atai Life Sciences Reports First Quarter 2023 Financial Results and Announces Pipeline Highlights and Updates

May 11, 2023

- *RL-007: First patient dosed in the Phase 2b study of RL-007 in Cognitive Impairment Associated with Schizophrenia.*
- *GRX-917: Presented PD data from the completed Phase 1 study, which suggest the potential for anxiolytic effects without the significant sedative effects seen with benzodiazepines.*
- *VLS-01: Well-tolerated in Parts 1 (IV) and 2 (OTF) of the on-going Phase 1 study. Amended protocol to expand study into Part 3, which is expected to further optimize the PK and PD of our proprietary OTF formulation.*
- *COMPASS Pathways announced an acceleration of the Pivotal Trial 1 (COMP 005) part of the Phase 3 program in TRD, with topline data from Pivotal Trial 1 now expected in the summer of 2024.*
- *The Company's $250M cash position and committed term loan funding is expected to fund operations into 1H 2026.*

NEW YORK and BERLIN, May 11, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, reported first quarter 2023 financial results and provided corporate updates.

"We continue to focus on our vision to heal mental health disorders so that everyone, everywhere can live a more fulfilled life," said Florian Brand, CEO and Co-Founder of atai. "This past quarter we made significant progress, including the dosing of the first patient with RL-007 in a randomized, placebo-controlled Phase 2 study. In addition, we shared detailed pharmacodynamic data from the Phase 1 study of GRX-917, underscoring its promise as an anxiolytic without the sedative side effects seen with benzodiazepines. On VLS-01, we are encouraged by the preliminary data we are seeing in the on-going Phase 1 study and look forward to further elucidating the PK and PD of our OTF formulation through the addition of Part 3 of the study."

Clinical Pipeline Recent Highlights and Updates:

RL-007 (Pro-Cognitive Neuromodulator for Cognitive Impairment Associated with Schizophrenia)

- In the first quarter of 2023, the first patient was dosed in the Phase 2b study of RL-007 in patients with Cognitive Impairment Associated with Schizophrenia (CIAS).
- The Phase 2b study is a randomized, placebo-controlled, double-blind, study of 6 weeks duration evaluating 20mg and 40mg of RL-007 vs placebo.
- The primary endpoint of the study is the change from baseline in the MATRICS Consensus Cognitive Battery (MCCB) neurocognitive composite score, a well-established regulatory endpoint.
- Topline results from this study are expected in the 2nd half of 2024.

GRX-917 (Deuterated Etifoxine for Anxiety Disorders)

- In January 2023, Phase 1 results were announced from the study of GRX-917 in healthy volunteers.
  - GRX-917 was well-tolerated, with no dose-limiting toxicities and sedation comparable to placebo.
  - GRX-917 had an improved pharmacokinetic (PK) profile relative to non-deuterated etifoxine and demonstrated pharmacodynamic (PD) evidence of GABA receptor target engagement.
- In April 2023, the company detailed PD data from the Phase 1 study in a poster presentation at the Society for Biological Psychiatry (SOBP) Annual Meeting.
  - As measured by EEG, GRX-917 demonstrated a statistically significant increase in beta power, a marker of potential anxiolytic effects, comparable to what is seen with exogenous neurosteroids and benzodiazepines.
  - Unlike benzodiazepines, however, GRX-917 was found to not reduce alpha power, a marker of potential sedative effects.
- The company expects to proceed GRX-917 into a Phase 2 study in patients living with anxiety disorder. More details of the Phase 2 clinical development plan will be provided upon study initiation.

