

# atai Life Sciences Reports Second Quarter 2022 Financial Results & Business Update

August 15, 2022

- Added an anticipated additional year of runway into 2025 through securing non-dilutive debt facility from Hercules combined with execution of cost optimizations by prioritizing atai's development programs with anticipated meaningful near-term clinical value inflections
- Key achieved R&D milestones include completion of the clinical phase of the Drug-Drug-Interaction (DDI) study of PCN-101, database lock for the GRX-917 Phase 1 trial, completion of SAD portion of ongoing KUR-101 Phase 1 trial, and initiation of VLS-01 Phase 1 trial
- Non-dilutive financing facility of up to \$175M, plus \$312M existing cash on hand as of June 30, 2022, gives atai access to up to \$487M to continue developing next generation mental health treatments

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

NEW YORK and BERLIN, Aug. 15, 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 June 30, 2022, and provided a business update.

"We have taken strong actions to extend our anticipated runway by one year into 2025. We further strengthened our already strong cash position of \$312M at end of Q2 by securing a non-dilutive term loan facility of up to \$175M, and we anticipate realizing significant cost savings from a company-wide cost optimization," said Florian Brand, Chief Executive Officer & Co-Founder of atai. "This additional runway provides us with the ability to achieve numerous proof-of-concept data readouts without additional dilutive financing."

"We continue to execute on our pipeline – having achieved multiple Phase 1 milestones over the last months. These include the completion of the clinical phase of the PCN-101 drug-drug interaction (DDI) study, database lock of the GRX-917 Phase 1 SAD/MAD trial, completion of the SAD portion of the KUR-101 Phase 1 trial, and the initiation of the VLS-01 Phase 1 trial. Going forward, we are focusing on R&D programs that we anticipate generating meaningful clinical data readouts over the next two years," said Srinivas Rao, Chief Scientific Officer & Co-Founder of atai. "We are excited about our refocused pipeline with 8 potential value generation events over the next 6-12 months starting with the PCN-101 Phase 2a read out in treatment-resistant depression (TRD) by end of year."

#### **Video Interview with Management**

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

The interview will also be accessible 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**

atai has completed a company-wide cost optimization initiative and an extensive pipeline review to both reduce its expected operating expenses and prioritize its capital resources on R&D programs anticipated to be potentially the most valuable and meaningful opportunities for patients in its pipeline. This portfolio review process is consistent with the Company's three-pillar strategic approach as it looks to achieve clinically meaningful and durable behavioral change in mental health patients.

As a result, the Company has streamlined its pipeline by decelerating programs and discontinuing funding beyond our obligations to several programs, including Revixia, Neuronasal, DemeRx NB, and certain discovery efforts. atai will opportunistically explore business development and partnering opportunities for these deprioritized programs.

atai's remaining refocused pipeline and enabling technologies are the following:

- 1. Drug development programs:
  - 1. COMP360
  - 2. PCN-101
  - 3. RL-007
  - 4. GRX-917
  - 5. KUR-101
  - 6. DMX-1002
  - 7. VLS-01
  - 8. EMP-01
- 2. Enabling technologies:
  - 1. Introspect
  - 2. InnarisBio
  - 3. IntelGenx
  - 4. EntheogeniX

In Q2, the Company continued to advance its programs and is looking forward to additional clinical milestones for the remainder of 2022 and beyond. The Company anticipates all 8 compounds listed above to be in clinical development by the end of this year. atai's development pipeline of pharmaceuticals, digital therapeutics, and precision mental health approaches are supported by a total of 293 issued patents and 125 pending non-provisional patents.

#### **Recent Developments**

# COMPASS Pathways - COMP360 (Psilocybin assisted therapy) to treat Treatment-Resistant Depression (TRD)

- Launched Phase 2 clinical trial of COMP360 in Anorexia Nervosa in July 2022.
- COMP360 Phase 3 program for TRD submitted to FDA and expected to commence by end of FY 2022.
- Kabir Nath, former Senior Managing Director of Global Pharmaceuticals at Otsuka, appointed as new CEO on August 1<sup>st</sup>, 2022.
- Investor Day scheduled for October 12th, 2022, during which details on Phase 3 will be presented.

