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): September 13, 2023

TALARIS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40384**	**83-2377352**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

93 Worcester St. **Wellesley, Massachusetts**	**02481**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (502) 398-9250

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:

☒ 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	Trade Symbol(s)	Name of each exchange on which registered
Series A Common Stock, $0.0001 par value per share	TALS	The Nasdaq Global Market

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 announced, on June 22, 2023, Talaris Therapeutics, Inc., a Delaware corporation ("Talaris"), Terrain Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Talaris ("Merger Sub"), and Tourmaline Bio, Inc., a Delaware corporation ("Tourmaline"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Tourmaline, with Tourmaline continuing as a wholly owned subsidiary of Talaris and the surviving corporation of the merger (the "Merger"). In connection with the Merger, on September 13, 2023, Tourmaline updated information reflected in an investor presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of Tourmaline will use the updated presentation in various meetings with investors from time to time.

The information in Item 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall Exhibit 99.1 furnished herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Forward-Looking Statements

This Current Report on Form 8-K and the exhibit furnished herewith contain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including but not limited to, express or implied statements regarding the structure, timing and completion of the proposed Merger; Talaris' cash position at December 31, 2022 and for subsequent periods; the combined company's listing on Nasdaq after closing of the proposed Merger; expectations regarding the ownership structure of the combined company; the anticipated timing of Closing; the expected executive officers and directors of the combined company; each company's and the combined company's expected cash position at the closing of the proposed Merger and cash runway of the combined company; the future operations of the combined company; the nature, strategy and focus of the combined company; the development and commercial potential and potential benefits of any product candidates or platform technologies of the combined company; the executive and board structure of the combined company; the location of the combined company's corporate headquarters; anticipated preclinical and clinical drug development activities and related timelines, including the expected timing for data and other clinical results; and other statements that are not historical fact. All statements other than statements of historical fact contained in this Current Report on Form 8-K are forward-looking statements. These forward-looking statements are made as of the date they were first issued, and were based on the then-current expectations, estimates, forecasts, and projections, as well as the beliefs and assumptions of management. There can be no assurance that future developments affecting Talaris, Tourmaline or the proposed transaction will be those that have been anticipated.

Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Talaris' control. Talaris' actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to (i) the risk that the conditions to the closing of the proposed Merger are not satisfied, including the failure to timely obtain shareholder approval for the transaction, if at all; (ii) uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of Talaris and Tourmaline to consummate the proposed Merger; (iii) risks related to Talaris' ability to manage its operating expenses and its expenses associated with the proposed Merger pending closing; (iv) risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the proposed Merger; (v) the risk that as a result of adjustments to the exchange ratio, Talaris shareholders and Tourmaline stockholders could own more or less of the combined company than is currently anticipated; (vi) risks related to the market price of Talaris' common stock relative to the value suggested by the exchange ratio; (vii) unexpected costs, charges or expenses resulting from the transaction; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed Merger; (ix) the uncertainties associated with Tourmaline's platform technologies, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; (x) risks related to the inability of the combined company to obtain

sufficient additional capital to continue to advance these product candidates and its preclinical programs; (xi) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (xii) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; (xiii) risks associated with the possible failure to realize certain anticipated benefits of the proposed Merger, including with respect to future financial and operating results; (xiv) risks associated with Talaris' financial close process; (xv) the risk that the pre-closing financing is not consummated; and (xvi) the risk that Talaris shareholders receive more or less of the cash dividend than is currently anticipated, among others. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section titled "Risk Factors" in Talaris' Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC, and in other filings that Talaris makes and will make with the SEC in connection with the proposed Merger, including the Proxy Statement described below under "Additional Information and Where to Find It." You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. Talaris expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. This Current Report on Form 8-K does not purport to summarize all of the conditions, risks and other attributes of an investment in Talaris or Tourmaline.

Participants in the Solicitation

This Current Report on Form 8-K and the exhibit filed or furnished herewith relate to the proposed merger transaction involving Talaris and Tourmaline and may be deemed to be solicitation material in respect of the proposed merger transaction. In connection with the proposed merger transaction, Talaris has filed relevant materials with the SEC, including a registration statement on Form S-4 (the "Form S-4") that contains a proxy statement (the "Proxy Statement") and prospectus. This Current Report on Form 8-K is not a substitute for the Form S-4, the Proxy Statement or for any other document that Talaris may file with the SEC and or send to Talaris' shareholders in connection with the proposed merger transaction. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS OF TALARIS ARE URGED TO READ THE FORM S-4, THE PROXY STATEMENT AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT TALARIS, THE PROPOSED MERGER TRANSACTION AND RELATED MATTERS.

No Offer or Solicitation

This Current Report on Form 8-K and the exhibit furnished herewith do not constitute an offer to sell or the solicitation of an offer to buy any securities nor a solicitation of any vote or approval with respect to the proposed transaction or otherwise. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U S. Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

Additional Information and Where to Find It

Investors and security holders may obtain free copies of the Form S-4, the Proxy Statement and other documents filed by Talaris with the SEC through the website maintained by the SEC at http://www.sec.gov. Copies of the documents filed by Talaris with the SEC are also available free of charge on Talaris' website at www.talaristx.com, or by contacting Talaris' Investor Relations at investors@talaristx.com. Talaris, Tourmaline, and their respective directors and certain of their executive officers may be considered participants in the solicitation of proxies from Talaris' shareholders with respect to the proposed merger transaction under the rules of the SEC. Information about the directors and executive officers of Talaris is set forth in its Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 31, 2023, and in subsequent documents filed with the SEC. Additional information regarding the persons who may be deemed participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, are also included in the Form S-4, the Proxy Statement and other relevant materials to be filed with the SEC when they become available. You may obtain free copies of this document as described above.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Document
99.1	Investor Presentation of Tourmaline Bio, Inc., dated September 13, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

TALARIS THERAPEUTICS, INC.

Date: September 13, 2023

By: /s/ Mary Kay Fenton
May Kay Fenton
Chief Financial Officer and Interim Chief Financial Officer

Exhibit 99.1

TOURMALINE

Corporate overview

September 2023

Disclaimer

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Tourmaline obtained the industry, market and competitive position data used throughout this presentation from its own internal estimates and research, as well as from industry and general publications, and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, Tourmaline's internal research and its industry experience, and are based on assumptions made by Tourmaline based on such data and its knowledge of the industry and market, which it believes to be reasonable. In addition, while Tourmaline believes the industry, market and competitive position data included in this presentation is reliable and based on reasonable assumptions, Tourmaline has not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors.

This presentation contains trademarks, services marks, trade names and copyrights of Tourmaline and other companies, which are the property of their respective owners. The use or display of third parties' trademarks, service marks, trade name or products in this presentation is not intended to, and does not imply, a relationship with Tourmaline, or an endorsement of sponsorship by Tourmaline. Solely for convenience, the trademarks, service marks and trade names referred to in this presentation may appear with the ®, TM or SM symbols, but such references are not intended to indicate, in any way, that the company will not assert, to the fullest extent under applicable law, their rights or the right of the applicable licensor to these trademarks, service marks and trade name.

