Clene Reports Full Year 2020 Operating and Financial Highlights

March 29, 2021

Interim Phase 2 data indicate that CNM-Au8 has a homeostatic effect on brain bioenergetics

Topline data from a Phase 2 ALS trial and two Phase 2 target engagement studies in MS and Parkinson's disease expected in 2H 2021

Full enrollment in Phase 3 registrational trial in ALS expected in mid-2021

Cash of $59.3 million as of December 31, 2020

SALT LAKE CITY, March 29, 2021 (GLOBE NEWSWIRE) -- Clene Inc. (NASDAQ: CLNN) (along with its subsidiaries, "Clene") and its wholly owned subsidiary Clene Nanomedicine, Inc., a clinical-stage biopharmaceutical company dedicated to revolutionizing the treatment of neurodegenerative disease using nanocatalysis, today reported its full year 2020 operating and financial results.

"We are thrilled to enter this new year as a public company following the recent close of our merger and concurrent financing, which was enabled by several key milestones achieved in 2020," said Rob Etherington, president and chief executive officer of Clene. "Over the last year, we continued advancing our clinical Phase 2 studies and Phase 3 study of CNM-Au8, a novel bioenergetic nanocatalyst, in ALS, multiple sclerosis (MS), and Parkinson's disease (PD) and are very pleased to have reported promising preliminary clinical results that support its neuroprotective and remyelinating properties. CNM-Au8's potential as a neuroprotective and neuro-reparative nanocatalyst is further validated by its selection as one of the first three therapies to be evaluated in the Phase 3 HEALEY ALS Platform trial, the first-ever platform trial for ALS. We are thankful to our patients, their care-givers, the MGH Healey ALS Center, the Northeast ALS Consortium clinical sites, and the entire Clene team, whose dedication throughout the pandemic drove this sustained progress."

Mr. Etherington continued, "Looking ahead, we are well-positioned to continue the momentum of our clinical programs. In 2021 we expect to report topline safety and efficacy data from our Phase 2 RESCUE-ALS trial, complete enrollment in the registrational HEALEY ALS Platform trial, and report topline data from our Phase 2 brain target engagement studies in MS and PD. We are grateful for the continued support of our investors, which has enabled Clene to fund these robust R&D efforts. It is with great energy and dedication that Clene will continue working towards its mission of developing bioenergetic nanocatalysts as a new class of drugs to treat significant unmet medical needs in neurodegenerative diseases while driving further value for its stakeholders."

Full Year 2020 and Recent Highlights

CNM-Au8 for the treatment of amyotrophic lateral sclerosis (ALS):

Presented blinded interim data from the Phase 2 RESCUE-ALS trial at the 31 st International Symposium on ALS/MND:
RESCUE-ALS is a Phase 2, multi-center, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8, a neuro-reparative nanocatalyst, in early symptomatic ALS patients. The study's primary endpoint evaluates improvements in muscle function using a sophisticated electromyography technique called Motor Unit Number Index over four muscles, MUNIX(4), which quantitatively reflects loss or preservation of motor neurons in ALS. Interim results from the trial showed that more than 40% of enrolled patients (active CNM-Au8 or placebo) who completed week 12 experienced improvements in motor neuron function as assessed by MUNIX(4). These data, though blinded, suggest that CNM-Au8 may have neuro-reparative potential in ALS patients. Clene expects to report topline data from the RESCUE-ALS study in the second half of 2021.

Full enrollment in Phase 3 registrational trial in ALS expected in mid-2021:

The HEALEY ALS Platform trial is a multi-center, multi-regimen, placebo-controlled, Phase 3 / registrational clinical program evaluating the safety and efficacy of multiple investigational products for the treatment of ALS. This first-ever ALS platform trial is designed to reduce trial time, reduce costs, and increase patient participation in developing novel therapies for ALS. It includes substantial financial support from philanthropic donors and foundations and provides access to 54 expert ALS clinical trial sites across the U.S. CNM-Au8 was selected as one of the first drug regimens to be evaluated in the HEALEY ALS Platform Trial. In the first quarter of 2021, the trial reached 50% of its target enrollment. Full enrollment of 160 patients into the CNM-Au8 portion of the trial is anticipated mid-2021, with topline data expected in the first half of 2022.

