atai Life Sciences Reports Third Quarter 2022 Financial Results and Business Update

November 10, 2022

- *Last patient dosed in the Phase 2a proof-of-concept trial of PCN-101 (R-ketamine) for treatment-resistant depression (TRD), with topline results expected around year-end 2022.*
- *Announced positive preliminary pharmacokinetics and pharmacodynamics results in a Phase 1 study of GRX-917 (deuterated etifoxine) being developed for generalized anxiety disorder (GAD), demonstrating target engagement based on qEEG.*
- *Announced positive preliminary results of the single ascending dose (SAD) portion of the Phase 1 study of KUR-101 (deuterated mitragynine) being developed for opioid use disorder (OUD), demonstrating dose-dependent pain relief with effects on respiration comparable to that of placebo.*
- *Announced the first patient dosed in the Phase 1 SAD trial of VLS-01 (DMT) being developed for TRD, initiation of the Phase 1 trial of EMP-01 (MDMA derivative) being developed for post-traumatic stress disorder (PTSD), and initiation of proof-of-concept Phase 1 clinical trial of a sol-gel based direct-to-brain drug delivery technology.*
- *Ended quarter with $304M in cash, which combined with the non-dilutive funding facility from Hercules provides anticipated runway into 2025.*

Video interview with Management to be posted today at 8:30 a.m. EST

NEW YORK and BERLIN, Nov. 10, 2022 (GLOBE NEWSWIRE) -- atai Life Sciences N.V. (Nasdaq: ATAI) (“atai” or “the Company”), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today reported financial results for the quarter ended September 30, 2022 and provided a business update.

“In addition to multiple study initiations this quarter, we have announced two positive clinical trial results, with more on the way,” said Florian Brand, Co-Founder and Chief Executive Officer of atai. “We’re excited about the upcoming Phase 2a topline results of PCN-101 that could represent a meaningful shift in the current treatment paradigm for patients.”

“The third quarter of 2022 demonstrated our strong capability to execute. Not only did we have first patient dosed of a Phase 1 trial of VLS-01 and initiation of a Phase 1 trial of EMP-01, we also began collecting data on our digital therapeutic app supporting ‘(mind)set-and-setting’ prior to dosing,” said Srinivas Rao, Co-Founder and Chief Scientific Officer. “Moreover, positive safety, tolerability, and pharmacodynamic results from both KUR-101 and GRX-917 Phase 1 trials reinforce our belief in our unique approach to drug selection, which emphasizes prior evidence in humans. Finally, we continue to strengthen our enabling technology capabilities through initiation of a proof-of-concept Phase 1 clinical trial of a sol-gel based technology which could enable direct-to-brain delivery of various compounds in development across atai’s pipeline.”

Video Interview with Management

A video interview with atai Life Sciences CEO & Co-Founder Florian Brand, CSO & Co-Founder Srinivas Rao, and CFO Stephen Bardin will be available today at 8:30 a.m. Eastern Time at https://vimeo.com/atailifesciences.

The interview will also be available for replay in the “Events” section of the Company’s website at www.atai.life. The archived copy of the interview will be available on the Company’s website for at least 30 days.

Pipeline Update and Highlights

In the third quarter, the Company continued to advance its programs and is looking forward to additional clinical milestones for the remainder of 2022 and beyond. Most significantly, eight compounds are now in clinical development, paving the way for significant additional value inflection points over the next 6 to 12 months. Foremost among these milestones was the dosing of the final patient in the Phase 2a Proof-of-Concept (PoC) trial of PCN-101 for TRD, positioning the company on track for topline results around the end of the year.

Recent Developments

Perception Neuroscience – PCN-101 (R-ketamine) for TRD

- Last patient dosed the in Phase 2a trial of PCN-101 PoC study in TRD with topline data expected around year-end 2022
- Patients were assessed for change in depressive symptomology using the Montgomery-Asberg Depression Rate Scale (MADRS) with the primary endpoint being at 24 hours and secondary assessments at 7 and 14 days post dosing
- In addition to monitoring vital signs and adverse events, the objective is to assess sedation and dissociation via the Modified Observer’s Assessment of Alertness (MOAA/S) scale and the Clinician-Administered Dissociative States Scale (CADSS), respectively
- A Phase 1 relative bioavailability bridging study of the current intravenous formulation to the subcutaneous formulation to support at-home use is expected to initiate H1 2023, with topline results available mid 2023