VLS-01 (N,N-dimethyltryptamine [DMT] for TRD)

- The company recently completed Part 1 and Part 2 of an ongoing Phase 1 open-label, single-ascending dose study of VLS-01 in healthy adult participants.
- The Phase 1 study is designed to evaluate the safety, tolerability, PK and PD of VLS-01 delivered by intravenous (IV) infusion and using our proprietary oral transmucosal film (OTF) formulation.
    - In Part 1 (IV) and Part 2 (OTF), VLS-01 was well-tolerated, with no dose-limiting toxicity and a favorable safety profile.
    - VLS-01 IV was consistent with the known pharmacological profile of DMT, producing robust exposure-dependent increases in the subjective intensity of psychedelic experience.
    - VLS-01 OTF produced generally dose-dependent increases in exposure, approaching that seen with IV administration. In addition, VLS-01 OTF administration resulted in subjective psychedelic experiences in the majority of subjects.
- To further optimize the PK and PD of our proprietary OTF formulation, a protocol amendment was implemented to add Part 3, which will explore further dose ranging.
- The company expects to report additional clinical data in Q3 2023.

COMP360 (Psilocybin Therapy for TRD, Anorexia Nervosa and PTSD)

- COMPASS Pathways announced an acceleration of the Pivotal Trial 1 (COMP 005) part of the Phase 3 program in TRD, with topline data from Pivotal Trial 1 now expected in the summer of 2024.
- The on-going Phase 3 program is composed of two pivotal trials, each of which will have a long-term follow-up component. The primary endpoint in both pivotal trials is the change from baseline in MADRS total score at week 6.

Consolidated Financial Results

Cash, Cash Equivalents, and Short-term investments: Cash and cash equivalents and short-term investments totaled $249.9 million as of March 31, 2023, compared to $273.1 million of December 31, 2022. The decrease of $23.2 million was primarily driven by net cash used in operating activities of $21.1 million and $3.0 million of loans to related parties, partially offset by $0.2 million of proceeds from stock option exercises. The Company expects its cash position and committed term loan funding will be sufficient to fund operations into 1H 2026.

Research and Development (R&D) Expenses: Research and development expenses were $19.3 million for the three months ended March 31, 2023, compared to $15.5 million for the same prior year period. The increase of $3.8 million was primarily attributable to a $2.3 million increase of contract research organization expenses related to the advancement of R&D programs, a $1.4 million net increase in personnel costs, which included a $0.3 million decrease in stock-based compensation and a $0.1 million increase in professional and consulting services fees.

General and Administrative (G&A) Expenses: General and administrative expenses were $14.0 million for the three months ended March 31, 2023, compared to $18.0 million for the same prior year period. The decrease of $4.0 million was largely attributable to a decrease of $2.0 million in VAT and other non-income taxes, $1.3 million decrease in stock-based compensation, $0.8 million decrease in accounting and legal fees, $0.8 million decrease in personnel related costs, $0.6 million decrease in D&O and other insurance costs, offset by $1.4 million of restructuring costs related to the reduction in force in February 2023.

Net Loss: Net loss attributable to shareholders was $33.1 million for the three months ended March 31, 2023, (including non-cash share-based compensation expense of $8.7 million) compared to $36.9 million (including non-cash share-based compensation expense of $10.2 million) for same prior year period.

About atai Life Sciences

atai Life Sciences is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. Founded in 2018 as a response to the significant unmet need and lack of innovation in the mental health treatment landscape, atai is dedicated to acquiring, incubating, and efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders.

By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies to achieve clinically meaningful and sustained behavioral change in mental health patients.

atai's vision is to heal mental health disorders so that everyone, everywhere can live a more fulfilled life. For more information, please visit www.atai.life.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements contained in this press release other than statements of historical fact are forward-looking statements, including without limitation statements regarding our future operating results and financial position; the success, cost, and timing of development of our product candidates, including the progress of preclinical studies and clinical trials and related milestones; the timing for announcing our study results and development plans, including for our clinical trials for RL-007, GRX-917 and VLS-01; the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue; the timing of and our ability to obtain and maintain

