



## Altamira Therapeutics Provides Business Update, Reports FY 2022 Financial Results

May 16, 2023 11:30 AM EDT

- ***Management will host an investor conference call today, May 16th, at 8 a.m. Eastern***
- ***Company is advancing OligoPhore™ / SemaPhore™ platform for extrahepatic RNA delivery and efficient endosomal release; expects first research collaborations with biopharmaceutical companies in 2023***
- ***Filed IND submission with FDA for AM-125 in acute vestibular syndrome***
- ***'Showcase' RNA development programs AM-401 and AM-411 progressing in KRAS-driven cancers and rheumatoid arthritis, targeting INDs in 2024***
- ***Divestiture or partnering of legacy assets remains a key strategic focus***
- ***Top-line data from full NASAR trial with Bentro in seasonal allergic rhinitis expected in the second quarter***

**HAMILTON, BERMUDA / ACCESSWIRE / May 16, 2023** / Altamira Therapeutics Ltd. (NASDAQ:CYTO) ("Altamira" or the "Company"), a company dedicated to addressing unmet medical needs, today provided a business update and reported its full year 2022 financial results ended December 31, 2022.

"We continue to make good progress on our journey to become a leading provider of innovative RNA delivery technology," stated Thomas Meyer, Altamira Therapeutics' founder, Chairman, and CEO. "Our OligoPhore / SemaPhore platforms are designed to address two major challenges in the development of RNA therapeutics. The first is delivery to tissues and organs other than the liver, for example for the treatment of cancers, autoimmune, or inflammatory disorders. The second is the effective and rapid release of the RNA payloads within target cells. We are excited to see interest in our technology growing steadily and, accordingly, we are confident we will enter into our first collaboration agreements this year with biopharmaceutical companies.

"At the same time, we are fast approaching important clinical and regulatory milestones with our legacy programs in OTC consumer health and in inner ear therapeutics," Mr. Meyer added. "This month, we expect to receive top-line data from the recently completed NASAR trial with Bentro in seasonal allergic rhinitis. We just submitted an Investigational New Drug (IND) filing to the Food and Drug Administration (FDA) for AM-125 in acute vestibular syndrome on which we expect to receive comments or clearance in the weeks ahead.

"These milestones will be important elements in our strategy to divest or partner the legacy programs as the second step in our transformation to become a leading pure-play technology platform company in RNA delivery technology. Through this process, we expect to unlock the intrinsic value of our legacy businesses. While it has taken longer than initially expected, we look forward to major progress and its conclusion this year."

### **RNA Delivery Technology Update**

Altamira has been making good progress with its strategic pivot to RNA delivery technology around its OligoPhore / SemaPhore platforms. The technology is based on a patented peptide for delivery of RNA in nanoparticles to extrahepatic tissues and efficient endosomal release inside target cells. It has been successfully tested in numerous animal disease models with both siRNA (short interfering RNA) and mRNA (messenger RNA). Recently, additional promising data were reported:

- At the 2023 Osteoarthritis Research Society International (OARSI) World Congress held in March in Denver, a Washington University research group presented data from a mouse model of meniscal injury. Systemic delivery of DNA-methyltransferase 3 beta (DNMT3B) mRNA with SemaPhore nanoparticles significantly reduced bone sclerosis, cartilage degeneration, and synovitis (inflammation of the connective tissue lining the inside of a joint capsule) compared to controls. In addition, functional studies showed significantly decreased pain sensitivity and improved weight bearing.
- In a March 2023 article preprint, another Washington University research group presented data from a mouse model of sarcoma and metastatic breast cancer. Systemic delivery of ZBTB46 (zinc finger and BTB domain containing 46) mRNA with SemaPhore nanoparticles promoted anti-tumor components in the tumor microenvironment and resulted in the restriction of tumor growth. When the nanoparticle treatment was combined with an anti-PD1 immune checkpoint inhibitor, significant synergistic effects in the control of tumor growth were observed, generating long-term complete remission of tumor mass in many of the treated animals.

Since 2022, Altamira has stepped up its efforts to present and promote its OligoPhore / SemaPhore platforms at international conferences and its business development activities targeted at potential partners in the biopharmaceutical industry. In general, consistent with its capital efficient RNA business model, the Company plans to focus on providing its nanoparticle technology to licensees rather than develop and commercialize its own drug products.

Concurrently, the Company continued the development work on its two 'showcase' development programs with the OligoPhore platform for siRNA delivery - AM-401 for the treatment of KRAS-driven tumors and AM-411 for the treatment of rheumatoid arthritis (NF-kB). In February 2023, Altamira expanded its intellectual property estate by filing a provisional patent application relating to single polyvalent siRNA sequences which as part of AM-401 can target different KRAS mutations (*polyKRAS<sup>mut</sup>*). If granted, the patent would extend IP coverage for the program to 2043. Altamira aims to advance both AM-401 and AM-411 to an IND filing with the FDA in 2024 and plans to out-license them either following the IND or after a Phase 1 clinical trial at the latest.

