

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): February 22, 2023

180 LIFE SCIENCES CORP.

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)	001-38105 (Commission File Number)	90-1890354 (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

As previously disclosed, beginning on February 16, 2023, 180 Life Sciences Corp. (the "Company"), began making presentations to potential institutional and other investors as part of ordinary course, non-deal "road shows". On February 16, 2023, the Company furnished a copy of a presentation pursuant to a Current Report on Form 8-K, which it planned to use during such presentations.

Subsequent thereto, the Company became aware of the matters discussed in Item 8.01 below and the press release incorporated therein, and the Company has updated its prior presentation, which provides an overview of its business, to reflect such recent events.

A copy of the updated presentation materials are furnished herewith as Exhibit 99.1, and have also been posted to the Company's website at <https://ir.180lifesciences.com/company-information/presentations>, although the Company reserves the right to discontinue that availability at any time.

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.

Item 8.01 Other Events.

On February 22, 2023, the Company filed a press release providing an update on the Company's anti-TNF frozen shoulder trial, including that recruitment of such trial has been closed by the United Kingdom National Institute of Health Research (NIHR), with only nine participants, versus the 84 which were originally sought.

A copy of the press release is included herewith as Exhibit 99.2 and the information in the press release is incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Revised February 2023 180 Life Sciences Corp. Presentation
99.2	Press Release of 180 Life Sciences Corp. dated February 22, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The inclusion of any website address in this Form 8-K, and any exhibit thereto, 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.

Forward-Looking Statements

The presentation furnished as [Exhibit 99.1](#) to this Current Report on Form 8-K and the Press Release attached as [Exhibit 99.2](#), contain 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 presentation and 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.

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: February 22, 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



NASDAQ: ATNF

Leading Research into Solving One of the World's
Largest Drivers of Disease: **INFLAMMATION**

Corporate Presentation
February 2023

Disclaimer

This Presentation is for informational purposes only and does not constitute an offer to sell, a solicitation of an offer to buy, or a recommendation to purchase any equity, debt or other financial instruments of 180 LIFE SCIENCES Corp. ("180 Life Sciences" or the "Company") or any of its affiliates. This Presentation has been prepared to assist interested parties in making their own evaluation with respect to the business of 180 LIFE SCIENCES and for no other purpose. The information contained herein does not purport to be all-inclusive. The data contained herein is derived from various internal and external sources. No representation is made as to the reasonableness of the assumptions made within or the accuracy or completeness of any projections or any other information contained herein. Any data on past performance or projections contained herein is no indication as to future performance. 180 LIFE SCIENCES assumes no obligation to update the information in this Presentation.

Forward-Looking Statements

This Presentation includes "forward-looking statements" within the meaning of U.S. securities laws. 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 the company's continued listing on the Nasdaq Stock Market; expectations regarding the future capitalization, resources and ownership structure of the company; the inability to recognize the anticipated benefits of the business, which may be affected by, among other things, the ability of the company to execute its plans to develop and market new drug products and the timing, costs and results of these development programs; estimates of the size of the markets for the company's potential drug products; potential litigation involving the company; the validity or enforceability of the company's intellectual property, including any challenges thereto; global economic conditions; geopolitical events and regulatory changes; access to additional financing; the duration and ongoing impact of the COVID-19 pandemic; and other risks and uncertainties indicated from time to time in the company's filings with the Securities and Exchange Commission (the "SEC"). The foregoing list of factors is not exclusive. Additional information concerning these and other risk factors is contained in the company's most recent filings with the SEC. All subsequent written and oral forward-looking statements concerning the company 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 company does not undertake 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.