# Perception Neuroscience - PCN-101 (R-ketamine) to treat Treatment-Resistant Depression (TRD)

- Completion of the clinical phase of the Phase 1 DDI study.
- Data from PCN-101 Phase 2 Proof-of-Concept (PoC) study in TRD expected by end of FY 2022.
- PCN-101 Phase 1 SQ to IV bioavailability bridging study is expected to initiate within the next few quarters.

#### Recognify Life Sciences - RL-007 to treat Cognitive Impairment Associated with Schizophrenia (CIAS)

• RL-007 Phase 2b PoC study for CIAS expected to commence in H2 2022.

#### GABA Therapeutics - GRX-917 (deuterated etifoxine) to treat Generalized Anxiety Disorder (GAD)

- Database lock of phase 1 SAD/MAD for GRX-917 achieved, and readout of results anticipated in H2 2022.
- GRX-917 PoC trial in healthy volunteers expected to initiate in H2 2022.

# Kures - KUR-101 (deuterated mitragynine) to treat Opioid Use Disorder (OUD)

- KUR-101 Phase 1 results expected in H2 2022.
- Enrollment completed in the SAD portion of the Phase 1 trial, and dosing in the second double-blind, placebo- and active-controlled relative efficacy and tolerability portion of the trial has commenced.

# DemeRx - DMX-1002 (ibogaine) to treat Opioid Use Disorder (OUD)

• DMX-1002 Phase 1 results expected in H2 2022.

# Viridia Life Sciences - VLS-01 (dimethyltryptamine) to treat Treatment-Resistant Depression (TRD)

- VLS-01 Phase 1 SAD trial initiation occurred in May of this year.
- The Phase 1 trial is the first application of Introspect's DTx to an atai pipeline product, and this technology will be used to support subjects before and after dosing.
- The objectives of this phase 1 trial will be to compare the safety, tolerability, and PK of intravenous versus oral transmucosal administration of DMT. The oral transmucosal film product being tested was developed in conjunction with IntelGenX.

#### EmpathBio - EMP-01 (MDMA derivative) to treat Post-Traumatic Stress Disorder (PTSD)

- EMP-01 Phase 1 SAD trial recently received ethics committee approval, and central regulatory approval is anticipated in H2 2022.
- This trial will incorporate Introspect's DTx to support subjects before and after dosing.

# InnarisBio - Nasal spray drug-delivery technology to effect direct-to-brain drug delivery for use in various mental health indications

• InnarisBio proof of mechanism trial results expected in H2 2022.

atai will host an R&D Day for investors on October 25<sup>th</sup>, 2022 to provide further updates and details on its innovative pipeline.

# **Team Expansion**

- Stephen Bardin joined atai as CFO Designate in June 2022 and will succeed Greg Weaver as CFO on August 16<sup>th</sup>, 2022.
   Mr. Weaver has agreed to stay on board as strategic advisor until the end of Q1 2023.
- Kures Therapeutics appointed Chad Beyer, PhD, MBA, as CEO in July 2022.
- GABA Therapeutics appointed Mario Saltarelli, MD, PhD, as CEO and CMO in April 2022.

#### **Consolidated Financial Results**

- On August 9<sup>th</sup>, atai entered into a term loan facility agreement for up to \$175 million with Hercules Capital, Inc. (NYSE:HTGC). More details are available in a separate press release filed by atai on August 15<sup>th</sup>.
- atai ended the second quarter of 2022 with a cash position of \$312 million, which combined with committed funding from 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 \$312.5 million as of June 30, 2022, compared to \$362.3 million as of December 31, 2021. The six-month net decrease of cash of \$49.8 million was primarily attributable to net cash used in operating activities of \$45.9 million, \$3.0 million of additional investments in the platform companies, offset by \$1.9 million received from the conversion of promissory notes and equity issuances.

#### Operating Costs & Expenses

Research and development expenses were \$17.9 million and \$33.4 million for the three and six months ended June 30, 2022, respectively, as compared to \$16.0 million and \$21.6 million for the same prior year periods. The increase of \$1.9 million and \$11.8 million, respectively, was primarily attributable to an increase in personnel costs, which included a decrease in stock-based compensation expense and increased contract research organization expenses related to the advancement of R&D programs.

