treatment-related SAEs, no adverse event-related discontinuation in obesity and only one adverse event-related discontinuation in T2DM. Furthermore, GSBR-1290 demonstrated significant reductions in hemoglobin A1c and weight at 12 weeks in T2DM. We further reported positive topline data from our Phase 2a obesity cohort in June 2024, in which GSBR-1290 achieved a clinically meaningful and statistically significant placebo-adjusted mean decrease in weight of 6.2% at 12 weeks and demonstrated generally favorable safety and tolerability results following repeated, daily dosing up to 120mg. Due to the preliminary, topline nature of these results and the length of the study and sample size, these results are not necessarily indicative of the results for our future clinical trials for GSBR-1290 and may not be comparable to other weight loss products or product candidates, including other oral selective GLP-1RAs. In addition, given the size of the Phase 2a obesity cohort, the primary efficacy endpoint of weight loss was calculated using LSM and analyzed based on the primary efficacy estimand using a mixed model for repeated measures. This means that we drew on all available data, including data from patients that did not follow-up at 12 weeks. The model estimates how patients with missing data would have responded based on patients who continued the study and had similar baseline characteristics (implicit imputation). Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted, or are conducting certain preclinical studies of our product candidates, the predictive value of these studies with respect to future testing in humans is limited, particularly in indications where animal models are less developed.

Even if our clinical trials are completed, the results may not be sufficient to obtain marketing approval for our product candidates. In clinical trials that are based on preclinical studies and early clinical trials, it is not uncommon to observe unexpected results, and many product candidates fail in clinical development despite very promising early results. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. In addition, in some cases, external experts or regulatory authorities disagreed with such companies' views and interpretations of the data and results from earlier preclinical studies or clinical trials. As we investigate GSBR-1290 for T2DM and obesity and ANPA-0073 for IPF, we may encounter new and unforeseen difficulties. Similarly any future product candidates we may develop may not be able to progress from preclinical to Phase 1 clinical development. For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful. Any of the foregoing occurrences may harm our business, financial condition and prospects significantly.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

In order to obtain FDA approval to market our product candidates, we must demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. In addition, before we can initiate clinical trials for any product candidate, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission, and we are also required to submit comparable applications to foreign regulatory authorities for clinical trials outside of the United States. We plan to submit an IND to the FDA for our planned Phase 2b study of GSBR-1290 for chronic weight management in the third quarter of 2024 and will need to receive allowance from the FDA to proceed before initiating this planned study.

Clinical testing is expensive, time-consuming and subject to uncertainty. Conducting preclinical studies and clinical trials represents a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies may cause us to incur additional operating expenses.

Clinical trials may not be conducted as planned or completed on schedule, if at all. For example, in September 2023 we reported that a data collection omission had occurred at a clinical site that impacted the obesity cohort (120 mg dose level) of the Phase 2a study for GSBR-1290, where weight was not collected at the final (week 12) visit for 24 of the 40 enrolled participants. Other safety and laboratory assessments were measured at all visits, including the week 12 visit as per protocol. We have completed the enrollment of additional participants in the Phase 2a obesity cohort to replace those for whom 12-week weight data was not collected. The replacement participants will follow the same study protocol, without changes in the titration schema or target dose (120 mg at once-daily dosing). However, as a result of this data collection omission, we reported interim Phase 2a obesity cohort data in December 2023, and the full 12-week obesity data in June 2024.

Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with applicable regulatory authorities on trial design or implementation;
- delays in obtaining regulatory authorization to commence a clinical trial;
- delays in reaching agreement on acceptable terms with prospective contact research organizations, other vendors, or clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different vendors and trial sites;
- delays in obtaining approval from one or more institutional review boards ("IRB") refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional participants, or withdrawing their approval of the trial;
- delays in recruiting suitable patients to participate in our ongoing and planned clinical trials;
- changes to the clinical trial protocol;

- clinical sites deviating from trial protocol such as the data collection omission we experienced at a clinical site as discussed above or dropping out of a trial;
- delays in manufacturing sufficient quantities of our product candidates for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- participants choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial;
- occurrence of adverse events or SAEs associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of SAEs in clinical trials of the same class of agents conducted by other companies;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- selection of clinical trial end points that require prolonged periods of clinical observation or analysis of the resulting data;
- clinical trials producing negative or inconclusive results;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or applicable foreign authorities to temporarily or permanently shut down due to violations of current good manufacturing practice ("cGMP") regulations or other applicable requirements, or contamination or cross-contaminations of product candidates in the manufacturing process;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol or other regulatory requirements or committing fraud; or
- changes in regulatory requirements, guidance, or feedback from regulatory agencies that require amending or submitting new clinical protocols or otherwise modifying the design of our clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or applicable foreign authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or applicable foreign authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination and approval, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory requirements, as well as political, currency exchange and other economic risks relevant to such foreign countries. Investigators and patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff which in turn could adversely impact our clinical trial operations. Additionally, we may experience interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with public health concerns. We have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical trials. We experienced delays in our patient enrollment and our supply chain as a direct result of COVID-19 on our suppliers' ability to timely manufacture and ship certain supplies such as reagents and other lab consumables and due to the data collection omission at a clinical site as discussed above. These delays have previously impacted and could in the future adversely affect our business, financial condition, results of operations and growth prospects.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales and regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. For example, to facilitate potential commercial-scale manufacturing, we expect to transition from capsule formulations of our product candidates used for early clinical trials to tablet formulations, including the addition of excipients, in later stage clinical trials. While these formulation transitions are common for small molecule drug candidates, we cannot guarantee that we will not encounter delays or unexpected results in bridging studies or implementing necessary changes to the manufacturing process. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Risks Related to our Reliance on Third Parties

We rely on third parties for the manufacture of our product candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Our active pharmaceutical ingredients and drug product for our product candidates are currently provided by a single-source supplier, WuXi STA, a subsidiary of WuXi AppTec, and we expect to rely on this supplier for the foreseeable future. However, certain Chinese biotechnology companies and CMOs may become subject to legislation, trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the recently proposed BIOSECURE Act introduced in the U.S. House of Representatives, and a substantially similar bill in the U.S. Senate, target U.S. government contracts, grants, and loans for entities that use equipment and services from specific named Chinese biotechnology companies, which currently include WuXi AppTec and WuXi Biologics and certain of their respective subsidiaries and affiliates, and authorizes the U.S. government to include additional Chinese biotechnology companies of concern. The current House version of the BIOSECURE Act provides a grandfathering provision with respect to a contract or agreement entered into with a designated biotechnology company of concern before the effective date until January 1, 2032. Given the current legislative climate, the pathway and timing for the BIOSECURE Act or its provisions to become law are uncertain. Should the BIOSECURE Act or its provisions become law with the currently proposed grandfathering provisions, we expect such grandfathering provisions will allow adequate time to identify and execute agreements with alternative manufacturers if necessary. In addition to the BIOSECURE Act, any additional executive action, legislative action or potential sanctions applicable to our current and any future suppliers could materially impact our relationship with such suppliers. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. If any current or future supplier is designated on any U.S. government prohibited party lists, such designation could impact and potentially restrict our engagement with such suppliers. We have contracted with, or are in the process of pursuing contracts with, alternative suppliers or manufacturers outside of China for our active pharmaceutical ingredients and drug product for our product candidates. While we believe that our current manufacturing plan will provide us with alternative sources for such supplies, there is a risk that, if supplies are interrupted, or the quality of ingredients provided by such alternative sources is not to our specification, it would cause delays in our supply chain and increase the cost of manufacturing our drugs, which could materially harm our business.

Furthermore, we do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or an applicable foreign authority does not approve these facilities for the manufacture of our product candidates or if the FDA or applicable foreign authority, withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.