

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): August 30, 2021

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

Delaware (State or Other Jurisdiction of Incorporation)	001-38105 (Commission File Number)	81-3832378 (IRS Employer Identification No.)
3000 El Camino Real, Bldg. 4, Suite 200 Palo Alto, CA (Address of Principal Executive Offices)		94306 (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 August 30, 2021, 180 Life Sciences Corp. (the "Company") issued a press release including a letter to stockholders from the Company's Chief Executive Officer, James Woody, MD, PhD.

A copy of the press release (which includes the letter to stockholders) is furnished hereto as Exhibit 99.1.

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 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 the 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 August 30, 2021](#)
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith.

1

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: August 30, 2021

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

2

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

PALO ALTO, CA. August 30, 2021 (GLOBE NEWSWIRE) -- 180 Life Sciences Corp. (NASDAQ: ATNF, the “Company”), a clinical-stage biotechnology company with its lead indication in Phase 2b clinical trial, focused on the development of novel drugs that fulfill unmet needs in inflammatory diseases, fibrosis and pain, today released the following letter to stockholders from its Chief Executive Officer, Dr. James Woody.

Dear Fellow Stockholder,

As you may recall, I previously authored a letter to you at the end of March 2021. I continue to believe ongoing communications with our stockholders is a foundational responsibility of being a public company; therefore, I wanted to take this opportunity to speak with you today.

Since my March letter, we have been hard at work further extinguishing legacy merger related issues and strengthening our balance sheet. I am pleased to report that we have been successful on both fronts. The \$11.6M private placement that we completed in February 2021 allowed us to clean up our balance sheet, negotiate down and pay off a significant amount of our liabilities that we had been carrying from the business combination. Additionally, our capitalization table has been cleared of all convertible debt.

With the successful completion of a \$15M private placement just last week, we have never been better positioned to execute on our stated business plan, including accelerating some of our clinical trials which are not funded by grants. Further, as you are aware, due to the legacy issues, we were delayed in filing our Form 10-K for the fiscal year ended December 31, 2020 and Form 10-Q for the quarter ended March 31, 2021. We have since filed both of these periodic reports, regained complete compliance with Nasdaq, and filed our Form 10-Q for the quarter ended June 30, 2021 on a timely basis. Going forward, we don’t expect to have any delays in our financial reporting and we are in the process of strengthening our accounting and financial reporting team.

Since my last letter to you, we have also gained increased visibility in the capital markets by our inclusion in the Russell Microcap Index on June 28, 2021.

Before I give you an update on our pipeline, I’d like to mention that our team has grown since my last communication. In recent months, we have amassed a high-quality group of professionals to complement our board of directors. In July 2021, we welcomed Pamela Marrone, PhD, Frank Knuettel II, MBA, Russell T. Ray, MBA and Teresa DeLuca MD, MBA to our board.

Russell Ray was formerly Managing Director and Co-Head of Global Health Care at Credit Suisse First Boston Corporation, where he led a 50-person team with offices in Baltimore, Chicago, London, New York and San Francisco, focused on providing corporate finance and M&A advisory services to private and public companies in the biotechnology, health care services and health care information technology sectors.

Teresa DeLuca, MD, MBA, comes to 180 Life Sciences as both a public independent board director and former senior executive Chief Medical Officer with significant management experience at global Fortune 50 companies. Dr. DeLuca has deep expertise in operations, M&A, regulatory submissions, divestures, spin outs and strategy.

Dr. Pam Marrone brings to 180 Life Sciences over 30 years’ experience innovating, commercializing, and building organizations. She is an experienced chief executive and corporate officer having started and run several companies, with the most recent, until August 2020, being a fast-growing agbiotech company, and since then, as Executive Chair of a pair of firms assisting agbio innovators with their go to market strategy and taking selected products to market. Dr. Marrone has traveled extensively globally, launching products and setting up distribution deals in more than 40 countries.

Frank Knuettel II comes to 180 Life Sciences with over 25 years of management experience in venture and PE-backed and public companies and with extensive experience in growing businesses, debt and equity financings, offerings and restructurings, M&A and leadership in, and management of, highly dynamic, swiftly growing companies. Mr. Knuettel is currently the CEO and serves on the board of directors of Unrivaled Brands and serves on the board of directors of two private companies, one developing an anti-viral platform and the other focused on smart intubation devices. Mr. Knuettel was formerly Director of Capital and Advisory at Viridian Capital Advisors.

We are pleased to have welcomed these four accomplished individuals to our team and expect that their unique skill sets and experience will be highly complementary to those of our existing board members and management team. I look forward to working with them, focusing on continuing to build sustainable stockholder value.