CNM-Au8 for the treatment of multiple sclerosis (MS):

Presented blinded interim data from the Phase 2 VISIONARY-MS trial at ACTRIMS Forum 2021:
VISIONARY-MS is a Phase 2, multi-center, double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of CNM-Au8 as a remyelinating and neuro-reparative treatment in stable relapsing MS patients with chronic visual impairment. Updated blinded interim data from VISIONARY-MS continue to support the potential of CNM-Au8 to drive meaningful neurological improvements in MS. Interim blinded data from all enrolled participants (randomized 2:1, active CNM-Au8 to placebo) showed clinically relevant mean improvements in overall Multiple Sclerosis Functional Composite (MSFC) scores and key MSFC sub-scales compared to a valid comparator group (EDSS ≤1.5) that presented with less neurological impairment than that of the overall study population at baseline (mixed-effects model; $p<0.0001$ vs. baseline). These data support CNM-Au8's potential to drive meaningful neurological improvements in MS patients. Subject to ongoing pandemic-related research restrictions at MS clinical trial sites, enrollment will advance through 2021.

Presented interim data from the Phase 2 REPAIR-MS trial at ACTRIMS Forum 2021:
REPAIR-MS is a single-center, active-only, sequential group, investigator-blinded study to assess the central nervous system (CNS) metabolic effects, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in MS patients. The study utilizes high-resolution magnetic resonance spectroscopy

(^{31}P-MRS) to evaluate the effects of orally administered CNM-Au8 on the metabolic profile of MS patient brains. Updated interim data demonstrate significant CNS target engagement of CNM-Au8 with catalytic bioenergetic improvements in NAD+/NADH ratio and adenosine triphosphate (ATP) levels, two key CNS metabolic markers. Together, these data indicate that orally administered CNM-Au8 has a homeostatic effect on brain bioenergetics. Clene expects to complete REPAIR-MS and report topline data in the second half of 2021.

CNM-Au8 for the treatment of Parkinson's disease (PD):

Presented interim data from the Phase 2 REPAIR-PD trial at MSVirtual2020 Meeting:
REPAIR-PD is a single-center, active-only, sequential group, investigator-blinded study to assess the CNS metabolic effects, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in PD patients. As described in the REPAIR-MS trial above, this study also utilizes high-resolution magnetic resonance spectroscopy (^{31}P-MRS) to evaluate the effects of orally administered CNM-Au8 on the metabolic profile within the brain. Preliminary data has demonstrated CNM-Au8-mediated modulation of key brain bioenergetic metabolites in PD patients. Clene expects to report topline data from REPAIR-PD in the second half of 2021 and to launch an additional Phase 2 PD efficacy trial (RESCUE-PD) by the end of 2021.

Awarded Michael J. Fox Foundation (MJFF) Grant to accelerate the development of CNM-Au8 in PD
The MJFF funding will support preclinical studies in two complementary models of PD that will be led by Dr. Karen Ho, head of translational medicine at Clene, in collaboration with Prof. Michela Deleidi, Helmholtz Young Investigator at the German Center for Neurodegenerative Diseases (DZNE), and Dr. James Koprich, chief scientific officer of Atuka, Inc. The project will further evaluate the effects of CNM-Au8 on the survival and bioenergetic profiles of human PD patient dopaminergic neurons in the presence of PD-related neurotoxins and characterize the effects of CNM-Au8 on motor behaviors and neuronal survival in an animal model of PD, both of which will facilitate the advancement of CNM-Au8 into Phase 2 efficacy trials in PD patients.

CNM-ZnAg for the treatment of infectious diseases, including COVID-19:

Initiated a Phase 2 study of CNM-ZnAg for patients with COVID-19 in Brazil:
CNM-ZnAg is Clene's second key asset intended for broad anti-viral and anti-microbial use. Clene has received official ANVISA approval in Brazil to commence its multicenter, randomized, double-blind, placebo-controlled study assessing the efficacy and safety of CNM-ZnAg liquid solution in a Phase 2 clinical study in acutely symptomatic, non-hospitalized COVID-19 patients. The primary endpoint will evaluate the incidence of hospitalization at day 28, with secondary endpoints assessing time to symptom resolution. The trial is expected to enroll approximately 276 patients randomized 1:1:2 to receive either a low or high dose of CNM-ZnAg or placebo in a double-blind fashion, in addition to standard supportive care. Enrollment in the trial is expected to be completed in mid-2021, with results anticipated in the second half of 2021.

Corporate Highlights:

Financing:
In December 2020, Clene closed a merger with Tottenham Acquisition I Limited, a special purpose acquisition company. Clene received proceeds of approximately $31.8 million from the transaction, which included funds held in Tottenham's trust account and a concurrent private investment in public equity financing led by existing Clene shareholders. Common stock of the merged company commenced trading on the NASDAQ Capital Market under the ticker symbol "CLNN" on December 31, 2020.

