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): **October 12, 2023**

180 LIFE SCIENCES CORP.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38105**	**90-1890354**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3000 El Camino Real, Bldg. 4, Suite 200 Palo Alto, CA	**94306**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(650) 507-0669**

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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	ATNF	The NASDAQ Stock Market LLC
Warrants to purchase shares of Common Stock	ATNFW	The NASDAQ Stock Market LLC

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.

180 Life Sciences Corp. ("180 Life Sciences" or the "Company"), reports that on October 12, 2023, the Company received a formal written scientific response from the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) regarding a meeting that was held on August 17, 2023 with the MHRA. 180 Life Sciences' management and regulatory team met with the MHRA to propose a path forward for approval of the Company's use of adalimumab as an anti-TNF (tumor necrosis factor) therapy for the potential prevention of the Dupuytren's contracture disability.

In the response, the MHRA (i) recognized the debilitating nature of the Dupuytren's Contracture; (ii) agreed with the Company's proposed primary and secondary endpoints for a proposed Phase 3 clinical trial (Phase 3 study); (iii) agreed that a single Phase 3 study could be sufficient to support a Marketing Authorization, if convincing evidence of efficacy and safety is observed; (iv) confirmed that the MHRA believes that the results of the Company's Phase 2b trial resulted in too much uncertainty to support a Conditional Marketing Authorization (CMA), because of the small number of trial participants, and that the MHRA would require the results of a Phase 3 study to consider a Marketing Authorisation; and (v) provided the Company guidance on the potential Phase 3 study, including that a treatment course consisting of four injections administered at 3-monthly intervals is acceptable.

The Company is also currently interacting with the U.S. Food and Drug Administration (FDA), and is ready to liaise with the European Medicines Agency (EMA), to attempt to obtain agreement on 180 Life Science's proposed clinical development plans, as outlined above for the MHRA guidance, and to work towards seeking approval of the use of adalimumab as an anti-TNF therapy for potential prevention of the Dupuytren's contracture disability, in all of these jurisdictions.

In support of our current FDA interaction, a leading pharmaceutical biosimilar manufacturer has agreed to participate with the Company in the FDA advice discussion regarding manufacturing and safety of the proposed biosimilar for adalimumab. In addition, such manufacturer has indicated that it wishes to supply the anti-TNF biosimilar drug to be used in the Phase 3 study; however, no definitive agreements with the supplier have been entered into to date. It is expected that any agreements with such supplier would be conditional upon the outcome of the aforementioned FDA discussions, and we may be unable to come to mutually agreeable definitive terms with such supplier.

The Company is currently taking into consideration the guidance from the MHRA in its discussions with the FDA and planning the potential Phase 3 study to be carried out, if necessary, provided that funding for such study is available.

Forward-Looking Statements

This Current Report on Form 8-K includes "forward-looking statements", including information about management's view of the Company's future expectations, plans and prospects, within the safe harbor provisions provided under federal securities laws, including under The Private Securities Litigation Reform Act of 1995 (the "Act"). Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue" and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results and, consequently, you should not rely on these forward-looking statements as predictions of future events.

These forward-looking statements and factors that may cause such differences include, without limitation, risks regarding current negative operating cash flows and a need for additional funding to finance our operating plans; the terms of any further financing, which may be highly dilutive and may include onerous terms, increases in interest rates which may make borrowing more expensive and increased inflation which may negatively affect costs, expenses and returns; the ability of the Company and a pharmaceutical biosimilar manufacturer to come to terms on such manufacturer's supply of a drug to be used in a planned Phase 3 study, the terms thereof and timing thereof; the timing, funding for, and outcome of a planned Phase 3 study; our ability to commercialize our drug candidates, if proven successful for treatment in trials; the timing of, outcome of, and results of, clinical trials; statements regarding the timing of a marketing authorization application (MAA) submission to the UK Medicines and Healthcare products Regulatory Agency (MHRA) and a New Drug Application submission (NDA) to the U.S. Food and Drug Administration (FDA), our ability to obtain approval and acceptance thereof, the willingness of the MHRA to review such MAA and the FDA to review such NDA, and our ability to address outstanding comments and questions from the MHRA and FDA; statements about the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results; the uncertainties associated with the clinical development and regulatory approval of 180 Life Sciences' drug candidates, including potential delays in the enrollment and completion of clinical trials, the costs thereof, closures of such trials prior to enrolling sufficient participants in connection therewith, issues raised by the FDA, the MHRA and the European Medicines Agency (EMA); the ability of the Company to maintain and renew licenses, the rights under certain situations of licensors to terminate licenses; the ability of the Company to persuade regulators that chosen endpoints do not require further validation; timing and costs to complete required studies and trials, and timing to obtain governmental approvals; the accuracy of simulations and the ability to reproduce the outcome of such simulations in real world trials; 180 Life Sciences' reliance on third parties to conduct its clinical trials, enroll patients, and manufacture its preclinical and clinical drug supplies; the ability to come to mutually agreeable terms with such third parties and partners, and the terms of such agreements; 180 Life Sciences' ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; the timing of filing, the timing of governmental review, and outcome of, planned Investigational New Drug (IND) applications for drug candidates; statements relating to expectations regarding future agreements relating to the supply of materials and license and commercialization of products; the availability and cost of materials required for trials; the risk that initial drug results are not predictive of future results or will not be able to be replicated in clinical trials or that such drugs selected for clinical development will not be successful; challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; the inherent risks in early stage drug development including demonstrating efficacy; development time/cost and the regulatory approval process; the progress of our clinical trials; our ability to find and enter into agreements with potential partners; changing market and economic conditions; changes to applicable laws and regulations, including global health care reforms; expectations with respect to future performance, growth and anticipated acquisitions; the continued listing of the Company's securities on The Nasdaq Stock Market, including the fact that the Company is not currently in compliance with such continued listing requirements; the ability of the Company to execute its plans to develop and market new drug products and the timing and costs of these development programs; estimates of the size of the markets for the Company's potential drug products; the outcome of current litigation involving the Company; potential future litigation involving the Company or the validity or enforceability of the intellectual property of the Company; global economic conditions; geopolitical events and regulatory changes; the expectations, development plans and anticipated timelines for the Company's drug candidates, pipeline and programs, including collaborations with third parties; access to additional financing, and the potential lack of such financing; and the Company's ability to raise funding in the future and the terms of such funding, and dilution caused thereby; and the effect of rising interest rates and inflation, economic downturns and recessions, declines in economic activity or global conflicts. These risk factors and others are included from time to time in documents the Company files with the Securities and Exchange Commission, including, but not limited to, its Form 10-Ks, Form 10-Qs and Form 8-Ks, and including the Annual Report on Form 10-K for the year ended December 31, 2022, and Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, and future SEC filings. These reports and filings are available at www.sec.gov and are available for download, free of charge, soon after such reports are filed with or furnished to the SEC, on the "Investors", "SEC Filings", "All SEC Filings" page of our website at www.180lifesciences.com.

Readers are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made, including the forward-looking statements included in this press release, which are made only as of the date hereof. The Company cannot guarantee future results, levels of activity, performance or achievements. Accordingly, you should not place undue reliance on these forward-looking statements. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, except as otherwise provided by law.

The inclusion of any website address in this Form 8-K is intended to be an inactive textual reference only and not an active hyperlink. The information contained in, or that can be accessed through, such website is not part of or incorporated into this Form 8-K.

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.

Date: October 18, 2023

180 LIFE SCIENCES CORP.

By: */s/ James N. Woody, M.D., Ph.D.*
Name: James N. Woody, M.D., Ph.D.
Title: Chief Executive Officer