COMPASS Pathways – COMP360 (Psilocybin assisted therapy) to treat TRD

- Announced Phase 3 program composed of two pivotal trials and one long-term outcomes study, the first of which is expected to commence by the end of 2022
- Phase 3 study design informs the development of atai's psychedelic compounds, including VLS-01
- Phase 2b trial results published in The New England Journal of Medicine
- Ongoing Phase 2 trials in anorexia nervosa and PTSD across world-leading research institutes in the UK and US

Recognify Life Sciences – RL-007 for Cognitive Impairment Associated with Schizophrenia (CIAS)

- RL-007 Phase 2b dose finding trial to be initiated by the end of this year, with results expected in the first half of 2024

GABA Therapeutics – GRX-917 (deuterated etifoxine) for GAD

- Completed Phase 1 SAD and multiple-ascending dose (MAD) study and found GRX-917 was well-tolerated with no dose-limiting toxicities, and both SAD & MAD showed only mild adverse events comparable to placebo
- Phase 1 data confirmed an improved pharmacokinetic profile of deuterated etifoxine compared to etifoxine, including longer half-life and greater bioavailability
- Dose-dependent increase in frontal beta power was demonstrated through quantitative electroencephalograph (qEEG), providing evidence of target engagement and mechanism of action
- Initiation of GRX-917 efficacy study in healthy volunteers is anticipated in H2 2022 with results expected H2 2023

Kures – KUR-101 (deuterated mitragynine) for OUD

- Announced positive initial results for the SAD component of the Phase 1 trial
- Results showed that oral dosing of KUR-101 produces dose-dependent pain relief, a measure of central opioid receptor function, with effects on respiration comparable to that of placebo
- Safety and analgesia data from Part 2 of the Phase 1 study, designed to be a head-to-head comparator trial versus the standard of care, are expected by the end of 2022

DemeRx – DMX-1002 (ibogaine) for OUD

- Last patient dosed for Cohorts 1 and 2 in Phase 1 SAD clinical trial with Cohort 3 expected to begin in the first half of 2023
- Safety data from the Phase 1 portion of the trial are expected in the first half of 2023

Viridia Life Sciences - VLS-01 (dimethyltryptamine) for TRD

- First patient dosed in Phase 1 open-label SAD trial of VLS-01 and topline results expected in the first half of 2023
- The objectives of this Phase 1 trial are to compare the safety and tolerability of VLS-01 and PK of intravenous versus buccal administration of DMT
- The Phase 1 trial is the first application of atai's app-based digital therapeutics technology (DTx) to a pipeline product, and this technology will be used to prepare subjects prior to dosing
- Initiation of a Phase 2a proof-of-concept study is expected in the first half of 2023, with results expected to follow in the first half of 2024

EmpathBio - EMP-01 (MDMA derivative) for PTSD

- Received Medsafe central regulatory approval and Health and Disability Ethics Committees (HDEC) approval to initiate a Phase 1 trial to assess the safety and tolerability of orally administered EMP-01 in up to 32 healthy volunteers
- This trial will incorporate atai's DTx to prepare subjects prior to dosing
- Topline results for this Phase 1 study anticipated in mid 2023

InnarisBio – Nasal spray drug-delivery technology to deliver drugs directly to the brain for use in various mental health indications

- Initiated a Phase 1 proof-of-concept clinical trial to demonstrate the safety, tolerability, and direct-to-brain delivery of intranasal INB-01, a sol-gel based drug-delivery technology.
- INB-01 may enable direct-to-brain delivery of various compounds in development across atai's pipeline
- Potential advantages may include increased patient compliance, lower dose requirements, rapid onset of action, and minimized systemic exposure
- Phase 1 proof-of-concept trial results expected in the first half of 2023

atai Life Sciences Virtual R&D Day

- Held a virtual R&D Day on October 25, 2022. Presentation and recording can be found on atai's investor website here: https://ir.atai.life/events/event-details/rd-investor-day.

Consolidated Financial Results

- On August 9th, atai entered into a non-dilutive term loan facility agreement for up to $175 million with Hercules Capital, Inc.
- atai ended the third quarter of 2022 with a cash position of $304.1 million, which combined with committed funding from the Hercules loan facility, is anticipated to provide cash runway into 2025.

