# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 6-K

# REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of May 2022

Commission File Number: 001-36582

Altamira Therapeutics Ltd. (formerly Auris Medical Holding Ltd.)

(Exact name of registrant as specified in its charter)

Clarendon House, 2 Church Street Hamilton HM 11, Bermuda (Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:
Form 20-F ⊠ Form 40-F □
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):
Yes □ No ⊠
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):
Yes □ No ⊠

#### INCORPORATION BY REFERENCE

This Report on Form 6-K, including the exhibit to this Report on Form 6-K, shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-228121, 333-249347, 333-261127 and 333-264298) and Form S-8 (Registration Number 333-232735 and 333-252141) of Altamira Therapeutics Ltd. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

## 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, thereunto duly authorized.

Altamira Therapeutics Ltd.

Date: May 17, 2022 By: <u>/s/ Thomas Meyer</u>

Name: Thomas Meyer Title: Chief Executive Officer

# EXHIBIT INDEX

Exhibit Number		
Number	Description	
99.1	Shareholder Letter dated Spring 2022	





Letter to Shareholders

Spring 2022

Dear Altamira Therapeutics Shareholders,

2021 was a transformational year for Altamira in which we acquired a powerful, innovative RNA therapeutics platform and related IP (Trasir Therapeutics). Since then, we have laid the foundation for repositioning our business toward what we strongly believe to be RNA's exciting, major growth potential and our opportunity to transform the treatment of cancer and other debilitating diseases.

At the same time, we have accomplished several important milestones with our non-RNA legacy assets, notably the launch of our Bentrio<sup>TM</sup> non-drug nasal spray for protection against airborne allergens and viruses. Here, we set the stage for global commercialization primarily through distributors, already covering over 20 countries so far. Concurrently, we have made excellent progress with AM-125, our betahistine nasal spray for vertigo. Both of these sprays are approaching important clinical and regulatory milestones in the weeks and months ahead.

I will start with a thorough summary of our RNA therapeutics business and cover its marketplace, our technology, and our strategy. I will follow that with a discussion of our two nasal sprays, Bentrio and AM-125, as well as their progress toward important catalysts in the current quarter.

#### Altamira Pivot to Become RNA Pure Play

We are currently in the process of pivoting our business toward becoming a pure-play RNA therapeutics company centered on technology designed to enable effective and safe delivery of RNA molecules to diseased tissues outside the liver - offering tremendous opportunities in this fast-growing and disruptive sector of human medicine. At the same time, we expect to unlock the intrinsic value of our legacy assets that includes the planned divestiture or spin-off of those assets targeted for the second half of 2022.

# RNA: Fast-Growing Medical Segment Attracting Capital

Over the last few years, the RNA therapeutics industry has gained worldwide attention. There is a substantially unmet need in the arena of RNA therapeutics that we expect to fulfill. According to recent market studies, the global market for messenger RNA (mRNA) therapeutics and vaccines is forecast to grow from \$46.7 billion in 2021 to more than \$100 billion by 2026. Additionally, the short interfering RNA (siRNA) market generated nearly \$5 billion in sales in 2021 and is projected to expand to nearly \$11 billion by 2026. We believe that this is only scratching the surface of RNA therapeutics' long-term growth potential.

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The RNA-based biotech sector has also piqued the interest of Big Pharma as seen through recent major capital investments via the following acquisitions:

- Tidal Therapeutics (mRNA delivery), in pre-clinical stage, was acquired in 2021 by Sanofi for \$160 million up front and up to \$310 million in milestone payments.
- Translate Bio (mRNA delivery) was recently acquired by Sanofi for \$3.2 billion.
- Dicerna (specializing in hepatic delivery) was recently acquired by Novo for \$3 billion.

#### Altamira RNA Technology - A Primer

Our main goal for Altamira is to become a leading biomedical company focused on developing and commercializing RNA therapeutics. The use of RNA therapeutics to control the expression of disease-relevant genes – be it either siRNA, mRNA, or other types – holds great promise.

Currently, delivery of RNA therapeutics into the right cell of the right tissue has been one of the key challenges preventing their more widespread adoption. So far, most RNA therapeutics have been directed at the liver, using delivery platforms based on lipid nanoparticles, while delivery to non-liver (extrahepatic) tissues has remained largely elusive.

Our proprietary nanoparticle delivery platform OligoPhore<sup>TM</sup> and its equivalent SemaPhore<sup>TM</sup> can engage any type of siRNA or mRNA, respectively, in rapid self-assembly. Our platform enables delivery to target tissues outside the liver, creating the potential for developing RNA-based therapies for a range of substantially underserved indications, giving us a substantial competitive advantage in the industry.

