Altamira Therapeutics Provides Business Update and First Half 2023 Financial Results

September 12, 2023 11:30 AM EDT

HAMILTON, BERMUDA, Sept. 12, 2023 (GLOBE NEWSWIRE) --

- Company hosts 1H 2023 Financial Results and Business Update call today at 8 a.m. ET
- First research collaboration with biopharmaceutical company initiated for OligoPhore™ platform
- Partnering discussions for legacy assets progressing with conclusion of clinical development program and opening of IND as key milestones for Bentrio® and AM-125
- Significant strengthening of shareholders' equity and balance sheet

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 first half 2023 financial results.

"We continue progressing with the strategic repositioning toward becoming a leading provider of innovative RNA delivery technology," commented Thomas Meyer, Altamira Therapeutics' founder, Chairman, and CEO. "We have achieved great strides in enhancing awareness and visibility of our OligoPhore™ / SemaPhore™ platforms for extrahepatic RNA delivery and efficient endosomal release; as a result, we recently entered into our first collaboration with a biopharmaceutical company. We look forward to working with Heqet Therapeutics, in the framework of this first collaboration, on their mission to develop treatments for cardiac regeneration, applying RNA with our OligoPhore™ platform. We are excited to see interest in our technology growing steadily and remain confident about the potential to develop further partnerships with biopharmaceutical companies.

"Meanwhile, we have reached important clinical and regulatory milestones in our legacy programs in OTC consumer health and inner ear therapeutics," Mr. Meyer added. "Our clinical trial with Bentrio in seasonal allergic rhinitis met the primary endpoint, adding further to our set of compelling efficacy data. In addition, the FDA cleared an IND for our AM-125 investigational drug in acute vestibular syndrome. These milestones are important elements in our ongoing partnering discussions."

"As part of our strategic pivot, we have adapted our organization, downsized activities especially in clinical development, and reallocated resources from our legacy programs towards our RNA delivery projects. This has allowed for a significant reduction in expense levels. At the same time, we have managed to significantly improve our shareholders' equity position while reducing financial liabilities."

RNA Delivery Technology

Altamira has continued to make progress with the further development of the RNA delivery technology around its OligoPhore™ / SemaPhore™ platforms, which are based on a patented peptide for delivery of RNA in nanoparticles to extrahepatic tissues and efficient endosomal release inside target cells. Two in vivo studies performed by independent research groups at Washington University School of Medicine (St. Louis, MO) using our SemaPhore™ platform provided further external validation of the technology. In a preprint, one research group presented animal data showing restriction of tumor growth with nanoparticles based on SemaPhore™ and ZBTB46 mRNA. Enforced ZBTB46 expression following treatment with the nanoparticles resulted in an immunostimulatory tumor microenvironment and restricted tumor growth. The effect was significantly potentiated when the treatment was combined with anti-PD1 immune checkpoint inhibition, suggesting that ZBTB46 mRNA delivered by SemaPhore™ nanoparticles could be an effective adjuvant therapy with immunotherapy in cancer management. Meanwhile, the other research group presented results from an animal study with DNMT3B mRNA nanoparticles based on Altamira's SemaPhore™ delivery technology at the Osteoarthritis Research Society International World Congress in Denver (CO). Local (intra-articular) administration of the nanoparticles to mice with meniscal injury resulted in strong induction of DNMT3B protein as well as significantly reduced bone sclerosis, cartilage degeneration, and synovitis (inflammation of the connective tissue lining the inside of a joint capsule). Functional studies showed significantly decreased pain sensitivity and improved weight bearing in active treated mice compared to controls.

At the same time, the Company advanced work on its two flagship development programs AM-401, for the treatment of KRAS-driven tumors, and AM-411, for the treatment of rheumatoid arthritis; targeting NF-kB, aiming for an IND submission in 2024. Altamira plans to out-license the two programs either following the IND or after a Phase 1 clinical trial at the latest. Importantly, the Company filed a provisional patent application relating to single polyvalent siRNA sequences which as part of AM-401 can target different KRAS mutations (*poly*KRAS^{mut}). If granted, the patent would extend IP coverage for the program to 2043.