Robust IP-Protected Product Pipeline with Large Market Potential

- **Three families of novel drugs** address significant market opportunities in inflammation, fibrosis and pain with multiple programs in synchronized stages of development
 - **Fibrosis & Anti-TNF**
 - **Synthetic CBD Analogs (SCAs)**
 - **a7nAChR**
- **Strong IP Portfolio:** 24 granted patents, 33 filed patent applications



Numerous Near-Term Inflection Points

- **Anti-TNF programs:** expecting to initiate a Phase 2 trial in Q2/Q3 2023 in POCD with initial data expected in Q2 2025
- **SCA programs:** validation ongoing, with a planned toxicity study



Scientific Pioneers Backed by Experienced Operators and Board

- **Founders:** pioneers with 100+ cumulative years of discovery and clinical experience; successes include Remicade and Tysabri
- **Board:** seasoned and diverse executives with broad skillsets that complement the Company's needs
- **Senior Management:** operators with decades of experience at large & small life sciences companies



Leading Research into Solving One of the World's Largest Drivers of Disease: **INFLAMMATION**



Three Therapeutic Families Targeting Multiple Indications

	Indication	Early-Stage Development		Late-Stage Development		Milestones
		Discovery/Validation	Phase 1	Phase 2	Phase 3	
<p>Fibrosis & Anti-TNF*</p>	Dupuytren's Contracture	adalimumab		[Solid Arrow]		Pursuing Conditional Marketing Authorization in UK
	Frozen Shoulder	adalimumab				UK feasibility study closed, new clinical trial site and country to be determined
	POCD	infliximab				Initiate Phase 2 Q2/Q3 2023
	NASH	[Solid Arrow]				Ongoing Validation
	HMGB1	[Solid Arrow]				Ongoing Validation
<p>Synthetic CBD Analogs (SCAs)</p>	Chronic Pain	[Solid Arrow]				Ongoing Validation
	Early Arthritis	[Solid Arrow]				Ongoing Validation
<p>Nicotine Acetylcholine Receptor (a7nAChR)</p>	Smoking Cessation Induced Ulcerative Colitis	[Solid Arrow]				Ongoing Validation

*Repurposed drugs in new indications may not need to follow standard regulatory approval pathways. Regulatory approvals obtained from the MHRA and CCMO and the relevant accredited ethics committees to perform clinical trials in the UK and the Netherlands. No meetings have been held with the FDA. Applications for approval have been submitted to the FDA for any products at this time.



Experienced Leadership Team

Management Team



James Woody, MD, PhD
Director, CEO



Jonathan Rothbard, PhD
Chief Scientific Officer



Ozan Pamir
Chief Financial Officer

Founders



Prof. Sir Marc Feldmann
Executive Co-Chairman
Co-Founder
University of Oxford



Prof. Lawrence Steinman
Executive Co-Chairman
Co-Founder
Stanford University



Prof. Raphael Mechoulam
Co-Founder
Hebrew University



Prof. Jagdeep Nanchahal
Co-Founder; Chair,
Clinical Advisory Board
University of Oxford

Board of Directors

Prof. Sir Marc Feldmann
Co-Chairman

Prof. Lawrence Steinman
Co-Chairman

James Woody, MD, PhD
Chief Executive Officer

Teresa DeLuca, MD, MBA
Independent Director

Frank Knuettel II, MBA
Independent Director

Pamela Marrone, PhD
Independent Director

Prof. Larry Gold, PhD
Independent Director

Donald McGovern, Jr.
Independent Director

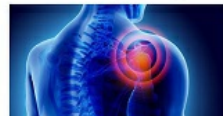
Russell Ray, MBA
Independent Director



Fibrosis & Anti-TNF Therapeutics: Lead Clinical Indications



Dupuytren's Contracture



Frozen Shoulder



POCD

Novel Treatments for TNF-Driven Conditions

- All three conditions are primarily driven by a pro-inflammatory protein called tumor necrosis factor (TNF)
- Proof-of-Concept in Dupuytren's Contracture has broader applications in Frozen Shoulder and POCD
 - No treatment options currently available that target and prevent early-stage fibrosis of the hand
 - Treating early-stage fibrosis can halt disease progression
 - Clinically significant Phase 2b data in Dupuytren's Contracture, published in The Lancet Rheumatology
 - Phase 2b clinical data in Dupuytren's Contracture provides a strong rationale to investigate anti-TNF treatment in Frozen Shoulder and POCD
- Shorter development timeline for repurposing drugs
 - Can leverage previous studies and clinical data of anti-TNF approved drugs
 - Studies typically commence at Phase 2 and are potentially pivotal



