

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 16, 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

Beginning on February 16, 2023, 180 Life Sciences Corp. (the “Company”) will make presentations to potential institutional and other investors as part of ordinary course, non-deal “road shows,” during which the Company will provide an overview of its business. A copy of the presentation materials to be used during such presentations is furnished herewith as [Exhibit 99.1](#), and has 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 9.01. Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1*	February 2023 180 Life Sciences Corp. Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith.

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, 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.

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 16, 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.



180 Life Sciences Overview



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)**
 - **α7nAChR**
- **Strong IP Portfolio:** 24 granted patents, 33 filed patent applications



Numerous Near-Term Inflection Points

- **Anti-TNF programs:** initiated a Phase 2 trial in Q3 2022 in frozen shoulder and expecting to initiate a Phase 2 trial in Q2/Q3 2023 in POCD with initial data expected in Q1 2024 and Q2 2025, respectively



- **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	
Fibrosis & Anti-TNF*	Dupuytren's Contracture	adalimumab		▶		Pursuing Conditional Marketing Authorization in UK
	Frozen Shoulder	adalimumab				Initiated Phase 2 Q3 2022
	POCD	infliximab				Initiate Phase 2 Q2/Q3 2023
	NASH	▶				Ongoing Validation
	HMGB1	▶				Ongoing Validation
Synthetic CBD Analogs (SCAs)	Chronic Pain	▶				Ongoing Validation
	Early Arthritis	▶				Ongoing Validation
Nicotine Acetylcholine Receptor (α7nAChR)	Smoking Cessation Induced Ulcerative Colitis	▶				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, and no applications or requests 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

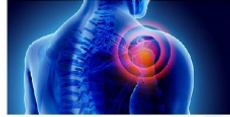




Fibrosis & Anti-TNF Therapeutics: Lead Clinical Indications



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





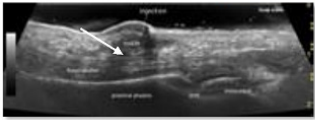
Phase 2a Completed: 40mg (in 0.4ml) Adalimumab is Effective **180** LIFE SCIENCES

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



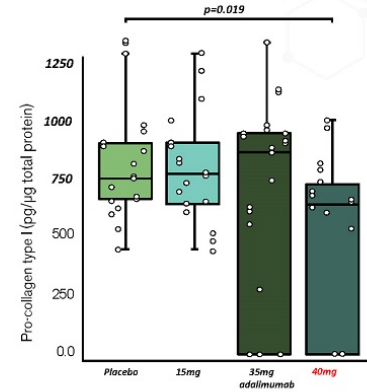
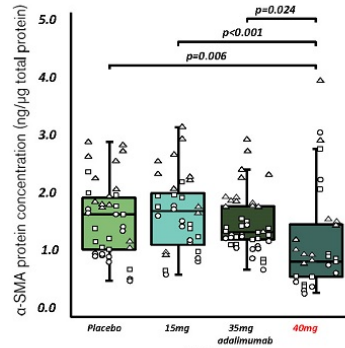
Adalimumab injected directly into the nodule

- 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/ μ g total protein mean \pm SD)

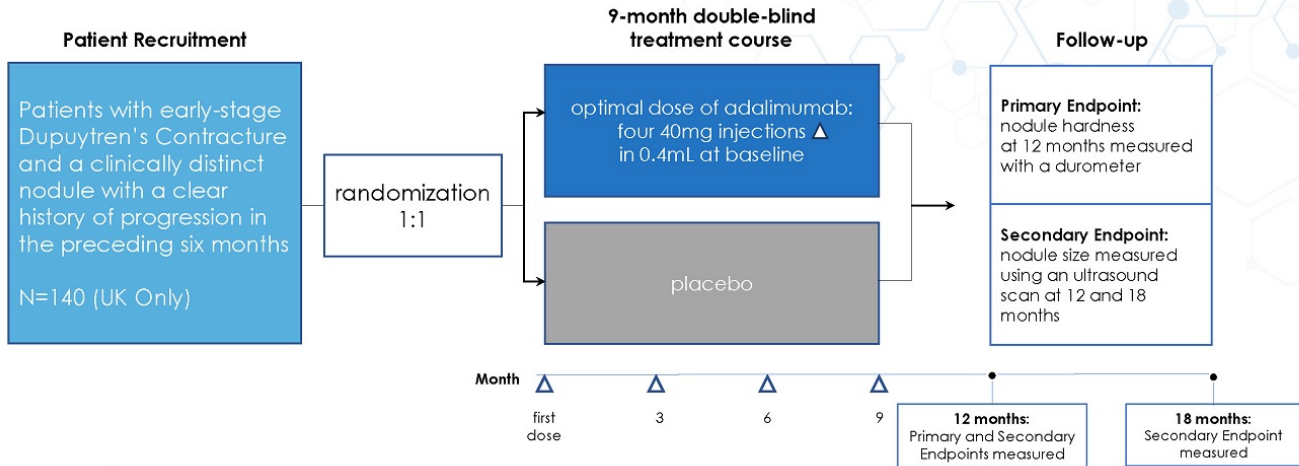


Treatment
 Placebo (1.51 \pm 0.65) 35mg in 0.7ml* (1.44 \pm 0.48)
 15mg in 0.3ml (1.60 \pm 0.67) 40mg in 0.4ml (1.09 \pm 0.89) *Leakage observed from site injection due to large volume