I’d like to now update you on the status of our exciting pipeline, which includes three clinical programs addressing the following indications:

1. Early Dupuytren’s contracture, a fibrotic disease of the hand, which is in Phase 2b clinical trial, with results of the 181-patient randomized, placebo-controlled trial expected in Q4 of 2021, as previously disclosed. In the entire trial, there were no related adverse events, and over 85% of patients received 3 or more injections. Dupuytren’s disease is estimated to impact over 11 million Americans and about the same number in the United Kingdom (UK)/European Union. Our trial, which is the largest ever clinical trial conducted on early stage Dupuytren’s disease, is focused on treating early-stage disease and preventing the progress of the disease to avoid the hand contracture disability. All other therapies are aimed at treating patients once the hand disability has occurred. This trial is entirely grant funded.
2. Frozen shoulder, with a grant to initiate the clinical study recently awarded by the National Institute for Health Research, UK. We plan to start the trial for frozen shoulder within the next few weeks. Again, our goal to try to have patients avoid experiencing the pain and disability associated with frozen shoulder by treating the condition in its early stage; we believe all other therapies are aimed at treating the condition in its later stage of pain and disability. We anticipate the first patients will receive their initial injection in October 2021, although continued COVID-19 outbreaks in the UK, may cause delays.
3. Post-operative cognitive delirium disorder and dysfunction, a major unmet clinical need occurring in the elderly patient population, most commonly following lengthy surgical procedures, for example, during hip fracture repair or after CABG (Coronary Artery Bypass Graft). We hope to be able to reduce or prevent this dysfunction by treating patients with anti-TNF agents at the time of surgery. We have applied for non-dilutive grant funding for this trial and are awaiting a response.

In addition to these pipeline updates, in September 2021, we plan to initiate conversations with the U.S. Food and Drug Administration (FDA), with the goal of potentially transitioning our trials to the U.S.

Additionally, our pre-clinical discovery programs include:

1. Nonalcoholic steatohepatitis (NASH), which started preclinical studies with Celgene-BMS in human tissue in Q2 2020. NASH which is present in about 5% of Americans, is most commonly caused by non-alcoholic fatty liver disease (NAFLD), which is estimated to affect approximately 25% of the US population. Our scientists are looking for the metabolic pathways that drive this disease and points where we can interrupt the progress of the disease. Stay tuned for more on this discovery program.

2. A program focused on the development of unique pharmaceutical-grade oral synthetic cannabidiol analogs to treat pain, and specifically focused on the chronic pain associated with arthritis, for which we would seek FDA approval. This project is being conducted in Israel and Oxford, England. We are working with Prof. Raphael Mechoulam, one of the foremost authorities on cannabis chemistry who discovered the body's own "cannabinoids", and who is also a co-founder of this program. To optimize uptake and bio-availability, we are collaborating with specialists in cannabinoid drug delivery, Prof. Avi Domb and Prof. Amnon Hoffman in Jerusalem, Israel. Following the hard work of our co-founders and scientists, we also filed composition of matter patents, and announced the selection of our lead Synthetic CBD Analogue ("SCA"). We expect to move forward in clinical development for both inflammation and pain, and plan to initiate Investigational New Drug (IND) Application enabling studies in Q1 2022.
3. The $\alpha 7nAChR$ program, which aims to develop $\alpha 7nAChR$ agonists for the treatment of inflammatory diseases, initially ulcerative colitis induced in ex-smokers. With the close of our current financing, this program will again be seeking to find lead candidates.

As we announced in April 2021, all patient data for the Phase 2b Dupuytren's disease clinical trial has been collected and submitted for analysis and review. We look forward to the anticipated publishing of top line results. As discussed above, the disease impacts a large total addressable market estimated to comprise over 22 million in the US and UK/EU. We anticipate these results in the fourth quarter of 2021. We believe that if we are able to successfully commercialize this drug, of which there can be no assurance, it has the potential to generate significant revenues for the Company.

I'd like to again reiterate an important distinguishing factor in our model, itself unique for a biotech company. Almost all of our clinical studies to date have been substantially funded through competitive, peer reviewed grants. While ultimately, we intend to fund some studies primarily internally, we anticipate our operating expenses will remain low relative to our peers. There are many advantages of doing clinical development mostly with academic leaders, both in cost, efficiency, and credibility. We have several potential additional innovative initiatives in progress, and you will hear about them in the upcoming months.

I'd like to close by telling you that while recent months have been challenging at times, my personal goal for 180 Life Sciences remains the same as always. My goal and the goal of the other members of management, is to benefit patients and build stockholder value by developing world leading products to solve unmet medical needs. As management and insiders currently continue to have a very vested equity interest in the Company, we believe our goals are directly aligned with the stockholders of the Company.

Now more than ever, we are looking forward and focused on execution. As you know, our team has previously developed not one, but many blockbuster drugs. Our goal for 180 Life Sciences is to execute on a model we all know well, building upon past success, experience, and relationships to bring our pipeline candidates to market. We look forward to working hard for our collective benefit and communicating with you regularly moving forward. Thank you again for your invaluable support.

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 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 relating to expectations regarding the capitalization, resources, and funding of the Company; 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 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; 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 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; potential 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. 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. These reports and filings are available at www.sec.gov. All subsequent written and oral forward-looking statements concerning the Company, the transactions described herein 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. The forward-looking statements included in this press release 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.

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