Based on positive results obtained with OligoPhore delivering various siRNA payloads in more than ten different pre-clinical disease models, we have selected KRAS-driven cancer as the first indication in which we will seek to demonstrate clinical proof of concept. Further, we expect to enhance our business and revenue model, and leverage our OligoPhore/SemaPhore platform, by out-licensing this technology to biotech and pharmaceutical companies in exchange for non-dilutive cash fees.



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#### Altamira's RNA Business and Tech Strategy

In order to execute fully on our RNA strategy, I'm delighted to note that our growing RNA business is led and managed by two outstanding executives with vast experience in the RNA field:



#### Samuel Wickline, MD, as Chief Scientific Officer.

Dr. Wickline is the founder of Trasir Therapeutics and lead inventor of the OligoPhore/SemaPhore technology. He has had a distinguished career at Washington University and the University of South Florida.



### Covadonga Paneda, Ph.D., as Chief Development Officer.

Dr. Paneda brings over 15 years of experience in drug development and over seven years of experience as an R&D manager at the clinical-stage RNA biopharma company Sylentis.

Next, I will discuss our plans for our project AM-401 to achieve its first clinical proof of concept utilizing our proprietary RNA therapeutic platform and siRNA for targeting KRAS genes in cancer.

For background, the KRAS gene encodes the RAS protein, which controls cellular functions such as cell growth, maturation, and death like an "on/off switch." The RAS proteins can be rendered persistently active, causing cancer cells to grow and spread in the body, which is why it has been called "the beating heart of cancer." KRAS-driven cancers involve mutations of KRAS genes and are associated with poor prognosis in several types of cancers.

There is a substantial body of evidence supporting the role of KRAS in the initiation and maintenance of cancer. Mutated forms of KRAS are found in one-fifth of all human cancers, including 32% of non-small-cell lung cancers (NSCLCs), 40% of colorectal cancers (CRCs), and 85–90% of pancreatic cancers. Although the role of KRAS mutations in cancer has been known for decades, they have remained a challenging target for therapeutic interventions.

KRAS was long considered "undruggable," in part because its surface lacked obvious binding sites. Our therapeutic objective for AM-401 is to slow down KRAS-driven tumor cell growth and proliferation, or to stop it altogether by delivering siRNA specifically inside tumor cells. We intend to review and discuss plans for IND-enabling preclinical studies with the FDA and aim to file for an IND in 2023 to conduct a Phase 1 clinical trial in patients with KRAS-driven cancer.

As we invest in our transition to RNA, we have also made substantial progress in our legacy businesses.



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#### Altamira's Bentrio Program

Last year, we launched Bentrio, a drug-free nasal spray, classified as an OTC medical device, into early global commercialization to help protect against airborne allergens and viruses. We are excited about the significant opportunities that are available to us to penetrate both the airborne allergy and viral infection markets. In the wintertime alone, we inhale over 10,000 bacteria and 100,000 virus particles per hour, which highlights the permanent exposure to potentially harmful pathogens even in the absence of a pandemic. According to scientists, there are more than 1,400 human pathogens known, and on average two new viruses are added per year. COVID-19 made people more aware of the risk of viral infections and has created a renewed interest and demand for protection.





#### **Bentrio Global Commercialization**

Over the last several months, we have made solid progress expanding Bentrio's market footprint. So far, we have entered into marketing and distribution agreements covering more than 20 international markets, primarily in Asia and MENA countries. As usual, regulatory clearance has to be obtained in all of these markets prior to starting the commercialization.

I would like to highlight that we entered into a strategic agreement with Nuance Pharma covering China, Hong Kong, Macau, and South Korea. For that, we received an upfront payment of USD \$1 million and may receive development and commercial milestones of up to \$22.5 million and, upon production transfer in a few years, a staggered royalty on net sales at a high-single to low-double-digit percentage.

For the important US market, in October 2021 we filed a 510(k) application with the FDA for premarket clearance for treatment of hay fever and allergy sufferers. The review process is ongoing, and we look forward to working with the Agency to bring Bentrio to the more than 20 million allergic rhinitis sufferers in the US.

We plan to cover all the major global markets, primarily through top-tier regional distributors that excel in OTC product marketing and distribution to exploit their expertise and economies of scale – thereby relieving Altamira of the out-of-pocket expense of such distribution.

#### **Bentrio Clinical Studies and Data Readouts**

In terms of our Bentrio clinical trials for the allergy indication, we expect readouts from the house dust mite challenge study in Canada in the second quarter of this year, and we expect the NASAR trial in Australia for seasonal allergies to report data either in the fourth quarter of 2022 or the first quarter of next year.

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Regarding the viral indication, our COVAMID clinical trial in Bulgaria rapidly reached the midpoint for enrollment of patients with acute COVID-19. Recently, we also received regulatory approval from the North Macedonia Ministry of Health to extend the trial there, strengthening our ability to meet our recruitment objective of 136 patients. Based on a blinded interim analysis to confirm the validity of statistical assumptions, we may increase the target to up to 180 subjects. We estimate that the trial may be completed by the third quarter of 2022.