Phase 2b Study in Patients with Dupuytren's Contracture



Description

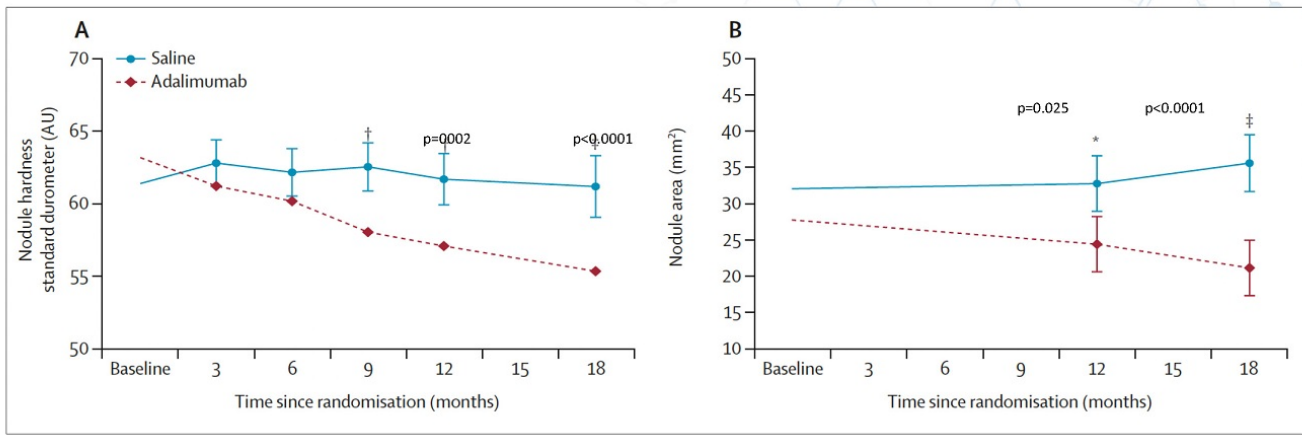
- Randomized, placebo-controlled clinical trial in patients with early-stage Dupuytren's injected with optimal dose adalimumab
- Every 3 months for 1 year (4 injections), following for a total of 18 months
- Outcome measures include nodule hardness, size and disease progression
- Randomized 181 patients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

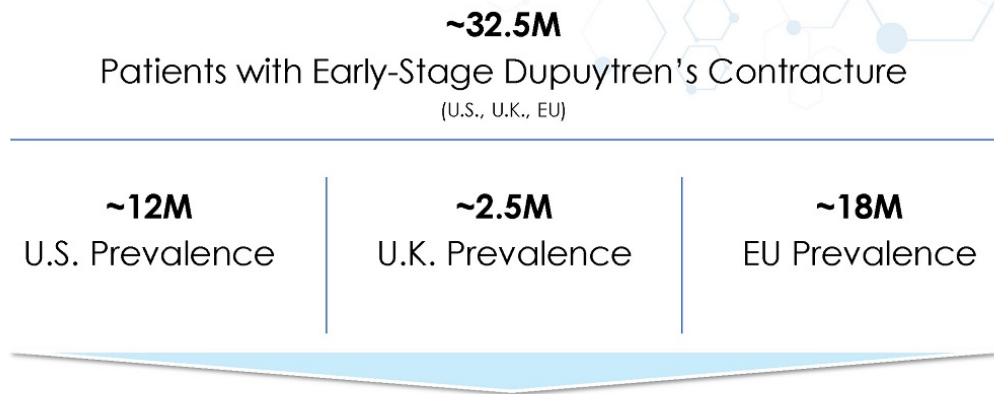
Nodule size -8.4mm² at 12 months
Nodule size -14.4mm² at 18 months

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

(1) <https://www.cdc.gov/homeandrecreationalafety/falls/adulthipfx.html>

(2) Walker-Bone K et al (2004) Arthritis Rheum 51 (4):642-651



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
- **Phase 2** clinical trial for local injection of anti-TNF; first patient dosing started Q3 2022
- Trial protocol completed and NIHR grant received





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**





α7nAChR Family: Novel Platform for Ulcerative Colitis

α7nAChR is a nicotine acetylcholine receptor and a central factor in evolutionarily ancient neural circuit to control of inflammation^(1,2)

- Large pharma initially touted α7 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 α7nAChR for inflammation
 - Nicotine binds α7 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

α7nAChR 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 K.J. 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	<p>1H Phase 2b POC data</p> <p>2H Consult with regulatory authorities to determine approval pathway</p>		
	Frozen Shoulder	<p>2H Initiated Phase 2</p>		Q1 2024 Phase 2 Data
	POCD	<p>2H Initiate Phase 2</p>	Q2/Q3 Initiate Phase 2	
	HMGB1	<p>2H Begin validating</p>		
 <p>Synthetic CBD Analogs (SCAs)</p>	Chronic Pain		Toxicity study planned	



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



Thank you

www.180lifesciences.com