In line with the Company's strategy of leveraging the OligoPhore™/SemaPhore™ through out-licensing and partnering rather than commercializing its own drug products, Altamira has significantly expanded its business development activities. This includes the engagement of Maria Grunwald, PhD, MBA, a highly experienced business developer based in Boston, as Senior Business Advisor.

On July 5, 2023 the Company announced that it entered into a collaboration and option agreement with Heqet Therapeutics s.r.l. ("Heqet"), a biotech spin-out from King's College London. Under the terms of the agreement, Heqet will test nanoparticles based on Altamira's OligoPhore™ delivery platform and comprising certain non-coding RNAs (ncRNAs) in the regeneration of damaged heart tissue following myocardial infarction in animal models. Upon successful conclusion of the experiments, Heqet will, under certain conditions, have the option to negotiate with Altamira for a license to use the Company's technology and intellectual property to translate its findings into the development of therapeutics for cardiac regeneration.

Bentrio® Nasal Spray

On May 24, 2023, Altamira announced positive results from the randomized controlled NASAR clinical trial evaluating Bentrio® nasal spray in patients with seasonal allergic rhinitis (SAR). The NASAR trial enrolled 100 SAR patients in Australia who were randomized at a 1:1 ratio to receive either Bentrio® or saline nasal spray for two weeks via self-administration three times per day, or as needed. For eligibility, patients had to have a baseline

reflective Total Nasal Symptom Score (rTNSS) of at least 5 points out of 12, referring to the worst level of nasal congestion, sneezing, nasal itching, and rhinorrhea (runny nose) within the past 24 hours averaged over a one-week treatment-free run-in period. The primary efficacy endpoint was defined as the difference in the average rTNSS over the subsequent 2-week treatment period between Bentrio® and saline nasal spray, the current standard of care in drug-free SAR management.

The rTNSS decreased in the Bentrio® group from 6.9 points in the pre-treatment period to an average of 5.0 points over the 14-day treatment period (i.e. -1.9 points), while the saline spray group showed a decrease from 6.9 to 6.2 points (i.e. -0.8 points). The reduction in nasal symptoms conferred by Bentrio® was thus 2.4 times larger than with saline nasal spray. The difference in rTNSS reduction of 1.1 points in favor of Bentrio® was statistically significant in the ANCOVA model (LSmeans; p = 0.012; 95% confidence interval -2.0 to -0.3), and the study thus met the primary efficacy endpoint. 63.3% of Bentrio®-treated study participants rated treatment efficacy as either good or very good vs. 29.2% of saline-treated participants. 73.5% of Bentrio®-treated study participants rated tolerability of the treatment as either good or very good vs. 85.5% of saline-treated participants.

The Company expects to release further results from the NASAR trial shortly and to submit an article for publication in a peer-reviewed medical journal. The data read-out from the NASAR trial completes the Bentrio® development program in allergic rhinitis. Previous clinical trials demonstrated the safety, tolerability and efficacy of Bentrio in patients exposed to grass pollen or house dust mites under controlled conditions and the extended nasal residence time of more than three hours in human volunteers. The accumulated data suggest that Bentrio®, based on a drug-free and preservative-free formulation, can help to effectively reduce the most common symptoms of allergic rhinitis similar to the reduction observed in response to medicated nasal sprays, but without the tolerability issues frequently experienced with the use of such sprays.

On July 20, 2023, Altamira announced that it entered into an exclusive agreement with Pharma Nordic AS for the marketing and distribution of Bentrio® in Norway and potentially further Scandinavian countries. The collaboration agreement will allow Pharma Nordic to market and commercialize Bentrio® in Norway beginning in the first quarter of 2024, and, subject to meeting certain milestones, also in Sweden, Finland, and Denmark later on. Discussions with potential marketing and distribution partners for the US and other key markets have continued to move forward and are still ongoing at this time. In the context of these partnering discussions, it has suspended preparations for launching the product in the US on its own and minimized marketing and sales activities in Europe.

