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): December 29, 2022

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 7.01. Regulation FD Disclosure

On December 29, 2022, 180 Life Sciences Corp. (the "Company") issued a letter to stockholders from the Company's Chief Executive Officer, Dr. James Woody. A copy of the press release (which includes the letter to stockholders) is furnished hereto as Exhibit 99.1, and incorporated by reference into this Item 7.01.

The information in Item 7.01 of this Form 8-K and Exhibit 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 the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing. The furnishing of this Report is not intended to constitute a determination by the Company that the information is material or that the dissemination of the information is required by Regulation FD.

The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K, contains forward-looking statements within the safe harbor provisions of the federal securities laws, including under The Private Securities Litigation Reform Act of 1995, and, as such, may involve known and unknown risks, uncertainties and assumptions. These forward-looking statements relate to the Company's current expectations and are subject to limitations and qualifications set forth in the press release, as well as in the Company's other filings with the Securities and Exchange Commission, including, without limitation, that actual events and/or results may differ materially from those projected in such forward-looking statements. These statements also involve known and unknown risks, which may cause the results of the Company, its divisions and concepts to be materially different than those expressed or implied in such statements. Accordingly, readers should not place undue reliance on any forward-looking statements. Forward-looking statements may include comments as to the Company's beliefs and expectations as to future financial performance, events and trends affecting its business and are necessarily subject to uncertainties, many of which are outside the Company's control. More information on potential factors that could affect the Company's financial results is included from time to time in the "Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's periodic and current filings with the SEC, including the Form 10-Qs and Form 10-Ks, filed with the SEC and available at www.sec.gov. Forward-looking statements speak only as of the date they are made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise that occur after that date, except as otherwise provided by law.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1*	Press Release dated December 29, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith.

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: December 29, 2022

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

180 Life Sciences Corp. CEO James Woody, MD, PhD Issues Letter to Shareholders

Dear Fellow Shareholder,

As we come to the end of 2022, I am pleased to provide an update for our shareholders. In keeping with good corporate practice and US Securities and Exchange Commission (SEC) regulations, we have refrained from answering individual queries from shareholders until we were able to provide information to all shareholders at the same time.

Our priorities continue to be our clinical programs, repurposing anti-Tumor Necrosis Factor (TNF) drugs for treating Dupuytren's disease, frozen shoulder and post-operative delirium.

The Dupuytren's contracture trial phase 2B trial, led by Prof Nanchahal, the results of which we have previously announced, exceeded our expectations. It also showed that the treatment is likely to be cost-effective. Now, after obtaining scientific advice from the UK Medicines and Healthcare products Regulatory Agency ("MHRA"), the UK equivalent of the US Food and Drug Administration ("FDA"), and after discussions with our regulatory consultants in the United States and United Kingdom, we made the decision to begin preparing all the material necessary to seek marketing authorization in the UK. Based on the guidance received from our regulatory consultants on the time required to prepare the marketing authorization application, we currently plan on filing the application in mid-2023. In seeking a marketing authorization, we plan to engage a specialized consultant, Dr. Keith Watson, who spent nearly five years with the MHRA as a reviewer of biologics product applications, later serving as Director of Global Regulatory Affairs, Biologics Strategic Development Group at AbbVie, and more recently Vice President of Regulatory Affairs for Celltrion Inc. He now manages his own regulatory consulting practice. After reviewing our program and data, Dr. Watson stated, "This is re-purposing of an approved medicine for a new indication. Since Dupuytren's contracture may be considered a seriously debilitating disease where there is an unmet medical need to be fulfilled, it may be possible to seek a Conditional Marketing Authorization (CMA) to include in our submission a real-world data (RWD) study comparing adalimumab to current standard of care in Dupuytren's contracture with the objective of showing superiority."

Dupuytren's disease begins as a small nodule in the palm of the hand. Over time, the cells in this nodule generate fibrous cords, that pull the fingers into the palm. The team led by Professor Nanchahal discovered that injecting anti-TNF drugs into the nodule may have the potential to stop this process. All current therapies, of which surgery is the most common, can be used only when the fingers are contracted and the patient already has the disability. The participants recruited to the phase 2b clinical trial had nodules of early-stage Dupuytren's disease, which were injected with anti-TNF or placebo. The trial met the primary endpoint of nodule hardness and the secondary endpoint of nodule size at 12 months. It is noteworthy that both the hardness and size of the nodules continued to decrease further for a period of 9 months after the final injection. Because it is a slowly progressing disease, participants would need to be followed for many years to show a significant difference in the development of finger contractures or progression to surgery, which is not practical given the very slow progression of the disease.

