atai Life Sciences Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Clinical Pipeline Highlights

March 24, 2023

- *atai's development candidates, such as RL-007 and GRX-917, all represent significant opportunities to address unmet medical needs of patients living with mental health conditions*
- *Continued operational progress on robust clinical pipeline, with multiple phase 1 and phase 2 proof-of-concept datasets expected in the next two years*
- *$273 million in cash, cash equivalents and short-term investments at end of 2022 and access to a term loan facility of up to an additional $160 million provide anticipated runway into the first half of 2026*

NEW YORK and BERLIN, March 24, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, reported fourth quarter and full year 2022 financial results and provided clinical pipeline highlights.

"With multiple clinical-stage programs aimed at addressing significant unmet patient needs in mental health and the capital to fund us into the first half of 2026, we believe we are in a strong position to advance our clinical candidates towards proof of concept in patients," said Florian Brand, CEO and Co-Founder of atai. "Recently we announced dosing the first patient in our Phase 2 study of RL-007 in CIAS and the modification of the GRX-917 clinical development plan to advance directly into a proof-of-concept study in patients with anxiety."

Clinical Pipeline Highlights

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

- The first patient was recently dosed in the phase 2b study of RL-007 in patients with CIAS and topline results from this study are expected in the 2nd half of 2024.
- The phase 2b US-based study is a randomized, placebo-controlled, double-blind, 3-arm study evaluating 20mg and 40mg of RL-007 vs placebo in approximately 230 patients with CIAS. 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, at week 6.
- RL-007 is an orally available compound that modulates cholinergic, glutamatergic and GABA-B receptors, thereby putatively altering the excitatory/inhibitory balance in the brain to produce pro-cognitive effects. It has previously been evaluated in 10 clinical studies with over 500 unique participants dosed to-date and in which it was well tolerated at all doses tested.
- Notably, in four clinical studies that assessed cognition, including one in patients with CIAS, the compound consistently demonstrated pro-cognitive effects. In atai's previous Phase 2a proof-of-mechanism study in CIAS of RL-007, the compound showed a large effect size on Symbol Coding, a sub-component of the MCCB that correlates with the overall composite.

GRX-917 (Deuterated Etifoxine for Anxiety Disorders)

- The clinical development plan was modified to proceed with a phase 2 study in patients, which is intended to generate the robust clinical data needed to best inform a future registrational program. More details of the phase 2 clinical development plan will be provided upon initiation of the study.
- In January 2022, positive results were announced from the phase 1 single and multiple ascending dose study of GRX-917. In this study, GRX-917 was well-tolerated. Additionally, GRX-917 had an improved pharmacokinetic profile relative to etifoxine and provided pharmacodynamic evidence of GABA receptor target engagement through qEEG.
- GRX-917 is a deuterated version of etifoxine, a drug used for anxiety and first approved in France in 1979. Etifoxine has a rapid onset and efficacy comparable to benzodiazepines, which are currently considered standard of care. In contrast to benzodiazepines, etifoxine appears to be non-addictive, less sedating, and better tolerated. It is believed that etifoxine achieves its anxiolytic activity by increasing the endogenous production of brain neurosteroids like allopregnanolone.

COMP360 (Psilocybin Therapy for Treatment-Resistant Depression (TRD))

- COMPASS Pathways (“COMPASS”) recently announced an acceleration of the Pivotal Trial 1 (COMP 005) part of the phase 3 program in TRD, with top line data from Pivotal Trial 1 now expected in the summer 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.
- COMP360 is a proprietary formulation of synthetic psilocybin that is administered in conjunction with psychological support. Previously, COMPASS completed a phase 2b study with top line data showing a statistically significant ($p<0.001$) and clinically relevant improvement in depressive symptom severity after three weeks for patients who received a single high dose of COMP360 psilocybin with psychological support.

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

- In the fourth quarter of 2022, the first subject was dosed in a Phase 1 study of VLS-01. Initial results from the study are expected in the 1st half of 2023.
- The phase 1 study is a two-part single-ascending dose study designed to evaluate the safety, tolerability and relative bioavailability of oral transmucosal film (OTF) versus intravenous (IV) formulations of VLS-01.
- The study includes atai’s IDEA-1 companion digital therapeutic for psychological support to be used in combination with VLS-01. The app-based support comprises “(mind)set-and-setting” prior to dosing and limited post-dose integration appropriate for healthy volunteers.
- VLS-01 is an OTF formulation of DMT. DMT is a partial agonist of the 5-HT 1A/2A/2C receptors, characterized by an intrinsically short duration of psychedelic effect, with a serum half-life estimated at less than 10 minutes. DMT results in rapid-acting antidepressant effects when administered via IV infusion in patients with major depressive disorder (MDD). VLS-01 is formulated for oral delivery, potentially eliminating the need for IV infusion.

DMX-1002 (Ibogaine for Opioid Use Disorder)

- In the third quarter of 2022, the first subject was dosed in a phase 1/2 study of Ibogaine. Initial results from the Phase 1 portion of the study are expected in the 1st half of 2023.

