



atai Life Sciences Announces Fourth Quarter and Full Year 2021 Financial Results, Reports on R&D Progress and Highlights Strategic Focus Areas of its Innovative Mental Health Platform

March 30, 2022

- Highlights included positive Phase 2b data with COMP360 from a ground-breaking treatment resistant depression (TRD) trial, highly encouraging Phase 2a proof-of-mechanism data with RL-007 in cognitive impairment associated with schizophrenia (CIAS), clinical trial initiations with PCN-101, GRX-917 and DMX-1002, and successful completion of 2 cohorts in the Introspect Digital Therapeutics ketamine trials
- Eight new programs added to platform since January 2021 bringing total, as of today, to 13 discovery and drug development programs and four enabling technologies
- Ended 2021 very well capitalized with \$362 million to execute our strategy to achieve clinically meaningful and sustained behavioral change in mental health patients through the combination of rapid acting interventions, ongoing digital support and biomarker-driven precision mental health
- At least 14 drug development and enabling technology catalysts anticipated over the next two years, including Phase 2a proof-of-concept topline data from PCN-101 in TRD

Conference call to be held today at 8:30 a.m. EST

NEW YORK and BERLIN, March 30, 2022 (GLOBE NEWSWIRE) -- [atai Life Sciences N.V.](#) (Nasdaq: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today reported financial results for the fourth quarter and full year ended December 31, 2021 and provided business updates.

"2021 was a transformative year for atai. We expanded our pipeline with the launch of seven new programs, bringing our total number of development programs to 12 by end of 2021. Meanwhile, our approach to value creation and capture was validated through a significant licensing deal with Otsuka Pharmaceuticals for PCN-101. We raised over \$410 million in our June 2021 IPO, Series D and other financings, and closed out 2021 well-capitalized with a cash position of \$362 million," said Greg Weaver, Chief Financial Officer of atai Life Sciences.

"From an R&D perspective, in addition to hitting many discovery and pre-clinical milestones, we initiated Phase 1 studies with GRX-917 and DMX-1002 and a Phase 2a proof-of-concept study with PCN-101 in TRD. Additionally, we announced pro-cognitive effects of RL-007 in our Phase 2a proof-of-mechanism study in CIAS, an indication where patients have currently no approved treatment options. We also increased our strategic investment in COMPASS Pathways following their positive Phase 2b data with COMP360 in TRD," said Srinivas Rao, Chief Scientific Officer & Co-founder of atai Life Sciences.

"This exciting momentum continues in 2022 and our cash runway of approximately 2 years enables us to work towards our goal of achieving clinically meaningful and sustained behavioral change in mental health patients. We will focus on three strategic pillars: namely, rapid acting intervention, ongoing digital support and a biomarker-driven precision mental health," said Florian Brand, Chief Executive Officer & Co-founder of atai Life Sciences.

The Company anticipates at least 14 drug development and enabling technology catalysts over the next two years, including the Phase 2a proof-of-concept topline data readout with PCN-101 for TRD and results from the Phase 1 relative bioavailability study with PCN-101 designed to bridge between the current intravenous formulation to a subcutaneous formulation to support at-home use.

atai also expects data from the Phase 1 element of a combined Phase 1/2 trial of DMX-1002 by the end of 2022 as well as topline data from a Phase 1 trial with GRX-917 by mid of this year. Just this month, the first subject in a Phase 1 with KUR-101 was dosed, and atai anticipates topline results for this study later this year. The initiation of Phase 2a proof-of-concept trials with RL-007 and GRX-917 and Phase 1 trials with EMP-01 and RLS-01 are anticipated in the second half of this year. The initiation of a Phase 1 trial with VLS-01 is expected by mid of this year.

atai also expects further advancement in its ongoing patient support technologies and precision mental health approaches. With this ongoing positive traction across the Company's platform, atai will continue delivering on its vision to heal mental health disorders and tackle the escalating global mental health crisis head on.