### **Bentrio® Nasal Spray**

The clinical development program for Bentrio, the Company's novel drug-free nasal spray for protection against harmful airborne particles such as allergens, is nearly complete. In February 2023, data from three clinical studies were presented at the Annual Meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) in San Antonio, TX. In two randomized controlled crossover studies, Bentrio was shown to provide effective protection for patients in both seasonal and perennial allergic rhinitis under controlled exposure to grass pollen and house dust mites, respectively, for several hours. These positive outcomes were corroborated by a third study which demonstrated in healthy volunteers that Bentrio has a significantly longer nasal residence time within the nasal cavity and, compared to a classic saline nasal spray (3.5 hours vs. 1 hour), provides wider distribution and coverage therein.

The data read-out from the NASAR trial in Australia will complete the Altamira development program in allergic rhinitis. The study enrolled 100 patients suffering from seasonal allergic rhinitis who were treated for two weeks either with Bentrio or with a classic saline nasal spray as the current standard of care in drug-free treatments. In January 2023, the Company reported that an interim analysis based on the data from the first 53 NASAR participants showed a statistically significant reduction of nasal symptoms with Bentrio vs. the control as well as good tolerability and safety. The results from the complete trial are expected to become available in the month of May.

In contrast, the outcomes from the COVAMID trial with Bentrio in 160 patients suffering from acute COVID-19 which were reported in January 2023, were inconclusive under the specific test conditions. Although a trend for faster and more pronounced reduction in nasal viral load and symptoms was observed with Bentrio vs. the untreated controls, the differences were not deemed statistically significant. Altamira considers that the more benign outcomes from the Omicron variant resulted in more pronounced spontaneous recovery, and treatment may have started too late in the trial (about 4.5 days after infection). As previous studies with Bentrio on cultured human nasal epithelia cells exposed to various types of viruses had shown best results from prophylactic treatment application, the Company concluded that Bentrio is best used right before or while being exposed to virus particles. No further studies in viral infection are ongoing or planned.

As part of its strategic pivot to a pure-play RNA delivery technology company, Altamira initiated discussions last year with several well-established OTC consumer health companies for partnering on Bentrio for North America, Europe, and other key international markets. These discussions and related due diligence have extended into 2023 and are still ongoing at this point. In the context of these partnering discussions, the Company suspended preparations for launching the product in the US on its own and minimized marketing and sales activities in Europe. Meanwhile, the Company's existing distribution partners launched Bentrio in several Asian geographies, including Singapore, Malaysia, Indonesia, the Philippines, and Hong Kong.

### **Inner Ear Therapeutics**

In June 2022, the Company announced positive top-line data from its Phase 2 TRAVERS trial with AM-125, a patented nasal spray formulation of betahistine for the treatment of acute vestibular syndrome (AVS). Detailed results were published in a peer-reviewed article in *Otology & Neurotology*, one of the leading journals in scientific and clinical inner ear research, in April 2023. AVS is characterized by the sudden onset of continuous vertigo lasting days to weeks and may be associated with nausea, head motion intolerance, and unstable balance. The randomized, double-blind, placebo-controlled TRAVERS trial enrolled a total of 124 patients, at more than 10 study sites across Europe, who suffered from AVS following surgery for the removal of a tumor. The trial demonstrated good tolerability of AM-125. Further, administration of AM-125 resulted in a dose- and time-dependent improvement in balance, and signs and symptoms of vestibular dysfunction.

Based on the positive outcomes from TRAVERS, the Company filed an IND application this past week with the FDA. The IND, if granted, would allow conducting clinical trials with AM-125 in the US as well. The submission includes the protocol for a Phase 2 trial in the treatment of posterior canal benign paroxysmal positional vertigo (BPPV), which is the most common type of vertigo and characterized by repeated episodes of vertigo produced by changes in the head position relative to gravity. A recently published meta-analysis shows statistically significant improvement in dizziness handicap for BPPV patients when treated with oral betahistine over the standard of care procedure alone. By avoiding the fast metabolism after oral intake, intranasal delivery of AM-125 achieves higher bioavailability of betahistine (5-to-29 times higher).

In the context of its strategic pivot to RNA delivery technology, Altamira intends to divest or partner the AM-125 program for further development and commercialization that includes the implementation of a Phase 2 clinical study. To this end, the Company has initiated discussions with a number of potential partners and expects to intensify such efforts following now that the IND has been submitted.