A published study from the Netherlands showed that increase in nodule size correlates with finger flexion deformity and we reason that a reduction in nodule size would conversely mean that fingers are less likely to contract. As previously disclosed, the MHRA reviewed the primary and secondary endpoints in the phase 2b trial and the data provided by the Company and noted that it has not been shown that reducing nodule size via treatment would lead to improvements in terms of Dupuytren's disease progression. We plan to continue to collect all available data to address the point made by the MHRA. In addition, we may conduct a follow-on study to address the requirements of the MHRA, the EU, and the US FDA. We expect Dr. Watson will provide us advice regarding the best path forward assuming we receive Conditional Marketing Authorization (CMA). With the recent financing complete, the Company is proceeding with the preparation of the necessary CMA application documents. It is a very substantial, but worthwhile task.

When the Dupuytren's trial was started, the only available high concentration, citrate free preparation of adalimumab was Humira from AbbVie. However, we are now aware of seven other companies with similar preparations and we are in contact with several of them with a view towards a potential future partnering arrangement.

Enrollment to the trial of anti-TNF for early-stage frozen shoulder is slower than anticipated in the UK as patients typically present to physical therapists and the processes are subject to delays. In the USA, all such patients are seen by orthopedic physicians, who are relatively easy to access. The trial team has implemented several strategies to improve recruitment and we hope that these will be effective.

Preparation for the trial of anti-TNF to prevent the development of postoperative delirium remains on track and we anticipate that the first patient will be recruited in the first half of 2023.

Our focus remains on our clinical portfolio which is the three new indications for TNF blockade discussed above and we plan to continue to evaluate the timing and cost/benefit of additional ongoing research for our early discovery programs.

Our HMGB1 program continues to advance slowly. The molecular dynamics for the binding of this molecule are extremely complex and potentially need more extensive research in order to identify a lead candidate.

The synthetic cannabinoid program is also moving along, albeit slower than expected, with an emphasis on more effective formulations to ensure that the cannabinoids are much more orally available, as they are currently very poorly absorbed. We are continuing with our research in this field towards the development of a treatment for chronic pain. Assuming that the oral formulation research efforts are successful, we may initiate early trials in patients suffering from chronic pain, perhaps in early 2024.

As most of you know, we remain in some ongoing litigation and at this point we have no further update on such matters other than what has been reported in extensive detail in our most recent Quarterly Report on Form 10-Q.

With the recent 1-for-20 reverse stock split being completed in December, the Company expects to be in compliance with Nasdaq's ongoing listing rules. With a reduced burn rate and the financing we have just completed, the Company is in a stronger cash position to move forward with the programs outlined above, with the caution that drug development and the process of dealing with regulatory agencies is a slow and methodical process that may move slower and be more difficult than we and our shareholders would desire. However, we remain confident that we will be able to move our products ahead as we have described.

Sincerely,
James Woody MD, PhD
CEO, 180 Life Sciences

About 180 Life Sciences Corp.

180 Life Sciences Corp. is a clinical-stage biotechnology company focused on the development of novel drugs that fulfill unmet needs in inflammatory diseases, fibrosis and pain by leveraging the combined expertise of luminaries in therapeutics from Oxford University, the Hebrew University and Stanford University. 180 Life Sciences is leading the research into solving one of the world's biggest drivers of disease – inflammation. The Company is driving groundbreaking studies into clinical programs, which are seeking to develop novel drugs addressing separate areas of inflammation for which there are no effective therapies. The Company's primary platform is a novel program to treat fibrosis using anti-TNF (tumor necrosis factor).

Forward-Looking Statements

This press release 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, statements regarding the timing of our planned marketing authorization application (MAA) submission to the UK Medicines and Healthcare products Regulatory Agency (MHRA), our ability to obtain approval and acceptance thereof, the willingness of MHRA to review such MAA, and our ability to address outstanding comments and questions from the MHRA; 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, issues raised by the U.S. Food and Drug Administration (FDA) and MHRA; the ability of the Company to persuade MHRA that chosen endpoints do not require further validation; timing 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; estimates of patient populations for 180 Life Sciences planned products; unexpected adverse side effects or inadequate therapeutic efficacy of drug candidates that could limit approval and/or commercialization, or that could result in recalls or product liability claims; 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; 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; 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; our ability to attract and retain key personnel; changing market and economic conditions; our ability to produce acceptable batches of future products in sufficient quantities; unexpected manufacturing defects; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; 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; expectations regarding the capitalization, resources and ownership structure of the Company; expectations with respect to future performance, growth and anticipated acquisitions; 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 its 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 the effect of rising interest rates and inflation, and economic downturns and recessions. 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, 2021, and Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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. All subsequent written and oral forward-looking statements concerning the Company, the results of the Company's clinical trial results and studies or other matters and attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements above. 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.