Initial Indication Targeting Dupuytren's Contracture

Characteristics

- Common localized fibrotic condition of the hand, develops over years
- Nodules form under skin – eventually creating a thick cord pulling one or more fingers
- Can limit hand functions
- Unlike liver and lung fibrosis, can be identified early

Early Disease



No approved treatment
Large unmet need
Phase 2b trial treated early disease

Late Disease – Results in Impaired Hand Function



Current treatment options suboptimal:⁽¹⁾

- Surgery – long (3 month) recovery, 6% recurrence at 5yr
- Needle perforation – less invasive, 30% recurrence at 5yr
- Collagenase injections – office procedure, 47% recurrence at 5yr

(1) Layton T & Nanchahal J. F1000Research 2019, 8(F1000Faculty Rev): 231

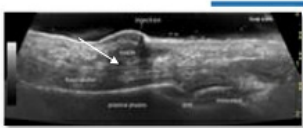


Phase 2a Completed: 40mg (in 0.4ml) Adalimumab is Effective

The First Trial of Any Targeted Therapy in Early Dupuytren's Contracture

EBioMedicine *Published by THE LANCET* Anti-Tumour Necrosis Factor Therapy for Dupuytren's Disease: A Randomized Dose Response Proof of Concept Phase 2A Clinical Trial⁽¹⁾

Trial Overview



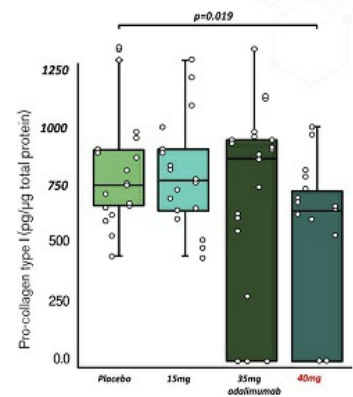
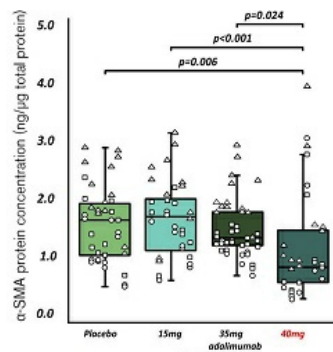
Adalimumab injected directly into the nodule

- Dose ranging with 28 patients
- **40 mg in 0.4ml – effective dose**
- Funded by HICF (Wellcome Trust + Dept of Health) and 180 Life Sciences

(1) EBioMedicine 33 (2018) 282-288

Demonstrated Efficacy at High Concentration & Dose

(ng α-SMA/μg total protein mean±SD)