In parallel to its R&D activities, in October 2021, atai launched its philanthropic arm, atai Impact. atai Impact's first initiative, in December 2021, was the establishment of the atai Fellowship Fund in Psychedelic Neuroscience at Massachusetts General Hospital's Center for the Neuroscience of Psychedelics. This year, atai Impact has already made sizeable donations to the Multidisciplinary Association for Psychedelics Studies (MAPS) and to leading non-profit organizations supporting humanitarian efforts in the Ukraine, with a special focus on mental health.

Conference Call and Webcast

A live webcast for today's corporate update and fourth quarter 2021 financial results will take place today at 8:30 a.m. EST. To access the webcast, please log in at <https://wsw.com/webcast/cc/atai/1358298>.

The conference call will also be accessible live and for replay in the "[Events](#)" section of the Company's website www.atai.life. The archived copy of the webcast will be available on the Company's website for at least 30 days following the conclusion of the conference call.

Pipeline Highlights

Leveraging atai's platform for innovation and accelerating mental healthcare solutions, the Company continues to execute on its pipeline of pharmacologically diverse candidates with the potential for rapid-acting interventions that address the unmet needs of mental health patients.

Treatment Resistant Depression (TRD)

COMPASS Pathways - *COMP360*: In November, atai's strategic investment COMPASS Pathways announced Phase 2b data for COMP360 in TRD. The 233-patient trial met its primary endpoint, showing a 6.6-point reduction on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to 3 weeks when comparing the 25mg dose to the 1mg dose. COMP360 also showed both rapid response and durability of efficacy and was generally well tolerated. In Q4-2021, atai increased its holdings in COMPASS Pathways to 22.8%. COMPASS plans to hold an end-of-Phase 2 meeting with the FDA in April 2022 to discuss their Phase 3 program, which is anticipated to commence in the second half of this year.

Perception Neuroscience – *PCN-101*: In December 2021, the FDA gave Investigational New Drug (IND) clearance for the development of PCN-101 for the treatment of TRD. In September 2021, the Phase 2a proof-of-concept trial of PCN-101 for TRD was initiated. This randomized, double-blind, placebo-controlled Phase 2a proof-of-concept trial is designed to assess the efficacy, safety, dose response, and duration of response in patients with TRD. A topline data readout of this trial is expected by the end of 2022. The initiation of a Phase 1 relative bioavailability study, which is designed to bridge the intravenous formulation to a subcutaneous formulation of PCN-101, is anticipated for late 2022.

Viridia Life Sciences – *VLS-01*: VLS-01 is in preclinical development for TRD with a Phase 1 trial expected to be initiated in the middle of 2022.

Revixia Life Sciences – *RLS-01*: RLS-01 is in preclinical development for TRD with a Phase 1 trial expected to be initiated in the second half of 2022.

Cognitive Impairment Associated with Schizophrenia (CIAS)

Recognify Life Sciences - *RL-007*: In December of last year, atai announced positive biomarker data from the Phase 2a proof-of-mechanism study of RL-007 in CIAS patients. RL-007 was well tolerated and demonstrated a clinically meaningful behavioral pro-cognitive profile consistent with previous Phase 1 and 2 trials of this compound. Changes in quantitative electroencephalogram (qEEG) consistent with a previous Phase 1 trial involving a scopolamine challenge were noted. These results support the progression of RL-007 to a double-blind, placebo-controlled Phase 2a proof-of-concept trial in CIAS, which is anticipated to be initiated in the second half of 2022.

Generalized Anxiety Disorder (GAD)

GABA Therapeutics – *GRX-917*: In June 2021, GABA initiated a Phase 1 single and multiple ascending dose trial of GRX-917. Topline data for this trial is expected by mid of this year and the initiation of a Phase 2a proof-of-concept trial is anticipated to follow in the second half of this year.