EMP-01 (MDMA Derivative for PTSD)

- In the third quarter of 2022, a phase 1 study of EMP-01 was initiated. Initial results from this study are expected in the 2nd half of 2023.

Consolidated Financial Results

Cash, Cash Equivalents, and Short-term investments: Cash and cash equivalents and short-term investments were $273.1 million as of December 31, 2022, as compared to $362.3 million as of December 31, 2021. The decrease of $89.2 million was primarily driven by net cash used in operating activities of $104.5 million and $3.6 million additional investment in platform companies, partially offset by $15.0 million draw on the Hercules debt, $4.6 million of proceeds from the conversion of notes and $2.9 million of proceeds from stock sales and stock option exercises. The Company expects its cash position, combined with access to up to $160M in additional capital from its term loan facility with Hercules Capital, Inc., will be sufficient to fund operations into 1H 2026.

Research and development (R&D) expenses: R&D expenses were $21.9 million and $74.3 million for the three and twelve months ended December 31, 2022, respectively, as compared to $13.0 million and $48.0 million for the same prior year periods. The year-over-year full-year increase of $26.3 million was primarily attributable to an increase of $22.2 million of contract research organization expenses related to advancements of R&D programs and $3.5 million increase in R&D personnel costs.

General and administrative (G&A) expenses: G&A expenses for the three and twelve months ended December 31, 2022 were $15.7 million and $70.4 million, respectively, as compared to $25.9 million and $92.7 million in the same prior year periods. The year-over-year decrease of $22.3 million was primarily attributable to a decrease of $18.0 million in non-cash stock compensation expense, $9.8 million decrease in value added tax expense, $4.0 million decrease in professional consulting services. These decreases were partially offset by an increase of $7.3 million in personnel expenses and $1.9 million increase in insurance expense.

Net loss: Net loss attributable to shareholders for the three and twelve months ended December 31, 2022 was $45.0 million and $152.4 million, respectively, as compared to $88.9 million and $167.8 million for the comparable prior year periods.

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 should be considered 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 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 and short-term investments 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, and are subject to a number of important factors that could cause actual results 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 expect to incur losses for the foreseeable future and may never be profitable; if we are unable to obtain funding when needed and on acceptable terms, we could be forced to delay, limit or discontinue 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 rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing; 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 candidates, 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; our product candidates are in preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes, and 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; the production and sale of our product candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may also have consequences for the legality of investments from foreign jurisdictions; we face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before we do or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition; if we are unable to obtain and maintain sufficient intellectual property protection for our existing product candidates or any other product candidates that we may identify, or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our existing product candidates and any other product candidates that we may pursue may be impaired; 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; our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel; 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; if we fail to maintain an effective system of disclosure controls and internal control over financial reporting our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired; our business is subject to economic, political, regulatory and other risks associated with international operations; 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, and other 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.

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 BALANCE SHEET
(Amounts in thousands)

	December 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 190,613	$ 362,266
Securities carried at fair value	82,496	—
Prepaid expenses and other current assets	14,036	11,903
Short term notes receivable	—	913
Property and equipment, net	928	149
Equity method investments	—	16,131
Other investments	6,755	11,628
Long term notes receivable - related parties	7,262	3,835
Other assets	3,351	7,341
Total assets	$ 305,441	$ 414,166
Liabilities and Stockholders' Equity		
Accounts payable	2,399	6,004
Accrued liabilities	17,306	14,829
Current portion of contingent consideration liability - related parties	—	51
Other current liabilities	192	51
Non-current portion of contingent consideration liability - related parties	953	2,432
Convertible promissory notes - related parties, net of discounts and deferred issuance costs	415	743
Long-term debt, net	14,702	—
Other liabilities	3,708	4,097
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	260,740	376,908
Noncontrolling interests	5,026	9,051
Total liabilities and stockholders' equity	$ 305,441	$ 414,166

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

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
	(unaudited)			
License revenue	$ 38	$ 230	$ 233	$ 20,376
Operating expenses:				
Research and development	21,876	12,982	74,313	47,956
Acquisition of in-process research and development	—	6,546	357	15,480
General and administrative	15,727	25,877	70,350	92,745
Total operating expenses	37,603	45,405	145,020	156,181
Loss from operations	(37,565)	(45,175)	(144,787)	(135,805)
Other income (expense), net	(1,756)	(3,404)	9,605	(796)
Loss before income taxes	(39,321)	(48,579)	(135,182)	(136,601)
Benefit from (provision for) income taxes	(6,002)	4,421	(6,229)	3,989
Gain on dilution of equity method investments	—	—	—	16,923
Losses from investments in equity method investees, net of tax	(1,326)	(49,115)	(16,006)	(58,555)
Net loss	(46,649)	(93,273)	(157,417)	(174,244)
Net loss attributable to redeemable noncontrolling interests and noncontrolling interests	(1,638)	(4,396)	(5,032)	(6,436)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (45,011)	$ (88,877)	$ (152,385)	$ (167,808)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	$ (0.28)	$ (0.55)	$ (0.98)	$ (1.21)

Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	158,703,781	160,199,975	155,719,585	138,265,859