Acquisition of in-process R&D expense for the six months ended June 30, 2022 of \$0.4 million was related to IPR&D acquired from Kures. Acquisition of in-process R&D expense for the six months ended June 30, 2021 was \$8.9 million, which was related to IPR&D acquired from InnarisBio and Neuronasal.

General and administrative expenses for the three and six months ended June 30, 2022, were \$17.2 million and \$35.2 million, respectively, as compared to \$37.3 million and \$46.6 million in the same prior year periods. The decrease of \$20.1 million and \$11.4 million, respectively, was primarily attributable to a decrease in stock-based compensation expense and professional fees, partially offset by an increase in insurance costs, and personnel and facilities costs.

Net loss attributable to shareholders for the three months ended June 30, 2022, was \$36.6 million (including non-cash share-based compensation expense of \$9.5 million) as compared to \$48.5 million (including non-cash share-based compensation expense of \$37.5 million) for the comparable prior year period.

Net loss attributable to shareholders for the six-months ended June 30, 2022, was \$73.5 million (including non-cash share-based compensation expense of \$19.7 million) as compared to \$47.8 million (including non-cash share-based compensation expense of \$37.7 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 <a href="https://www.atai.life">www.atai.life</a>.

# **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 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, the plans and objectives of management for future operations and capital expenditures, and our participating 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") and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as updated by our subsequent filings with the SEC, 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.

# **Contact Information**

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# ATAI LIFE SCIENCES N.V. CONDENSED CONSOLIDATED BALANCE SHEET (Amounts in thousands, except share and per share amounts)

	June 30, 		December 31, 2021	
Assets				
Cash and cash equivalents	\$	84,132	\$	362,266
Debt Securities carried at fair value		228,354		_
Prepaid expenses and other current assets		11,122		11,903
Short term notes receivable		_		913
Property and equipment, net		303		149
Equity method investments		1,162		16,131
Other investments		9,233		11,628
Long term notes receivable - related parties		7,040		3,835
Other assets		7,590		7,341
Total assets	\$	348,936	\$	414,166
Liabilities and Stockholders' Equity				
Accounts payable		2,738		6,004
Accrued liabilities		18,913		14,829
Current portion of contingent consideration liability - related parties		_		51
Other current liabilities		306		51
Non-current portion of contingent consideration liability - related parties		2,338		2,432
Convertible promissory notes - related parties, net of discounts and deferred issuance costs		619		743
Other liabilities		3,900		4,097
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders		311,675		376,908
Noncontrolling interests		8,447		9,051
Total liabilities and stockholders' equity	\$	348,936	\$	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 June 30,				Six Months Ended June 30,					
2022		2021		2022		2021			
\$	170	\$			\$		170	\$	19.880

Operating exp	penses:
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Research and development	17,949	16,026	33,409	21,611
Acquisition of in-process research and development	357	7,962	357	8,934
General and administrative	17,221	37,331	35,203	46,604
Total operating expenses	35,527	61,319	68,969	77,149
Loss from operations	(35,357)	(61,319)	(68,799)	(57,269)
Other income (expense), net:	4,551	(5,982)	6,072	(4,279)
Loss before income taxes	(30,806)	(67,301)	(62,727)	(61,548)
Provision for income taxes	(51)	(58)	(92)	(64)
Gain on dilution of equity method investment	_	16,923	_	16,923
Losses from investments in equity method investees, net of tax	(6,652)	(2,937)	(12,248)	(4,640)
Net loss	(37,509)	(53,373)	(75,067)	(49,329)
Net loss attributable to redeemable noncontrolling interests and noncontrolling interests	(891)	(4,912)	(1,580)	(1,556)
Net loss attributable to ATAI Life Sciences N.V. stockholders	\$ (36,618)	\$ (48,461)	\$ (73,487)	\$ (47,773)
Net loss per share attributable to ATAI Life Sciences N.V. stockholders — basic and diluted Weighted average common shares outstanding attributable to	\$ (0.24)	\$ (0.37)	\$ (0.48)	\$ (0.38)
ATAI Life Sciences N.V. stockholders — basic and diluted	153,971,202	132,265,075	153,751,456	125,797,732