Opioid Use Disorder (OUD)

DemeRx IB – *DMX-1002*: DMX-1002 is being tested in an ongoing Phase 1/2 trial to evaluate its safety, tolerability, pharmacokinetics, and efficacy. Safety data from the phase 1 element of this trial are expected in the second half of 2022.

Kures – *KUR-101*: A Phase 1 single ascending dose trial to evaluate the maximum tolerable dosage was initiated, with first patient dosed in March and topline results expected in the second half of 2022.

Post-Traumatic Stress Disorder (PTSD)

EmpathBio – *EMP-01*: EMP-01 is in preclinical development for PTSD with a Phase 1 trial expected to be initiated in the second

half of 2022

Drug Discovery

atai is conducting robust drug discovery through four subsidiary companies, including two newly added companies – TryptageniX (December 2021) and Invyxis (January 2022). TryptageniX will develop new chemical entities through a unique bioprospecting and synthetic biology approach, while Invyxis brings proven medicinal chemistry and comprehensive biological evaluation capabilities to our discovery efforts. These new approaches complement atai's existing drug discovery efforts at EntheogeniX, which uses an AI-based computational chemistry platform to create structurally differentiated molecules. Finally, PsyProtix is a discovery stage company that is developing compounds to treat specific subsets of TRD patients that are characterized by mitochondrial dysfunction, thus representing an important first step towards our goal of delivering biomarker-driven precision mental health.

Ongoing digital patient support and precision mental health

atai's digital efforts include digital therapeutics that are focused on improving the safety, efficacy and scalability of our compounds by providing continuous digital care to patients before, during and after treatment. In addition, our efforts include a multimodal data analytics platform designed to better characterize mental health indications and that may facilitate more personalized treatments. Psyber is developing interventions that use brain computer interface-based technology to induce rapid behavioral change through biofeedback. Introspect Digital Therapeutics is focused on providing personalized, digitally delivered, evidence-based psychotherapy to patients receiving our compounds. As announced in September 2021, Introspect launched a user acceptability trial in TRD patients undergoing ketamine therapy to validate the combination of a digital app and drug in improving treatment outcomes.

Consolidated Financial Results

atai ended the year with a strong cash position of \$362 million which it anticipates will be sufficient to provide a cash runway of approximately two years, including funding of additional anticipated business development activity.

Cash and Cash Equivalents

Cash and cash equivalents totaled \$362.3 million as of December 31, 2021, compared to \$97.2 million as of December 31, 2020. The twelve-month increase of \$265.1 million is attributed to net proceeds of \$409.9 million from the June IPO, Series C and Series D equity raises and other financing activities, and \$20.0 million of license revenue proceeds. Offsetting were cash payments of \$52.5 million of additional investment in Compass Pathways, \$14.9 million investment in and loan to IntelGenx, \$10.6 million additional investment in GABA, \$3.5 million for investments in other platform companies and assets, and \$83.3 million in net operating expenses and effect of foreign exchange rate changes.

Operating Costs and Expenses

Research and development (R&D) expenses were \$13.0 million and \$48.0 million for the three and twelve months ended December 31, 2021, respectively, as compared to \$3.4 million and \$11.4 million for the same prior year periods. The year-over-year full-year increase of \$36.6 million was attributable to an increase of \$23.4 million in R&D personnel costs, including a \$19.1 million increase in stock-based compensation expense, and \$13.2 million of increased contract research organization expenses related to advancements of R&D programs.

Acquisition of in-process R&D expense was \$6.5 million and \$15.5 million for the three and twelve months ended December 31, 2021, respectively, relating to investments in TryptageniX, InnarisBio, and Neuronasal. Acquisition of in-process R&D expense was \$11.9 million and \$12.0 million for the three and twelve months ended December 31, 2020, respectively, relating to its investments in Recognify and Kures.