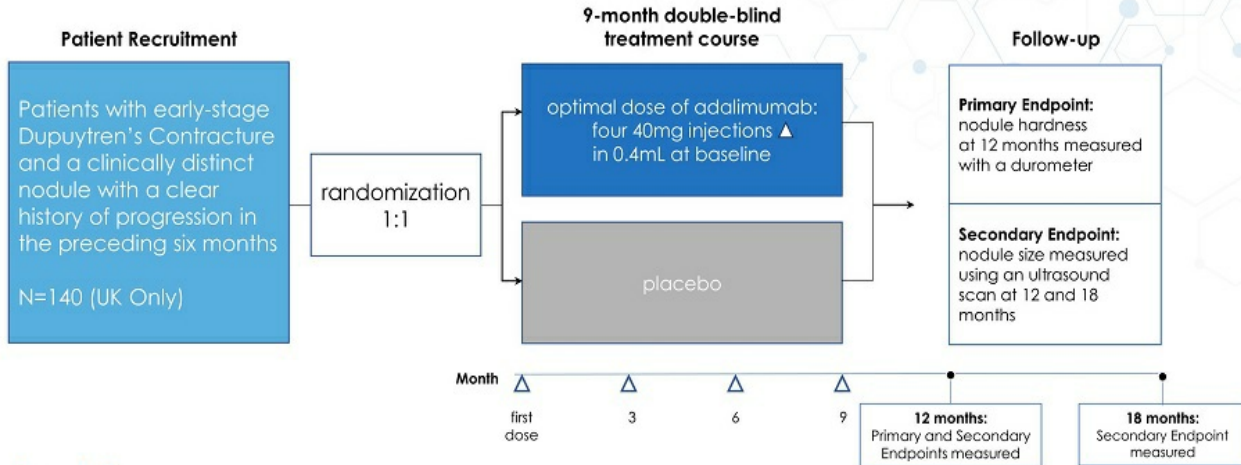


Legend: Placebo (1.51 ± 0.65), 15mg in 0.3ml (1.60 ± 0.67), 35mg in 0.7ml* (1.44 ± 0.48), 40mg in 0.4ml (1.09 ± 0.89) *Leakage observed from site injection due to large volume





Phase 2b Study in Patients with Dupuytren's Contracture



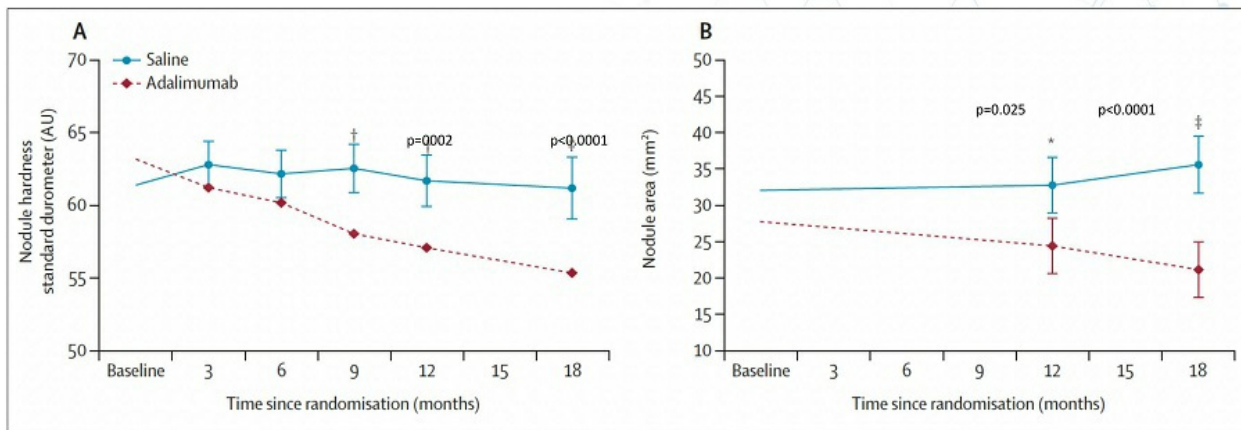
Description

- Randomized, placebo-controlled clinical trial in patients with early-stage Dupuytren's injected with optimal dose adalimumab
- Every 3 months for 1 year (4 injections), following for a total of 18 months
- Outcome measures include nodule hardness, size and disease progression
- Randomized 181 patients across 3 sites in the UK (Oxford, Edinburgh) and Netherlands (Groningen)



Phase 2b: Primary and Key Secondary Endpoint Met

Endpoints selected as reductions potentially indicate disease no longer progressing



Nodule hardness -4.6 AU at 12 months
Nodule hardness -5.8 AU at 18 months

Nodule size -8.4mm² at 12 months
Nodule size -14.4mm² at 18 months

Results were clinically significant vs. placebo





Early-Stage Dupuytren's Contracture Prevalence



Approximately 20-35% of patients with a palmar nodule progress to finger contractures



Additional Near-Term Anti-TNF Indications



Post Operative Delirium/Cognitive Deficit (POCD)

- Over 300,000 hip fractures each year in the US alone⁽¹⁾
- Strong **clinical evidence** for anti-TNF as preventative therapy
- Patent claims granted, patent is licensed from Kennedy Trust, UK
- **Phase 2** multi-center trial of pre-operative anti-TNF in hip fracture surgery planned to initiate by Q3 2023; single dose administered just prior to surgery; to be completed in 2 years



Frozen Shoulder

- Affects 9% of the of the population aged 25-64yr, more common in diabetics⁽²⁾
- Only treatment for early stage is local steroid injection for short term relief
- Trial protocol completed and NIHR grant received for feasibility study. Feasibility study closed for enrollment
- **Phase 2** clinical trial site and country will be determined in 2023