### **Full Year 2022 Financial Results**

- Revenues for the full year of 2022 were CHF 0.3 million compared to CHF 0.1 million for the full year of 2021. The 2022 revenues exclude a non-refundable upfront license fee of CHF 0.9 million from Nuance Pharma related to the marketing and distribution of Bentrio in Mainland China, Hong Kong, Macau and South Korea which was deferred for revenue recognition.[1]
- Total operating loss for the full year of 2022 was CHF 26.1 million, or CHF 13.7 million before a one-time non-cash write-off (impairment) of capitalized development expenditures for the AM-125 project based on impairment testing under IFRS, compared with CHF 16.8 million for the full year of 2021.
- Research and development expenses for the full year of 2022 were CHF 19.7 million, or CHF

7.3 million before the aforementioned one-time non-cash write-off (impairment) of capitalized development expenditures for the AM-125 project, compared with CHF 8.4 million for the full year of 2021.

- General and administrative expenses for the full year of 2022 were CHF 3.6 million compared with CHF 4.9 million for the full year of 2021.
- Net loss for the full year of 2022 was CHF 26.5 million, or CHF 14.1 million before the aforementioned one-time non-cash write-off (impairment) of capitalized development expenditures for the AM-125 project, compared with CHF 17.1 million for the full year of 2021.
- Cash and cash equivalents on December 31, 2022 totaled CHF 15 thousand compared with CHF 1.0 million at December 31, 2021.

*[1]Revenue recognition for the upfront payment is deferred until transfer of production to Nuance, which will occur 4 years after Nuance obtaining the first national registration of Bentrío® in the territory or upon Nuance's cumulative orders for Bentrío® reaching a contractually defined minimum quantity of Bentrío® from the Company, whichever comes later. The upfront payment was incorrectly recorded as revenue in the Unaudited Condensed Consolidated Interim Financial Statements of the Company as of June 30, 2022 and for the six months ended June 30, 2022, furnished with the Securities and Exchange Commission on November 30, 2022. The Company will reflect the adjustment in the comparatives included in the June 30, 2023 financial statements, and will reflect the adjustment in restated financial statements as of June 30, 2022 and for the six months ended June 30, 2022 to be filed with a Form 6-K/A at a later date.*

In April 2023, the convertible loan issued to Altamira 14 months earlier by FiveT Investment Management was converted by the lender into common shares, resulting in a reduction in financial liabilities of CHF 5.6 million. The Company expects its additional cash need for FY 2023 to be in the range of CHF 15 million to 17 million, which it intends to fund through a combination of the planned divestiture or partnering of its legacy assets, equity offerings, debt financings, and grants.

During the first four months of 2023, Altamira raised CHF 4.5 million from share issuances under the "at the market" program with A.G.P. and the equity line with Lincoln Capital Partners. Further, in early May 2023, the Company raised CHF 2.5 million through a convertible loan provided by FiveT Investment Management. The loan bears interest at the rate of 10% per annum and matures 22 months from May 4, 2023.

#### **FY2022 Investor Teleconference Details**

Altamira management will hold an investor call **today, Tuesday, May 16, 2023, at 8:00 a.m. ET** to discuss its business update and full-year 2022 results. The presentation will be available via teleconference or webcast with audio <https://www.webcaster4.com/Webcast/Page/2797/48448>.

- **Date: Tuesday, May 16, 2023**
- **Time: 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time)**
- **Webcast URL:** <https://www.webcaster4.com/Webcast/Page/2797/48448>
- **Toll-free dial-in number:** 888-506-0062
- **International dial-in number:** 973-528-0011
- **Participant Access Code:** 250106

#### **Conference Call Replay**

A replay of the call will be available after the live event and archived for two weeks until Tuesday, May 30, 2023.

- **Toll-free dial-in number:** 877-481-4010
- **International dial-in number:** 919-882-2331
- **Replay Passcode:** 48448

#### **Consolidated Statement of Profit or Loss and Other Comprehensive Income/(Loss)**

For the Years Ended December 31, 2022 and 2021

(in CHF)

	2022	2021 <sup>1)</sup>
<b>Revenue</b>	<b>305,616</b>	<b>63,882</b>
Cost of Sales	(1,443,855 )	(2,240,554 )
<b>Gross profit</b>	<b>(1,138,239 )</b>	<b>(2,176,672 )</b>
Other operating income	709,449	214,217
Research and development	(19,677,756 )	(8,360,821 )
Sales and marketing	(2,381,384 )	(1,498,218 )
General and administrative	(3,644,549 )	(4,946,576 )
<b>Operating loss</b>	<b>(26,132,479 )</b>	<b>(16,768,070 )</b>
Interest income	969	3,219
Interest expense	(911,869 )	(189,695 )