General and administrative (G&A) expenses for the three and twelve months ended December 31, 2021 were \$25.9 million and \$92.7 million, respectively, as compared to \$72.0 million and \$80.7 million in the same prior year periods. The year-over-year full year increase of \$12.0 million was attributable to an increase of \$25.3 million in G&A personnel cost and professional consulting fees, and \$9.7 million of other G&A costs related to supporting platform growth and public company requirements. These increases were partially offset by a decrease of \$22.9 million in stock-based compensation expense.

Total stock-based compensation expense for the three and twelve months ended December 31, 2021 was \$13.4 million and \$63.4 million, respectively, as compared to \$67.2 million for the fourth quarter and prior year periods, reflecting the recognition of expense in 2021 related to the achievement of IPO performance-based partial vesting conditions and the issuance of convertible notes in 2020.

Net loss attributable to shareholders for the three and twelve months ended December 31, 2021 was \$88.9 million and \$167.8 million, respectively, as compared to \$86.6 million and \$169.8 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.

atai's business model combines funding, technology, scientific, and regulatory expertise with a focus on innovative compounds, including psychedelic therapy and other drugs with differentiated safety profiles and therapeutic potential. 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. atai has offices in New York, San Diego, Boston, London and Berlin. 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," "anticipate," "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, including 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, and the plans and objectives of management for future operations and capital expenditures, are forward-looking statements. 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 because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond our control and which could cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by 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, 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, and the plans and objectives of management for future operations and capital expenditures. Other risk factors include the important factors described in the section titled "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"), as updated by our subsequent filings with the SEC, that may cause our actual results, performance or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements.

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.

Contact Information

Media Contact:
Camilla Dormer
VP, Communications
camilla@atai.life

Investor Contact:
Greg Weaver
Chief Financial Officer
greg.weaver@atai.life

(Amounts in thousands, except share and per share amounts)

	Year Ended December 31,	
	2021	2020
License revenue	\$ 20,376	\$ -
Operating expenses:		
Research and development	47,956	11,408
Acquisition of in-process research and development	15,480	12,020
General and administrative	92,745	80,734
Total operating expenses	156,181	104,162
Loss from operations	(135,805)	(104,162)
Other income (expense), net	(796)	2,349
Net loss before income taxes	(136,601)	(101,813)
Benefit from (provision for) income taxes	3,989	(305)
Gain on investment dilution	16,923	-
Losses from investments in equity method investees, net of tax	(58,555)	(76,507)
Net loss	(174,244)	(178,625)
Net income loss) attributable to redeemable noncontrolling interests and noncontrolling interests	(6,436)	(8,782)
Net loss attributable to ATAI Life Sciences N.V. stockholders	\$ (167,808)	\$ (169,843)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders-- basic and diluted	\$ (1.21)	\$ (1.83)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic and diluted	138,265,859	93,019,072

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

	December 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	\$ 362,266	\$ 97,246
Prepaid expenses and other current assets	11,903	2,076
Short term notes receivable	913	-
Short term notes receivable - related party	-	226
Property and equipment, net	149	71
Deferred offering costs	-	1,575
Equity method investments	16,131	-
Other investments	11,628	8,044
Long term notes receivable	-	911
Long term notes receivable - related parties	3,835	1,060
Other assets	7,341	339
Total assets	\$ 414,166	\$ 111,548
Liabilities and Stockholders' Equity		
Accounts payable	\$ 6,004	\$ 3,083
Accrued liabilities	14,829	9,215
Current portion of contingent consideration liability - related parties	51	-
Other current liabilities	51	-
Non-current portion of Contingent consideration liability - related parties	2,432	1,705
Convertible promissory notes - related parties, net of discounts and deferred issuance costs	743	1,199
Convertible promissory notes and derivative liability	-	978

Other liabilities	4,097	-
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	376,908	90,822
Noncontrolling interests	9,051	4,546
Total liabilities and stockholders' equity	<u>\$ 414,166</u>	<u>\$ 111,548</u>