[1] <https://www.cdc.gov/homeandrecreationalafety/falls/adulthipfx.html>
 [2] Walker-Bone K et al (2004) Arthritis Rheum 51 (4):642-651





SCA Family: Synthetic CBD Analogs for Pain & Inflammation

Developing proprietary compounds which aim to be:

- Safe & non-psychoactive
- Formulated to offer improved oral bioavailability (>3x)
- Rigorously tested in clinical trials for inflammatory pain (efficacy and dosing)
- Granted market approval by FDA, EMA and others
- A real alternative to unregulated consumption of medical cannabis or OTC CBD (no clinical evidence, not FDA approved, unreliable composition, unpredictable dosing and safety)

Challenges with Medical Cannabis / OTC CBD

Variable composition, potency, and may contain undesirable contaminants

Side effects can be triggered by THC (e.g., psychosis)

Little clinical data from approved drugs exist (outside of epilepsy) to determine dosing

Variable uptake and low absorption (~4 - 9%) due to lipophilic properties of CBD / CBD-like

180 Life Sciences Solution

Use **SYNTHETIC** >99.5% pure SCAs

Use synthetic CBD Analogs (SCAs) – **no THC**

Planning blinded clinical trials initially in musculoskeletal pain and arthritis

Developing novel, patented ProNanoLipospheres (PNL) which **enhance bioavailability**



a7nAChR Family: Novel Platform for Ulcerative Colitis

a7nAChR is a nicotine acetylcholine receptor and a central factor in evolutionarily ancient neural circuit to control of inflammation^(1,2)

- Large pharma initially touted a7 as a pharmaceutical target for Alzheimer's disease and schizophrenia
 - Multiple specific agonists developed
 - All shown to be safe, but did not meet milestones in human clinical trials
- 180 Life Sciences aims to repurpose a7nAChR for inflammation
 - Nicotine binds a7 and is a known immune suppressive
 - A subgroup of patients who cease smoking subsequently acquire ulcerative colitis (a large, growing market: 2012 - \$4.2B; 2022 - \$6.6B)
 - Treatment has a high probability of therapeutic success (can be viewed as nicotine replacement therapy without issues of addiction)

Existing Therapies Sub-Optimal

Anti-inflammatory drugs (5-aminosalicylates, corticosteroids)	<ul style="list-style-type: none"> × Capability to induce remission is quite low × Known deleterious side effects of steroids
Immunosuppressants	<ul style="list-style-type: none"> × Long-term administration of thiopurine may correlate with increased risk of lymphoma × Cyclosporine leads to kidney damage
Infliximab (anti-TNF)	<ul style="list-style-type: none"> × Serious adverse events, such as opportunistic infections, including tuberculosis, as well as congestive heart failure in cardiopathic patients

a7nAChR Competitive Advantages

Better safety and efficacy	<ul style="list-style-type: none"> ✓ Fewer opportunistic infections ✓ Reduced risk of kidney damage ✓ Higher anticipated success rate
Faster time to market Lower development costs	<ul style="list-style-type: none"> ✓ Repurposing drugs previously proven safe (targeted Alzheimer's & Schizophrenia)
Novel therapeutic target	<ul style="list-style-type: none"> ✓ Drugs stimulate vagal nerve, leading to localized anti-inflammatory response, similar to nicotine's MoA
Targeted clinical trial	<ul style="list-style-type: none"> ✓ First clinical trial targeting patients who ceased smoking and developed ulcerative colitis

(1) Rothbard JB et al. Identification of a common immune regulatory pathway induced by small heat shock proteins, amyloid fibrils, and nicotine. Proc Natl Acad Sci U S A. 2018 115:7081-7086.