Cash, Cash Equivalents, and Short-term investments

Cash, cash equivalents and short-term investments totaled $304.1 million as of September 30, 2022, compared to $362.3 million as of December 31, 2021. The nine-month net decrease of cash of $58.2 million was primarily attributable to net cash used in operating activities of $73.9 million and $3.6 million additional investments in platform companies, net of $15 million draw on the Hercules debt, $4.6 million from conversion of notes, and $2.8 million from stock option exercises and equity issuance.

Operating Costs & Expenses

Research and development expenses were $19.0 million and $52.4 million for the three and nine months ended September 30, 2022, respectively, as compared to $13.4 million and $35.0 million for the same prior year periods.

Acquisition of in-process R&D expense for the nine months ended September 30, 2022 of $0.4 million related to additional investment in Kures. Acquisition of in-process R&D expense for the nine months ended September 30, 2021 of $9.0 million related to the InnarisBio acquisition and consolidation of Neuronasal.

General and administrative expenses for the three and nine months ended September 30, 2022, were $19.4 million and $54.6 million, respectively, as compared to $20.3 million and $66.9 million in the same prior year periods.

Net loss attributable to shareholders for the three months ended September 30, 2022 was $33.9 million (including non-cash share-based compensation expense of $10.5 million), as compared to $31.2 million (including non-cash share-based compensation expense of $12.2 million) for the comparable prior year period.

Net loss attributable to shareholders for the nine months ended September 30, 2022, was $107.4 million (including non-cash share-based compensation expense of $30.2 million), as compared to $78.9 million (including non-cash share-based compensation expense of $50 million) for the comparable 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, as amended. 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"). The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "initiate," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. 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, potential acquisitions, 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.

The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements. 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 subject to a number of risks, uncertainties, and assumptions that could cause actual results to differ materially from those 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; 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 cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; 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; 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 and other important factors described in the section titled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission ("SEC") as further updated in our Quarterly Reports on Form 10-Q, and subsequent filings with the SEC, from time to time, may cause our actual results, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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

	September 30, 2022 (unaudited)	December 31, 2021 (1)
Assets		
Cash and cash equivalents	$ 142,539	$ 362,266
Securities carried at fair value	161,518	—
Prepaid expenses and other current assets	13,425	11,903
Short term notes receivable	—	913
Property and equipment, net	728	149
Equity method investments	—	16,131
Other investments	8,498	11,628
Long term notes receivable - related parties	7,151	3,835
Other assets	8,738	7,341
Total assets	$ 342,597	$ 414,166
Liabilities and Stockholders' Equity		
Accounts payable	3,511	6,004
Accrued liabilities	22,142	14,829
Current portion of contingent consideration liability - related parties	—	51
Other current liabilities	260	51
Non-current portion of contingent consideration liability - related parties	1,908	2,432
Convertible promissory notes - related parties, net of discounts and deferred issuance costs	380	743
Other liabilities	3,695	4,097
Long-term debt, net	14,621	-
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	289,399	376,908
Noncontrolling interests	6,681	9,051
Total liabilities and stockholders' equity	$ 342,597	$ 414,166

(1) The condensed consolidated financial statements as of and for the year ended December 31, 2021 are derived from the audited consolidated financial statements as of that date.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
License revenue	$ 24	$ 266	$ 195	$ 20,146
Operating expenses:				
Research and development	19,028	13,363	52,437	34,974
Acquisition of in-process research and development	—	—	357	8,934
General and administrative	19,419	20,264	54,623	66,868
Total operating expenses	38,447	33,627	107,417	110,776
Loss from operations	(38,423)	(33,361)	(107,222)	(90,630)
Other income (expense), net	5,289	6,887	11,361	2,608
Loss before income taxes	(33,134)	(26,474)	(95,861)	(88,022)
Provision for income taxes	(135)	(368)	(227)	(432)
Gain on dilution of equity method investments	—	—	—	16,923
Losses from investments in equity method investees, net of tax	(2,432)	(4,800)	(14,680)	(9,440)
Net loss	(35,701)	(31,642)	(110,768)	(80,971)
Net loss attributable to redeemable noncontrolling interests and noncontrolling interests	(1,814)	(484)	(3,394)	(2,040)
Net loss attributable to ATAI Life Sciences N.V. stockholders	$ (33,887)	$ (31,158)	$ (107,374)	$ (78,931)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	$ (0.22)	$ (0.21)	$ (0.69)	$ (0.59)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	156,607,468	151,130,212	154,713,922	134,334,685