Leadership:
In December 2020, Clene appointed Dr. Ted (Tae Heum) Jeong as the company's chief financial officer. Dr. Jeong has more than 20 years of experience as a financial executive and venture capitalist. Dr. Jeong received his B.S. and M.S. in Chemistry from Pohang University of Science & Technology. He also holds an M.S. in Finance from Johns Hopkins University, and a Doctor of Management from the University of Maryland.

Intellectual Property:
Clene was issued a Notice of Allowance from the U.S. Patent and Trademark Office for methods of using CNM-Au8 for the treatment of patients with MS. The resulting patent will add to Clene's robust intellectual property protection in the field of clean-surfaced nanocrystal therapeutics, which includes over 100 patents issued and allowed and approximately 30 more applications pending.

Anticipated 2021 Milestones:

- HEALEY ALS Platform Trial full enrollment: mid-2021
- Phase 2 RESCUE-ALS topline data: 2H 2021
- Phase 2 REPAIR-MS topline data: 2H 2021
- Phase 2 REPAIR-PD topline data: 2H 2021
- Phase 2 CNM-ZnAg COVID-19 topline data: 2H 2021
- Initiation of Phase 2 RESCUE-PD efficacy trial: 2021

Full Year 2020 Financial Results

Cash Position:
Clene's cash totaled approximately $59.3 million as of December 31, 2020, compared to approximately $8.8 million as of December 31, 2019. The increase in cash during the year ended December 31, 2020 was primarily due to approximately $69.5 million net cash provided by financing activities, including $35.1 million of net proceeds from the issuance of preferred stock, $31.8 million of net proceeds from the private placement and from the reverse recapitalization, and $6.1 million of net proceeds from the issuance of convertible notes payable, offset by approximately $18.9 million of net cash used in operating activities. Clene expects that its cash as of December 31, 2020 will be sufficient to fund its operating expenses into mid-2022.

R&D Expenses:
Research and development expenses were $15.2 million for 2020, compared to $9.6 million for 2019. The increase is primarily due to the progression of our drug candidates through the clinical development process, including increased enrollment into the REPAIR-PD and the REPAIR-MS studies,

and calendar payments due for our participation in the HEALEY-ALS Platform Trial.

G&A Expenses:
General and administrative expenses were $5.2 million for 2020, compared to $6.8 million for 2019. The year over year decrease is primarily attributable to a decrease in legal and audit professional fees.

Net Loss:
Clene's loss from operations was $20.2 million and $16.3 million for the years ended December 31, 2020 and 2019, respectively. Clene's net loss was $19.3 million, or $1.10 per share, for the year ended December 31, 2020, compared to a net loss of $16.2 million, or $0.93 per share, for the year ended December 31, 2019. Included in the net loss for the years ended December 31, 2020 and 2019 is an unrealized loss from the change in fair value of preferred stock warrant liability of $14.6 million and $0.4 million, respectively, an unrealized gain from the change in fair value of contingent earn-out payments of $14.1 million in connection with the reverse recapitalization in 2020; and the Australian research and development tax credit of $3.2 million and $0.6 million, respectively.

About RESCUE-ALS
RESCUE-ALS is a Phase 2 multi-center, randomized, double-blind, parallel-group, placebo-controlled study examining the efficacy, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in patients with newly diagnosed amyotrophic lateral sclerosis (ALS). The trial completed enrollment in 2H 2020. 45 subjects were randomized 1:1 to receive either active treatment with CNM-Au8 (30 mg) or placebo in addition to their current standard of care over a 36-week treatment period. The objective of this study is to assess the impact of improving neuronal bioenergetics, reducing reactive oxygen species, and promoting protein homeostasis with CNM-Au8 on disease progression in patients with early ALS. CNM-Au8 was selected by FightMND of Australia and Clene was provided a substantial grant to investigate efficacy in ALS utilizing novel electromyography endpoints at two expert sites in Australia. Preliminary blinded data presented at the 31st International Symposium on ALS/MND showed that more than 40% of enrolled participants experienced improvements in motor neuron function at 12 weeks. Topline data are expected in 2H 2021. For more information, please see ClinicalTrials.gov Identifier: NCT04098406.