Disclaimer (continued)

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Company highlights

Our mission: developing transformative medicines that dramatically improve the lives of patients with life-altering immune diseases

Our product candidate: TOUR006, a Phase 2/pivotal-ready anti-IL-6 monoclonal antibody with potentially differentiated profile

- High affinity, long half-life, low immunogenicity; delivered in ≤1mL subcutaneous injection
- Completed multiple Phase 1 and Phase 2 clinical trials while under development by Pfizer (448 subjects dosed)
- Originally developed by Pfizer

Our focus: immune-mediated diseases where IL-6 blockers have been underexplored despite compelling signals of clinical activity

Our lead indication: thyroid eye disease (TED), an autoantibody disease that affects the tissue surrounding the eye

- TOUR006's potential administration profile (low volume, low frequency) and upstream mechanism of action could make it an ideal treatment option for TED
- Mechanism clinically validated after >300 TED patients treated with IL-6 blockers, showing autoantibody reductions and evidence of clinical benefit
- IND cleared in the US and Phase 2b TED study expected to begin in Q3 2023

Our second indication: atherosclerotic cardiovascular disease (ASCVD), a leading cause of global morbidity and mortality

- Emerging clinical evidence appears to validate decades-long research on IL-6 as a key cardiovascular risk factor
- TOUR006 could pursue a fast follower strategy, with potential for less frequent dosing than competitor IL-6 agents in ASCVD
- Phase 2 ASCVD biomarker trial expected to begin in 2024

$112 million Series A financing with participation from leading biotechnology investors

Transaction summary

Overview	• Talaris Therapeutics, Inc. (NASDAQ: TALS) to acquire 100% of outstanding equity interests of Tourmaline Bio, Inc. structured as a traditional reverse merger • Surviving entity name / proposed ticker: Tourmaline Bio (TRML) • Issuer of shares in private placement: Tourmaline
Transaction Summary	• $389.7M pro forma value of combined company — $230M value of Tourmaline — $84.7M value of Talaris including net of up to $64.6M dividend/equity award cash payout[1] — $75M private placement • ~$210M pro forma cash balance for combined company estimated at close excluding dividend • Pro forma ownership split: ~59.0% Tourmaline, ~21.7% Talaris, ~19.3% private placement • Private placement syndicate includes Acuta Capital Partners, Affinity Asset Advisors, Braidwell LP, Cowen Healthcare Investments, Deep Track Capital, Great Point Partners, LLC, KVP Capital, Logos Capital, Paradigm BioCapital, Qiming Venture Partners USA, RA Capital Management, LP, StemPoint Capital LP, TCGX, Vivo Capital, and other undisclosed investors
Use of Proceeds	• Expected to fund Tourmaline through 2026 and provide sufficient capital for key clinical programs including Phase 2b TED study, Phase 2 TED basket study, and Phase 2 CV study
Projected Timing	• Closing expected Q4 2023

1. Subject to certain adjustments at close, includes estimated $2.2M of Talaris Legacy Proceeds from the sale of certain clinical data and intellectual property

Leadership team

Sandeep Kulkarni, MD
Co-founder and Chief Executive Officer

Yung Chyung, MD
Chief Medical Officer

Brad Middlekauff, JD
Chief Business Officer and General Counsel

Susan Dana Jones, PhD
Chief Technology Officer

Kevin Johnson, PhD
Chief Regulatory Officer

Ryan Iarrobino
Senior Vice President, Product Development

Gerhard Hagn
Senior Vice President, Head of Commercial & BD

Dora Rau
Senior Vice President, Head of Quality

Board of directors, advisors, and investors

Board of Directors

Tim Anderson
Managing Director, Cowen Healthcare Investments

Caley Castelein, MD
Co-founder, Tourmaline Bio and Managing Partner, KVP Capital

Cariad Chester
Partner, TCG Crossover

Aaron Kantoff
Managing Partner, Scion Life Sciences

Rebecca Luse
Principal, Deep Track Capital

Parvinder Thiara
Chief Investment Officer, Athanor Capital

Sandeep Kulkarni, MD
Co-founder and Chief Executive Officer, Tourmaline Bio

Advisors

Burt Adelman, MD
Co-founder and Chairman of the Board, Verve Therapeutics and Clear Creek Bio; former EVP of R&D and Portfolio Strategy, Biogen; former Evp of R&D and CMO, Dyax Corp.

Pouya N. Dayani, MD
Vitreoretinal Surgery and Ocular Inflammation Retina-Vitreous Associates Medical Group; Adjunct Clinical Professor USC Keck School of Medicine, USC Roski Eye Institute

Kristine Erickson, OD
Former Global Ophthalmology Clinical Lead for sarilumab, Regeneron; former VP Clinical Research, Aerie Pharmaceuticals

Jarmila Heissigerová, MD, PhD
Head, Department of Ophthalmology, Charles University and General University Hospital in Prague

Quan Dong Nguyen, MD
Professor, Ophthalmology (Retina and Uveitis), Pediatrics (Rheumatology), and Medicine (Immunology / Rheumatology); Director, Uveitis and Ocular Inflammation Service, Byers Eye Institute at Stanford University

Marco Sales-Sanz, MD
Head of Orbital and Oculoplastic Surgery Unit, Hospital Universitario Ramón y Cajal (Madrid) and IMO Grupo Miranza (Madrid)

Stuart Seiff, MD
Professor, Ophthalmology, Senate Emeritus, University of California San Francisco; Medical Director and CEO, Pacific Center for Oculofacial and Aesthetic Plastic Surgery

Marius Stan, MD
Consultant in Endocrinology, Associate Professor in Medicine, and Chair of the Thyroid Core Group, Mayo Clinic (Rochester)

Edward J. Wladis, MD
Professor and Chair of the Lions Eye Institute, Department of Ophthalmology, Albany Medical College; Chief of Service for Ophthalmology, Albany Medical Center Hospital

Investors

AVEGO · BRAIDWELL · COWEN HEALTHCARE INVESTMENTS · DEEP TRACK CAPITAL · KVP CAPITAL · LOGOS CAPITAL · PETRICHOR · QIMING VENTURE PARTNERS · QVT Financial LP · rtw · TCGX · VIVO CAPITAL

TOUR006 (formerly PF-04236921), a fully human, high affinity antibody that neutralizes IL-6

Fully human antibody that neutralizes IL-6 levels with high affinity

- Kd of 6 pM
- Terminal half-life 47-58 days
- Generated from Medarex transgenic mouse platform

Robust existing clinical data package

- Two Phase 2 studies completed (SLE and Crohn's)
- 448 subjects have been dosed with TOUR006

Durable and deep IL-6 signaling blockade observed with infrequent dosing as low as 10mg every 4 weeks

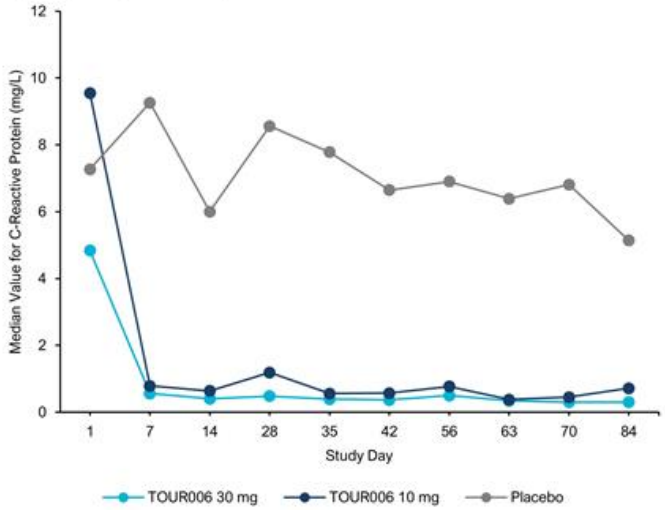
- As measured by C-reactive protein (CRP), a pharmacodynamic marker of IL-6 signaling

Limited immunogenicity

- Across 448 subjects dosed with TOUR006, only 2 subjects generated ADAs following treatment

Generally well-tolerated profile to date consistent with IL-6 class

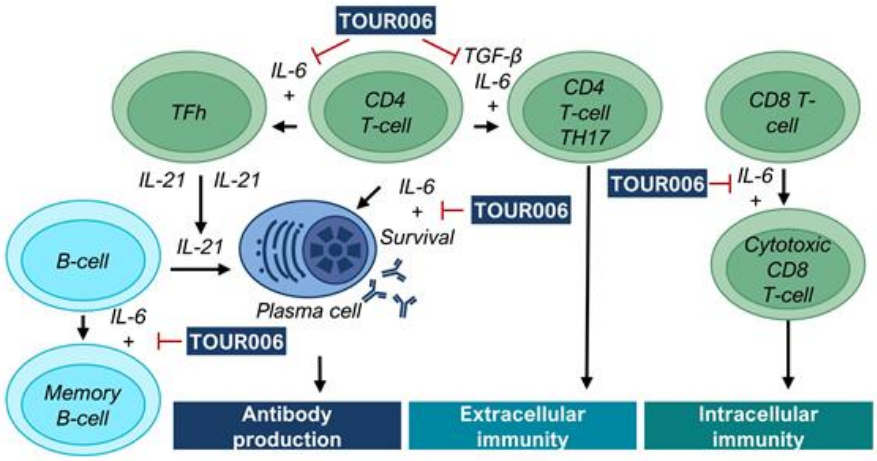
Median serum concentration time profile of CRP from all subjects following day 1, 28, and 56 following multiple intravenous doses of TOUR006 to RA subjects (Study B0151002)