(2) Tracey KJ. Reflex control of immunity. Nat Rev Immunol. (2009) 9:418-28



Advancing Multiple Programs into the Clinic

Advancing lead program towards commercialization and initiating new programs for additional Proof-of-Concept

	Indication	2022	2023	2024
 <p>Fibrosis & Anti-TNF*</p>	Dupuytren's Contracture	1H Phase 2b POC data	Pursue Conditional Marketing Authorization in UK	
	Frozen Shoulder		Determine clinical trial site and country for Phase 2	
	POCD		Q2/Q3 Initiate Phase 2	
	HMGB1	2H Begin validating		
 <p>Synthetic CBD Analogs (SCAs)</p>	Chronic Pain		Toxicity study planned	



180 Life Sciences Highlights

Leading Research into Solving One of the World's Largest Drivers of Disease: **INFLAMMATION**



Robust IP-Protected Product Pipeline with Large Market Potential



Numerous Near-Term Inflection Points



Scientific Pioneers Backed by Experienced Operators and Board



180^o LIFE SCIENCES

Thank you

www.180lifesciences.com



180 Life Sciences Provides Update Regarding Anti-TNF Frozen Shoulder Trial

PALO ALTO, Calif., February 22, 2023 -- 180 Life Sciences Corp. (NASDAQ: ATNF) (“180 Life Sciences” or the “Company”), today announced closure to recruitment of men and women across England with early stage Frozen shoulder for a trial to determine the feasibility of conducting a large randomized controlled trial to assess whether an intra-articular injection of anti-TNF (Adalimumab) can reduce pain and improve function in people with pain predominant early-stage frozen shoulder, which was called the Anti-Freeze-F trial. The Anti-Freeze-F trial is being run by the University of Oxford and originally sought to recruit 84 participants.

Frozen shoulder is an extremely painful and debilitating condition, affecting about 9% of adults in the UK. It is characterised by an initial pain predominant inflammatory phase that lasts around 3-9 months. This progresses to a stiffness predominant phase with restriction of shoulder movement, followed by slow improvement in motion and stiffness. Administration of steroids generally leads to improvement in pain and motion, but the effects do not typically extend beyond 6 weeks.

The Anti-Freeze-F trial opened to recruitment at the end of May 2022 following delays in gaining approvals due to backlogs in the National Institute of Health Research (NIHR) system due to COVID-19 and consequential staff vacancies. Nine participants were recruited for participation in the trial through mid-February 2023.

The UK research system has faced unprecedented challenges following the COVID-19 pandemic both in terms of support services and at the point of delivery of clinical care. This has resulted in the NIHR instituting their Recovery and Reset programme to identify and close trials that are facing challenges. Unfortunately, we recently learned that our Anti-Freeze-F trial was considered to be one of the very numerous trials deemed one of such trials, due to the considerable challenges we faced to open recruitment sites and enroll sufficient participants. Therefore, the NIHR has asked the chief investigators to close the trial for further recruitment. The participants enrolled to date will receive their injections and follow up according to the established protocol. The Company had previously requested a no-cost extension, which was denied. The result of the closure of the trial means that another trial will likely need to be undertaken at a future time to recruit additional participants.

“We are obviously disappointed that the trial was unable to recruit sufficient patients despite the best efforts of the team led by Professors Nanchahal and Hopewell at the University of Oxford”, said Professor Sir Marc Feldmann, Executive Co-Chairman of 180 Life Sciences.

Dr. James Woody, CEO of 180 Life Sciences, stated, “The challenges faced by the United Kingdom National Health Service and the systems associated with delivery of clinical research have made it extremely difficult to conduct some clinical trials, especially those initiated soon after the COVID-19 pandemic. We will assess the data from Anti-Freeze-F when available to refine the strategy for any subsequent trials for this unmet need. We are confident in the scientific rationale for the study, and in the future we may determine that this trial may be best conducted in another country where the health and research systems are less constrained, and patients are readily available. This option is currently under consideration.” The discontinuation of the Anti-Freeze-F trial will have no impact on the Post Operative Cognitive Delirium trial, which is currently in the process of obtaining final approvals to proceed.

About 180 Life Sciences Corp.

180 Life Sciences Corp. is a clinical-stage biotechnology company driving ground-breaking studies into clinical programs which are seeking to address major unmet medical needs. The Company’s focus is a novel program to treat several inflammatory disorders 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, outcome of, and results of, clinical trials, including those discussed above; 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, closures of such trials prior to enrolling sufficient participants in connection therewith; 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.

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