About the HEALEY ALS Platform Trial
The HEALEY ALS Platform trial is a perpetual multi-center, randomized, double-blind, placebo-controlled Phase 3 registration program designed to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of multiple investigational products in symptomatic amyotrophic lateral sclerosis (ALS) patients. Funded by philanthropic donors and led by Harvard's Massachusetts General Hospital, HEALEY is the first-ever ALS platform trial designed to reduce trial time, costs, and increase patient participation in developing novel therapies. This landmark platform trial tests multiple treatments utilizing a combined placebo group. CNM-Au8 was selected as one of the first drugs to be evaluated. Full enrollment of 160 patients into the CNM-Au8 study through 54 expert ALS U.S. clinical trial sites is expected in mid-2021. Subjects are randomized 3:1 to receive either active treatment or placebo daily for a 24-week treatment period. The primary endpoint is rate of change in disease severity over time as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R). Secondary endpoints include change in respiratory function over time as measured by slow vital capacity and change in muscle strength over time as measured isometrically using hand-held dynamometry. Topline data are expected 1H 2022. For more information, please see ClinicalTrials.gov Identifier: NCT04297683.

About VISIONARY-MS
VISIONARY-MS is a Phase 2, multi-center, double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of CNM-Au8 as a remyelinating and neuro-reparative treatment in stable relapsing multiple sclerosis (MS) patients with chronic visual impairment. 150 participants are being enrolled through 10 expert MS clinical trial sites in Australia. Subjects are randomized 1:1:1 (high-dose:low-dose:placebo). The primary endpoint is improvement in Low Contrast Letter Acuity (LCLA) from baseline to week-24. Key secondary endpoints include improvements from baseline to week-24 in the remaining modified-Multiple Sclerosis Functional Composite (MSFC) subscales (Symbol Digit Modalities Test, 9-Hole Peg Test, and Timed 25-Foot Walk). Interim blinded data from the Phase 2 VISIONARY-MS trial presented at ACTRIMS Forum 2021 Meeting demonstrated exposure-dependent, statistically significant improvements in both LCLA scores and across the averaged components of the modified MSFC scale for the study population in comparison to baseline values from the mildest sub-population ($p<0.001$). Subject to ongoing pandemic-related research restrictions at MS clinical trial sites, enrollment will advance through 2021. For more information see ClinicalTrials.gov Identifier: NCT03536559.

About REPAIR-MS and REPAIR-PD
REPAIR-MS and REPAIR-PD are Phase 2, single-center, active-only, sequential group studies examining the brain metabolic effects, safety, pharmacokinetics and pharmacodynamics of CNM-Au8 in patients who have been diagnosed with MS within 15 years of screening or in patients with PD who have been diagnosed within three years of screening. Investigators and participants are blinded to dose. Participants received orally delivered CNM-Au8, the concentrated nanocrystalline gold (Au) suspension, daily each morning for 12 weeks. Participants undergo ^{31}P-MRS brain imaging scans to semi-quantitatively measure CNS bioenergetic metabolites at baseline, prior to administration of drug, and at the end-of-study following at least 12 weeks of exposure to CNM-Au8. The objective of these studies is to demonstrate target engagement for CNM-Au8 on CNS biomarkers related to bioenergetics and neuronal membrane stability in patients with MS and PD. The studies are taking place at the University of Texas Southwestern Medical Center with a team of internationally recognized experts in brain imaging and treatment of disorders of the CNS. For more information see ClinicalTrials.gov Identifiers: NCT03993171 and NCT03815916.

About CNM-Au8
Clene's lead drug candidate, CNM-Au8, a bioenergetic nanocatalyst, is a stable, aqueous suspension of catalytically active gold (Au) nanocrystals. In a patented breakthrough, clean surfaced nanocrystalline CNM-Au8 drives critical cellular bioenergetic reactions in the brain to increase cellular energy, accelerate neurorepair, and improve neuroprotection. CNM-Au8 crosses the blood-brain barrier and is not associated with the toxicities related to synthetic gold compounds or nanoparticles manufactured via synthetic chemistry. CNM-Au8 is currently being evaluated in a Phase 3 registration trial in amyotrophic lateral sclerosis (ALS), a Phase 2 trial examining disease progression via a novel electromyography technique in patients with early ALS, a Phase 2 trial for the treatment of chronic optic neuropathy in patients with stable relapsing multiple sclerosis (MS), and Phase 2 brain target engagement studies in patients with Parkinson's disease (PD) and MS. CNM-Au8 has demonstrated safety in Phase 1 studies in healthy volunteers and has shown both remyelination and neuroprotective effects in multiple preclinical (animal) models. Preclinical data, both published in peer-reviewed journals and presented at scientific congresses, demonstrate that treatment of neuronal cultures with CNM-Au8 improves survival of neurons, protects neurite networks, decreases intracellular levels of reactive oxygen species and improves mitochondrial capacity in response to cellular stresses induced by multiple disease-relevant neurotoxins. Oral treatment with CNM-Au8 improved functional behaviors in rodent models of ALS, MS, and PD versus vehicle (placebo).