Source: PF-04236921 Investigator's Brochure, dated February 2015

IL-6 drives production of autoantibodies and inflammation

IL-6 mediated impacts on B and T cell pathways[1]



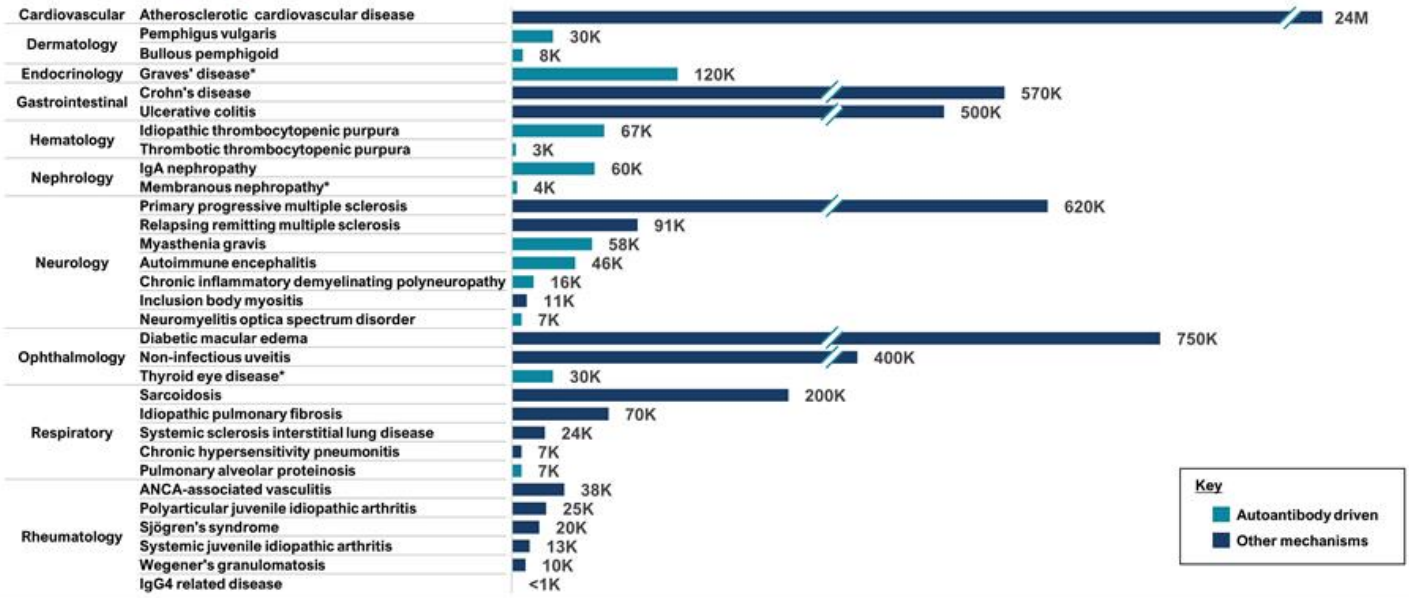
Translational evidence

- IL-6 enhances antibody production and induces plasma cell differentiation and survival[2]
- In *ex vivo* experiments using samples from patients with NMO, IL-6 shown to promote plasmablast survival and stimulate anti-AQP4 secretion[3]
- Extensive observations in TED and other autoantibody disease that IL-6 blockade suppresses autoantibody levels
- Recent approval of satralizumab in NMOSD offers strong evidence of anti-IL-6's potential in autoantibody driven diseases

1. Adapted from Cabezas et al., Front. Immunol. (2022)
2. Dienz et al., JEM (2009)
3. Chihara et al., Proc. Natl. Acad. Sci. U.S.A. (2019)

IL-6 has the potential to address a wide range of autoantibody driven and other inflammation meditated conditions

US Prevalence (2022)



*Incidence figure
Publications available upon request

TOUR006's potential profile: subcutaneous, low volume, low frequency injections

	TOUR006	Actemra (tocilizumab)		Kevzara (sarilumab)	Enspryng (satralizumab)	Sylvant (siltuximab)	Ziltivekimab	Clazakizumab	
Company	**Tourmaline**	Roche		Regeneron	Roche	EUSA	Corvidia / Novo	CSL	
Antibody Type	**Human**	Humanized		Human	Humanized	Chimeric	Human	Humanized	
Target	**IL-6**	IL-6 receptor		IL-6 receptor	IL-6 receptor	IL-6	IL-6	IL-6	
Stage of development	**In Phase 2b**	Approved		Approved	Approved	Approved	In Phase 3	In Phase 2/3	
Indications being pursued	**TED, ASCVD**	RA, GCA, PJIA, SJIA, CRS, SSc-ILD, COVID19		RA, PMR	NMOSD, AE, MG, MOGAD, TED	MCD	ASCVD (CKD), HF	AMR, ASCVD (ESKD)	
Black box warning	**Drug not approved**	Yes		Yes	No	No	Drug not approved	Drug not approved	
Terminal half-life	**47-58 days**	21.5 days		Up to 10 days	30 days	20.6 days	45-65 days	~30 days	
Anti-drug antibodies	**<1% of patients**	1-2% of patients		14-19% of patients	38-73% of patients (~20% increase in drug clearance)	0-2% of patients	6-13% of patients	2-10% of patients	
Injection site reactions	**0-9% of patients**	7-41% of patients		5-7% of patients	9% of patients	N/A	0-6% of patients	10-24% of patients	
Route of admin	**Subcutaneous (SC)**	IV	SC	SC	SC	IV	SC	IV	SC
Standard dose	**20 or 50mg**	8-12mg/kg	162mg	200mg	120mg	11mg/kg	15mg	TBD	12.5mg
Dosing regimen	**Q8W / Q12W**	Q4W	QW / Q2W	Q2W	Q4W	Q3W	Q4W	Q4W	Q4W

TOURMALINE

Source: company reports, publications, FDA review documents, package inserts
AE: Autoimmune Encephalitis; AMR: Antibody-Mediated Rejection; ASCVD: Atherosclerotic Cardiovascular Disease; CKD: Chronic Kidney Disease; COVID-19: Coronavirus Disease 2019; CRS: Cytokine Release Syndrome; ESKD: End-stage Kidney Disease; GCA: Giant Cell Arteritis; HF: Heart Failure; MCD: Multicentric Castleman's Disease; MG: Myasthenia Gravis; MOGAD: Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease; NMOSD: Neuromyelitis Optica Spectrum Disorder; PJIA: Polyarticular Juvenile Idiopathic Arthritis; PMR: Polymyalgia Rheumatica; RA: Rheumatoid Arthritis; SJIA: Systemic Juvenile Idiopathic Arthritis; SSc-ILD: Systemic Sclerosis-Associated Interstitial Lung Disease

Clinical development plan for TOUR006 by end of 2023

*The FDA may require Tourmaline to conduct a Phase 1 trial in ASCVD.