regulatory approvals; our business strategy and plans, including the benefits of our corporate restructuring; potential acquisitions, partnerships and other strategic arrangements; the sufficiency of our cash and cash equivalents to fund our operations; available funding under the Hercules Capital, Inc. loan facility; the plans and objectives of management for future operations and capital expenditures; and our participation in upcoming events and conferences.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and are subject to a number of important factors that could cause actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation: we are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts; our limited operating history may make it difficult to evaluate the success of our business and to assess our future viability; we have never generated revenue and may never be profitable; our product candidates contain controlled substances, the use of which may generate public controversy; clinical and preclinical development is uncertain, and our preclinical programs may experience delays or may never advance to clinical trials; we rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those clinical trials, including progress and related milestones, may be impacted by several factors including the failure by such third parties to meet deadlines for the completion of such trials, research, or testing, changes to trial sites and other circumstances; we currently rely on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates in our clinical trials and we expect this to continue upon approval, if any, of our current or future product candidate, and if third-party sites fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed; we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; research and development of drugs targeting the central nervous system, or CNS, is particularly difficult, and it can be difficult to predict and understand why a drug has a positive effect on some patients but not others; we face significant competition in an environment of rapid technological and scientific change; third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts; as a result of covenants to our loan agreement with Hercules Capital, Inc., our operating activities may be restricted and we may be required to repay the outstanding indebtedness in the event of a breach by us, or an event of default thereunder, which could have a materially adverse effect on our business; a change in our effective place of management may increase our aggregate tax burden; we identified material weaknesses in connection with our internal control over financial reporting; and a pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results. These forward-looking statements are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties, and assumptions described under “Risk Factors” in Item 1A of Part I, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7 of Part II and elsewhere in our Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (“SEC”), as may be updated by other filings we file with or furnish to the SEC.

Any forward-looking statements made herein speak only as of the date of this press release, and you should not rely on forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, performance, or achievements reflected in the forward-looking statements will be achieved or will occur. Except as required by applicable law, we undertake no obligation to update any of these forward-looking statements for any reason after the date of this press release or to conform these statements to actual results or revised expectations.

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ATAI LIFE SCIENCES N.V.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
License revenue	$ 37	$ —
Operating expenses:		
Research and development	19,281	15,460
General and administrative	13,970	17,982
Total operating expenses	33,251	33,442
Loss from operations	(33,214)	(33,442)
Other income (expense), net	58	1,521

Loss before income taxes	(33,156)	(31,921)
Provision for income taxes	(165)	(41)
Losses from investments in equity method investees, net of tax	(1,033)	(5,596)
Net loss	(34,354)	(37,558)
Net loss attributable to noncontrolling interests	(1,219)	(689)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (33,135)	$ (36,869)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	$ (0.21)	$ (0.24)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	155,792,490	153,529,268

ATAI LIFE SCIENCES N.V.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands)

	March 31 2023	December 31, 2022
	(unaudited)	(1)
Assets		
Cash and cash equivalents	$ 185,885	$ 190,613
Securities carried at fair value	63,998	82,496
Prepaid expenses and other current assets	9,199	14,036
Short term notes receivable - related parties, net	8,851	—
Property and equipment, net	1,114	928
Operating lease right-of-use asset, net	1,489	226
Other investments	5,846	6,755
Long term notes receivable - related parties, net	1,155	7,262
Other assets	3,180	3,125
Total assets	$ 280,717	$ 305,441
Liabilities and Stockholders' Equity		
Accounts payable	4,915	2,399
Accrued liabilities	13,819	17,306
Current portion of lease liability	317	180
Other current liabilities	902	12
Non-current portion of contingent consideration liability - related parties	918	953
Non-current portion of lease liability	1,185	44
Convertible promissory notes - related parties, net of discounts and deferred issuance costs	422	415
Long-term debt, net	14,783	14,702
Other liabilities	2,816	3,664
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	236,825	260,740
Noncontrolling interests	3,815	5,026
Total liabilities and stockholders' equity	$ 280,717	$ 305,441

(1) The condensed consolidated financial statements as of and for the year ended December 31, 2022 are derived from the audited consolidated financial statements as of that date.