About Clene

Clene, a clinical-stage biopharmaceutical company focused on neurodegenerative disease, is leading the way by using nanotechnology to treat bioenergetic failure, which underlies many neurological diseases. Clene has innovated a novel nanotherapeutic platform to create a new class of drugs—bioenergetic nanocatalysts. Clene's lead drug candidate, CNM-Au8, is a concentrated nanocrystalline gold (Au) suspension that drives critical cellular bioenergetic reactions in the CNS. CNM-Au8 increases cellular energy to accelerate neurorepair and improve neuroprotection. Currently, CNM-Au8 is being investigated for efficacy and safety in a Phase 3 registration trial for ALS and in Phase 2 trials for multiple sclerosis and Parkinson's disease. Clene has also advanced into the clinic an aqueous solution of ionic zinc and silver for anti-viral and anti-microbial uses. The company is based in Salt Lake City, Utah with R&D and manufacturing operations in Maryland. For more information, please visit www.clene.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Clene's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "might" and "continues," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant known and unknown risks and uncertainties, many of which are beyond Clene's control and could cause actual results to differ materially and adversely from expected results. Factors that may cause such differences include Clene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; Clene's ability to achieve commercial success for its marketed products and drug candidates, if approved; Clene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Clene's reliance on third parties to conduct drug development, manufacturing and other services; Clene's limited operating history and its ability to obtain additional funding for operations and to complete the licensing or development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on Clene's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in Clene's recently filed registration statement on Form S-4, as well as discussions of potential risks, uncertainties, and other important factors in Clene's subsequent filings with the U.S. Securities and Exchange Commission. Clene undertakes no obligation to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based, subject to applicable law. All information in this press release is as of the date of this press release. The information contained in any website referenced herein is not, and shall not be deemed to be, part of or incorporated into this press release.

CLENE INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands, except share and per share amounts)
(Audited)

	Year Ended December 31,	
	2020	**2019**
Revenue:		
Product revenue	$ 176	$ -
Royalty revenue	30	-
Total revenue	206	-
Operating expenses:		
Cost of revenue	65	-
Research and development	15,204	9,563
General and administrative	5,151	6,769
Total operating expenses	20,420	16,332
Loss from operations	(20,214)	(16,332)
Other income (expense), net:		
Interest expense	(950)	(88)
Gain on termination of lease	51	-
Change in fair value of preferred stock warrant liability	(14,615)	(361)
Change in fair value of derivative liability	29	-
Change in fair value of Clene Nanomedicine contingent earn-out	12,659	-
Change in fair value of Initial Shareholders contingent earn-out	1,465	-
Australia research and development credit	3,210	599
Loss on extinguishment of convertibles notes	(540)	-
Other income, net	34	27
Total other income (expense), net	1,343	177
Net loss before income taxes	(18,871)	(16,155)
Income tax expense	(406)	-
Net loss	(19,277)	(16,155)
Other comprehensive income (loss):		
Foreign currency translation adjustments	284	(3)
Total other comprehensive income (loss)	284	(3)

Comprehensive loss	$ (18,993)	$ (16,158)
Net loss per share-- basic and diluted	$ (1.10)	$ (0.93)

CLENE INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share amounts)
(Audited)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash	$ 59,275	$ 8,788
Inventory	191	28
Prepaid expenses and other current assets	3,523	661
Total current assets	62,989	9,477
Right-of-use assets	1,029	1,081
Property and equipment, net	4,225	4,319
TOTAL ASSETS	$ 68,243	$ 14,877
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,124	$ 889
Accrued liabilities	3,960	2,878
Income tax payable	164	-
Payable to related parties	-	131
Deferred revenue from related parties	112	-
Operating lease obligations, current portion	194	216
Finance lease obligations, current portion	190	200
Clene Nanomedicine contingent earn-out, current portion	5,924	-
Total current liabilities	11,668	4,314
Operating lease obligations, net of current portion	1,785	1,434
Finance lease obligations, net of current portion	205	389
Notes payable, net of current portion	1,949	640
Deferred income tax	260	-
Redeemable convertible preferred stock warrant liability	-	3,213
Clene Nanomedicine contingent earn-out, net of current portion	46,129	-
Initial Shareholders contingent earn-out	5,906	-
TOTAL LIABILITIES	67,902	9,990
Redeemable convertible preferred stock	-	72,661
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 59,526,171 and 17,357,505 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	6	2
Additional paid-in capital	153,571	1,754
Accumulated deficit	(153,561)	(69,571)
Accumulated other comprehensive income	325	41
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	341	(67,774)
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY	$ 68,243	$ 14,877

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Source: Clene Inc.

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