Additional indications under evaluation

TOUR006 regulatory exclusivity and intellectual property

Regulatory Exclusivity

- In the US, we expect to rely on 12 years' data exclusivity for biologics
  - Regulatory counsel has confirmed this is a reasonable expectation

Patent Protection

- We have filed 5 new patent applications on TOUR006
  - Incorporating claims on:
    - Indication-specific methods of use
    - Dosing regimens
  - If issued, will expire in 2043 (or later)
- Additional patent applications in process
- Pfizer has abandoned all previous Pfizer patents/applications relating to TOUR006
- No freedom to operate issues identified

Thyroid eye disease

Thyroid eye disease
(also called Graves' ophthalmopathy and Graves' orbitopathy)

Autoimmune disease associated with proliferation and inflammation of the cell types surrounding the eye

- Symptoms include proptosis, double-vision, and disfigurement
- Involvement of optic nerve can be sight-threatening and requires emergent surgery

Source: Getty Images

Approximately 30,000 new cases per year (of all severities), of which we estimate 15,000-20,000 are moderate-to-severe[1]

Pathophysiology driven by autoantibodies that bind to the TSH receptor, which is expressed on cell types surrounding the eye

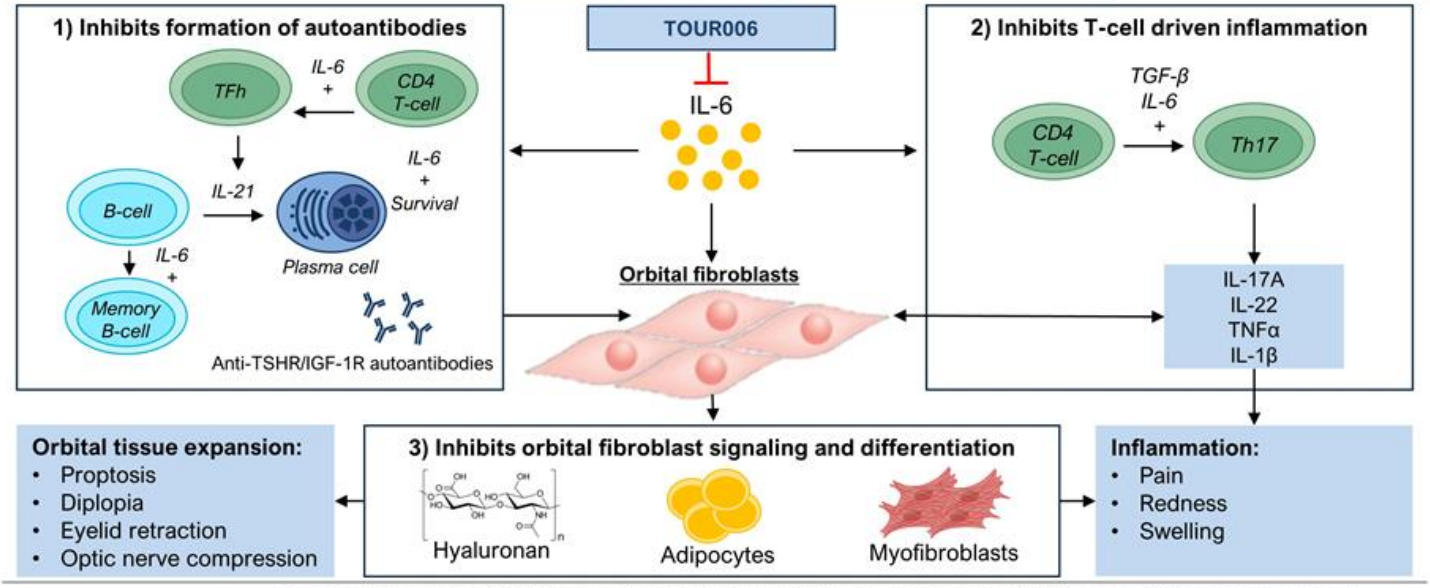
- Same autoantibody can also cause Graves' hyperthyroidism (GH); up to 95% of TED patients also have GH[2]

IL-6 is elevated in patients with TED and experimental evidence suggests a role in disease pathogenesis[3]

1. Bartalena et al., Front. Endocrinol. (2020); Lazarus, Best Pract. Res. Clin. Endocrinol. Metab. (2021)
2. Sabini et al., Eur. Thyroid J. (2018)
3. Hiromatsu et al., J. Clin. Endocrinol. Metab. (2000); Slowik et al., Endocr. Res. (2012); Jyonouchi et al., Thyroid (2001); Hwang et al., Invest Ophthalmol Vis Sci (2009)

IL-6 inhibition has potential to block multiple steps in TED pathogenesis

TOUR006 has been observed to inhibit IL-6, a key node in TED pathogenesis



Adapted from Huang et al., Eye (2018); Hodgson and Rajaii, Ophthalmol Ther (2020); Fang et al, Front Endocrinol (2021); Smith, Eye (2019); and Cabezas et al., Front. Immunol. (2022)

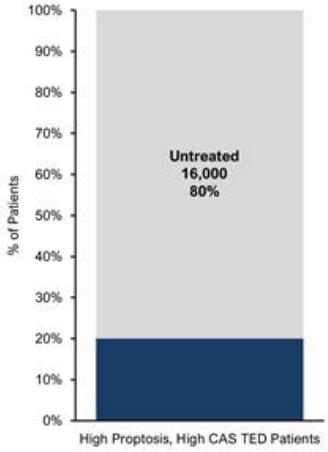
TED market remains vastly underpenetrated even as teprotumumab sales have stagnated

Sales stagnating over last 6 quarters

Teprotumumab sales by quarter ($M)[1]

Most patients not receiving tepro

Teprotumumab US LTM penetration[2]



Potential barriers to adoption

1. **Inconvenience:**
   - IV dosing every 3 weeks
   - Burdensome approval process[3]
   - Limited access to infusion centers[3]
2. **Limited durability:** high relapse rates observed in long-term follow-up[4]
3. **Safety**: potentially permanent side effects

1. Horizon company reports and filings
2. Horizon Q3 2022 earnings call; LTM = last twelve months
3. Horizon Q1 2023 10Q
4. Kahaly et al., Thyroid (2021) (ATA 2021 presentation)

Teprotumumab may cause increased risk of permanent hearing loss

- Hearing impairment likely represents an **on-target consequence** of IGF-1 pathway inhibition[1]
  - IGF-1 required for normal inner ear function
  - Likely just as relevant for SC as IV
- 15% of patients reporting hearing impairment across case reports[2]
  - Of these, **45% reported as persistent**
- **Ototoxicity appears cumulative**, emerging after mean of 3.6 infusions in one series[3]
- Some investigators recommending **serial audiograms** to monitor hearing loss[4]
- **Ongoing legal actions** filed by patients suffering hearing impairments attributed to teprotumumab across **over 50 lawsuits**[5]
- As of May 2023, there have been **384 ear and hearing-related adverse events** captured in the FAERS database, including reports of permanent deafness

----------**WARNINGS AND PRECAUTIONS**----------

- Infusion Reactions: If an infusion reaction occurs, interrupt or slow the rate of infusion and use appropriate medical management (5.1)
- Exacerbation of Preexisting Inflammatory Bowel Disease (IBD): Monitor patients with preexisting IBD for flare of disease; discontinue TEPEZZA if IBD worsens (5.2)
- Hyperglycemia: Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with TEPEZZA. Ensure patients with hyperglycemia or pre-existing diabetes are under appropriate glycemic control before and while receiving TEPEZZA (5.3)
- Hearing Impairment Including Hearing Loss: TEPEZZA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients (5.4)

In July 2023, the FDA updated Tepezza's label to reflect its potential for permanent hearing loss, recommending assessment of patients' hearing before, during, and after treatment with Tepezza

1. Yamamoto et al, Front Pharmacol (2014); Gao et al, Front Cell Neurosci (2020)
2. Bartalena et al., J. Endocrinol. Invest. (2022)
3. Kossler et al., J. Endocrinol (2021)
4. Chow et al., BMJ Case Rep (2022)
5. Tourmaline research as of August 2023

TOUR006 has the potential to address the unmet need in TED

Elements of ideal 1st line therapy for TED	Potential improvements to standard of care
Broad, deep, and durable effects	• Meaningful benefits on multiple outcome measures: proptosis, CAS, diplopia • Low rates of relapse
Well-tolerated safety profile	• Expected avoidance of permanent or irreversible side effects • Safety concerns can be managed with routine monitoring • Finite treatment course for majority of patients
Resolution of underlying biology	• Mechanistically acts upstream in disease cascade to stop disease • Limited time window to achieve maximal effect • Clinical data supporting early versus delayed treatment initiation
Patient-centric experience	• Ease of access and ease of use • Suitable for longer term usage, if indicated

The characteristics presented reflect outcomes that may not be representative of TOUR006. The results of past clinical trials may not be indicative of future results, and the results of future or ongoing clinical trials may not demonstrate some or any of the characteristics presented.