#### Clinical Data from AM-125 for Vertigo

Lastly, I will touch on the developments of the AM-125 program for vertigo. We remain excited about the prospects of our drug to fill an important gap in the US market and address a potential \$1 billion global vertigo treatment market. The product is an intranasal formulation of betahistine, widely used for decades in an oral (tablet) form as a vestibular stimulant and standard of care in vertigo treatment. Our AM-125 nasal spray has been shown to provide 5 to 29 times higher bioavailability than orally administered betahistine.

AM-125 is currently being evaluated in the phase 2 TRAVERS clinical trial with patients experiencing acute vertigo following neurosurgery. The interim analysis after the first part of the trial demonstrated a dose-dependent improvement in balance as well as good safety and tolerability of ascending doses of AM-125. At its highest dosage of 20 mg, 3x daily, patients treated with AM-125 demonstrated a 2.6-fold improvement in the tandem Romberg test performance from baseline to six weeks compared to those receiving placebo (i.e., they maintained their balance for much longer).

We expect to receive topline data of the full trial, i.e., including the second part, in the current quarter. Additionally, we are preparing to submit an IND to the FDA for the next steps in AM-125's clinical development. Similar to the KRAS AM-401 product business model, we expect to pursue partnership opportunities to scale the business and expand our market share in the vertigo market.

#### To summarize, our key catalysts over the next few quarters include:

- Plan to submit an IND to the FDA in 2023 for KRAS-driven cancer treatment using our OligoPhore platform with siRNA targeting KRAS.
- Expect readouts on the Bentrio house dust mite challenge study with allergic rhinitis patients in 2Q-22.
- Topline data reporting from our AM-125 TRAVERS Phase 2 is anticipated in 2Q-22.
- Prepare submission of an IND to the FDA for AM-125 for its further clinical development in vertigo.
- Expect to report topline date from Bentrio seasonal allergic rhinitis NASAR clinical trial either in 4Q-22 or 1Q-23.
- Expect to complete the Bentrio COVAMID trial in acute COVID-19 in 3Q-22.
- Anticipate FDA feedback on our Bentrio 510(k) pre-market clearance submission.

I am proud of our team's hard work and dedication to lay the groundwork for our pivot toward the highly attractive RNA therapeutics market, while at the same time unlocking value in our legacy business. I am excited to be part of the ongoing RNA revolution in medicine as well as for the potential of both of our nasal sprays to help many people protect themselves against airborne allergens and viruses, or to regain their sense of balance.

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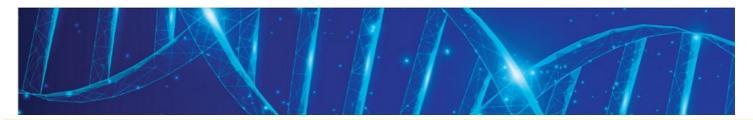
On behalf of everyone at Altamira, I want to thank all of our fellow shareholders for their patience and support. I am confident that we have set the right strategy and will build value for our shareholders near- and long-term.

Sincerely yours,

Thomas Meyer CEO and Chairman

#### Safe Harbor Disclosure

This shareholder letter may contain statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical facts and may include statements that address future operating, financial or business performance or Altamira Therapeutics' strategies or expectations. In some cases, you can identify these statements by forward-looking words such as "may", "might", "will", "should", "expects", "plans", "anticipates", "estimates", "predicts", "projects", "potential", "outlook" or "continue", or the negative of these terms or other comparable terminology. Forward-looking statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments, and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include, but are not limited to, the approval, timing of commercialization, and commercial success of AM-301; Altamira Therapeutics' need for and ability to raise substantial additional funding to continue the development of its product candidates; the timing and conduct of clinical trials of Altamira Therapeutics' product candidates; the clinical utility of Altamira Therapeutics' product candidates; the timing or likelihood of regulatory filings and approvals; Altamira Therapeutics' intellectual property position; and Altamira Therapeutics' financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions, or changes to Altamira Therapeutics' capital structure, including future securities offerings. These risks and uncertainties also include, but are not limited to, those described under the caption "Risk Factors" in Altamira Therapeutics' Annual Report on Form 20-F for the year ended December 31, 2021, and in Altamira Therapeutics' other filings with the SEC, which are available free of charge on the Securities Exchange Commission's website at: www.sec.gov. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated. All forward-looking statements and all subsequent written and oral forward-looking statements attributable to Altamira Therapeutics or to persons acting on behalf of Altamira Therapeutics are expressly qualified in their entirety by reference to these risks and uncertainties. You should not place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date they are made, and Altamira Therapeutics does not undertake any obligation to update them in light of new information, future developments, or otherwise, except as may be required under applicable law.



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