Inner Ear Therapeutics

On June 29, 2023, the FDA completed its review of Altamira's IND application for AM-125 (betahistine nasal spray) in acute vestibular syndrome (AVS) and concluded that the proposed Phase 2 clinical trial with AM-125 in the treatment of posterior canal benign paroxysmal positional vertigo (BPPV), the most common type of vertigo, may proceed. The regulatory clearance opened the way for the clinical evaluation of AM-125 also in the United States. An earlier Phase 2 clinical trial conducted in Europe (the TRAVERS trial) demonstrated that a four-week treatment course with AM-125 in AVS patients, following surgical removal of a tumor behind the inner ear, was well tolerated and helped to accelerate vestibular compensation enabling patients to regain balance and recover faster. The new Phase 2 trial is designed to demonstrate AM-125's tolerability and clinical utility also in BPPV.

As previously announced, Altamira intends to divest or partner the AM-125 program for further development and commercialization in the context of its strategic pivot to RNA delivery technology. To this end, the Company has initiated discussions with a number of potential partners based on a structured approach.

First Half 2023 Financial Results and Financial Guidance

- Revenues for the first half of 2023 were CHF 0.1 million compared to CHF 0.3 million for the first half of 2022, reflecting the waning of SARS-CoV-2 infections and, more importantly, the aforementioned strategic decision to temporarily reduce commercial activities around Bentrio® in anticipation of partnering transactions for key markets.
- Total operating loss for the first six months of 2023 was CHF 4.6 million compared with CHF 8.4 million for the first six months of 2022, a reduction of 45.5%. The improvement was primarily driven by lower expenditures for research and development (CHF 2.3 million vs. CHF 3.6 million) as clinical trials wound down, and for marketing and sales (CHF 0.2 million vs. CHF 2.1 million) as commercial activities were reduced. General and administrative expenses slightly increased in the first half of 2023 to CHF 2.2 million from CHF 2.1 million in the first half of 2022 as higher costs related to capital market projects outweighed reductions in administrative expenditures.
- Net loss for the first half of 2023 was CHF 5.4 million compared with CHF 8.2 million for the first half of 2022.
- Financial liabilities decreased from CHF 5.9 million at the end of 2022 to CHF 3.1 million at June 30, 2023. Shareholders' equity improved at the same time from CHF -8.3 million to CHF -1.8 million. Cash and cash equivalents on June 30, 2023 totaled CHF 50 thousand compared with CHF 15 thousand at December 31, 2022.

In early July 2023 Altamira raised $5.0 million in equity through the public offering of 11,111,112 common shares (or pre-funded warrants) at $0.45 each and 11,111,112 warrants with an exercise price of CHF 0.40 and a 5-year duration. The transaction yielded net proceeds of CHF 3.7 million. The Company expects its total cash need in 2023 to be in the range of CHF 12 to 14 million and in the 12 months from the issuance date of these financial statements to be in the range of CHF 12 to 14 million.

First Half 2023 Investor Conference Call & Webcast Details

Altamira management will hold an investor teleconference **today, Tuesday, September 12, 2023, at 8:00 a.m. ET** to discuss its business update and first half 2023 results. Founder, Chairman, and CEO Thomas Meyer and COO Covadonga Pañeda will deliver prepared remarks followed by a Q&A session where they will address questions from investors and analysts.

Event: Altamira Therapeutics First Half 2023 Financial Results and Business Update Call
Date: Tuesday, September 12th
Time: 8am ET (5am PT)

Access:

Toll Free: 888-506-0062
International: 973-528-0011
Participant Access Code: 500382
Webcast URL: https://www.webcaster4.com/Webcast/Page/2797/48993

Investors can begin accessing the webcast 15 minutes before the call, where an operator will register your name and organization. The call will be in listen-only mode.

A replay of the call will be available 30 minutes after the live call via the Investors section of the Altamira website at https://ir.altamiratherapeutics.com/.