Studies using tocilizumab in steroid-refractory TED patients demonstrate consistent evidence of clinical benefit

Study Details				Key Endpoints		
First author	Year	Study type	Number treated	Proptosis response rate	CAS response rate	% reduction in autoantibodies
Perez-Moreiras	2021	Retrospective	54	78	89	75
Sánchez-Bilbao	2020	Observational	48	NR	NR	NR
Atienza-Mateo	2018	Retrospective	29	NR	NR	NR
Perez-Moreiras	2014	Prospective	18	72	100	76
Perez-Moreiras	2018	Randomized Controlled	15	93	60	NS
de la Fuente Bursón	2020	Retrospective	15	NR	NR	NR
Pereira	2023	Retrospective	14	NR	NR	NR
Boutzios	2023	Observational	12	NR	NR	64
Pamplin-Sánchez	2022	Retrospective	11	75	73	NR
Moi	2022	Retrospective	10	Clear improvement	80	75
Cortez	2022	Prospective	10	10	100	81
Silkiss	2020	Case Series	9	Clear improvement	56	74
Smith	2021	Retrospective	9	78	100	54
Bielefeld	2019	Observational	8	NR	NR	NR
Ceballos-Marcias Jose	2020	Case Series	8	NR	75	41
Moás	2022	Observational	7	NR	NR	92
Toro-Tobon	2023	Retrospective	6	50	NR	NR
Bennedjai	2020	Retrospective	7	NR	NR	73
de Pablo Gomez	2018	Case Series	5	NR	60	NR
Ribi	2017	Case Series	3	33	67	NR
Maldney	2020	Case Series	3	67	NR	NR
Stevens	2022	Retrospective	3	100	67	NR
Russell	2017	Case Series	2	NR	0	NR
Sy	2017	Case Series	2	Clear improvement	50	69
Copperman	2019	Case Series	2	100	0	NR
Coy	2019	Case Series	2	NR	50	NR
Park	2021	Case Series	2	100	100	NR
Abeillon-du Payrat	2022	Case Series	2	100	50	NR
Butnaru	2013	Case Report	1	NR	100	NR
Gómez Rodríguez	2014	Case Report	1	NR	100	NR
Bielefeld	2017	Case Report	1	Clear improvement	NR	NR
Canas	2018	Case Report	1	100	NR	NR
Pascual-Camps	2018	Case Report	1	NR	NR	NR
Garreta Fontelles	2019	Case Report	1	NR	NR	93
Mehmet	2020	Case Report	1	0	NR	NR
Kaplan	2020	Case Report	1	NR	0	85
Cayon-Blanco	2020	Case Report	1	NR	100	NR
Tran	2020	Case Series	1	NR	NR	NR
Ruiz	2021	Case Report	1	NR	NR	NR
Albrashdi	2022	Case Report	1	100	NR	NR
Cezara	2022	Case Report	1	NR	0	NR
Mohamed	2022	Case Series	1	0	0	NR
Moleiro	2022	Case Report	1	100	NR	86
Almarzouei	2023	Case Report	1	NR	NR	NR
Cuculescu	2023	Case Report	1	Clear improvement	0	NR
Nirmalan	2023	Case Series	1	NR	NR	NR
			Weighted mean	**72%**	**78%**	**74%**
			Smith 2017 (Tepro Phase 2)	**71%**	**69%**	**N/A**
			Douglas 2020 (Tepro Phase 3)	**83%**	**59%**	**N/A**

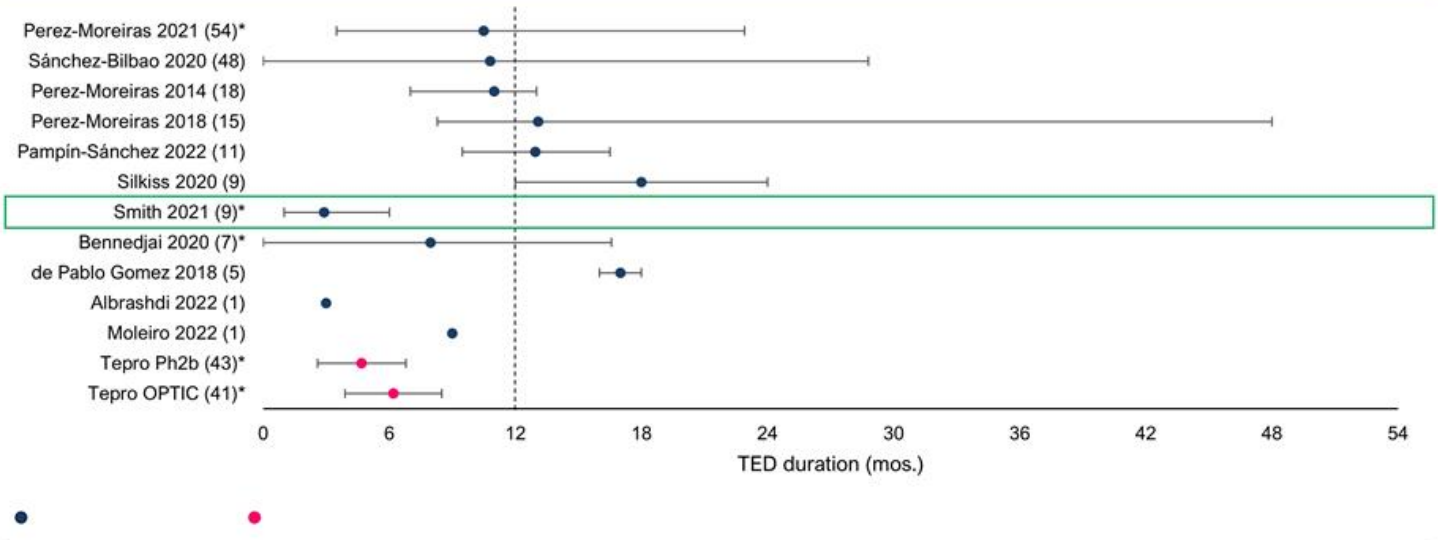
We believe these reports may be understating true efficacy of IL-6 blockade

- Most studies enrolled steroid-refractory patients
- Most patients treated were >9 months out from symptom onset, i.e. their disease may have exited the active phase
- Exposure to treatment may have been suboptimal (<6 months)

Proptosis response rate is generally defined in the data outlined here as a ≥2 mm proptosis improvement in the worse eye at baseline without any worsening in the other eye. CAS response rate is generally defined in the data outlined here as a CAS of 0 or 1. Studies referenced in this table represent investigator-led studies and were not designed with the intent of generating evidence for an approval of tocilizumab in TED. The majority of these studies were not designed with power to detect statistical significance. NR: not reported. NR: not reported. NS: not significant. Publications available upon request

TED patients had mostly long disease durations before starting tocilizumab, likely impacting efficacy of IL-6 blockade

Median (IQR) duration of TED symptoms at time of enrollment (n)