Foreign currency exchange gain/(loss), net	54,645	328,641
Revaluation gain/(loss) from derivative financial instruments	451,131	(410,918 )
Transaction costs	(1,137 )	-
<b>Loss before tax</b>	<b>(26,538,740 )</b>	<b>(17,036,823 )</b>
Income tax gain/(loss)	10,329	(21,620 )
<b>Net loss attributable to owners of the Company</b>	<b>(26,528,411 )</b>	<b>(17,058,443 )</b>
<b>Other comprehensive income/(loss):</b>		
Items that will never be reclassified to profit or loss		
Remeasurements of defined benefit liability, net of taxes of CHF 0	441,277	264,984
<b>Items that are or may be reclassified to profit or loss</b>		
Foreign currency translation differences, net of taxes of CHF 0	61,046	772
<b>Other comprehensive income/(loss), net of taxes of CHF 0</b>	<b>502,323</b>	<b>265,756</b>
<b>Total comprehensive loss attributable to owners of the Company</b>	<b>(26,026,088 )</b>	<b>(16,792,687 )</b>
Basic and diluted loss per share	(29.13 )	(25.76 )

1) Revised 2) Weighted average number of shares outstanding: 2022: 910,723; 2021: 662,314.

### Consolidated Statement of Financial Position

As of December 31, 2022 and 2021  
(in CHF)

	December 31, 2022	December 31, 2021 <sup>1)</sup>
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property and equipment	1	1
Right-of-use assets	445,827	564,714
Intangible assets	3,893,681	14,314,877
Other non-current financial assets	194,263	199,105
<b>Total non-current assets</b>	<b>4,533,772</b>	<b>15,078,697</b>
<b>Current assets</b>		
Inventories	11,644	839,221
Trade receivables	6,525	21,746
Other receivables	755,987	917,833
Prepayments	709,266	996,910
Derivative financial instruments	270,176	0
Cash and cash equivalents	15,395	984,191
<b>Total current assets</b>	<b>1,768,993</b>	<b>3,759,901</b>
<b>Total assets</b>	<b>6,302,765</b>	<b>18,838,598</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Share capital	236,011	149,643
Share premium	192,622,406	188,511,476
Foreign currency translation reserve	258,044	62,069
Accumulated deficit	(201,431,272 )	(175,686,937 )
<b>Total shareholders' (deficit)/equity attributable to owners of the Company</b>	<b>(8,314,811 )</b>	<b>12,704,528</b>
<b>Non-current liabilities</b>		
Derivative financial instruments	0	1,233
Non-current lease liabilities	343,629	461,485
Employee benefit liability	336,206	668,319
Deferred income	932,200	0
Deferred tax liabilities	125,870	142,484
<b>Total non-current liabilities</b>	<b>1,737,905</b>	<b>1,273,521</b>
<b>Current liabilities</b>		

Loan	5,869,797	0
Current lease liabilities	117,856	114,251
Trade and other payables	4,914,404	3,697,723
Accrued expenses	1,977,614	1,048,575
<b>Total current liabilities</b>	<b>12,879,671</b>	<b>4,860,549</b>
<b>Total liabilities</b>	<b>14,617,576</b>	<b>6,134,070</b>
<b>Total equity and liabilities</b>	<b>6,302,765</b>	<b>18,838,598</b>

1) Revised

## About Altamira Therapeutics

Altamira Therapeutics (Nasdaq:CYTO) is dedicated to developing and commercializing RNA delivery technology for extrahepatic targets (OligoPhore™ / SemaPhore™ platforms). The Company currently has two flagship siRNA programs in preclinical development beyond *in vivo* proof of concept: AM-401 for KRAS driven cancer and AM-411 for rheumatoid arthritis. The versatile delivery platform is also suited for mRNA and other types of RNA therapeutics and is planned to be leveraged via out-licensing to pharma or biotech companies. In addition, Altamira is in the process of divesting and/or out-licensing its legacy assets in allergology and viral infection (Bentrio® OTC nasal spray; commercial) and inner ear therapeutics (AM-125 nasal spray for vertigo; post Phase 2; Keyzilen® and Sonuvi® for tinnitus and hearing loss; Phase 3). Founded in 2003, Altamira is headquartered in Hamilton, Bermuda, with its main operations in Basel, Switzerland. For more information, visit: <https://altamiratherapeutics.com/>

## Forward-Looking Statements

This press release 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", "believes", "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 success of the continued commercialization of Bentrio and success of strategic transactions, including licensing or partnering, with respect to Bentrio or any other legacy assets, 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, 2022, 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](http://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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