Replay Access:
Toll Free replay number: 877-481-4010
International: 919-882-2331
Replay Passcode: 48993
Expiration: September 26, 2023, 11:59 PM ET

Condensed Consolidated Interim Statement of Profit or Loss and Other Comprehensive Income or Loss (unaudited)

For the Six Months Ended June 30, 2023 and 2022 (in CHF)

	SIX MONTHS ENDED JUNE 30	
	2023	**2022**
Revenue	105,469	290,798
Cost of Sales	(212,181)	(1,192,232)
Gross profit	**(106,712)**	**(901,434)**
Other operating income	111,405	255,820
Research and development	(2,261,154)	(3,563,883)
Sales and marketing	(160,936)	(2,129,881)
General and administrative	(2,168,953)	(2,076,383)
Operating loss	**(4,586,350)**	**(8,415,761)**
Finance expense	(861,118)	(377,985)
Finance income	37,018	509,143
Loss before tax	**(5,410,450)**	**(8,284,603)**
Income tax gain/(loss)	(10,596)	46,085
Net loss attributable to owners of the Company	**(5,421,046)**	**(8,238,518)**
Other comprehensive income:		
Items that will never be reclassified to profit or loss		
Remeasurement of defined benefit liability, net of taxes of CHF 0	(28,847)	209,526
Items that are or may be reclassified to profit or loss		
Foreign currency translation differences, net of taxes of CHF 0	137,747	(63,477)
Other comprehensive income, net of taxes of CHF 0	**108,900**	**146,049**
Total comprehensive loss attributable to owners of the Company	**(5,312,146)**	**(8,092,469)**

Condensed Consolidated Interim Statement of Financial Position (unaudited)

As of June 30, 2023 and December 31, 2022 (in CHF)

	JUNE 30, 2023	**DECEMBER 31, 2022**
ASSETS		
Non-current assets		
Property and equipment	1	1
Right-of-use assets	387,737	445,827
Intangible assets	3,893,681	3,893,681
Other non-current financial assets	192,958	194,263
Total non-current assets	**4,474,377**	4,533,772
Current assets		
Inventories	270,503	11,644
Trade receivables	31,813	6,525
Other receivables	756,234	755,987
Prepayments	374,376	709,266
Derivative financial instruments	247,090	270,176

Cash and cash equivalents	49,569	15,395
Total current assets	**1,729,585**	**1,768,993**
Total assets	**6,203,962**	**6,302,765**
EQUITY AND LIABILITIES		
Equity		
Share capital	1,590,801	236,011
Share premium	15,560,642	192,622,406
Other reserves	871,633	258,044
Accumulated deficit	(19,847,641)	(201,431,272)
Total shareholders' equity attributable to owners of the Company	**(1,824,565)**	**(8,314,811)**
Non-current liabilities		
Loan	930,561	-
Non-current lease liabilities	287,808	343,629
Employee benefits	381,362	336,206
Deferred income	932,200	932,200
Deferred tax liabilities	129,291	125,870
Total non-current liabilities	**2,661,222**	**1,737,905**
Current liabilities		
Loan	2,130,340	5,869,797
Current lease liabilities	118,229	117,856
Trade and other payables	1,964,139	4,914,404
Accrued expenses	1,154,598	1,977,614
Total current liabilities	**5,367,305**	**12,879,671**
Total liabilities	**8,028,527**	**14,617,576**
Total equity and liabilities	**6,203,962**	**6,302,765**

About Altamira Therapeutics
Altamira (Nasdaq: CYTO) is dedicated to developing RNA-based therapeutics for extrahepatic targets (OligoPhore™ / SemaPhore™ delivery 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 Sonsuvi® 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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are statements other than historical facts and may include statements that address future operating, financial or business performance or Altamira's 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's 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's product candidates, the clinical utility of Altamira's product candidates, the timing or likelihood of regulatory filings and approvals, Altamira's intellectual property position and Altamira's financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions or changes to Altamira's 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's Annual Report on Form 20-F for the year ended December 31, 2022, and in Altamira's other filings with the Securities Exchange Commission ("SEC"), which are available free of charge on the SEC'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 or to persons acting on behalf of Altamira 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 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.

Investor Contact Hear@altamiratherapeutics.com 800-460-0183