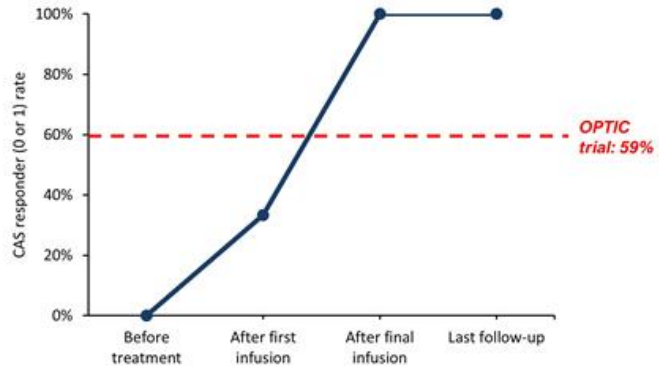
TOURMALINE

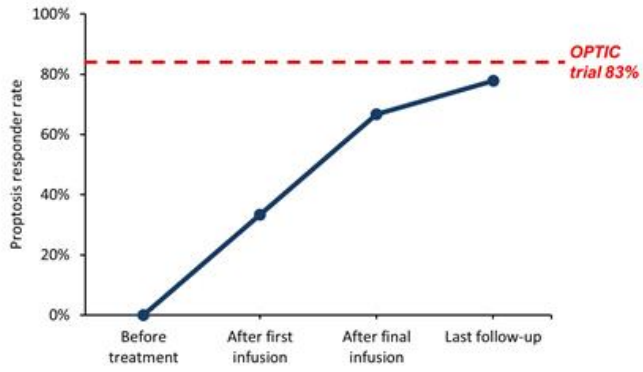
Only includes publications which reported complete disease duration data. * Perez-Moreiras 2021: range, not IQR; Smith 2021: mean and range; Bennedjai 2020 & tepro trials: mean +/- one standard deviation

Recent case series demonstrate IL-6 inhibition's potential in first-line TED patients

Investigator-led retrospective analysis using tocilizumab

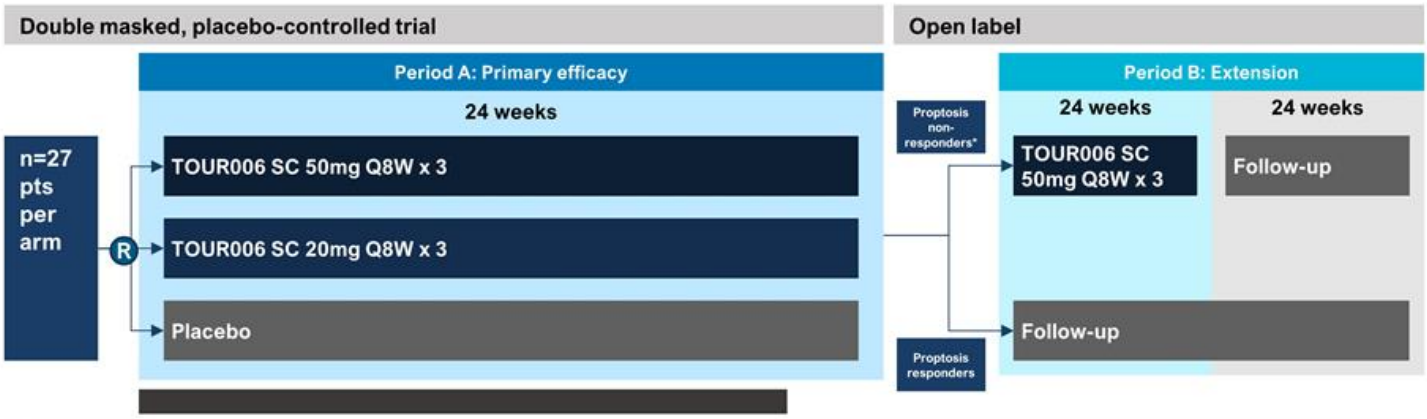
- 9 subjects included in analysis
- Average CAS: 6 (out of 7)
- Treatment with tocilizumab 8mg/kg monthly
- Mean time from symptom onset to first treatment: 2.89 months
- Mean number of infusions: 4.2
- Median change in autoantibody levels from baseline: 61% decline





Smith et al., *Ophthalmic Plast Reconstr Surg* (2021)

Planned Phase 2b: dose-ranging study in first-line TED



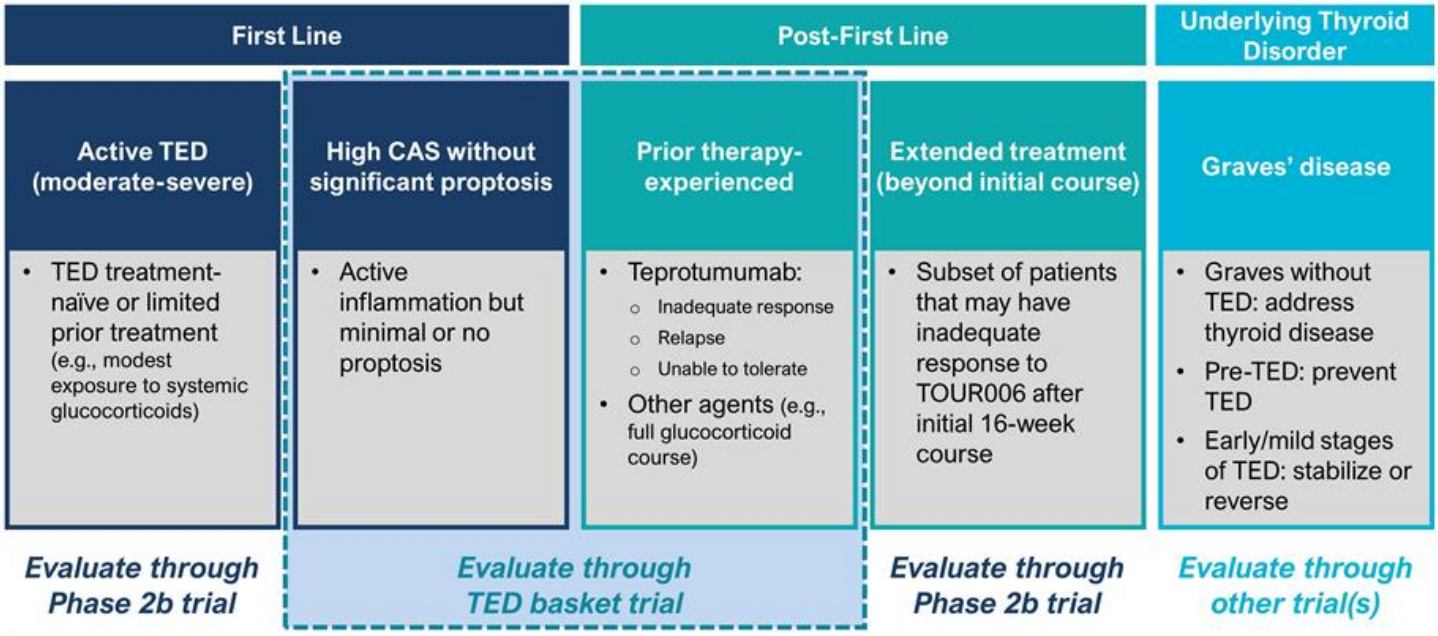
Study population:
- Moderate-severe TED, with proptosis ≥ 3mm above normal (based on race and gender)
- Active phase, with symptom onset ≤ 12 months, CAS ≥ 4 and positive TSI
- First-line setting, with cap on prior corticosteroid use (< 1g methylprednisolone or equivalent)

Primary efficacy endpoint:
- Proptosis response rate at week 20

Additional endpoints:
- CAS
- Diplopia
- QoL, safety, PK/PD/ADA

*Any patient who receives rescue therapy/intervention in Period A will not receive TOUR006 in Period B and will instead undergo follow-up only

TOUR006: Therapeutic potential to address broad segments of the TED population (and beyond)



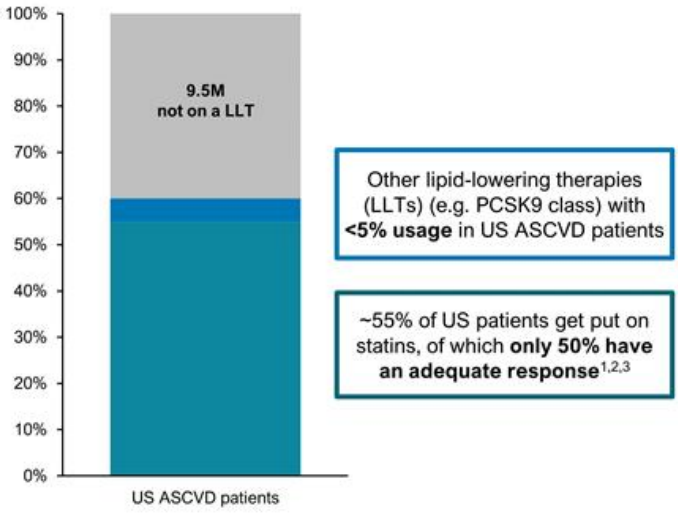
TOUR006 has the potential to offer a differentiated profile in TED

	TOUR006	Teprotumumab	Batoclimab	Efgartigimod IV or SC	Satralizumab	VRDN-001	Linsitinib	Lonigutamab
Company	TOURMALINE	HORIZON	IMMUNOVANT	argenx	Roche	VIRIDIAN	Sling Therapeutics	ACELYRIN
Mechanism of action	IL-6 antibody	IGF-1R antibody	FcRn antibody	FcRn antibody fragment	IL-6R antibody	IGF-1R antibody	IGF-1R inhibitor	IGF-1R antibody
Stage of development	Planned Phase 2b start in Q3 2023	Approved	Phase 3	Registrational trial expected to start in Q4 2023	Phase 3 expected to start in Sep 2023	Phase 3	Phase 2/3	Phase 1/2
Route of delivery	SC	IV	SC (up to 4mL per administration)	IV or SC	SC	IV	Oral	SC
Frequency	Q8W	Q3W	QW	QW	Q4W	Q3W	BID	Q4W
Market cap	Private	~$26B	~$3.0B	~$29B	~$208B	~$1.1B	Private	~$2.5B

Source: company reports
Market data as of close on August 31, 2023

Atherosclerotic Cardiovascular Disease (ASCVD)

ASCVD continues to be underserved despite the wide availability of statins



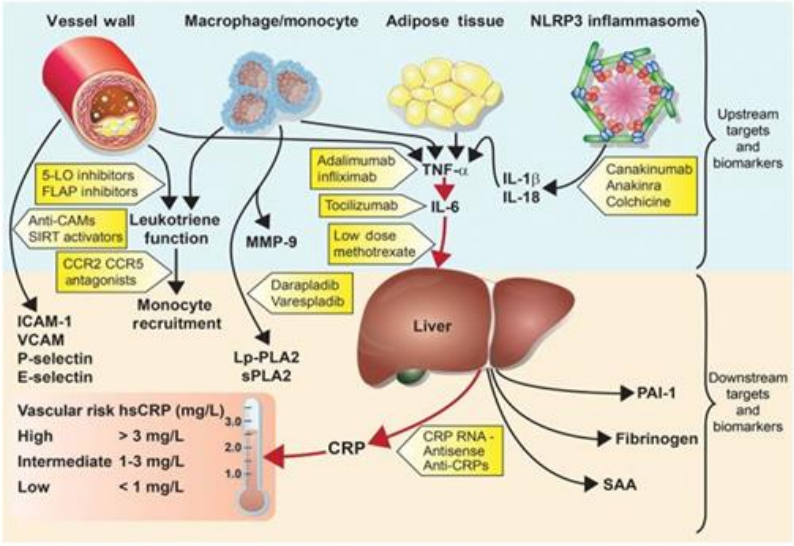
Other lipid-lowering therapies (LLTs) (e.g. PCSK9 class) with **<5% usage** in US ASCVD patients

~55% of US patients get put on statins, of which **only 50% have an adequate response**[1,2,3]

- ASCVD consists of major adverse cardiovascular events including heart attacks, coronary heart disease, and stroke, resulting in ~700k deaths per year in the US[4]
- Some patients on statins do not reach their LDL-C goals and those that do may maintain major residual risk from other factors like inflammation[5]
- Despite their wide availability, patient adherence to statins is low due to adverse side effects and perceived lack of benefit[6]
- There remains a large untapped patient population who may be better addressed by an infrequently administered therapy targeting other key risk factors such as inflammation

1. Gu et al. Am J Prev Cardiol (2022).
2. Nelson et al. JACC (2022)
3. Akeya et al. Heart (2018)
4. CDC, Heart Disease
5. Ridker. Circ Res (2017)
6. Colantonio et al. JAHA (2018)

IL-6 inflammation emerging as key cardiovascular risk factor

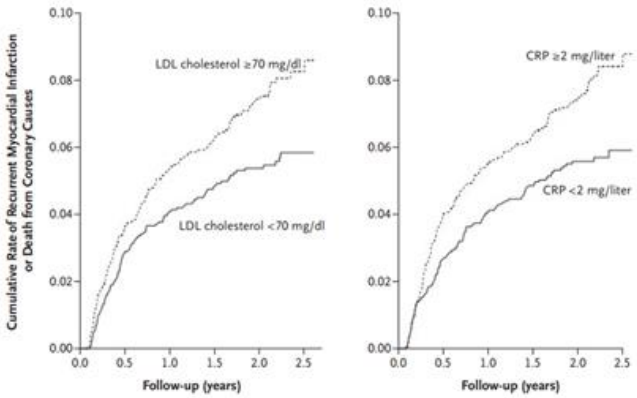


- Inflammation has an established role in plaque formation and disruption
- CRP thought to be a key biomarker of inflammation-related CV risk
  - CRP is a marker of IL-6 pathway activation
  - CRP levels often elevated in patients with CV disease
- Genetic experiments demonstrate that certain IL-6R polymorphisms are associated with lower levels of CRP and reduced CV risk

Ridker PM and Luscher TF. European Heart Journal, Volume 35, Issue 27, 14 July 2014, Pages 1782–1791

Decades of research have indicated elevated CRP as a predictor of major CV events

- High levels of CRP are a known risk factor for ASCVD, nearly tripling risk of occurrence of MACE in one study[1]
- CRP levels ≥2.0 mg/L is listed as a risk-enhancing factor alongside elevated LDL-C and other well-known risk factors by the ACC & AHA[2]
- Chronic inflammatory conditions associated with elevated CRP such as RA are also included along with primary hypercholesterolemia and metabolic disorders as potential risk factors[2]
- Multiple large cardiovascular outcome studies have demonstrated reductions in CRP were associated with improved outcomes and has been a powerful predictor for therapeutic benefit[3]



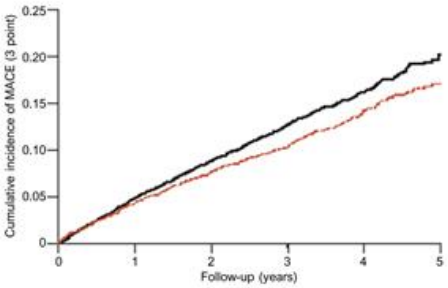
1. Ridker et al., NEJM (2000)
2. Arnett et al., J Am Coll Cardiol (2019)
3. CARE (pravastatin); JUPITER (rosuvastatin); CANTOS (canakinumab); CLEAR (bempedoic acid)
4. Ridker et al., PROVE-IT (atorvastatin vs pravastatin), NEJM (2005)

Analysis from CANTOS highlights the therapeutic potential of IL-6 inhibition in ASCVD

In canakinumab's Phase 3 CV outcomes trial (CANTOS) greater IL-6 and hsCRP reductions associated with greater CV benefit

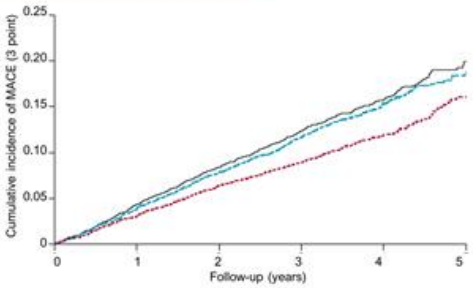
CANTOS primary endpoint[1]

	HR	(95% CI)	p
Placebo	1	(ref)	(ref)
Canakinumab, 150 mg	**0.85**	(0.74-0.98)	P=0.021



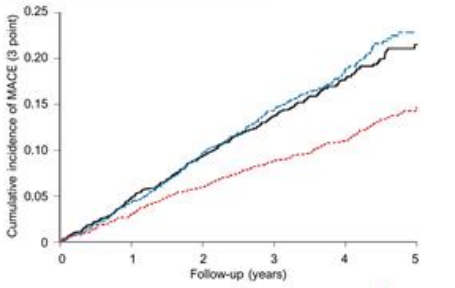
CANTOS stratified by hsCRP reductions[2]

	HR	(95% CI)	p
Placebo	1	(ref)	(ref)
On-treatment hsCRP ≥ 2.0 mg/L	0.95	(0.84-1.09)	0.48
On-treatment hsCRP <2.0mg/L	**0.75**	(0.66-0.85)	<0.0001



CANTOS stratified by IL-6 reductions[3]

	HR	(95% CI)	p
Placebo	1	(ref)	(ref)
On-treatment IL-6 ≥ 1.65 ng/L	1.06	(0.90-1.25)	0.49
On-treatment IL-6 < 1.65 ng/L	**0.64**	(0.54,0.77)	<0.0001

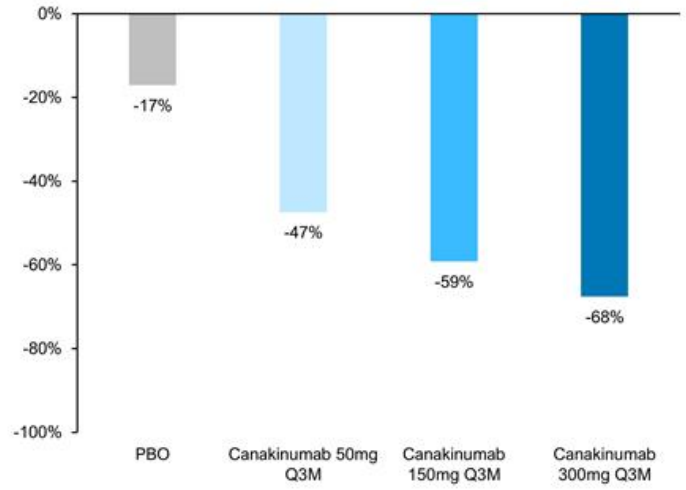


Hazard ratio improvement

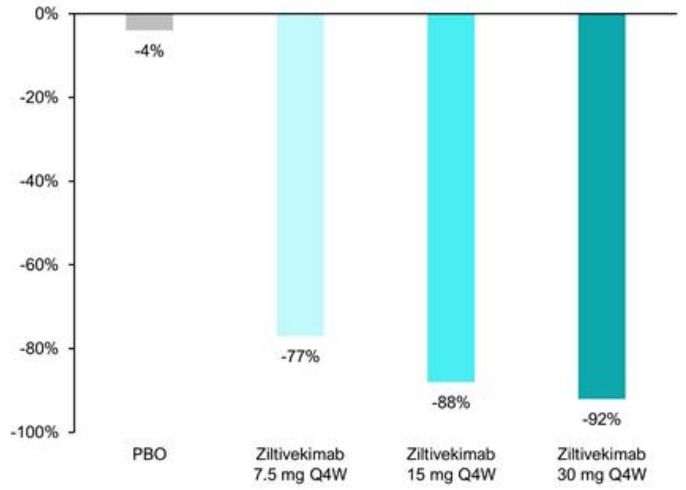
1. Ridker et al., N. Engl. J. Med. (2017)
2. Ridker et al., Lancet (2018)
3. Ridker et al., Eur. Heart J. (2018)

Ziltivekimab, an anti-IL-6 antibody developed by Corvidia, produced deeper CRP reductions than canakinumab

Canakinumab only achieved 59-68% median CRP reduction at higher doses at week 12[1]



Primary endpoint of Phase 2b RESCUE study: 92% reduction in median CRP at week 12[2]



1. Ridker et al, NEJM (2017)
2. Ridker et al., Lancet (2021)

Novo studying ziltivekimab in ZEUS, a Ph3 CV outcomes trial in ASCVD patients with kidney disease[1]

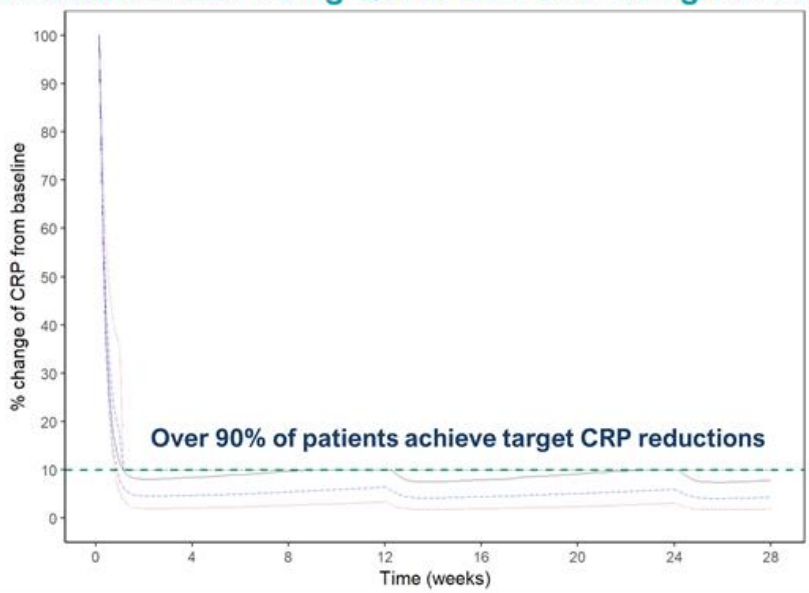
*Composite CKD endpoint includes: ≥ 40 GFR reduction, kidney death, CKD stage 5, dialysis treatment or kidney transplant
CVOT: Cardiovascular outcomes trial; ASCVD: Atherosclerotic cardiovascular disease; CKD: Chronic kidney disease; hsCRP: High-sensitivity c-reactive protein; MACE: Major adverse cardiovascular event; HF: Heart failure

Potential opportunity for TOUR006 to enter market with a less frequently administered product

1. Novo Nordisk R&D Day Investor Deck June 28, 2021
2. Estimated primary completion date listed on Clinicaltrials.gov: NCT05021835

PK/PD modeling for TOUR006 supports potential for quarterly administration

Simulations with 50mg Q12W with CRP >2mg/L & <10mg/L



Black straight line is the median

Red dotted lines are the 5th and the 95th percentiles

Blue dotted lines are the 25th and 75th percentiles

Green dashed line 90% decline of the CRP from baseline

Note: To mitigate against ceiling effects from CRP levels entering into the normal range, any patient with CRP attaining a value < 2 mg/L was considered to have achieved a 90% decrease from baseline in CRP

Source: Tourmaline PK/PD modeling, conducted by Certara

Potential Phase 2 CV trial*

SC monthly treatment: Day 1, Month 1, Month 2, & Month 3

Note: arms with quarterly administered TOUR006 will receive placebo on Months 1 and 2

Follow-up through Month 12 visit

Study population:

- Study population similar to RESCUE trial
- Exclude patients at higher risk for safety complications (e.g., immunocompromised patients)

Key endpoints:

- PD: hsCRP and other biomarkers
- PK, ADA
- Safety

*Trial design is preliminary and subject to change

Next Steps

Near-term catalysts

Indication	Milestone	Expected timing	Status
TED	Gain FDA alignment on proposed TED program	Q2 2023	☑
	File TED IND	Mid-2023	☑
	Initiate Phase 2b TED trial	Q3 2023	☐
	Initiate TED basket trial	Early 2024	☐
ASCVD	Gain FDA alignment on proposed CV program	Q4 2023	☐
	Initiate Phase 2 CV trial	2024	☐


TOURMALINE